

John R. Borzilleri, MD
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[REDACTED]

Peter Mucchetti
Chief, Healthcare and Consumer Products Section
Antitrust Division
United States Department of Justice
450 Fifth Street NW, Suite 4100
Washington, DC 20530

COPY ALSO SENT
TO JUDGE LEON'S
CHAMBERS
Sincerely, [Signature]

December 1, 2018

Re: Proposed CVS Health/Aetna Merger and Part D Divestiture to Wellcare

Mr. Mucchetti:

I am writing to oppose the merger of CVS Health and Aetna, which has unfortunately been approved by the Department of Justice. Further horizontal and vertical integration in the US PBM industry will only worsen US drug pricing, which is already a national crisis causing severe patient and taxpayer harm. In addition, the divestiture of Aetna's Part D business to Wellcare does nothing to lessen competitive concerns because both Aetna and Wellcare are partnered with CVS to provide PBM services to their government health plans. I am surprised and disappointed that this already existing CVS/Wellcare PBM partnership was not disclosed to the DC Federal Court in the Department of Justice filings regarding the CVS/Aetna merger.

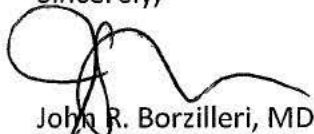
As a professional healthcare equity analyst, based upon now more than 5 years of intensive investigation, I have determined that the driver of massive US brand drug price inflation is a secretive price collusion scheme between drug manufacturers and the handful of dominant PBMs that already control the drug benefits for almost all Americans. Just four PBMs (Express Scripts, CVS Health, UnitedHealth Group and Humana) already control the drug benefits for 80-90% of Americans, including in the key Medicare Part D program. In addition, Aetna has a nontransparent, long-standing PBM partnership with CVS Health. In early 2016, Wellcare also formed a non-transparent PBM partnership with CVS Health.

In the scheme, drug manufacturers are paying PBMs massive "service fees" directly-linked to massive price increases. The scheme began with the Medicare Part D program in 2006, due to its little-known financial incentives. The PBMs now make most of their US brand drug profits from these secretive manufacturer "fee" payments, not from "rebates" as remains the broad perception. The public harm from this secretive and ongoing scheme is severe – estimated at more than \$200 billion over the past decade and increasing every day. As widely indicated in the media, every day Americans face loss of life, loss of access to drugs and severe financial hardship directly resulting from the massive drug prices driven by this scheme.

Based upon my investigation, I currently have two *qui tam* cases in active litigation in federal courts in the Southern District of New York (15-Civ 7881 (JMF)) and the District of Rhode Island (CV-14-031-WES). Both cases include major drug manufacturers and all the major PBMs, including CVS Health and Aetna. I have included the court documents from both cases with this correspondence. The documents describe the scheme and severe public harm in extensive detail. Surprisingly, despite well-pleaded allegations, recent briefing and massive fraud estimates, neither CVS Health nor Aetna has disclosed these *qui tam* cases in their recent SEC filings.

I hope the antitrust division will review these *qui tam* case documents and re-open investigation regarding this harmful merger, as well as the Express Scripts/Cigna combination. The patient and public harm from severe US drug prices will further escalate if these PBM/health insurer mergers proceed.

Sincerely,

A handwritten signature in black ink, appearing to read 'John R. Borzilleri', with a stylized flourish extending to the right.

John R. Borzilleri, MD

DOT ANTITRUST: ALSO JUST FILED
2nd SEC WHISTLEBLOWING
No follow up from first filing April 2018
98

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

OMB APPROVAL	
OMB Number: 3235 0686	
Expires: October 31, 2018	
Estimated average burden hours per response	1

FORM TCR
TIP, COMPLAINT OR REFERRAL

A. INFORMATION ABOUT YOU

COMPLAINANT 1:

1. Last Name

Borzilleri

First

John

M.I.

R

2. Street Address

[REDACTED]

Apartment/
Unit #

City

Ortchoque

State/
Province

NY

ZIP/
Postal Code

11935

USA

3. Telephone

[REDACTED]

Alt. Phone

E-mail Address

[REDACTED]

4. Occupation

HEALTHCARE EQUITY ANALYST

Preferred
method of
communication

email

COMPLAINANT 2:

1. Last Name

First

M.I.

2. Street Address

Apartment/
Unit #

City

State/
Province

ZIP/
Postal Code

Country

3. Telephone

Alt. Phone

E-mail Address

4. Occupation

Preferred
method of
communication

B. ATTORNEY'S INFORMATION (If Applicable - See Instructions)

1. Attorney's Name

N/A

2. Firm Name

3. Street Address

City

State/
Province

ZIP/
Postal Code

Country

4. Telephone

Fax

E-mail Address

C. TELL US ABOUT THE INDIVIDUAL OR ENTITY YOU HAVE A COMPLAINT AGAINST

INDIVIDUAL/ENTITY 1:

If an individual, specify profession:

1. Type: ☐ Individual ☒ Entity

If an entity, specify type:

Public Corporations

MULTIPLE - SEE ATTACHED QUI TAM COMPLAINTS

2. Name BAYER, BIOGEN, EMD SERONO

3. Street Address NOVARTIS, Pfizer, TEVA

Apartment/
Unit #

City

State/
Province

ZIP/
Postal Code

Country

4. Phone

E-mail Address

Internet Address

INDIVIDUAL/ENTITY 2:

If an individual, specify profession:

1. Type: ☐ Individual ☒ Entity

If an entity, specify type:

Public Corporations

MULTIPLE - SEE ATTACHED QUI TAM COMPLAINTS

2. Name ABBVIE, AMGEN, BRISTOL-MYERS

3. Street Address EL LILLY, SANOFI, AETNA, CIGNA

Apartment/
Unit #

City

State/
Province

ZIP/
Postal Code

Country

4. Phone

E-mail Address

Internet Address

D. TELL US ABOUT YOUR COMPLAINT

2006 to Present

SEC. MATERIAL FINANCIAL NONDISCLOSURE

1. Occurrence Date (mm/dd/yyyy): / /

2. Nature of complaint:

3a. Has the complainant or counsel had any prior communication(s) with the SEC concerning this matter?

YES ☒ NO ☐

SEC FORM TCR 15236-000-089 - SEC 4/18

3b. If the answer to 3a is "Yes," name of SEC staff member with whom the complainant or counsel communicated

4a. Has the complainant or counsel provided the information to any other agency or organization, or has any other agency or organization requested the information or related information from you?

DEPT OF JUSTICE, FEDERAL TRADE COMMISSION YES ☒ NO ☐

4b. If the answer to 4a is "Yes," please provide details. Use additional sheets if necessary.

2 FILED QUI TAM CASES ACTIVE
IN SDNY (IS-CIV 7881 (JMF))
RHODE ISLAND (CV-14-031-WES)

4c. Name and contact information for point of contact at agency or organization, if known

LI YU - SDNY DOJ
ZACHARY CUNHA - RI DOJ

10. Describe how and from whom the complainant obtained the information that supports this claim. If any information was obtained from an attorney or in a communication where an attorney was present, identify such information with as much particularity as possible. In addition, if any information was obtained from a public source, identify the source with as much particularity as possible. Attach additional sheets if necessary.

THE INFORMATION WAS OBTAINED VIA
EXTENSIVE INVESTIGATION, VERIFIED
BY INDUSTRY "INSIDERS"
-DETAILS IN COURT DOCUMENTS.

11. Identify with particularity any documents or other information in your submission that you believe could reasonably be expected to reveal your identity and explain the basis for your belief that your identity would be revealed if the documents were disclosed to a third party.

PLEASE SEE QUI TAM DOCUMENTS.
I AM FILING THIS 2ND TCR
SINCE NO ~~PER~~ FOLLOW-UP FROM SEC
AFTER 1ST FILING IN APRIL 2018.
THESE NEW AMENDED COMPLAINTS &
PROVIDE FAR MORE RELATED
EVIDENCE & INDICATE FAR
GREATER PUBLIC HARM. DOCS

5a. Does this complaint relate to an entity of which the complainant is or was an officer, director, counsel, employee, consultant or contractor?

YES ☐ NO ☒

5b. If the answer to question 5a is "Yes," has the complainant reported this violation to his or her supervisor, compliance office, whistleblower hotline, ombudsman, or any other available mechanism at the entity for reporting violations?

YES ☐ NO ☐

5c. If the answer to question 5b is "Yes," please provide details. Use additional sheets if necessary.

5d. Date on which the complainant took the action(s) described in question 5b (mm/dd/yyyy):

/ /

6a. Has the complainant taken any other action regarding your complaint?

YES ☐ NO ☐

6b. If the answer to question 6a is "Yes," please provide details. Use additional sheets if necessary.

7a. Does your complaint relate to a residential mortgage-backed security?

YES ☐ NO ☒

7b. Type of security or investment, if relevant

7c. Name of issuer or security, if relevant

7d. Security/Ticker Symbol or CUSIP no.

8. State in detail all facts pertinent to the alleged violation. Explain why the complainant believes the acts described constitute a violation of the federal securities laws. Use additional sheets if necessary.

THESE PBM DEFENDANTS MAKE THE MAJORITY OF
THEIR PROFITS FROM SECRETIVE "SERVICE FEE" PAYMENTS
FROM DRUG MANUFACTURERS - NEITHER OF
WHICH ARE DISCLOSING THE MATERIAL
INFORMATION IN THEIR SEC FINANCIAL STATEMENT.

9. Describe all supporting materials in the complainant's possession and the availability and location of any additional supporting materials not in complainant's possession. Use additional sheets, if necessary.

- PLEASE SEE EXTENSIVE DETAILS IN
ATTACHED COURT QUI TAM DOCUMENTS

12. Provide any additional information you think may be relevant.

IN ADDITION THESE PBM +
MANUFACTURER QUI TAM DEFENDANTS
ARE NOT DISCLOSING THESE POTENTIALLY
HIGHLY MATERIAL LOSSES IN THEIR
SEC DISCLOSURES

TOTAL ESTIMATED GOVERNMENT
FALSE CLAIMS FILAED > \$ 200 Billion

E. ELIGIBILITY REQUIREMENTS AND OTHER INFORMATION

1. Are you, or were you at the time you acquired the original information you are submitting to us, a member, officer or employee of the Department of Justice, the Securities and Exchange Commission, the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office of Thrift Supervision, the Public Company Accounting Oversight Board, any law enforcement organization, or any national securities exchange, registered securities association, registered clearing agency, or the Municipal Securities Rulemaking Board?

YES ☐ NO ☒

2. Are you, or were you at the time you acquired the original information you are submitting to us, a member, officer or employee of a foreign government, any political subdivision, department, agency, or instrumentality of a foreign government, or any other foreign financial regulatory authority as that term is defined in Section 3(a)(52) of the Securities Exchange Act of 1934 (15 U.S.C. §78c(a)(52))?

YES ☐ NO ☒

3. Did you acquire the information being provided to us through the performance of an engagement required under the federal securities laws by an independent public accountant?

YES ☐ NO ☒

4. Are you providing this information pursuant to a cooperation agreement with the SEC or another agency or organization?

YES ☐ NO ☒

5. Are you a spouse, parent, child, or sibling of a member or employee of the SEC, or do you reside in the same household as a member or employee of the SEC?

YES ☐ NO ☒

6. Did you acquire the information being provided to us from any person described in questions 1 through 5?

YES ☐ NO ☒

7. Have you or anyone representing you received any request, inquiry or demand that relates to the subject matter of your submission (i) from the SEC, (ii) in connection with an investigation, inspection or examination by the Public Company Accounting Oversight Board, or any self-regulatory organization; or (iii) in connection with an investigation by the Congress, any other authority of the federal government, or a state Attorney General or securities regulatory authority?

YES ☐ NO ☒

8. Are you currently a subject or target of a criminal investigation, or have you been convicted of a criminal violation, in connection with the information you are submitting to the SEC?

YES ☐ NO ☐

9. If you answered "yes" to any of the questions 1 through 8, use this space to provide additional details relating to your responses. Use additional sheets if necessary.

F. WHISTLEBLOWER'S DECLARATION

I declare under penalty of perjury under the laws of the United States that the information contained herein is true, correct and complete to the best of my knowledge, information and belief. I fully understand that I may be subject to prosecution and ineligible for a whistleblower award if, in my submission of information, my other dealings with the SEC, or my dealings with another authority in connection with a related action, I knowingly and willfully make any false, fictitious, or fraudulent statements or representations, or use any false writing or document knowing that the writing or document contains any false, fictitious, or fraudulent statement or entry.

Print name

John R Borzilleri, MD

Signature



Date

12/1/18

G. COUNSEL CERTIFICATION (If Applicable—See Instructions)

I certify that I have reviewed this form for completeness and accuracy and that the information contained herein is true, correct and complete to the best of my knowledge, information and belief. I further certify that I have verified the identity of the whistleblower on whose behalf this form is being submitted by viewing the whistleblower's valid, unexpired government issued identification (e.g., driver's license, passport) and will retain an original, signed copy of this form, with Section F signed by the whistleblower, in my records. I further certify that I have obtained the whistleblower's non-waivable consent to provide the Commission with his or her original signed Form TCR upon request in the event that the Commission requests it due to concerns that the whistleblower may have knowingly and willfully made false, fictitious, or fraudulent statements or representations, or used any false writing or document knowing that the writing or document contains any false fictitious or fraudulent statement or entry; and that I consent to be legally obligated to do so within 7 calendar days of receiving such a request from the Commission.

Signature

Date

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA, *ex rel.*
JOHN R. BORZILLERI, M.D.,

Plaintiffs,

v.

BAYER HEALTHCARE
PHARMACEUTICALS, INC., *et al.*,

Defendants.

C.A. No. 1:14-cv-00031-WES-LDA

**ORAL ARGUMENT REQUESTED
ESTIMATED TIME OF TWO
HOURS**

**MANUFACTURER DEFENDANTS' JOINT MOTION
TO DISMISS THE SECOND AMENDED COMPLAINT**

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Defendants Bayer Healthcare Pharmaceuticals, Inc., Biogen Inc., EMD Serono, Inc., Novartis Pharmaceuticals Corporation, Pfizer Inc., Teva Neuroscience, Inc. and Teva Pharmaceuticals USA, Inc. (collectively the “Manufacturer Defendants”) hereby move pursuant to Federal Rules of Civil Procedure 8(a), 9(b), 12(b)(1), and 12(b)(6) and 31 U.S.C. § 3730(e)(4) to dismiss Relator John Borzilleri, M.D.’s Second Amended Complaint (Dkt. 95) with prejudice as to all Manufacturer Defendants. In support of this Joint Motion, the Manufacturer Defendants rely upon the legal arguments set forth herein and the accompanying exhibits attached hereto. Pursuant to Local Rule 7(c), the Manufacturer Defendants respectfully request a hearing on their Joint Motion and estimate that the hearing will last no more than one hour.

PRELIMINARY STATEMENT

In this *qui tam* action, Relator John Borzilleri, M.D.—an opportunistic short seller and corporate outsider—sets forth an unsupported hypothesis conjured entirely from public information. Borzilleri alleges a “secret” agreement between seven “Manufacturer Defendants” that manufacture multiple sclerosis (MS) drugs approved by the U.S. Food and Drug Administration and seven “Pharmacy Benefit Manager (PBM) Defendants” that provide services in connection with the Medicare Part D prescription drug benefit program.¹ Based entirely on conjecture, Borzilleri’s Second Amended Complaint (SAC) alleges that the Manufacturer Defendants paid the PBM Defendants service fees in excess of fair market value. Borzilleri speculates that these service fees were not properly reported to the Centers for Medicare & Medicaid Services (CMS) by Medicare Part D plan sponsors, that they also were kickbacks to PBM Defendants, and that plan sponsors submitted false claims to CMS as a result.

¹ Borzilleri refers to Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc., and UnitedHealth Group, Inc. as the “PBM Defendants.” SAC ¶ 1.

Although Borzilleri has amended his complaint three times, his 808-paragraph SAC offers no factual support for his theories and fails to plead plausibly the violations he asserts, as required by Fed. R. Civ. P. 8(a). The SAC also falls far short of pleading fraud with the particularity required by Fed. R. Civ. P. 9(b). It does not plead any particularized facts about any alleged contract between a Manufacturer Defendant and a PBM Defendant, any service fee paid under such a contract, or any basis for concluding that any such service fee (even if paid) exceeded fair market value. The SAC is also devoid of facts that might connect any hypothetical excess service fee to an actual claim submitted by a Medicare Part D sponsor, such as details of how a particular alleged above fair market value service fee was misreported by a PBM Defendant to a Medicare Part D plan sponsor, or by a plan sponsor to CMS. Indeed, Borzilleri does not plead any facts demonstrating that any false claims actually were submitted. Rather, Borzilleri admits that his theory is based on “estimates,” “assumptions,” and “conclusions” drawn from publicly available data about drug pricing and service fees, which he hopes will be validated through discovery. Rule 9(b), however, requires Borzilleri to plead facts, not theories, and precludes the type of unfounded fishing expedition Borzilleri seeks to undertake here.

The SAC’s lack of factual support is not surprising. Borzilleri is not a Manufacturer or PBM Defendant insider with personal knowledge of any Defendant’s operations; instead, he is an opportunistic former health care investment fund manager who admits his SAC (like his largely duplicative second lawsuit filed in the U.S. District Court for the Southern District of New York against many of the same Defendants here (*see infra* Section B.2) is based entirely on public information he compiled in an effort to profit from large short positions that he took in the Defendants’ stock. Borzilleri’s attempt to manipulate the *qui tam* provision of the False Claims Act (FCA) for personal gain not only is antithetical to the provision’s intent, but also runs afoul

of the FCA's "public disclosure" bar. As the SAC confirms, Borzilleri's primary allegation—that service fees paid by drug manufacturers to PBMs might be excessive or misreported—was publicly disclosed in qualifying sources (including sources cited in the SAC) before Borzilleri filed suit. Because Borzilleri cannot qualify as an original source of his allegations, his SAC is foreclosed as a matter of law.

For each of these reasons, as well as those set forth in the PBM Defendants' Motion to Dismiss, the SAC should be dismissed with prejudice. After more than *four* years and *four* attempts to plead a viable FCA claim against the Defendants, Borzilleri is unable to cure the SAC's basic pleading deficiencies because, as he admits, he lacks actual knowledge of any conduct by any Defendant. The Court should not grant him leave to amend again.

BACKGROUND

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Borzilleri filed this *qui tam* suit under seal in January 2014 and a First Amended Complaint on May 1, 2014. Dkt. 6. Following a lengthy investigation, the Department of Justice, all 29 named states, and the District of Columbia declined to intervene in this action, and the First Amended Complaint was unsealed on April 4, 2018. Dkts. 36, 37. Borzilleri then filed the SAC on July 6, 2018 against thirteen Manufacturer and PBM Defendants. Dkt. 57. Borzilleri re-filed the Second Amended Complaint on August 17, 2018, correcting the misjoinder of three parties and making other changes to the allegations. Dkts. 69, 95. The crux of

² In considering a motion to dismiss, the Court may consider facts incorporated by reference in the SAC, matters of public record and those susceptible of judicial notice. *See Lister v. Bank of Am., N.A.*, 790 F.3d 20, 23 (1st Cir. 2015); *see also In re Colonial Mortgage Bankers Corp.*, 324 F.3d 12, 15 (1st Cir. 2003). In particular, the Court may consider any document "integral to or explicitly relied upon in a complaint, even if that document is not annexed to the complaint." *Rederford v. U.S. Airways, Inc.*, 586 F. Supp. 2d 47, 50 (D.R.I. 2008) (Smith, J.), *aff'd sub nom. Rederford v. U.S. Airways, Inc.*, 589 F.3d 30 (1st Cir. 2009) (citations omitted). Copies of such documents are cited herein as "Ex. __" and submitted herewith.

Borzilleri's complaint is his contention that the Manufacturer Defendants paid service fees to PBMs in excess of fair market value in violation of the Federal Anti-Kickback Statute (AKS), and which Medicare Part D plan sponsors did not properly report to CMS. *See* SAC ¶¶ 27, 29, 81, 88–89, 107, 152–53.

A. Regulatory Framework

1. The Medicare Part D Program

Medicare is a federal government health insurance program for the elderly and those with certain disabilities. The Department of Health and Human Services (HHS) operates Medicare through CMS. 42 U.S.C. § 1395 *et seq.* There are four parts to the Medicare program, Parts A through D. *Id.* The SAC concerns only the Medicare Part D program.

Medicare Part D is a voluntary prescription drug benefit program established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pub. L. No. 108-173, 117 Stat. 2066 (2003). Part D plans are operated by plan sponsors, which are private health insurers that contract with CMS to offer health plans with outpatient drug benefits to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-111(b). After contracting with CMS, plan sponsors negotiate drug prices with pharmaceutical manufacturers, establish formularies, and apply utilization management tools, sometimes using the services of PBMs. *See generally* 42 C.F.R. § 423.514. CMS pays plan sponsors in part based on their costs for reimbursing drug claims for their Part D enrollees. Plan sponsors report these costs to CMS in annual cost estimates they submit over the course of a year. *See* 42 C.F.R. § 423.265.

CMS needs to know about discounts that plan sponsors receive from drug manufacturers that may offset costs incurred by the plan sponsors. SAC ¶ 30. As a result, Part D plan sponsors are required to report direct and indirect remuneration (DIR) to CMS, to capture the discounts they receive from manufacturers. 42 C.F.R. § 423.308; Ex. A, CMS Memo to All Part D Plan

Sponsors, *Final Medicare Part D DIR Reporting Requirements for 2016*, at 1 (June 23, 2017) (the “CMS 2016 Reporting Memo”). DIR includes “discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants or other price concessions or similar benefits to some or all purchasers.” *Id.* DIR ultimately reduces CMS’s payments to plan sponsors by offsetting their costs. *See* Ex. B, CMS Memo to All Part D Plan Sponsors, *Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation*, at 9 (June 10, 2010).

Under the Part D program, PBMs may perform services for drug manufacturers, and receive bona fide service fees (BFSFs) in exchange. BFSFs are defined as “fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer.” *See* 42 C.F.R. § 423.501. Borzilleri repeatedly admits that drug manufacturers may pay BFSFs to PBMs for a “wide array” of support services, such as “rebate administration, inventory management, drug shipping/delivery, reimbursement/financial assistance, patient educations/clinical programs, drug adherence programs, phone support, data reports, etc.” SAC. ¶¶ 35, 138. As Borzilleri further acknowledges, BFSFs are a recognized part of the Part D Program. *Id.* ¶¶ 14, 138.

Plan sponsors also may receive BFSFs and must report them to CMS. *See, e.g.,* Ex. A, CMS 2016 Reporting Memo at 28-29 (directing plan sponsors to “[i]nclude in this column of the Summary DIR Report the portions of all fees that meet the definition for “bona fide service fees”). Notably, CMS excludes BFSFs from the definition of DIR, and BFSFs are not treated as discounts by CMS if they are consistent with fair market value.³ 42 C.F.R. § 423.514(d)(4)

³ CMS has repeatedly confirmed that manufacturers are to be given flexibility in determining the fair market value of BFSFs. *See, e.g.,* Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,191 (July 17, 2007) (withdrawn Nov. 2010) (explaining that “in the

(stating that DIR is to “exclude[e] bona fide service fees”); 42 C.F.R. § 423.501. BFSFs that exceed fair market value, however, should be reported as DIR. *See* Ex. A, CMS 2016 Reporting Memo at 29.

So that plan sponsors can accurately report DIR to CMS, PBMs are obligated to provide certain information to plan sponsors. 42 C.F.R. § 423.514 (explaining that “[e]ach entity that provides pharmacy benefits management services must provide to Part D sponsors” information about rebates, discounts and price concessions). Critically, however, *manufacturers have no reporting obligations* for DIR or BFSFs under Part D. *See generally* Ex. A, CMS 2016 Reporting Memo (discussing only plan sponsor obligations to report direct and indirect remuneration to Medicare Part D); *see also* SAC ¶ 244 (citing 42 C.F.R. § 423.514 and referencing reporting requirements that are applicable only to “[e]ach entity that provides pharmacy benefits management services” (emphasis added)). Thus, Borzilleri is simply wrong when he alleges, without support, that “service fees” purportedly in excess of fair market value should be reported “by the Drug Manufacturer to the plan sponsor in Medicare Part D.” SAC ¶ 31; *see also id.* ¶ 152(5).

2. The Federal Anti-Kickback Statute

The Federal AKS prohibits the knowing and willful payment, receipt, or solicitation of “remuneration” to induce the purchase or recommendation of “any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.” 42

absence of specific guidance, manufacturers may make “reasonable assumptions consistent with the statute, regulations and general business practices”); Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318 (February 2, 2012) (“[d]ue to the rapidly changing market in which new types of arrangements arise, we believe that manufacturers should appropriately determine fair market value.”); Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5179 (Feb. 1, 2016) (“Given the continually changing pharmaceutical marketplace, we will continue to allow manufacturers the flexibility to determine the fair market value of a service when evaluating whether the service fee is bona fide or not.”).

U.S.C. § 1320a-7b(b)(1) (B), (2)(B). Because the AKS potentially sweeps in a wide swath of legitimate conduct, the AKS protects a variety of arrangements through statutory exceptions. For example, discounts and rebates are protected under a statutory exception. 42 U.S.C. § 1320a-7b(b)(3)(A). Separately, Congress delegated authority to HHS's Office of Inspector General (OIG) to create regulatory safe harbors that likewise protect various arrangements under the AKS. 42 U.S.C. § 1320a-7b(b)(3)(E).⁴

B. Factual Background

1. Borzilleri's Allegations

Borzilleri describes himself as a professional healthcare "investment fund manager." SAC ¶ 116. While employed at the investment firm of Shepherd Kaplan Krochuk, LLC (SKK), Borzilleri managed and was the largest investor in a health care hedge fund with a short-side focus. Borzilleri came to believe that rising pharmaceutical drug prices were caused by "a straightforward price collusion scheme" between certain pharmaceutical companies and PBMs. SAC ¶ 12.

Borzilleri alleges that large price increases for drugs used to treat multiple sclerosis are primarily caused by contracts between the Manufacturer Defendants and PBMs that provided for excessive service fees. SAC ¶¶ 7, 15, 27. He speculates that service fees paid by Manufacturer Defendants to PBM Defendants are suspect because they purportedly are based upon a

⁴ Although Borzilleri asserts, without support, that BFSFs paid by Manufacturer Defendants are not protected by any statutory exception or regulatory safe harbor, SAC ¶¶ 263, 560-574, various safe harbors may apply depending upon the facts. In particular, one safe harbor protects payments made to Group Purchasing Organizations (GPOs) and explicitly protects percentage-based fees paid by a vendor, such as a pharmaceutical manufacturer, to a GPO. 42 C.F.R. § 1001.952(j)(1). OIG specifically has stated that payments from manufacturers to PBMs can be protected by complying with the GPO safe harbor. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003) (GPO "rebates or other payments" are afforded "[p]rotection" under the AKS by "structuring such arrangements to fit in the GPO Safe Harbor at 42 CFR § 1001.952(j)").

percentage of the drugs' list prices, which he asserts facilitated price inflation, benefitting both the Manufacturer and PBM Defendants. *Id.* ¶ 36. He alleges that, as drug prices increased over time, so too did the service fees, to the point where they exceeded the fair market value of the services provided by the PBMs. *Id.* ¶¶ 35–40. Borzilleri claims that the “service fees in excess of [fair market value] should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D,” but were not, and also asserts that they constituted illegal kickbacks. *Id.* ¶ 31. Borzilleri also alleges that the Manufacturer Defendants routinely forgave a cost-sharing obligation that is triggered for Part D plan sponsors when a drug cost exceeds a threshold amount, *id.* ¶¶ 34, 305–310, in order to “advance the now pervasive ‘service fee’ pricing scheme.” *Id.* ¶ 424. Borzilleri, however, does not plead any allegations regarding a specific contract between any manufacturer and any PBM, any specific BFSF provision, or any reports submitted by any Part D plan sponsors that purportedly mischaracterized any BFSF.

Putting aside that these allegations fail to identify any specific contract, service fee, or false claim involving any of the Manufacturer Defendants, Borzilleri's allegations are also based entirely on publicly available documents and information and raw speculation. Borzilleri relies, for instance, on press releases (SAC ¶¶ 182, 197); congressional documents (*id.* ¶¶ 409, 640); SEC filings (*id.* ¶¶ 80, 99–105, 492, 554, 556, 666–674, 677–690); publicly disclosed PBM contracts (*id.* ¶¶ 112(d), 176, 509–593); reports and other publications from OIG (*id.* ¶¶ 205, 302, 548, 649); court filings (¶¶ 92, 259–262, 287–289); and other publicly available reports, articles, and disclosures (*id.* ¶¶ 68, 70–72, 76, 97, 161–165, 167–173, 181, 189, 409, 498, 638). Borzilleri also heavily relies on alleged statements purportedly made during an October 2013 compliance conference that was open to the public. *See id.* ¶¶ 450–478. Indeed, as Borzilleri acknowledged in connection with a recent suit his former employer SKK filed against him, “the

DOJ indicated that Dr. Borzilleri's investigation and [the] Qui Tam actions were not based upon 'insider information,'" but rather on "Dr. Borzilleri's extensive proprietary research, based upon public information." See Ex. C, Answer & Counterclaims, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418-BLS1, ¶ 32 (Mass. Super. Ct. May 26, 2018).

2. Borzilleri's Second Qui Tam Lawsuit

While DOJ was still investigating the allegations in this action—and in a poorly disguised effort to forum shop—Borzilleri filed a second, nearly identical *qui tam* action in the Southern District of New York (SDNY). See Ex. D, Second Amended Complaint, *Borzilleri v. Abbvie, Inc.*, 15-cv-7881-JMF (S.D.N.Y. Apr. 13, 2018) (the "SDNY SAC"). The action, filed on October 6, 2015, named eight of the same defendants named in this case, as well as five additional manufacturers who are not defendants here. *Id.* Hundreds of paragraphs in the two operative complaints are materially identical to one another, the product of simplistic cutting-and-pasting and only minor editing to reflect different parties and products. Compare, e.g., SAC ¶¶ 3-7, 11-47, 51-68, 81-96, 98-112, with Ex. D, SDNY SAC ¶¶ 3-7, 10-46, 50-67, 79-94, 114-28. In fact, the SAC in this case asserts facts that are wholly irrelevant to this case and applicable only to Defendants or drugs named in the SDNY case. See, e.g., SAC ¶¶ 661-662.

On March 13, 2018, just five days after the government declined to intervene in this case, the Department of Justice, all of the named states, and the District of Columbia declined to intervene in the SDNY action. See *Borzilleri*, 15-cv-7881-JMF (S.D.N.Y.), Dkt. 19. The Complaint in that case was unsealed on April 13, 2018. *Id.* On October 1, 2018, the SDNY Defendants filed two joint motions to dismiss the SDNY SAC, which are now pending. *Borzilleri*, 15-cv-7881-JMF (S.D.N.Y.), Dkts. 258, 259.

3. Borzilleri's Short Selling

Armed with the knowledge that his two complaints would soon be unsealed, Borzilleri undertook a scheme of his own that ultimately resulted in his termination. After the government declined to intervene in either of Borzilleri's actions, but before the two *qui tam* complaints were unsealed, Borzilleri significantly increased the short positions of his hedge fund against the securities of the defendants in the two *qui tam* lawsuits. Ex. E, Complaint, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418-BLS1, ¶¶ 32, 35 (Mass. Super. Ct. May 8, 2018). In fact, "[b]y April 17, 2018, the seven largest short positions in the Fund were against the securities of the defendants" named in one or both of Borzilleri's complaints. *Id.* ¶ 37.

Upon the complaints being unsealed, Borzilleri sent the complaints to major media and financial institutions, along with a press release, which Borzilleri admits, "make substantially negative allegations about the defendants in those actions." See Ex. E, ¶¶ 38–40 (SKK Complaint); Ex. C, ¶¶ 38–40 (Answer & Counterclaims). Once SKK became aware of Borzilleri's press release and his conduct, the firm investigated Borzilleri's conduct and terminated him for "aggressive trading during the period in which he knew that information about the [lawsuits] would soon be made available to the public," and ultimately filed a lawsuit against him on May 9, 2018. *Id.* ¶ 52. Borzilleri's blatant attempt to capitalize from his *qui tam* complaints is further evidence of his opportunistic motives.

ARGUMENT

I. THE SAC IS DEFICIENTLY PLED UNDER RULES 9(b) AND 8(a)

The SAC is subject to dismissal for an assortment of pleading deficiencies. An FCA complaint must satisfy both Rule 9(b)'s heightened pleading standard and Rule 8(a)'s plausibility pleading standard; those that fail to do so are subject to dismissal under Rule 12(b)(6). To satisfy Rule 9(b)'s particularity requirement, a False Claims Act complaint must set forth the "who,

what, when, where, and how” of the alleged fraud. *United States ex rel. Ge v. Takeda Pharm. Co., Ltd.*, 737 F.3d 116, 123 (1st Cir. 2013) (citation omitted). “The FCA penalizes those who present, or cause to be presented, ‘false or fraudulent claim[s] for payment or approval’ to the federal government.” *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016) (quoting 31 U.S.C. § 3729(a)(1)). Thus, fraud alleged under the FCA must contain two components pled with particularity in accordance with Rule 9(b): “the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent.” *Id.* The heightened pleading standard therefore applies both to the underlying fraudulent scheme and to allegations that a defendant submitted or caused the submission of a false claim.

Recognizing that the FCA at times attracts “parasitic” relators, the First Circuit has oft explained:

[A] relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity.

Ge, 737 F.3d at 123 (quoting *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 232–233 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. Inc. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)). While this information does not “constitute a checklist,” a relator must include at least some of it to satisfy Rule 9(b). *Ge*, 737 F.3d at 123.

Critically, a relator may not merely “rais[e] facts that suggest fraud was possible,” but instead must provide evidence beyond possibility. *United States ex. rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 13 (1st Cir. 2016). Similarly, allegations that fraud “could have”

taken place fail under Rule 9(b). *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 6–7 (1st Cir. 2016).

Furthermore, “[c]onclusory allegations and references to ‘plans and schemes’ are not sufficient” to satisfy Rule 9(b). *Kelly*, 827 F.3d at 13; *see also United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) (“Conclusory allegations . . . are not sufficient to satisfy Rule 9(b).”) (alteration in original) (internal quotations omitted). In short, arguments that proceed from insinuation or surmise instead of facts fail under Rule 9(b). *Hagerty*, 844 F.3d at 33.

To adequately plead a false claim in an action where “the defendant is alleged to have induced third parties to file false claims with the government,” a relator must, at a minimum, provide “‘factual or statistical evidence to strengthen the inference of fraud beyond possibility,’” if he or she is unable to provide “‘details as to each false claim.’” *Ge*, 737 F.3d at 123–24. In such cases, the First Circuit has made clear that where relators offer only “aggregate expenditure data” for the drug at issue without “identify[ing] specific entities who submitted claims . . . much less times, amounts, and circumstances,” their claim falls far short. *Ge*, 737 F.3d at 124. And “[m]erely alleging that a scheme was wide-ranging—and, therefore, that a fraudulent claim was presumably submitted—will not suffice” either. *Kelly*, 827 F.3d at 13–14.

In addition to Rule 9(b)’s rigorous pleading standards, an FCA complaint must satisfy Rule 8(a)’s plausibility standard. In considering a motion to dismiss, “a court must accept all factual allegations in the complaint as true,” but the Court need not accept as true conclusory allegations, and “a formulaic recitation of the elements of a cause of action will not do.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Accordingly, a complaint’s well-pled factual content must “allow[] the court to draw the reasonable inference that the defendant is liable for the

misconduct alleged.” *Id.* The Court must dismiss claims that do not cross the line “from conceivable to plausible.” *Id.* at 680.

**A. The SAC’s Allegations Regarding A
“Service Fee” Scheme Do Not Satisfy Rule 9(b) Or 8(a)**

**1. The SAC Fails To Plead A Fraudulent
Service Fee Scheme Plausibly And With Particularity**

Borzilleri alleges a scheme in which the Manufacturer Defendants contractually agreed to pay a percentage of their drugs’ list price as “service fees” to the PBM Defendants. SAC ¶ 15, 27. He claims that at least a portion of the service fees are not BFSFs within the meaning of Part D because, as the drugs’ prices increased over time, the percentage-based service fees exceeded the fair market value of any services being provided by the PBM. *See generally id.* ¶¶ 35–47. He asserts that Part D plan sponsors failed to properly report service fees exceeding fair market value to CMS. *Id.* ¶ 31. His theory is that Medicare Part D plan sponsors’ misreporting of service fees affected the amount that CMS paid plan sponsors, making plan sponsors’ requests to CMS for payment “false claims” within the meaning of the FCA.

The SAC pleads a daisy chain of hypotheses, and nothing more. Because the prices of certain drugs have increased over time, Borzilleri believes that the Manufacturer Defendants *must have* entered into secret contracts with PBMs to pay service fees that exceed fair market value for any services, which *must have* led to above fair market value service fees, which a PBM *must not have* properly reported to the plan sponsor, which the plan sponsor *must not have* properly reported to CMS. But, strikingly, Borzilleri does not allege the amount of any service fee paid by any Manufacturer Defendant, nor the details of any contract between any PBM and any Manufacturer Defendant, nor how PBMs reported these service fees to a plan sponsor, nor how that plan sponsor ultimately reported these fees to the government. He readily admits that he lacks all of these details. *See, e.g.,* SAC ¶ 162 (“the individual ‘service fee’ contracts between

the Manufacturer and the PBM Defendants remain a closely guarded secret”) (emphasis omitted); *see also id.* ¶¶ 223, 265; *id.* ¶ 197 (same); *id.* ¶ 434 (noting need to rely on discovery for information concerning reporting). Without such details, the SAC is devoid of facts that could move Borzilleri’s allegations from the realm of the possible to the plausible, *Iqbal*, 556 U.S. at 679, let alone provide the particularity required by Rule 9(b).

Borzilleri admits that whether a manufacturer pays a service fee to a PBM for a given drug—and if so, whether the fee is a percentage of the list price or something else—“depend[s] upon specific contractual terms” of contracts that he is only speculating exist. SAC ¶¶ 225-226; *see also id.* ¶ 537 (“[W]e anticipate a thorough investigation of these fraud allegations must include a review of all economic transfers between the Manufacturer and PBM Defendant, starting with their contractual agreements.”). Borzilleri clearly has never seen the contracts about which he spends nearly 200 pages postulating. He knows nothing about their terms and has not read even one. Not surprisingly, then, the SAC omits any allegation regarding any actual contract between any Manufacturer Defendant and any PBM Defendant. The SAC also fails to plead any facts suggesting that any hypothetical service fees paid by any Manufacturer Defendant exceeded fair market value. The SAC certainly does not plead that any Manufacturer Defendant paid any PBM a service fee that was not properly reported to a plan sponsor or CMS. The SAC thus fails to plead—even plausibly, let alone with particularity—the fraudulent scheme Borzilleri alleges.

Lacking any specific details that might make his allegations plausible, Borzilleri relies on speculation. *See, e.g.*, SAC ¶ 363 (“Without the pricing scheme, we *estimate* that overall combined US sales for the 7 Defendant MS drugs would have remained flat in the \$2.5 billion range between 2005 and 2017. We *assumed* a US launch prices of \$30,000 patient/year for

Gilenya and Tecfidera, far higher than the \$17-19,000 range in Europe”) (emphasis added); *see also* SAC ¶¶ 364–395. While building assumptions onto hypotheticals onto guesswork, Borzilleri’s SAC “ignores the fact that it is the fraud itself which must be pled with particularity.” *Gagne*, 565 F.3d at 47; *see also United States ex rel. Cavallino Consulting, LLC v. Smith & Nephew, Inc.*, No. 17-CV-11517-IT, 2018 WL 3966301, at *2 (D. Mass. Aug. 17, 2018) (holding that under the First Circuit “fraud itself must be pled with particularity, and the complaint must connect the fraud alleged to an effort to get false claims paid or approved by the government, including some details on the alleged fraudulent submissions to the government”). Here, Borzilleri simply hypothesizes that a fraudulent scheme occurred and that the Manufacturer Defendants would have benefited from his speculative fraud. This does not suffice to plead a fraudulent scheme under Rule 8(a) or Rule 9(b).

2. The SAC Fails To Plead Any False Claims Plausibly And With Particularity

Even if the SAC pleaded plausibly and with particularity that the Manufacturer Defendants paid PBMs service fees in excess of fair market value that should have been reported as discounts by a Part D plan sponsor, Borzilleri would still need to plead facts sufficient to suggest that such fees actually were improperly reported to Medicare and that false claims resulted. As the First Circuit has explained, “the defendant’s presentation of false or fraudulent claims to the government is a central element of every False Claims Act case. A health care provider’s violation of government regulations or engagement in private fraudulent schemes does not impose liability under the FCA unless the provider submits false or fraudulent claims to the government for payment based on these wrongful activities.” *Karvelas*, 360 F.3d at 232; *see id.* at 225 (“[T]he statute attaches liability, not to the underlying fraudulent activity or to the government’s wrongful payment, but to the claim for payment. Evidence of an actual false claim

is the *sine qua non* of a False Claims Act violation.” (citation and internal quotation marks omitted)).⁵ Simply put, the SAC fails because it is devoid of *any* factual allegations that might tie any purported service fees paid by a Manufacturer Defendant to any hypothetical claims submitted by a Part D plan sponsor or that create an inference that such claims were submitted.

The SAC fails to specifically identify a single false claim, and does not even plausibly plead that any false claims were submitted. The SAC contains no facts whatsoever regarding the information purportedly provided by any PBM to any plan sponsor, and certainly never alleges with particularity that any plan sponsor improperly characterized a service fee in its reports to CMS. Borzilleri does not claim to know *who* prepared or submitted any DIR report, *what* service fees were or should have been included in any report, *how* any reported amount was calculated, *why* any calculation was improper, or *whether* any Manufacturer Defendant had any knowledge of what was reported. *See id.* ¶ 31. These are gaping holes in his theory, and are fatal to the SAC. *See D’Agostino*, 845 F.3d at 10.

In *D’Agostino*, the First Circuit held that to plead the submission of a false claim with particularity, a relator generally needs to provide “examples of actual false claims submitted to the government.” *Id.* “By doing so, the relator conveys that if the facts alleged are true, the filing of a false claim is not merely a possibility, but rather, necessarily occurred.” *Id.* While the First Circuit has recognized a limited exception to this rule in cases in which a defendant is alleged to have caused a third party to submit a false claim, such cases must still be supported by “factual or statistical evidence to strengthen the inference of fraud beyond possibility.” *Id.* (internal quotation marks omitted); *see also Ge*, 737 F.3d at 124. The SAC fails to satisfy this

⁵ For that reason, “Rule 9(b)’s particularity requirement applies with full force” to alleged false claims asserted under sections 31 U.S.C. §§ 3729(a)(1) and (a)(2), (*see* SAC ¶¶ 693-694, 709-715). *Ge*, 737 F.3d at 129 n.5; *Karvelas*, 360 F.3d at 232; *Gagne*, 565 F.3d at 46.

limited exception. It offers only generalized data regarding the pharmaceutical industry, none of which provides a basis for inferring that the Manufacturer Defendants induced plan sponsors to submit false claims. *See, e.g.*, SAC ¶ 3 (asserting that pharmaceutical spending consumes 17% of the U.S. economy); ¶ 9 (asserting that list prices for four of the drugs at issue in this case have increased from 2005 to 2018 while prescriptions and usage have plummeted 40–70%). To the contrary, the data the SAC cites is precisely the type of generalized statistics that the First Circuit has repeatedly found insufficient to support an inference of fraud. *See Ge*, 737 F.3d at 124 (dismissing claim where plaintiff provided “aggregate expenditure data for one of the four subject drugs, with no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances.”); *Lawton ex rel. United States v. Takeda Pharm. Co., Ltd.*, 842 F.3d 125, 132 (1st Cir. 2016) (holding that allegations regarding the percentage of off-label sales and the amounts of Medicare and Medicaid funds spent on the drug at issue were insufficient to create an inference of fraud). As further demonstrated below, nothing in the SAC provides either the statistics or the facts necessary to establish the strong inference of submission of a false claim by a third party. *See Kelly*, 827 F.3d at 14; *Ge*, 737 F.3d at 124.

(a) **The SAC’s Few Allegations About Individual Manufacturer Defendants Are Insufficient And Group Pleading Does Not Satisfy Rule 9(b)**

The SAC’s allegations that relate to the individual Manufacturer Defendants are small in number, narrow in scope, and, at best, weave a conclusory theory based on general information about the distribution of pharmaceuticals. Borzilleri offers purported data about the list prices, revenues and profits of the Manufacturer Defendants’ drugs, asserts that there has been “staggering” harm to the public fisc, and guesses, without any factual support, that “30%” of the

sales of the Manufacturer Defendants' products is "attributable to the Part D program." SAC ¶ 94. None of this suffices to plead either a fraudulent scheme or a false claim.

For each of the products at issue, Borzilleri alleges (at length) that the drug's list price, revenues, and profits have increased over time. *See, e.g., id.* ¶¶ 227–234; 301–396. He alleges that usage has decreased over time and constructs charts depicting how (according to him) the total dollar value of sales for those drugs would have been lower without price increases. *See, e.g., id.* ¶¶ 301–396. Finally, for some of the drugs, he makes allegations about other available drugs in the same drug class and market share. *See, e.g., id.* ¶¶ 313, 321, 327. These allegations have one thing in common: they say nothing about any supposedly fraudulent service fee paid by any Manufacturer Defendant or any allegedly false claims submitted to Medicare Part D. Rather, Borzilleri's allegations regarding the Manufacturer Defendants' drugs amount to mere speculation about a market that Borzilleri admits is complex and influenced by numerous factors. They certainly do not plead a fraudulent scheme with particularity or provide any inference to suggest any false claims were submitted to the government. They therefore do not meet the requirements of either Rule 8(a) or Rule 9(b).

Lacking specific facts about any Manufacturer Defendants' conduct, the SAC relies on impermissible group pleading. Many of the SAC's allegations refer only to the "Manufacturer Defendants"—seven separate companies—and "PBM Defendants"—six separate companies. *See, e.g.,* SAC ¶¶ 27, 29, 32, 34, 36, 38, 41, 48, 49, 68, 72, 73, 79–81, 85, 89, 96, 123, 152–153, 157–159, 164, 243, 249, 268, 290, 308–310, 313, 386, 388, 392, 394, 431, 435, 525, 538, 558, 623. Using those terms, the SAC then makes the sweeping allegation that drug manufacturers and PBMs have defrauded the government through percent-of-list-price service fees that are not reported appropriately to plan sponsors or CMS. *E.g., id.* ¶ 36 ("The fraudulent Manufacturer

Defendant ‘service fee’ payments to the PBM Defendants are standardly calculated via secretive ‘percent of revenue’ contracts[.]”). Such group pleading fails to satisfy Rule 9(b)’s heightened pleading standard.

As this Court has previously explained, “it is well established that ‘[w]here multiple defendants are involved, each person’s role in the alleged fraud must be particularized in order to satisfy Rule 9(b).’” *W. Reserve Life Assur. Co. of Ohio v. Caramadre*, 847 F. Supp. 2d 329, 343 (D.R.I. 2012) (Smith, J.) (citations omitted) (collecting cases). A plaintiff may not allege wholesale fraud on the part of multiple defendants absent “particularized allegations of each [d]efendant’s role.” *Id.*; see also *Rick v. Profit Mgmt. Assocs., Inc.*, 241 F. Supp. 3d 215, 224 (D. Mass. 2017) (dismissing fraud claim against multiple defendants because the plaintiff failed to allege with particularity the specific role of each in the alleged fraud). Indeed, the purpose of Rule 9(b)’s particularity requirement “is to ‘give notice to defendants of the plaintiffs’ claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage ‘strike suits,’ and to prevent the filing of suits that simply hope to uncover relevant information during discovery.’” *Karvelas*, 360 F.3d at 226 (quoting *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996)).

The SAC’s group pleading contravenes each of these purposes. The SAC repeatedly acknowledges that Borzilleri cannot offer individualized allegations absent discovery. *E.g.*, SAC ¶ 162 (Borzilleri has no knowledge of individual contracts absent discovery), ¶ 196 (noting financial terms and transactions will be key part of discovery in case.) And each Manufacturer Defendant is entitled to know—specifically—the PBM(s) with which it is being accused of committing service-fee fraud, during what time period, and with what supposedly improper service-fee terms. Further, each Manufacturer Defendant is entitled to know—specifically—

what plan sponsor ultimately submitted an allegedly false claim, when the plan sponsor submitted the claim, and how the Manufacturer Defendants knew the plan sponsor would submit the claim. Courts have repeatedly made clear that fraud claims against multiple defendants must separately set forth each defendant's allegedly fraudulent acts to advise each defendant of the nature of the allegations against it. *See, e.g., Ezell v. Lexington Ins. Co.*, No. 17-10007-NMG, 2018 WL 4654706, at *5 (D. Mass. Sept. 27, 2018) (granting motion to dismiss against various insurance companies because “where there are multiple defendants, the specific role of each must be alleged”); *Rick*, 241 F. Supp. 3d at 224. As a result, Borzilleri's reliance on group pleading renders the SAC deficient—and subject to dismissal—under Rule 9(b).

**(b) The SAC's “Sources” Contradict
Its Allegations, Do Not Ascribe Conduct
To Any Manufacturing Defendant, Or Both**

Nor can Borzilleri meet Rule 9(b)'s requirements by virtue of the “sources” underlying his allegations. None of these sources comes close to pleading with particularity any fraudulent service fee paid by any Manufacturer Defendant or any resulting false claim for any drug.⁶

To the contrary, the SAC is replete with citations to sources that contradict Borzilleri's allegations. For example, the SAC claims that an “incriminating” report published by PhRMA “discloses” that drug manufacturers pay PBMs a “standard,” “typical,” or “average” service fee of 8% of a “specialty” drug's list price. SAC ¶¶ 68, 161–172 (citing “PhRMA Report” attached as Ex. F). Curiously, Borzilleri then compares this 8% “average” to estimates he made in earlier filings with the Court, apparently trying to draw an inference based on his own faulty assumptions. SAC ¶¶ 68, 97, 163, 165–178, 174. Far from being “incriminating,” the PhRMA

⁶ Equally importantly, as these sources were previously publicly disclosed, Borzilleri's reliance upon them precludes his SAC under the FCA's public disclosure bar. *See infra* Section II.

report directly contradicts Borzilleri's position that it "disclosed average contract terms for 'service fees.'" *Id.* ¶ 163 (emphasis omitted). The report describes complexities in the drug distribution and payment system and emphasizes that "[b]ecause payment terms are determined through confidential, private negotiations, the terms of individual contracts are highly variable[.]" PhRMA Report at 2 (emphasis added); *see also id.* at 1, 9. While the report offers "illustrative examples" depicting what three patients might pay for a drug under different cost-sharing mechanisms (copayment, deductible, and coinsurance), the report says nothing about standard, typical, or average levels of service fees in Part D contracts. *Id.* at 10–15. And the report certainly does not mention any conduct by any Manufacturer Defendant. The report thus contradicts Borzilleri's claim that it provides a basis to infer a standard service fee across manufacturers and contracts, and cannot help Borzilleri survive dismissal.⁷

Borzilleri relies on a second document that he describes as "definitively incriminat[ing] both Defendant parties in the 'service fee' scheme." SAC ¶ 179. This document, a report prepared for the Pharmaceutical Care Management Association (PCMA) also does not help him establish an inference of fraudulent service fees paid by any Manufacturer Defendant. *See Ex. G.* The document is limited to discussing rebates and price increases; it contains no discussion—none—of service fees, much less any fraudulent service fees. It therefore provides no support

⁷ As this Court has summarized: "when the complaint adverts to specific written instruments but does not attach them, the court may credit the actual terms of the instruments and reject the plaintiff's inconsistent conclusory characterization of them in granting a motion to dismiss." *Pimental v. Wells Fargo Bank, N.A.*, C.A. No. 14-494S, 2015 WL 5243325, at *4 (D.R.I. Sept. 4, 2015), report and recommendation adopted, 2016 WL 70016 (D.R.I. Jan. 6, 2016); *see also Newman v. Lehman Bros. Holdings Inc.*, 901 F.3d 19, 27 (1st Cir. 2018) (noting that a plaintiff may plead himself out of court through documents referenced in complaint because when a written instrument contradicts the allegations of the complaint, the instrument trumps the complaint).

for an allegation that any Manufacturer Defendant violated the FCA through service fee payments.

The remaining sources of “information” on which Borzilleri’s speculative theory is based fare no better. He claims to rely on consultants who he alleges told him “that they had never seen or reviewed a single ‘service fee’ contract between a PBM and a drug manufacturer.” SAC ¶ 175. As a result, those consultants plainly have not seen or reviewed any service-fee contract that Borzilleri theorizes might exist for the drugs at issue. Similarly, Borzilleri’s alleged discussion with the CEO of a company *not named as a defendant* (*id.* ¶¶ 446–47) does nothing to make plausible Borzilleri’s speculative theory that each Manufacturer Defendant paid kickbacks in the form of service fees or caused false claims. Nor does his description of an industry conference—which was open to anyone interested in attending—at which there was general discussion about service fees and various fair market valuation methodologies (*id.* ¶¶ 450–87) provide an indication that any manufacturer generally, or any Manufacturer Defendant specifically, paid Part D service fees that were improperly reported. Certainly nothing about this conference indicates that any Manufacturer Defendant participated in a price collusion scheme designed to cheat Medicare.

Finally, the handful of contracts between PBMs and employers providing employees insurance referenced in the SAC (*id.* ¶¶ 575–99) also provide no information from which the Court could infer that any Manufacturer Defendant paid fraudulent service fees. The contracts between payers and PBMs say nothing about the Manufacturer Defendants other than that service fee arrangements may exist. *Id.* ¶¶ 581, 595. These payer contracts do not identify the amount of the service fees, the details of any service fee paid, or the submission of any claim to

the government. That leaves Borzilleri with just his own self-serving speculation and conclusions.

**(c) Borzilleri Cannot Rely Upon Discovery
To Generate The Facts Missing From His SAC**

Borzilleri believes that he can use discovery to fill in the following holes: to obtain contracts from the Defendants, to analyze financial transactions between the parties, to determine the propriety of DIR reporting by plan sponsors, and to find false claims. *E.g., id.* ¶¶ 105, 162, 196, 197, 349, 434. He is wrong. The First Circuit emphasizes that courts do not permit relators to use discovery to meet the requirements of Rule 9(b), recognizing “a concern that a *qui tam* plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs.” *Karvelas*, 360 F.3d at 231 (“[W]e hold that a *qui tam* relator may not present general allegations in lieu of the details of actual false claims in hopes that such details will emerge through subsequent discovery.”); *see also Cavallino Consulting*, 2018 WL 3966301, at *3 (dismissing *qui tam* action under Rule 9(b) and noting that a “*qui tam* relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery”); *Driscoll v. Simsbury Assocs., Inc.*, No. 17-CV-12373-ADB, 2018 WL 2139223, at *4 (D. Mass. May 9, 2018) (dismissing FCA claims under Rule 9(b) because a “[p]laintiff may not present general allegations and seek to amend the complaint after discovery, but rather, she is required to plead her claims with particularity at the outset”).

Precisely because of this concern that *qui tam* plaintiffs will file lawsuits without particularized allegations to gain access to discovery fishing expeditions, an FCA relator cannot plead generally as Borzilleri has done here. The breadth of the discovery Borzilleri proclaims would be necessary exemplifies the danger of allowing a relator to spin a fantastic tale of

wrongdoing in hopes of propounding discovery. *See* SAC ¶ 537 (asserting that Borzilleri's theory about service fees requires examination of "all economic transfers between the Manufacturer and PBM Defendants"). Such an outcome would run counter to Rule 9(b). Borzilleri can offer nothing but his conjecture that a contract might exist between some Manufacturer Defendant and some PBM Defendant, that under this hypothetical contract some service fee may have been paid, that the hypothetical service fee may have exceeded the fair market value for the services provided, that the hypothetical amount over fair market value may not have been appropriately reported to CMS, and that false claims may exist. That is a far cry from the particularity necessary to satisfy Rule 9(b). *See D'Agostino*, 845 F.3d at 10; *Gagne*, 565 F.3d at 47.

(d) **Borzilleri's False Certification Theory Does Not Plead A False Claim Plausibly And With Particularity**

As an apparent alternative theory, Borzilleri half-heartedly alleges the Manufacturer Defendants violated the FCA based on the "express certification" theory of liability. An express certification claim may arise when the party making the claim for payment expressly represents compliance with a statute or regulation, *U.S. ex rel. Bierman v. Orthofix Int'l, N.V.*, 113 F. Supp. 3d 414, 420 (D. Mass. 2015), and compliance is material to the Government's decision to pay. *See United States ex rel. Escobar v. Universal Health Servs. Inc.*, 842 F.3d 103, 109 (1st Cir. 2016). Borzilleri, however, fails to plead any actual express certification. In one brief sentence, Borzilleri alleges that Manufacturer Defendants are liable because of a supposed express certification requirement. SAC ¶ 152(8). But that is the only reference in the SAC to an express certification requirement for Manufacturer Defendants, and Borzilleri provides no other detail. Indeed, the only support that Borzilleri provides regarding an express certification requirement generally are citations to 42 C.F.R. § 423.505, which imposes certification requirements on only

Part D plan sponsors and subcontractors of Part D plan sponsors, *not drug manufacturers*. See, e.g., *id.* ¶¶ 135–36, 151, 153, 257–58. An FCA case based on the express false certification theory rises or falls on the existence of actual certifications. *United States ex rel. Gelbman v. City of New York*, No. 14-CV-771 (VSB), 2018 WL 4761575, at *7 (S.D.N.Y. Sept. 30, 2018) (dismissing claim based on express certification theory because relator failed to plead an actual certification that was either signed or caused to be signed by the defendant). Yet, Borzilleri fails to allege any express certification requirement for Manufacturer Defendants or an actual express certification that Manufacturer Defendants made to the Government that relates to service fees or any other conduct alleged in the SAC. Accordingly, to the extent Borzilleri’s FCA claims are predicated on an express certification theory, those claims fail under Rules 8(a) and 9(b) as well.

B. The SAC’s Catastrophic Cost-Sharing Theory Does Not Satisfy Rule 9(b) or 8(a)

Borzilleri also speculates that Manufacturer Defendants engaged in “cost-sharing fraud” by “fraudulently excusing” a cost-sharing obligation that exists for Part D plan sponsors when a participant’s drug costs exceed a certain threshold amount. SAC ¶¶ 423–33. Borzilleri theorizes that because drug prices have increased in recent years, Defendants must have entered into a “secretive fraudulent financial arrangement” to avoid “unforeseen ‘cost sharing’ exposure.” *Id.* ¶ 423. Borzilleri’s speculative discussion about supposed “cost-sharing fraud” lacks any specific facts sufficient to satisfy Rule 9(b)’s pleading requirements.

First, this theory inappropriately relies entirely on group pleading, referring to Defendants (both Manufacturer and PBM) collectively. (See *supra* Section I.A.2(a).)

Second, Borzilleri’s discussion regarding the alleged cost-sharing scheme is rife with speculation, conjecture, and assumptions. For example, he speculates that “[t]he only way the PBM Defendants could avoid tremendous dislocation” from increased cost-sharing obligations is

through a fraudulent scheme. SAC ¶ 423. Borzilleri further hypothesizes, “[i]f the Manufacturer Defendants are commonly ‘forgiving’ the PBM Defendants from their Part D catastrophic exposure, these amounts should be properly reported as discounts . . . to CMS, serving to lower program ‘negotiated’ drug prices.” *Id.* ¶ 431 (emphasis added). Such baseless allegations cannot plausibly state a claim because they are mere conjecture. *Twombly*, 550 U.S. at 555 (2007). And they certainly are insufficient to plead an inference of fraud beyond possibility as required under Rule 9(b) because it is “not enough simply to ‘raise facts that suggest fraud was possible.’” *Kelly*, 827 F.3d at 13 (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). Accordingly, all claims related to alleged “cost-sharing fraud” should be dismissed.

C. The SAC’s Kickback Theory Fails To Satisfy Rule 9(b) And 8(a)

In addition to alleging that service fees purportedly paid by Manufacturer Defendants to PBMs exceeded fair market value and should have been reported by plan sponsors as discounts, Borzilleri characterizes those service fees as kickbacks to PBMs in exchange for “formulary access” and their alleged agreement to forego “standard PBM cost-savings practices that would lead to far lower Defendant drug prices.” SAC ¶¶ 80, 81, 152(2), 709–15. Yet he identifies no payments made by any Manufacturer Defendant to any PBM, let alone any facts or circumstances to indicate any such payment was intended as an inducement for formulary access or to avoid cost-saving measures. Generalized assertions that the Manufacturer Defendants paid unlawful kickbacks for formulary access fall woefully short of what Rule 9(b) requires. *Ge*, 737 F.3d at 123 (a complaint must set forth the “who, what, when, where, and how” of the alleged fraud).

Indeed, Borzilleri’s kickback theory amounts to “no more than conclusions, [which] are not entitled to the assumption of truth” and do not even suffice under Rule 8(a). *Iqbal*, 556 U.S. at 679. Borzilleri appears to hypothesize kickbacks predicated on the difference between the

service fees actually paid and the presumably lower fair market value of the underlying services. SAC ¶¶ 81, 153(2). The SAC, however, identifies neither the service fees actually paid nor the fair market value of the services. As such, Borzilleri's kickback theory is not even superficially plausible.

D. The SAC Fails To Adequately Allege Scienter

To establish liability under the FCA, Borzilleri must prove that the Manufacturer Defendants, as entities that do not submit claims to the Government, "knowingly" caused the submission of false claims. An entity acts "knowingly" if it "(i) had actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (ii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA's scienter requirements are "stringent." *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989, 2002 (2016). The SAC, which contains no specific, plausible allegations regarding Manufacturer Defendants' knowledge, falls far short of meeting this requirement.⁸

Although Rule 9(b) allows a plaintiff to allege intent "generally" rather than "with particularity," conclusory allegations and speculation are insufficient to plead scienter. *See Greenstone v. Cambex Corp.*, 975 F.2d 22, 25 (1st Cir. 1992) ("The courts have uniformly held inadequate a complaint's general averment of the defendant's 'knowledge' of material falsity, unless the complaint *also* sets forth specific facts that make it reasonable to believe that defendant knew that a statement was materially false or misleading." (emphasis in the original) (citation omitted), *superseded by statute on other grounds*; see also *U.S. ex rel. Pilecki-Simko v.*

⁸ In addition, to the extent that the SAC attempts to assert an FCA claim predicated upon an AKS violation, it must plead that the Manufacturer Defendants "knowingly and willfully" paid excessive service fees in exchange for formulary access or PBM acquiescence to price increases. 42 U.S.C. § 1320a-7b(b). The SAC also fails to meet this requirement.

Chubb Inst., 443 F. App'x 754, 761 (3d Cir. 2011) (affirming dismissal of FCA claims where plaintiff failed to allege facts such as how the defendant companies “documented, or were aware or informed of the [alleged] violations, that would support a plausible claim that they knowingly submitted false claims”).

Borzilleri fails to allege the Manufacturer Defendants’ knowledge of any step of Borzilleri’s attenuated hypothetical scheme, let alone any knowledge of “obvious risks” that false claims were being submitted. The SAC does not allege with any specificity that Manufacturer Defendants knew or should have known that any fees paid to PBM Defendants were fraudulent. Moreover, even if Borzilleri’s speculation regarding the alleged fraudulent scheme is correct and Part D plan sponsors submitted inaccurate reports, the SAC does not include any allegations that the Manufacturer Defendants knew or should have known anything about the reports submitted by Part D plan sponsors, let alone whether they mischaracterized service fees. *See United States ex rel. Modglin v. DJO Glob. Inc.*, 114 F. Supp. 3d 993, 1024 (C.D. Cal. 2015), *aff’d sub nom. United States v. DJO Glob., Inc.*, 678 F. App'x 594 (9th Cir. 2017) (finding that scienter was not adequately alleged and dismissing FCA complaint where relator alleged no facts giving rise to a reasonable inference that medical device manufacturers were on notice of alleged false claims). Instead, Borzilleri relies solely on his own hypotheses and conjecture to allege implausibly that Defendants “knew or should have known” about various aspects of an alleged scheme to submit false claims. *See, e.g.*, SAC ¶¶ 43, 152. In short, the SAC is devoid of facts regarding Manufacturer Defendants’ knowledge of any alleged scheme. For this additional reason, Borzilleri’s FCA claims should be dismissed.

E. The SAC’s Other Federal FCA Claims Fail

1. The SAC Fails To State An FCA Conspiracy Claim Plausibly And With Particularity

Borzilleri also attempts to plead an FCA conspiracy. Like other FCA liability theories, conspiracy under the FCA must be pled with particularity. *Gagne*, 565 F.3d at 45. For all of the reasons discussed above, the SAC fails to plead an underlying FCA violation with the requisite particularity; it therefore cannot state a claim for a conspiracy to violate the FCA. *See United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 269 (D. Mass. 2015) (“Because the complaint does not state allegations of fraud under the FCA with the particularity required by Rule 9(b), the conspiracy claim under the FCA must fall as well.”). The SAC also must be dismissed because it offers no particularized allegations of a conspiracy to defraud the government. *Id.*

The SAC’s conspiracy claim fails because Borzilleri has not even plausibly alleged facts showing an unlawful agreement between any Manufacturer Defendant and any PBM Defendant or any overt act taken pursuant to that agreement. *See United States ex rel. Estate of Cunningham v. Millennium Labs. of California*, No. 09-12209-RWZ, 2014 WL 309374, at *2 (D. Mass. Jan. 27, 2014) (holding relator’s complaint failed to allege agreement and actions in furtherance of agreement and therefore should be dismissed). Borzilleri instead vaguely claims collusion exists and offers the entirely conclusory statement that Defendants conspired “to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims” and “took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.” SAC ¶ 700. The SAC never details any Defendant’s entry into an agreement to violate the FCA—*when* the agreement occurred, *who* was involved, *how* it originated, and *what* the details of it were—or what overt acts in furtherance of the agreement followed. This does not suffice. *See United States ex rel. Gagne v. City of*

Worcester, No. 06-40241-FDS, 2008 WL 2510143, at *5 (D. Mass. June 20, 2008) (dismissing conspiracy and other FCA claims where complaint was “rife with abstract, repetitive, and somewhat incoherent allegations of conspiracy and administrative wrongdoing”). Count Two of the SAC therefore must be dismissed.

**2. The SAC Fails To State A
Reverse False Claim Plausibly And With Particularity**

Count Three of the SAC alleges that the Manufacturer Defendants violated 31 U.S.C. § 3729(a)(7) (now 31 U.S.C. § 3729(a)(1)(G)), which provides a cause of action where the defendant has made what is commonly known as a “reverse false claim.” Whereas a traditional false claim action involves a false or fraudulent statement made to the Government to support a claim for money *from* the Government, a typical reverse false claim action involves a defendant knowingly making a false statement to avoid a payment *to* the Government when payment is otherwise due. *Id.* Here, Borzilleri alleges the “Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government.” SAC ¶ 705. An “obligation” is an established duty, whether fixed or not, arising from . . . the retention of any overpayment.” 31 U.S.C. § 3729(b)(3); *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc.*, No. 15-13065-PBS, 2018 WL 4539684, at *6 (D. Mass. Sept. 21, 2018). There “is no liability for obligations to pay that are merely potential or contingent.” *Id.*

Count Three is misplaced because there is nothing “reverse” about the conduct alleged in the SAC. Instead, it is redundant of Borzilleri’s traditional FCA claims under Count One. Borzilleri cannot simply recast his claims under §§ 3729(a)(1) and (a)(2) as “reverse” false claims under § (a)(7). *See S. Bay Mental Health Ctr., Inc.*, 2018 WL 4539684, at *6 (dismissing reverse false claims count because, in part, “FCA liability [cannot] be premised solely on the

same conduct that gives rise to traditional presentment or false-statement claims”). Thus, Borzilleri’s reverse false claim should be dismissed.

But even if this were a reverse false claims action, Borzilleri’s claim still fails because the SAC includes no allegation, let alone one pleaded with particularity, regarding any Manufacturer Defendant’s obligation to pay the government money, or any false record or statement used to avoid such an obligation. Borzilleri also fails (1) to specify the parameters of the obligation, such as what triggers the duty to repay, what sort of repayment it requires, and the amounts owed, and (2) to allege that Defendants undertook some action to avoid repaying that obligation. *See id.* (dismissing reverse FCA claim because, in part, “[r]elator had not adequately explained how any of the other defendants had an ‘established’ – as opposed to a potential or contingent – ‘obligation’ to repay funds to the government”); *see also, e.g., Chesbrough v. VPA, P.C.*, 655 F.3d 461, 473 (6th Cir. 2011) (dismissing reverse false claim because relator failed to identify “any concrete obligation owed to the government by” defendant); *Wood ex rel. United States v. Applied Research Assocs., Inc.*, 328 F. App’x 744, 748 (2d Cir. 2009) (affirming dismissal of reverse false claim because the complaint did not allege any financial obligation that contractor defendants owed to the government). Further, Borzilleri has failed to allege any details that might suggest any Manufacturer Defendant’s involvement in a Part D plan sponsor’s failure to pay any allegedly owed amounts. For example, the SAC is devoid of allegations regarding any action undertaken by Manufacturer Defendants to cause any alleged failure by Part D plan sponsors to repay any allegedly owed payments, or any allegations regarding any “false record or statement” used in such an effort. This, too, requires dismissal of the claim. Because Borzilleri’s conclusory allegations fail to plead a “reverse false” claim plausibly or particularly, Count Three should be dismissed.

F. Borzilleri Lacks Standing To Pursue Claims For Unjust Enrichment And Common Law Fraud

Borzilleri's common law claims for unjust enrichment (Count Thirty-Three) and common law fraud (Count Thirty-Four) should be dismissed because Borzilleri lacks standing to assert them. Borzilleri brings these claims to recover damages to the Government. *See, e.g.*, SAC ¶ 696. While the FCA permits private citizens to bring a civil action for a violation of the FCA on behalf of the Government, the FCA does not give relators the right to assert common law claims on behalf of the Government. *See United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 149 (D. Mass. 2000). Courts have consistently held that a *qui tam* relator lacks standing under the FCA to assert common law claims, including payment, on behalf of the Government. *See id.* (“[T]he Relator lacks standing to bring any common law claims on behalf of the United States.”); *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, 2007 WL 4287572, at *5 (D. Mass. Dec. 6, 2007) (“Ven-A-Care, as a relator, cannot separately assert claims for fraud or unjust enrichment on behalf of the government.”). Because Borzilleri lacks standing to assert Counts Thirty-Three and Thirty-Four of the SAC, these counts must be dismissed with prejudice.

G. The State FCA Counts Fail To State A Claim

In addition to his federal claims, Borzilleri asserts reverse false claims under the false claims act statutes of 27 states and the District of Columbia.⁹ *See* SAC ¶¶ 716–99. His theory appears to be that Manufacturer Defendants, via the alleged service-fee scheme, caused states to

⁹ Relator initially named 29 states and the District of Columbia. However, Borzilleri removed claims under the false claims act statutes of New Hampshire and Maryland in the SAC. With respect to Maryland, the Maryland False Health Claims Act provides that “[i]f the State does not elect to intervene and proceed with the action . . . before unsealing the complaint, the court shall dismiss the action [as to the Maryland claims].” Md. Code Ann., Health Gen., § 2-604 (a)(7).

overpay the federal government because states pay the federal government to fund a portion of its Part D spending on certain state beneficiaries.

Where, as here, a relator does not include allegations about how a state law analogue differs from the FCA, the state laws “may be construed consistently with the [FCA].” *Hagerty*, 95 F. Supp. 3d at 270 (citation omitted). Thus, Borzilleri’s state law claims should be dismissed for the same reasons as the federal claims. *See United States ex rel. Ge v. Takeda Pharma. Co.*, Nos. 10-11043-FDS, 11-10343, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) (dismissing state law claims where complaint did not differentiate state claims from the dismissed FCA claims). This is not a reverse false claims case and, even if it was, Borzilleri has failed to state a claim, as he has not alleged any Manufacturer Defendant had any obligation to pay any state government or that any Manufacturer Defendant undertook some action to avoid repaying that obligation. These claims also fail for an additional reason. Borzilleri’s reverse false claims theory is predicated on the Manufacturer Defendants actually having engaged in service-fee fraud. But because, as discussed above, Borzilleri has failed to plead adequately any service-fee fraud, Borzilleri’s reverse false claims theory has no foundation on which to stand.

Moreover, Borzilleri’s state law claims fail to satisfy Rule 9(b) independent of the federal FCA claims’ deficiencies. *See, e.g., Rost*, 507 F.3d at 734 n.8 (“The heightened pleading standard of Rule 9(b) generally applies to state law fraud claims brought in federal court.”). Borzilleri must include state-specific allegations for each state law claim. *See, e.g., Ge*, 2012 WL 5398564, at *6 (dismissal of the state law FCA claims is appropriate “because the complaints fail to plead with specificity the details of any claims for payment made to any of the states”); *see also United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 357 (D. Mass. 2011) (relator “must allege some specificity with respect to each asserted state”).

Borzilleri's state law claims do not satisfy these requirements. They do not add any substantive allegations to the federal claims, which themselves do not comply with Rule 9(b) for the reasons stated in Section I.A. Indeed, they contain no state-specific information about any state claims, aside from generalized allegations in the counts themselves. Instead, the SAC's state FCA claims are comprised entirely of legal conclusions that state statutes were violated, and thus they should be dismissed.

II. THE PUBLIC DISCLOSURE BAR MANDATES DISMISSAL OF THE FCA CLAIMS

The SAC is subject to dismissal for yet another reason: it is barred by the FCA's public-disclosure bar. 31 U.S.C. § 3730(e)(4). That bar precludes "parasitic" lawsuits by those who allege fraud based on publicly available information. *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 (1st Cir. 2010). It applies when (1) a relator's allegations are "substantially similar" to prior public disclosures, and (2) the relator is not an "original source." *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 205, 211 (1st Cir. 2016). The bar is "broad" and applies to claims "based *even partly* upon public disclosures." *United States ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 317 (D. Mass. 2009) (internal quotation marks omitted) (emphasis added).

Remarkably, Borzilleri *admits* that his allegations are based entirely on a mosaic of public disclosures, and the disclosures themselves include the elements from which he infers fraud.¹⁰ Far from being an insider or "original source," Borzilleri is a quintessential

¹⁰ Because Borzilleri admits that he based his allegations entirely on qualifying public disclosures, the Court need not look beyond the SAC to dismiss. *See, e.g., Iqbal*, 556 U.S. at 678 ("[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." (internal quotation marks omitted)); *Torres-Negron v. J & N Records, LLC*, 504 F.3d 151, 162 (1st Cir. 2007) (noting that a defendant can make a "facial" or a "factual" challenge to the Court's jurisdiction under Rule 12(b)(1), and that "[f]acial attacks on a complaint require the court merely to look and see if the plaintiff has sufficiently alleged a

“opportunistic plaintiff[] who ha[s] no significant information to contribute of [his] own.”

Graham Cty. Soil & Water Conservation Dist. v. United States, ex rel. Wilson, 559 U.S. 280, 294 (2010) (citation omitted). He is a former investment fund manager who, with no affiliation with any Defendant, filed this action in an attempt to drive Defendants’ stock prices down and improve his short positions. (*See supra* Section Background B.3.) As such, the FCA’s public-disclosure bar requires dismissal of the SAC.

**A. The SAC Should Be Dismissed Under Both
The Pre- And Post-ACA Public-Disclosure Bars**

Given the span of alleged conduct, two versions of the public-disclosure bar preclude Borzilleri’s allegations in this case. Before the Affordable Care Act (ACA) took effect on March 23, 2010,¹¹ the public disclosure bar stated that “[n]o court shall have jurisdiction over [a False Claims Act *qui tam* action] based upon the public disclosure of allegations or transactions” from a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media unless “the person bringing the action is an original source of the information.” 31 U.S.C. § 3730(e)(4)(A) (2009).¹² Following the ACA, the public-disclosure bar now provides in pertinent part that “[t]he court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim

basis of subject matter jurisdiction” (internal quotation marks omitted)). Even if Borzilleri had not admitted this, however, the disclosures themselves, of which the Court should take judicial notice, reveal that the complaint is based on qualifying public disclosures, also requiring dismissal.

¹¹ Patient Protection & Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901–02 (2010) (codified at 31 U.S.C. § 3730(e)(4)(A) (2012)).

¹² Under this pre-ACA version, “original source” means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information. *Id.*

were publicly disclosed [in certain enumerated sources] unless . . . the person bringing the action is an original source of the information.” 31 U.S.C. § 3730(e)(4)(A).

The ACA made three primary changes to the public-disclosure bar. *First*, it removed the language that deprived a court of subject-matter jurisdiction over a case based on public disclosures.¹³ *Second*, it altered the list of enumerated sources.¹⁴ *Compare* 31 U.S.C. § 3730(e)(4)(A) *with id.* § 3730(e)(4)(A) (2009). *Third*, as discussed in Section II.C. below, it changed the definition of “original source.” Because the ACA amendment was not retroactive, it does not apply to the SAC’s alleged pre-ACA conduct. *See, e.g., Graham Cty.*, 559 U.S. at 283 n.1; *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 n.2 (1st Cir. 2010); *accord United States ex rel. Patriarca v. Siemens Health Care Diagnostics, Inc.*, 295 F. Supp. 3d 186, 195 (E.D.N.Y. 2018). Therefore, this Court should apply the pre-ACA version for conduct

¹³ Although the First Circuit has not expressly determined whether the ACA rendered the public disclosure bar non-jurisdictional, *Winkelman*, 827 F.3d at 205, 211, courts in this district and elsewhere have concluded that it is no longer jurisdictional. *See United States ex rel. Winkelman v. CVS Caremark Corp.*, 118 F. Supp. 3d 412, 420 (D. Mass. 2015), *aff’d*, 827 F.3d 201 (1st Cir. 2016) (post-ACA public disclosure bar requires dismissal under Rule 12(b)(6); *but see United States ex rel. D’Agostino v. EV3, Inc.*, No. 10-11822-RGS, 2014 WL 4926369, at *5 (D. Mass. Sept. 30, 2014) *rev’d on other grounds, United States ex rel. D’Agostino v. EV3, Inc.*, 802 F.3d 188, 195 (1st Cir. 2015) (treating amended public disclosure bar as jurisdictional). In any event, the analysis remains the same: the Court can consider under Rule 12(b)(6) the same matters of public record and facts susceptible to judicial notice that it could consider under Rule 12(b)(1). (*See supra* Background n.2.)

¹⁴ Following the ACA’s amendments, the enumerated sources now include (i) a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) news media. 31 U.S.C. § 3730(e)(4)(A). The ACA’s amendments to the enumerated sources do not alter the analysis here, as Borzilleri’s claims are derived exclusively from public disclosures in sources that qualify under either version of the statute.

that allegedly occurred before March 23, 2010, and the post-ACA version for conduct after that date. *See Patriarca*, 295 F. Supp. 3d at 196.¹⁵

Under either version of the public disclosure bar, however, the Court must perform the same two-step analysis and determine: (1) whether the allegations in the complaint are “substantially similar”¹⁶ to the allegations contained in prior “public disclosures,” and, if so, (2) whether the suit may nonetheless go forward because the relator is an “original source” of the information on which he bases his allegations. Borzilleri’s SAC is foreclosed under both versions of the statute. His purported inference of fraud—pre- and post-ACA—is based *entirely* on qualifying public disclosures, and he is not an “original source” under either definition. The public-disclosure bar requires his SAC to be dismissed.

**B. Borzilleri’s Allegations Are
Substantially Similar To Prior Public Disclosures**

A relator’s allegations are substantially similar to prior public disclosures where, as here, the “essential elements” of the purported fraudulent transaction were publicly disclosed.

Winkelman, 827 F.3d at 208. This includes instances where a relator like Borzilleri alleges that he “infer[s]” a fraudulent transaction from facts revealed in public disclosures. *United States ex*

¹⁵ Consequently, the Court should decide whether it has subject-matter jurisdiction over the pre-ACA claims before reaching the Manufacturing Defendants’ other arguments as to why those claims must be dismissed. *See, e.g., Steel Co. v. Citizens for A Better Env’t.*, 523 U.S. 83, 94 (1998); *Northeast Erectors Ass’n of the BTEA v. Sec’y of Labor, Occupational Safety & Health Admin.*, 62 F.3d 37, 39 (1st Cir. 1995). In addition, Borzilleri has the burden of establishing jurisdiction as to the pre-ACA claims. *Poteet*, 619 F.3d at 109 (holding that the relator, “as the proponent of federal jurisdiction, bears the burden of proving its existence by a preponderance of the evidence.”)

¹⁶ Although the pre-ACA version requires dismissal of actions that were “based on” qualifying public disclosures, and the post-ACA version requires dismissal of actions that are “substantially similar” to allegations in qualifying public disclosures, that change merely codified how the First Circuit had interpreted the pre-ACA version and thus the analysis remains the same. *Winkelman*, 827 F.3d 206, 208 (citing *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 57 (1st Cir. 2009)).

rel. Conrad v. Abbott Labs., Inc., No. 02-11738-RWZ, 2013 WL 682740, at *4 (D. Mass. Feb. 25, 2013). “[T]he public disclosure bar contains no requirement that a public disclosure use magic words or specifically label disclosed conduct as fraudulent.” *Winkelman*, 827 F.3d at 209 (citing *United States ex rel. Findley v. FPC-Boron Emps. ’ Club*, 105 F.3d 675, 688 (D.C. Cir. 1997), *overruled on other grounds*, *Rockwell Int’l Corp. v. United States*, 549 U.S. 547 (2007) (“A relator’s ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed.”)). Rather, a public disclosure occurs when the relevant disclosure:

present[s] either a direct allegation of fraud, or else both a misrepresented state of facts and a true state of facts such that the recipient may infer fraud. The misrepresented facts and the true facts may also appear in several separate disclosures that combine to create an inference of fraud.

Conrad, 2013 WL 682740, at *3 (internal citation omitted). In these circumstances, the public-disclosure bar applies even if the relator’s “expertise makes h[im] the first to understand the alleged fraud.” *Id.* at *4. That “a person studying all of these sources would likely need substantial expertise in the field” to understand the alleged fraud is immaterial because “the only question is whether the material facts exposing the alleged fraud are already in the public domain, not whether they are difficult to recognize.” *Id.*; *see also Winkelman*, 827 F.3d at 209.

The SAC is barred for two independent reasons: (1) Borzilleri admits in his allegations that he relies on public disclosures to establish the alleged fraudulent scheme; and (2) the essential elements of Borzilleri’s allegations are disclosed in pre-complaint public sources.

1. A Facial Review Of The SAC Demonstrates Borzilleri Relied On Qualifying Public Disclosures

The SAC on its face confirms that Borzilleri did not uncover the alleged fraudulent scheme through insider information, but instead is inferring it from his review of public sources—federal regulations and administrative reports, SEC filings, and published drug-pricing

and sales data—that existed before he filed suit. Indeed, the SAC specifically cites to public disclosures to support the allegations of fraud. If Borzilleri’s allegations are taken as true, then the essential elements of his purported fraud theory necessarily derive from public disclosures.

First, Borzilleri alleges that the Manufacturer Defendants must have paid inflated service fees to the PBM Defendants because various federal administrative reports¹⁷ reveal that PBMs earned high profits, despite retaining minimal rebates and allegedly facing high catastrophic cost-sharing exposure. Based on public sources, Borzilleri alleges:

- PBMs retained minimal rebates for drugs reimbursed by Part D, which were less than rebates for drugs reimbursed by Medicaid, *see* SAC ¶¶ 205–209, 646–657 (citing 2011 OIG Report, Ex. H); U.S. Dept. of Health & Human Services-OIG, OEI-03-13-00650, *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin* (2015)); *id.* ¶¶ 212, 644, 656–663 (citing U.S. Gov’t Accountability Office, GAO-10-242, *Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier* (2010));
- PBMs had high catastrophic cost-sharing exposure that should have negated profits, absent a fee scheme, *id.* ¶¶ 397–442 (citing *Medicare Payment Advisory Comm’n, Report to the Congress: Medicare and the Health Care Delivery System* (June 2015));
- PBM Medco generated significant profits from service fees and relied less on rebates for profits, *id.* ¶¶ 664–690 (citing Medco Health, Annual Reports (SEC Forms 10-K) (2003–2011)); and
- Profits of Defendant Express Scripts nearly tripled between 2013 and 2017, *id.* ¶¶ 99–104 (citing unidentified “SEC-reported financial statements of Express Scripts”).¹⁸

¹⁷ An OIG report is a “paradigmatic example” of a qualifying public source. *United States ex rel. J. Cooper & Assocs., Inc. v. Bernard Hodes Grp., Inc.*, 422 F. Supp. 2d 225, 235 (D.D.C. 2006) (dismissing relator’s FCA complaint because allegations were disclosed in an OIG report, among other sources); *United States ex rel. Waris v. Staff Builders, Inc.*, No. CIV. A. 96-1969, 1999 WL 788766, at *4 (E.D. Pa. Oct. 4, 1999) (explaining that “the Inspector General’s audit report is a paradigmatic example of an ‘administrative audit,’ which is rendered a public disclosure by the plain wording” of the bar). SEC filings also qualify as public disclosures under 31 U.S.C. § 3730(e)(4)(A). *See United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App’x 244, 257 (4th Cir. 2012).

¹⁸ Borzilleri also alleges that two industry news publications released after he filed this action, but before he filed the SAC, “publicly corroborated” his suspicions of inflated service fees. *See* SAC ¶¶ 68, 72, 76, 97–98, 164–166, 168, 178–191 (citing PhRMA and PCMA

Second, Borzilleri alleges that these service fees could not have been fair market value or BFSFs because SEC filings reveal that a non-defendant pharmacy received more modest service fees, and one PBM Defendant spent little on performing actual services. For example, Borzilleri alleges that:

- “SEC filings . . . of Diplomat Pharmacy, Inc., verify that the appropriate ‘arm’s length’ compensation to the PBM Defendants for providing manufacturer services should be very modest, even for ‘complex’ specialty drugs,” *id.* ¶¶ 554–559 (citing Diplomat Pharmacy, Inc., Registration Statement (SEC Form S-1) (July 3, 2014)); and
- Expenditures of Defendant Express Scripts allocated to “Selling, General and Administrative” in 2013–2017 “sharply declin[ed],” *id.* ¶¶ 99–104 (citing unidentified “SEC-reported financial statements of Express Scripts”).

Third, Borzilleri alleges that the fees must have been kickbacks in exchange for favorable formulary placement, in violation of the AKS, because various federal administrative reports and published drug pricing and sales data¹⁹ reveal that the Manufacturer Defendants’ drug prices and sales have risen despite the availability of cheaper alternative drugs. *See, e.g., id.* ¶¶ 7–13, 22, 84–85, 107, 644, 655, 656, 685 and Exs. 1–12 incorporated therein (citing “public” CMS data; and drug pricing and sales data published by Truven Health Analytics Inc., *Red Book*, IMS Health, PhRMA, and company reports). The alleged fraudulent scheme, Borzilleri concludes, is “the only viable explanation.” *Id.* ¶ 107.

Thus, even according to Borzilleri himself, the essential elements of his allegations are taken from public disclosures. As such, the SAC should be dismissed.

reports). To the extent the SAC makes new allegations based on inferences he is drawing from those publications, those new allegations are equally barred by the public-disclosure bar.

¹⁹ Data published by CMS qualifies as a public disclosure under 31 U.S.C. § 3730(e)(4)(A). *See, e.g., Conrad*, 2013 WL 682740 at *5. The same holds for drug-pricing data published in nongovernmental sources. *See United States v. CSL Behring, L.L.C.*, 855 F.3d 935, 945–46 (8th Cir. 2017) (affirming dismissal under public disclosure bar and determining that *Red Book* data is a public disclosure); *United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (holding that “publicly available websites . . . intended to disseminate information . . . qualify as news media”).

2. A Factual Review Of The SAC Further Confirms Borzilleri's Reliance On Public Disclosures

Not only do Borzilleri's allegations affirmatively state his reliance on public disclosures, but the "essential elements" of the alleged scheme in fact appear in public disclosures. *Ondis*, 587 F.3d at 54. Borzilleri alleges that the Manufacturer and PBM Defendants have entered into secretive contracts that provide for the payment of service fees to PBMs that exceed fair market value. SAC ¶¶ 27–29. Moreover, Borzilleri claims Defendants are intentionally not reporting the payments in excess of fair market value in order to increase drug prices and maximize profits. *Id.* ¶ 31. These allegations are disclosed in several different public sources, many of which were published by the government itself. Therefore, there can be no doubt that "the government has received fair notice, prior to the suit." *Winkelman*, 827 F.3d at 208.

Indeed, a March 2011 report of the U.S. Department of Health and Human Services Office of Inspector General entitled, "Concerns with Rebates in the Medicare Part D Program" (2011 OIG Report) "requires hardly an inferential step to connect the allegedly true and allegedly misrepresented facts." *Winkelman*, 827 F.3d at 209; *see generally*, 2011 OIG Report, Ex. H. The 2011 OIG Report examined administrative fees received by PBMs and found that, among other things:

- "Selected sponsors reported that their PBMs collected fees from drug manufacturers that were not always passed on to the Part D program," 2011 OIG Report, Ex. H, at 18; SAC ¶ 47;
- The "fees were structured like rebates in that they were generally based on a fixed percentage of WAC [the drug's list price]," 2011 OIG Report, Ex. H, at 18–19; SAC ¶¶ 36–37, 210;
- In some cases "the sponsors did not report the fees to CMS and therefore they were not passed on to the program" because "the PBMs considered these fees to be bona fide services fees, which CMS does not consider price concessions if they are at fair market value," 2011 OIG Report, Ex. H, at 19; SAC ¶¶ 31, 152(5)–(6); and

- “Because sponsors may not always be able to verify whether these fees should be considered rebates or bona fide service fees, they may be inaccurately reporting this information to CMS,” 2011 OIG Report, Ex. H, at 19; SAC ¶¶ 176–177.

The government was thus acutely aware of the potential for fraud like that alleged by Borzilleri.

This disclosure alone is sufficient to bar Borzilleri’s claims.

Likewise, several additional sources—including sources not referenced in the SAC that the Court may take judicial notice of—disclose the essential elements of Borzilleri’s alleged fraudulent scheme. The following chart outlines Borzilleri’s core allegations and the corresponding public disclosures.

<u>“Essential Element” of Borzilleri’s Allegations</u>	<u>Relevant Public Disclosure</u> ²⁰
Manufacturer rebates are not the primary source of PBM profits. SAC ¶¶ 70–72, 77, 165, 169, 205–206, 222.	<u>January 2010 GAO Report</u> : “All seven of the plan sponsors we surveyed reported that they were unable to obtain price concessions from manufacturers on 8 of the 20 specialty tier-eligible drugs in our sample between 2006 and 2008. For most of the remaining 12 drugs in our sample, plan sponsors who were able to negotiate price concessions reported that they were only able to obtain price concessions that averaged 10 percent or less, when weighted by utilization, between 2006 and 2008.” ²¹
Drug prices continue to rise, despite the availability of cheaper drugs. SAC ¶¶ 7, 10, 32, 312–396.	<u>January 2010 GAO Report</u> : “GAO reports that, on average, negotiated prices of the sample specialty tier drugs increased by 36 percent between CY 2006 and CY 2009. We would like to note that price increases are not unique to specialty tier drugs. An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both

²⁰ “The general rule is that a disclosure is ‘public’ if it is generally available to the public.” *Poteet*, 619 F.3d at 110. DOJ press releases and articles published in BusinessWire and various healthcare industry and academic publications constitute “news media.” See *Nowak*, 806 F. Supp. 2d at 330 (“industry or national news media” qualify as sources of public disclosures); see also *Winkelman*, 827 F.3d at 209 (AG press release and news articles reporting on the Change to Win report were sources of public disclosures). CBO, GAO, and OIG reports qualify as administrative “report[s], . . . audit[s], or investigation[s].” 31 U.S.C. § 3730(e)(4)(A)(ii).

²¹ Ex. I, January 2010 GAO Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High Cost Drugs Eligible for a Specialty Tier (the “January 2010 GAO Report”) at 22.

	specialty and non-specialty tier drugs) between January 2006 and October 2009.” ²²
PBM fees are not always passed on to the Part D program. SAC ¶¶ 28–31, 38, 60, 274.	<u>2010-2011 OIG Semiannual Report</u> : “Our review also revealed that some sponsors reported large differences in rebates across their plans and received manufacturer rebates when they encouraged beneficiaries to use certain drugs. Some sponsors had complex contractual relationships with their third-party pharmacy benefit managers that sometimes lacked transparency, and some reported that their pharmacy benefit managers collected fees from drug manufacturers that were not always passed on to the Part D program.” ²³
Defendants must be paying high, percentage-based fees that are above fair market value in return for favorable formulary treatment. SAC ¶¶ 81–86, 152(2), 153(3), 195–196, 223–224, 239, 244–45, 287–290, 520–523.	<p><u>2005 Medicare Prescription Drug Benefit Rule</u>: “In the preamble to the proposed rule, we said that to the extent the administrative fees paid to Part D plans (or their subcontractors, such as PBMs) are above the fair market value of the services rendered, this differential will be considered a price concession. . . . [A]s fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not masked as administrative fees.”²⁴</p> <p><u>January 2007 CBO Report</u>: “Manufacturers also make other types of payments to PBMs in addition to rebate payments. For example, manufacturers commonly pay a fee to PBMs for the service of administering formularies. Such fees are frequently equal to about 3 percent of wholesale list prices.”²⁵</p> <p><u>2012 Medicaid Program Proposed Rule</u>: “We continue to be concerned that [bona fide service fees] could be used as a vehicle to provide discounts, as opposed to fees at ‘fair market value’ for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but have chosen not to define ‘fair market value’ at this time.”²⁶</p>

²² Ex. I, January 2010 GAO Report at 36.

²³ Ex. J, October 1, 2010–March 31, 2011, OIG Semiannual Report to the Congress (the “2010-2011 OIG Semiannual Report”) at I-16.

²⁴ Ex. K, Medicare Prescription Drug Benefit Rule, 70 Fed. Reg. 4194, 4308–4309 (January 28, 2005) (the “2005 Medicare Prescription Drug Benefit Rule”).

²⁵ Ex. L, January 2007, Congressional Budget Office (CBO), Prescription Drug Pricing in the Private Sector (the “January 2007 CBO Report”) at 12.

²⁶ Ex. M, Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318–01 (Proposed Rule) (February 2, 2012) (the “2012 Medicaid Program Proposed Rule”).

	<p><u>2013 Specialty Pharmacy Times</u>: “Bona Fide Service Fees (BFSFs) is one of the most important industry terms today, with a dramatic impact across pharmaceutical manufacturers, . . . specialty pharmacy and specialty distributors, and GPOs, as well as CMS and oversight agencies such as the [OIG] and [DOJ]. . . . If the government pays more than it thinks it should for pharmaceutical products under these programs, it can apply the False Claims Act, which is legal action [sic] related to the pharmaceutical manufacturer submitting incorrect data which causes the government to pay more than it should. . . . [T]he treatment of fees impacts all of the statutory pricing. . . .”²⁷</p> <p><u>Spring 2013 OIG Semiannual Report</u>: Disclosing OIG review of three plan sponsors’ BFSFs.²⁸</p>
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These disclosures are more than sufficient to trigger the public-disclosure bar. Numerous courts have recognized that a prior disclosure does not need to identify a specific defendant to be a sufficient disclosure. *See, e.g., In re Natural Gas Royalties*, 562 F.3d 1032, 1043 (10th Cir. 2009); *United States v. Alcan Elec. & Eng’g, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 569-72 (10th Cir. 1995).

In sum, because Borzilleri “infer[red]” the alleged fraudulent scheme entirely from qualifying public disclosures, and the disclosures themselves confirm this, the public-disclosure bar precludes his FCA claims unless he is an “original source”—which he is not. *Conrad*, 2013 WL 682740, at *3.

C. Borzilleri Is Not An “Original Source”

Borzilleri is not an “original source” under either the pre-ACA or post-ACA versions of the public disclosure bar. Under the pre-ACA version of the bar, the FCA defined an “original

²⁷ Ex. N, January-February 2013, Specialty Pharmacy Times, *Why We Care About Bona Fide Service Fees* (the “2013 Specialty Pharmacy Times”), at 1–2.

²⁸ Ex. O, April 2013-September 2013, OIG’s Semiannual Report to Congress (the “Spring 2013 OIG Semiannual Report”), at 95-96 (App’x B).

source” as an “individual who . . . has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action.” 31 U.S.C. § 3730(e)(4)(B) (2006). Under the post-ACA version, an “original source” is “an individual who either (1) prior to a public disclosure . . . , voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action.” 31 U.S.C. § 3730(e)(4)(B) (2012).

Borzilleri fails to qualify as an “original source” under the pre-ACA version of the public-disclosure bar because the core information he alleges derives exclusively from third-party disclosures, and he does not allege having “something more than secondhand information or collateral research and investigations.” *United States ex rel. Banigan v. PharMerica, Inc.*, No. 07-12153-RWZ, 2018 WL 2012684, at *2 (D. Mass. Apr. 30, 2018) (dismissing FCA action where relator was aware of alleged scheme through his job experience) (internal quotation marks omitted); *see also Ondis*, 587 F.3d at 59 (“If a relator merely uses his or her unique expertise or training to conclude that the material elements already in the public domain constitute a false claim, then a *qui tam* action cannot proceed.” (internal quotation marks omitted)). Borzilleri is far from an insider with direct and independent knowledge. Rather, he was a “professional healthcare industry investment analyst”—his job was to analyze public disclosures and identify profitable health care investments for his clients. His “knowledge was simply a compilation of publicly disclosed information,” and “based on research into public records, review of publicly disclosed materials, or some combination of these techniques,” and therefore does not constitute direct and independent knowledge. *Ondis*, 587 F.3d at 59.

Borzilleri also fails to qualify as an “original source” under the post-ACA public-disclosure bar. He neither disclosed his alleged information to the government prior to its public disclosure, nor has “knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions.” 31 U.S.C. § 3730(e)(4)(B) (2012); *see Winkelman*, 827 F.3d at 211 (“[T]he relators’ allegedly new information [must be] sufficiently significant or essential so as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures.”). His suit is based entirely on preexisting, publicly disclosed information, and he contributes no inside or valuable information.²⁹

Accordingly, as demonstrated by Borzilleri’s own admissions in the SAC and a review of the public disclosures themselves, Borzilleri’s allegations have already been disclosed in statutorily enumerated sources. The information in the public domain is substantially similar to the allegations in the SAC, and Borzilleri is not an “original source” of the disclosures. Therefore, the public-disclosure bar applies, and the SAC should be dismissed.

III. THE SAC SHOULD BE DISMISSED WITH PREJUDICE

Borzilleri’s claims should be dismissed with prejudice. A district court may refuse leave to amend where there is, among other factors, “repeated failure to cure deficiencies” or “futility

²⁹ Because the Court lacks jurisdiction over the pre-ACA FCA claims, the Court also lacks jurisdiction over all of the pre-ACA state-law claims. 31 U.S.C. § 3732(b). In addition, for substantially the same reasons that the FCA’s public-disclosure bar precludes the FCA claims in this case, various state public-disclosure bars preclude the state-law claims. *See* Cal. Gov’t Code § 12652(d)(3)(A); Colo. Rev. Stat. § 25.5-4-306(5)(c); Conn. Gen. Stat. § 4-282(b); 6 Del. Code Ann. tit. 6, § 1206(b); D.C. Code § 2-381.03(c-1)(1); Fla. Stat. § 68.087(3); Ga. Code Ann. § 23-3-122(j)(3); Haw. Rev. Stat. Ann. § 661-31(b); 740 Ill. Comp. Stat. 175/4(e)(4)(A); Ind. Code § 5-11-5.5-7(f); Iowa Code § 685.3(5)(c); La. Stat. Ann. § 439.1(D); Mass. Gen. Laws, ch. 12 § 5G(c); Mich. Comp. Laws. § 400.610a(13); Minn. Stat. § 15C.05(f); Mont. Code Ann. § 17-8-403(6)(a); Nev. Rev. Stat. Ann. § 357.100; N.H. Rev. Stat. § 167:61-e(III); N.J. Stat. Ann. § 2A:32C-9(c); N.M. Stat. Ann. § 27-14-10(C); N.Y. State Fin. Law § 9(b); N.C. Gen. Stat. § 1-611(e); Okla. Stat. § 5053.5(B); R.I. Gen. Laws § 9-1.1-4(e)(4)(A); Tenn. Code Ann. § 4-18-104(d)(3); Tex. Code Ann. § 36.113(b); Va. Code Ann. § 8.01-218.8; Wash. Rev. Code § 74.66.080(2).

of amendment.” *Gagne*, 565 F.3d at 48. Here, Borzilleri filed his action in January 2014 and had nearly *five years* to develop a viable FCA claim against the Manufacturing Defendants. He has failed to do so, despite a multi-year government investigation (in which the government declined to intervene) and *four* attempts at his complaint. *See* Dkt. Nos. 1, 6, 57, 95. Justice does not require granting Borzilleri leave to amend to “try to get it right” in what would be his fifth complaint in this action. *Gagne*, 565 F.3d at 48 (affirming denial of relators’ request to amend for the fourth time “based on relators’ repeated failure to cure the deficiencies in their pleadings” in three prior complaints).

Moreover, it is clear that granting Borzilleri leave to further amend would be futile. In Borzilleri’s action pending in the Southern District of New York based upon a nearly-identical complaint, he was explicitly given leave to amend his complaint in response to the defendants’ motions to dismiss—and advised that no further amendments would be permitted. *Borzilleri*, No. 15-cv-7881-JMF (S.D.N.Y.), Dkt. 265. Borzilleri failed to amend his complaint in the SDNY case, confirming that he cannot cure his complaints’ numerous pleading deficiencies. His inability to do so is not surprising given his status as a short-selling corporate outsider, who does not—and cannot—rely on anything other than publicly available information. After four prior attempts, Borzilleri remains unable to cure the SAC’s basic pleading deficiencies, and any prospective amendment would be futile. Accordingly, the SAC should be dismissed in its entirety, with prejudice.

CONCLUSION

WHEREFORE, for the foregoing reasons, and those set forth in the Joint Motion to Dismiss filed by the PBM Defendants, Borzilleri’s SAC should be dismissed with prejudice pursuant to Fed. R. Civ. P. 8(a), 9(b), 12(b)(1), and 12(b)(6) and 31 U.S.C. § 3730(e)(4).

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CERTIFICATE OF SERVICE

I hereby certify that I filed the within Motion through the ECF system on the 19th of November, 2018, and that notice will be sent electronically to the counsel who are registered participants identified on the Mailing Information for Case No. 14-cv-31.

/s/ Patricia K. Rocha

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND**

UNITED STATES OF AMERICA,
ex rel. JOHN R BORZILLERI, M.D. et al.,

Plaintiffs,

vs.

BAYER AG, et al.,

Defendants.

Case No. 14-cv-00031-WES-
LDA

**MEMORANDUM OF LAW IN SUPPORT OF
THE PHARMACY BENEFIT MANAGER DEFENDANTS' JOINT MOTION TO
DISMISS RELATOR'S SECOND AMENDED COMPLAINT**

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<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007)	8
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<i>U.S. ex rel. Zeibell v. Fox Valley Workforce Dev. Bd., Inc.</i> , 806 F.3d 946 (7th Cir. 2015)	25 n. 15
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FEDERAL STATUTES AND REGULATIONS

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Drug Rebate Program, Medicaid Release No. 14 (Dec. 21, 1994), https://www.medicaid.gov/medicaid-chip-program-information/by- topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-014.pdf	4 n. 3
Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (2003)	3
Medicare Program Revisions to Payment Policies, 71 Fed. Reg. 69624 (Dec. 1, 2006)	4 n. 4

INTRODUCTION

In this *qui tam* action, in which the United States and all named States have declined to intervene, Relator John Borzilleri alleges that “secretive” “service fees” paid by drug manufacturers to pharmacy benefit managers (“PBMs”) and plan sponsors are to blame for the high cost of prescription drugs. Relator’s theory is that, for years, drug manufacturers have agreed to pay excessive service fees to PBMs and plan sponsors in exchange for favorable placement on the PBMs’ covered drug lists (formularies) and acquiescence by the PBMs in the manufacturers’ price increases. Relator contends, in turn, that these excessive fees have not been reported to the government as discounts, thus causing the government to overpay Medicare Part D (“Part D”) plans for the drugs those plans provide to enrollees.

Despite its length, the Second Amended Complaint (“SAC” or “Complaint”) fails to satisfy the most elemental pleading standards for bringing a civil case—and certainly for alleging fraud. It does not contain a *single* specific allegation about any of the defendants or any of the particular fees in their contracts with the manufacturers for the Part D drugs. Instead, the Complaint is based on speculation about what Relator might uncover “only via discovery.” SAC ¶ 162. Governing federal pleading standards prohibit that kind of “fishing expedition[]” approach to litigation. *McCloskey v. Mueller*, 446 F.3d 262, 271 (1st Cir. 2006) (“[P]laintiffs should not be permitted to conduct fishing expeditions in hopes of discovering claims”). To the contrary, “it is only after stating a valid claim that a plaintiff can insist upon a right to discovery.” *Nestor Colon Medina & Sucesores, Inc. v. Custudio*, 964 F.2d 32, 39 (1st Cir. 1992). That would be true in any case, but it is particularly true where, as here, Rule 9(b)’s heightened pleading requirements apply.

The reason for the Complaint’s shortcomings is obvious. Relator is not a well-meaning *qui tam* plaintiff who used inside information to build his case. He is a former hedge fund

manager whose only connection to the Defendants was that he specialized in “short selling” their stocks so he could profit from bad news about them. As described in a related lawsuit recently brought against Relator by his former employer, this case is about securities-market opportunism, not sincere whistleblowing activity aimed at remedying alleged fraud against the government.

The stark pleading deficiencies alone are grounds for dismissal with prejudice. Relator filed his initial complaint on January 16, 2014, and has since filed two subsequent amended complaints as the government investigated his case (at considerable cost to the defendants). If he had viable theories or relevant facts, that was the place to offer them. Given Relator’s lack of personal knowledge and his failure to plead adequately a cognizable claim across three complaints spanning more than four years, this Court should readily conclude that any further amendment would be futile.

The Complaint should be dismissed with prejudice for the additional and independent reason that it violates the “public disclosure” bar of the False Claims Act (“FCA”). Information, concerns, and investigations regarding service fees—including whether they have been excessive, miscalculated, or misreported—have appeared in multiple public reports dating back to 2002. Indeed, Relator relies upon and cites too many of these public reports to support his speculative theory. Where, as here, a relator builds his complaint on information that was already publicly available (and thus readily open to government inquiry), the False Claims Act sensibly provides that he cannot maintain an action on the government’s behalf if the government does not want to proceed. *See* 31 U.S.C. § 3730(e)(4)(A).

For these reasons, as well as those set forth in the Manufacturer Defendants’ Motion to Dismiss, the Complaint should be dismissed with prejudice.

BACKGROUND

I. REGULATORY BACKGROUND

Under Part D of the Medicare program, the elderly and disabled can obtain prescription drug benefits relating to “covered part D drugs.” *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (2003). The Centers for Medicare and Medicaid Services (CMS) contracts with private insurance companies—“plan sponsors”—who agree to administer drug benefits to Part D beneficiaries in accordance with CMS rules. *See* 42 U.S.C. § 1395w-102(e).

Plan sponsors contract with PBMs to deliver prescription drug benefits. *See* Ex. A, CENTERS FOR MEDICARE AND MEDICAID SERVICES, MEDICARE BENEFIT POLICY MANUAL, CMS Pub. 100-18, Ch. 9, § 20, Definitions at 3 (2018), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf> (hereinafter “Prescription Drug Benefit Manual”). PBMs perform important services for plan sponsors such as negotiating and administering drug rebate programs, establishing and administering claims processing systems, offering formulary design and management tools that a plan sponsor may use in determining what drugs will be covered by a given insurance plan, performing drug utilization reviews, and negotiating reimbursement rates with pharmacies. *See id.*; *see also* SAC ¶ 137. Plan sponsors pay PBMs for those services. *See, e.g.*, SAC ¶ 137. Some PBMs also provide certain services to drug manufacturers to facilitate rebate programs, such as monitoring plan sponsor compliance with rebate eligibility requirements and compiling data reports about the usage of various drugs. *See* SAC ¶ 138. Drug manufacturers may pay PBMs service fees for performing these tasks. *See id.*

Service fees are relevant in the Medicare Part D context to how much CMS pays (or reimburses) plan sponsors for drugs they procure for Part D enrollees. Payments to plan sponsors

under Part D are based in part on the sponsors' cost to provide drugs dispensed to their Part D beneficiaries, which are reported to CMS in two ways: (1) annual cost estimates called "bids" and (2) cost data submitted periodically to CMS during the year and after the end of the plan year. *See* 42 C.F.R. § 423.265 and § 423.301 *et seq.* To identify a plan sponsor's costs, CMS needs to know about discounts that plan sponsors receive from manufacturers that may offset costs.¹ *E.g.*, SAC ¶ 31. Drug price discounts often take the form of rebates, but CMS classifies certain other payments plan sponsors or their PBMs receive from drug manufacturers as discounts, including certain payments contracted PBMs receive from manufacturers. *See* 42 C.F.R. § 423.308.² For more than twenty years—first in Medicaid,³ then in Medicare Part B,⁴ and most recently in Medicare Part D⁵—CMS has wrestled with how to determine whether a given payment is properly viewed as a discount on a drug's price (in which case it decreases the sponsor's costs) versus compensation for services rendered (in which case it does not impact the sponsor's drug costs). Under Part D, CMS has decided that bona fide service fees need not be treated as discounts unless the amount paid exceeds fair market value compensation for the services. *See* 42 C.F.R. § 423.501; *see also* 77 Fed. Reg. 22170 (Apr. 12, 2012) (regulatory definition of bona fide service fees for purposes of Part D, Incorporated into 42 C.F.R. § 423.501). If the amount of a service fee exceeds fair market value, the payment is still permissible, but the portion that exceeds fair market value must be disclosed to CMS by the plan

¹ *See, e.g.*, Ex. B, Final Medicare Part D DIR Reporting Requirements for Plan Year 2017.

² Plan sponsors, typically via their contracted PBMs, negotiate with manufacturers to reduce the price paid by the plan sponsor for the manufacturers' drugs, often in the form of rebates. These rebates may be retained by the PBMs or passed through to the plan sponsor. Over time, plan sponsors have obtained a higher percentage of manufacturer rebates (and PBMs have retained a lower share). Regardless of whether the plan sponsor actually obtains the rebate, all manufacturer rebates are reported by the plan sponsor to CMS as discounts. SAC ¶ 145.

³ *See* Drug Rebate Program, Medicaid Release No. 14, at 1 (Dec. 21, 1994), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-014.pdf> (discussing services and fees paid by manufacturers for them).

⁴ *See* Medicare Program Revisions to Payment Policies, 71 Fed. Reg. 69624, 69667 (Dec. 1, 2006) (regulation defining BFSF for purposes of determining the "Average Sales Price" used in the Medicare Part B program).

⁵ *See, e.g.*, Ex. B, Final Medicare Part D DIR Reporting Requirements for Plan Year 2017.

sponsor through an annual process known as Direct and Indirect Remuneration (“DIR”) Reporting.⁶ The part of a service fee that exceeds fair market value is reported to CMS and CMS considers that portion of the service fee to be a discount that decreases plan sponsor’s costs and ultimately, reduces Medicare’s payments to the plan sponsor.⁷

II. RELATOR’S SECOND AMENDED COMPLAINT

Relator filed this *qui tam* action in 2014, and initiated a nearly identical case in the Southern District of New York approximately eighteen months later. *See U.S. ex rel. Borzilleri v. Abbyvie, Inc., et al.*, No. 15-cv-07881-JMF (S.D.N.Y.). The two cases differ only in the drugs Relator has chosen to focus on in each complaint and in the identity of some of the defendants. The Department of Justice investigated the allegations in each complaint and chose not to intervene. Similarly, no state named by the Relator as a co-plaintiff in his complaints chose to intervene. After the government agencies informed this Court and the district court in New York of their decisions, the cases were unsealed.

The operative Complaint represents the Relator’s third attempt at pleading a viable case. Relator alleges that six drug manufacturers named as defendants (the “Manufacturer Defendants,” SAC ¶ 123) have been paying excessive service fees to PBMs named as the other six defendants (the “PBM Defendants,” *id.* at ¶ 130) in connection with eight drugs used to treat multiple sclerosis. *See, e.g.*, SAC ¶ 27. The Complaint speculates that the Manufacturer Defendants paid these excessive service fees in exchange for favorable placement of their drugs

⁶ DIR includes, for example, discounts, chargebacks or rebates, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities, obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted (such as a PBM), regardless of whether the intermediary has retained or passed on to the plan sponsor all or a portion of those discounts or other benefits. 42 C.F.R. § 423.308.

⁷ *See* Ex. C, CMS, Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation, at 9 (June 10, 2010). Prior to this time, CMS was well aware of service fees, as reflected in sub-regulatory program guidance. For example, CMS discussed these fees in its 2007 guidance and has required reporting of bona fide service fees since the 2009 Plan Year. *See* Ex. D, CMS, Final Medicare Part D DIR Reporting Requirements for 2007 Payment Reconciliation, at 2 (June 13, 2008); Ex. C at 9.

on the PBMs' Part D formularies and for the PBMs' acquiescence to the manufacturers' price increases. *See, e.g., id.* ¶ 81. The Complaint assumes that these alleged excessive service fees must not have been disclosed to CMS through the DIR reporting process. *See, e.g., id.* ¶ 88.

Based on this alleged scheme, Relator speculates that all Defendants must be submitting a "myriad of false claims . . . for reimbursement in the Medicare Part D program, including Prescription Drug Event (PDE) reports, [DIR] reports, Part D annual plan bids, . . . [and] financial data required for Part D subsidy reconciliation." *Id.* ¶¶ 88, 89; *accord, e.g., id.* ¶¶ 29–30. Relator also appears to present the alternative theory that the Manufacturer Defendants forgave unidentified debts, allegedly owed by the PBM Defendants' affiliated Part D plan sponsors in connection with expensive drugs that triggered "catastrophic coverage" requirements, and that the plan sponsors then failed to report those forgiven debts to the government as discounts or rebates. *See, e.g., id.* ¶¶ 397–442.

Under any theory, the Complaint is notably lacking in concrete specifics. For example, it does not describe the amount of any service fees actually paid by any Manufacturer Defendant to any PBM Defendant at all, let alone with respect to any particular drug. It does not identify the services actually provided by any PBM Defendant in exchange for any such fees or allege the fair market value of any such services. It does not describe any specific debt that is (or was) actually owed by any PBM Defendant to any Manufacturer Defendant, let alone any specific debt actually forgiven by a Manufacturer Defendant. In place of specific allegations about the Defendants in this action, Relator's Complaint uses what Relator contends are industry wide "average" service fee amounts to "illustrate" what the fraud he claims exists *might* look like. *See, e.g., SAC* ¶¶ 162, 227, 232. Revealing a complete absence of any factual basis for the Complaint, Relator announces that he "expect[s] discovery to

determine that the manufacturer ‘service fee’ scheme has been a primary driver” of the PBM Defendants’ “profit growth over the past decade.” *Id.* ¶ 106.

The absence of any specific allegations about the service fees paid or received by any of the Defendants in connection with any of the eight drugs listed in the Complaint is not surprising here. Relator has never worked at any of the Defendants and has no “inside” information about their operations. Rather, at the time he initiated this lawsuit and drafted the operative Complaint, Relator managed—and invested heavily in himself—a health care hedge fund with a short-side focus at Shepherd Kaplan Krochuk, LLC (“SKK”). That role provided him with no inside information about any of the Defendants that might have been indicative of fraud, but it did give him a separate reason to file this lawsuit. According to a related lawsuit SKK filed against Relator earlier this year, “throughout 2016 and 2017, and escalating in early 2018, Borzilleri established highly significant short positions” against the “stock value” of certain of the Defendants in this FCA lawsuit and those in the nearly identical suit he filed in the Southern District of New York. *See* Ex. E, SKK Compl. at 1, 33, 35.⁸ By April 2018, the seven largest short positions in the fund were against the securities of the Defendants in these cases, including a number of the PBM Defendants. Ex. E ¶ 37.

This case was unsealed on April 5, 2018. *See* ECF No. 37. Just days later, Relator authored and distributed a press release to major media outlets and financial institutions, attaching the freshly unsealed complaints in this case and in the similar matter pending in the Southern District of New York. Relator admits that his complaints “make substantially negative allegations about the defendants . . . against which [he] had established large short positions in

⁸ Relator and SKK currently are engaged in two lawsuits, one in Massachusetts Superior Court and one in the Southern District of New York (Sullivan, J.). This Court may rely on items in the public record in evaluating a motion to dismiss, including pleadings in other actions. *See, e.g., Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 2001); *E.I. Du Pont de Nemours & Co. v. Cullen*, 791 F.2d 5, 7 (1st Cir. 1986) (taking judicial notice of a complaint filed in a state action).

the Fund.” Ex. E ¶ 40; Ex. F, Borzilleri Ans. & Counterclaim at 9 ¶ 40.⁹ When SKK learned that Relator had used his *qui tam* filings under the FCA to attempt to depress the price of stocks that he had shorted through his fund at SKK, it summarily terminated Relator, liquidated his fund, and sued him in state court. Relator’s trading misconduct and SKK’s subsequent termination of his employment are the subject of two ongoing lawsuits, one in Massachusetts Superior Court and one in the Southern District of New York (Sullivan, J.). Complaint, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418, (Mass. Super. Ct. May 8, 2018), Dkt. 1; Complaint, *John R. Borzilleri, MD, v. Shepherd Kaplan Krochuk, LLC*, No. 18-cv-04654-RJS (S.D.N.Y. May 25, 2018), Dkt. 1.

ARGUMENT

I. THE COMPLAINT FAILS BASIC PLEADING REQUIREMENTS AND SHOULD BE DISMISSED WITH PREJUDICE.

To survive a motion to dismiss under Rule 12(b)(6), a complaint must “contain enough facts to state a claim to relief that is plausible on its face.” *A.G. ex rel. Maddox v. Elsevier, Inc.*, 732 F.3d 77, 80 (1st Cir. 2013) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). “‘The plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully.’” *Iqbal*, 556 U.S. at 678. A statement of facts that “merely creates a suspicion [of] a legally cognizable right of action,” is insufficient, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and “stops short of the line between possibility and plausibility of entitlement to relief,” *Iqbal*, 556 U.S. at 678.

In addition, “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). The requirement applies to

⁹ Unsurprisingly, given his intent, Relator named as Defendants the holding companies that issue shares to the public, such as UnitedHealth Group, Inc., Humana, Inc., CVS Health Corporation, and Express Scripts Holding Co., rather than the respective operating subsidiaries that actually perform the activities challenged in the Complaint. Several companies have raised this issue with Relator, identifying the correct subsidiary and requesting that the correct party be named; however, Relator’s counsel has refused.

complaints, like this one, alleging violations of the FCA and its state-law analogues. *See, e.g., U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 n.8 (1st Cir. 2007) (overruling on other grounds recognized by *Hagerty ex rel. U.S. v. Cyberonics, Inc.*, 844 F.3d 26, 34 (1st Cir. 2016)). And because one essential element of any such violation is the submission of a false claim or statement to the government, it is not enough to “merely alleg[e] facts related to a defendant’s alleged misconduct”; instead, the plaintiff in an FCA case “must ‘sufficiently establish that false claims were submitted for government payment’ as a result of defendant’s alleged misconduct.” *U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 124 (1st Cir. 2013); *see U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 57 (1st Cir. 2017) (“[T]hat is, even when a relator can prove that a defendant engaged in ‘fraudulent conduct affecting the government,’ FCA liability attaches only if that conduct resulted in the filing of a false claim for payment from the government.”). Moreover, the relator must also identify an allegedly false record or fraudulent statement that was made or used that caused a false or fraudulent claim to be paid by the government. *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 n.7 (1st Cir. 2009).

A. The Complaint’s Speculative Allegations Lack Plausibility and Particularity as to Even the Most Basic Elements of the Schemes It Purports to Plead.

The Complaint is a textbook example of the sort of speculative allegations Rules 12(b)(6) and 9(b) exist to foreclose. Far from identifying facts that could plausibly support his allegations or specific instances of fraud by specific defendants in connection with specific drugs, the Complaint pleads literally no facts specific to any of the PBM Defendants and their Part D contracts. Instead, it espouses pure hypothesis and repeatedly seeks to “conduct fishing expeditions in hopes of discovering claims.” *McCloskey v. Mueller*, 446 F.3d 262, 271 (1st Cir. 2006); *see, e.g., SAC ¶ 106* (“For all the PBM Defendants, we expect discovery to determine that

the manufacturer ‘service fee’ scheme has been a primary driver of both their PBM and overall corporate profit growth over the past decade.”).¹⁰

Relator’s speculative complaint puts the cart before the horse. A plaintiff may not, under Rule 9(b), plead high-level generalizations on the off chance that discovery will turn up fodder for a claim. *See Rost*, 507 F.3d at 733. Indeed, Rule 9(b) applies for the very purpose of “discourage[ing] plaintiffs from filing allegations of fraud merely in the hopes of conducting embarrassing discovery and forcing settlement,” since “[i]t is a serious matter to accuse a person or company of committing fraud.” *Id.* Yet that is *precisely* what Relator has done here. Over the course of almost 160 pages, Relator offers little more than generic, industry-wide assertions that lack any connection to the drugs at issue here, the contractual relationships between the Defendants, the disclosures made by any of the Defendants to CMS, or, for that matter, any specific conduct of any PBM Defendant.

Given the length of the pleading, the absence of actual facts is staggering. Relator never *once* identifies a particular Part D contract or sub-contract, an allegedly false statement made by any Defendant, or a specific false claim submitted, or caused to be submitted, by any of the PBM Defendants (or anyone else); never once identifies the services performed by or service fees actually paid to any PBM Defendants; never once identifies what he believes the fair market value for those services truly was; and never once alleges specific facts showing that any alleged excessive service fee was not disclosed to CMS (let alone how, when, or by whom). On Relator’s ancillary theory regarding “catastrophic coverage” debt forgiveness, he does not identify a single forgiven debt, much less one that he claims was not properly reported to the government. Particularly given the government’s own investigation and declination of this case, this Court

¹⁰ *See also* SAC ¶ 196 (“Close scrutiny of the financial terms and transactions related to these secretive arrangements will be a key part of case discovery.”); *id.* ¶ 432 (“[W]e expect discovery will indicate wide-ranging reporting violations for Avonex and the other Defendant MS drugs.”).

should reject Relator's plan to submit the Defendants to further discovery merely to explore for himself his unsupported hypotheses.

1. The Complaint Lacks Plausible and Particularized Allegations about the Allegedly Unlawful Service Fees.

Relator's theory that Defendants unlawfully concealed excessive service fee payments from CMS relies on at least three key factual premises that Relator must plead with plausibility under Rule 8 and with particularity under Rule 9(b). *First*, Relator must identify the service fees a particular PBM Defendant received for services provided to a Manufacturer Defendant in connection with a particular drug provided under a particular Part D plan. *Second*, Relator must identify the fair market value of those services and the amount by which the fee exceeded that fair market value. *Third*, Relator must plausibly allege that the PBM Defendant caused a plan sponsor not to report the above-fair-market-value amount to CMS. The Complaint, however, does not contain particularized allegations about *any* of those essential facts and thus fails to satisfy the rigorous pleading standard that Relator must meet to escape dismissal under Rule 9(b). *See, e.g., Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) ("Dismissal for failure to state a claim is appropriate if the complaint fails to set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory.").

a. Relator Admits He Does Not Know the Amounts of Any Service Fees.

Relator acknowledges that the compensation structure for service fees can vary from one contract to the next, with many industry participants using "[a] 'percent of revenue' arrangement" while others employ "flat fees and lump sum payments" instead. SAC ¶ 546. He thus recognizes (as he must) that "the PBM Defendant compensation for any particular . . . drug

will depend upon specific contractual terms.” *Id.* ¶¶ 224-25. Yet Relator concedes that he does not know what the terms of *any* of those contracts are. *Id.* ¶ 162.

Unable to allege the actual contract terms or fee rates agreed between any of the PBM Defendants and Manufacturer Defendants, if any, Relator relies instead on what he claims are the “average contract terms for ‘service fees.’” *Id.* ¶ 162. Relator plugs this supposed “average” service fee rate into a series of hypotheticals that purport to “illustrate” how his theory would work in connection with specific drugs—Avonex, Rebif, Betaseron and Copaxone. *See id.* ¶¶ 227–75.

This approach fails for two separate reasons. The first is that this supposed “average” rate has nothing to do with Medicare Part D, the very program that forms the basis of Relator’s entire Complaint. Rather, the “average” figures are from a report about fees in the *private* insurance market. *Id.* ¶ 162; *see also id.* ¶ 173 (acknowledging that the data relates to “private insurance”). But private insurance purchased by individuals, employers, and unions is subject to an entirely separate set of statutes and regulations than Part D coverage paid for by Medicare. *See generally* BERNADETTE FERNANDEZ, VANESSA C. FORSBERG, & RYAN J. ROSSO, CONG. RESEARCH SERV. R45146, FEDERAL REQUIREMENTS ON PRIVATE HEALTH INSURANCE PLANS 2 (2002), available at <https://fas.org/sgp/crs/misc/R45146.pdf> (explaining that “States are the primary regulators of health insurance” in the private market, and that “Federal requirements for health plans are codified in three statutes: The Public Health Service Act (PHSA), the Employee Retirement Income Security Act of 1974 (ERISA), and the Internal Revenue Code (IRC).”). Relator offers no basis whatsoever for concluding that service fees paid in connection with drugs covered under private insurance plans and regulated under distinct legal standards are somehow interchangeable with service fees paid in connection with drugs covered by Part D plans.

The second flaw is that even if Relator's "average" fee rates were applicable to the Part D program, Relator offers no particularized allegations that the *specific* contracts at issue here utilized those rates in connection with the specific MS drugs on which Relator's claims rest. Instead, he offers three hypotheticals in which he simply *assumes*, in order to "illustrate" his theory, that the supposed industry-wide "average" fee for the private insurance market is applicable to individual drugs in the Part D market. *See, e.g.,* SAC ¶ 232 ("*Using the '8% of sales' PhRMA average 'specialty' contract rate, the PBM/specialty pharmacy 'service fee' payment would be \$1,200 for each Avonex-treated patient in 2006*" (emphasis added)). Relator does not actually allege that those are the applicable rates in any of the individually negotiated contracts between the manufacturers of those drugs and any of the PBM Defendants, let alone—as his theory requires—that those are the applicable rates in *all* of those individually negotiated contracts.

Relator's reliance on industry-wide averages is the antithesis of the "particularity" that Rule 9(b) demands. For this reason, courts have repeatedly rejected attempts to leap from alleged conduct is common in a given industry to the conclusion that, because of that industry-wide trend, any given participant in the industry is more likely than not to have engaged in that conduct. This sort of "probabilistic reasoning," courts have concluded, "fails under Rule 9(b)'s heightened pleading standard." *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 257 (6th Cir. 2012) (reasoning that plaintiff's reliance on "the industry-wide existence of questionable appraisal practices" is insufficient because "this argument involves only probabilities"); *see also, e.g., Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 774 (1st Cir. 2011) (allegation that "other banks engaged in such practices, some of which probably distorted loans, and therefore this may have happened in

this case” was insufficient because “there is no allegation that any specific bank that supplied mortgages to the trusts did exert undue pressure”). Relator has not alleged, and has no basis to say, whether any given Defendant’s contractual fee rate for Part D services resembles the industry-wide “average” figure that he asserts. Without that, his claims fail.

In an attempt to fill the critical factual void concerning contracts in effect between the PBM Defendants and the Manufacturer Defendants, Relator points to a pair of contracts to which PBM Defendants CVS and Express Scripts allegedly entered into with *non-defendant* parties. Once again, the contracts used by the Relator are not relevant to Part D; they are contracts with private employers relating to coverage for their employees. *See* SAC ¶¶ 575–99. Even setting aside the absence of any relevance to Part D services, Relator makes no allegation or any reference *at all* to the amount of service fees that CVS was receiving from manufacturers through the contract (let alone the amounts that any of the other PBM Defendants were receiving). *See id.* ¶¶ 590–91. As to the Express Scripts contract, meanwhile, Relator alleges that it provides a *ceiling* for service fees from manufacturers, but does not identify the fees actually paid in connection with any particular drug (which, of course, could be significantly lower than the ceiling described). *Id.* ¶ 578. These contracts are thus irrelevant because they relate to private employer-sponsored plans – not Part D – and do not contain any of the specific facts that Relator must allege to support his theory in this case, against CVS and Express Scripts or otherwise.

Relator cannot satisfy even the most basic pleading requirements. The Complaint does not allege with any specificity the amount of any service fees paid by a Manufacturer Defendant to any PBM Defendant related to Part D, or the terms of any Part D contractual relationships between these parties. Relator has advanced a hypothesis in hopes of capitalizing on his short sale investment strategy, but a hypothesis does not state a cause of action for false claims or

kickbacks—both sounding in fraud—under Rules 12(b)(6) and 9(b). *Grajales v. P.R. Ports Auth.*, 682 F.3d 40, 44-45 (1st Cir. 2012) (“To cross the plausibility threshold a claim . . . must give rise to *more than a mere possibility* of liability.” (emphasis added)).

b. Relator Does Not Allege the Fair Market Value of the Services PBMs Provided and Does Not Even Know What Those Services Were.

The second essential component of Relator’s theory is that the Manufacturing Defendants paid the PBM Defendants amounts that exceeded fair market value for service fees. Relator does not back up this claim with any of the requisite particularity. In fact, it appears that Relator does not even know what services PBMs generally, let alone these PBM Defendants specifically, provide in exchange for service fees. He is thus unable to (and does not) plead what the fair market value for the services allegedly should have been. *See, e.g.*, SAC ¶ 606 (describing what he “expect[s] discovery to uncover” about what “support services” the PBM Defendants supply to their clients).

This failure, too, provides grounds for dismissal. Courts have consistently held that where a relator asserts that a defendant has violated the FCA by paying or receiving compensation in excess of fair market value without disclosing that compensation, the relator “must allege a benchmark of fair market value against which Defendants’ [compensation arrangements] . . . can be tested.” *U.S. ex rel. Schaengold v. Mem’l Health, Inc.*, No. 4:11-cv-58, 2014 WL 7272598, at *11 (S.D. Ga. Dec. 18, 2014) (bracket and internal quotation marks omitted); *see also U.S. ex rel. Schubert v. All Children’s Health Sys., Inc.*, No. 8:11-cv-1687, 2013 WL 6054803, at *11 (M.D. Fla. Nov. 15, 2013); *U.S. ex rel. Dennis v. Health Mgmt. Assocs., Inc.*, No. 3:09-cv-484, 2013 WL 146048, at *13 (M.D. Tenn. Jan. 14, 2013); *U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253, 2012 WL 2871264, at *7 (S.D. Fla. July 12, 2012).

Relator offers no such comparative benchmark here, nor does he allege what the fair market value payment should have been for any specific contract or for any specific services. To the contrary, the SAC admits that CMS has “purposely not defin[ed] methods for BFSF fair market value assessment in the Part D program” and that as a result “each drug manufacturer must determine its own process based upon acceptable practices in the private marketplace.”¹¹ SAC ¶ 539.

Relator attempts to salvage his claims by offering his own view that “the appropriate ‘arm’s length’ compensation to the PBM Defendants for providing manufacturer services should be very modest, even for ‘complex’ specialty drugs.” *Id.* ¶ 554. In support, Relator points to a statement by an entity he identifies as Diplomat Pharmacy—“the largest remaining independent specialty pharmacy”—made in an SEC filing: “[W]e incur significant costs in providing these services and receive minimal service fees in return.” *Id.* ¶¶ 554, 557 (emphasis omitted). But Diplomat Pharmacy is not a PBM akin to any of the Defendants in this case, nor do Diplomat’s statements relate to services provided by PBMs in connection with the Part D program. Diplomat is, the Complaint acknowledges, a specialty pharmacy and, in this role, provides a different scope and type of services than the PBM Defendants provide. *See id.* ¶¶ 554–55. Moreover, a single statement by Diplomat Pharmacy hardly establishes a fair market value benchmark, as is required.

In sum, the Complaint never offers a particularized allegation of the services at issue under any Part D contract; what the fair market value of those services was for even a single one

¹¹ Even if a “cost approach” were the only acceptable method for determining fair market value of a PBM’s administrative services in the Part D context, as Relator suggests, *see* SAC ¶¶ 458, 469, the Complaint would still be inadequately pleaded. Relator never describes what a fair market value payment for the PBM Defendants’ services on any of the drugs in question would be using the “cost approach” method.

of the drugs at issue; or whether or why any particular payments by particular Defendants for particular services under particular contracts exceeded fair market value.

c. Relator Lacks Any Particularized Allegations that the PBM Defendants' Service Fees Were Not Properly Reported to CMS.

Finally, Relator equally fails to offer adequate allegations that any PBM Defendant's service fees were not properly reported to CMS—the third critical component to his legal theory.

In a plan sponsor's Part D DIR reports to CMS, the plan sponsor is required to report as a price concession any portion of a service fee that exceeded fair market value. *See, e.g.*, SAC ¶ 31. ("As per [CMS] regulations, 'service fees' in excess of fair market value should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D. In turn, the plan sponsor . . . should report 'service fees' in excess of fair market value to CMS in [its DIR] report as [a] 'discount,' leading to lower Part D 'negotiated' drug prices."). In other words, CMS regulations *permit* fees to be set at above fair market value, so long as the difference is reported to CMS as a discount (and thus inures to CMS's benefit by lowering its costs). Relator's FCA theory thus depends on establishing not only that any service fees charged by the PBM Defendants were excessive, but also that these excessive fees—through the actions of the PBM—were not reported to CMS as required under Part D DIR guidance and regulations and thus led to the submission of false claims by the plan sponsors. Relator fails to plead any such allegations, with particularity or otherwise.

Relator offers only a vague and cursory allegation that "[t]he Defendants are intentionally not doing so"—i.e., not reporting service fees in excess of fair market value to the government. *Id.* But he alleges no specific facts *at all* to support this crucial aspect of his case. For this reason, too, Relator's claims should be dismissed.

2. Relator Also Fails to Present Particularized Allegations About Supposed Catastrophic Coverage Payment Waivers.

Relator's speculative catastrophic coverage theory fails under Rule 9(b) for the same reasons as his service fees theory, and the Court should readily dispose of these allegations. As discussed above, Relator cannot support this theory without alleging facts showing that (1) PBM Defendants incurred and owed "catastrophic coverage" payments in Part D in connection with the expensive drugs that trigger "catastrophic coverage" requirements; (2) the Manufacturer Defendants forgave the "catastrophic coverage" debts allegedly owed by the PBM Defendants' affiliated Part D plan sponsors; and (3) the PBM Defendants failed to report those forgiven amounts to the government as discounts or rebates. *See, e.g.*, SAC ¶¶ 397–442. Like his allegations about the service fees, however, Relator fails to plead any particularized allegations to support any of these key factual components of his theory. This theory, as well, is purely speculative.

First, Relator offers no particularized allegations that any catastrophic coverage payments were actually owed by any of the PBM Defendants, nor that any of the Manufacturer Defendants has ever forgiven any such debts, let alone any debts related to any of the drugs at issue in this suit or in relation to a Part D contract or subcontract. Instead, he merely hypothesizes that (a) the PBMs are more profitable than his analysis of their SEC disclosures suggests that they should be, and (b) receiving massive debt forgiveness from the Manufacturer Defendants (apparently, in addition to excessive service fees) must be the explanation. *See, e.g.*, SAC ¶¶ 415–23. Based on that speculation, Relator alleges that "[w]e concluded that the Manufacturer Defendants, *in many instances*, are 'forgiving' the PBM Defendants for this 'catastrophic exposure' in order to further the 'service fee' pricing scheme." *Id.* ¶ 309 (emphasis added); *see also id.* ¶ 424 ("We concluded that, *in many instances*, manufacturers are fraudulently excusing the PBM Defendants from their 15% 'catastrophic' cost-sharing exposure" (emphasis added)). Tellingly, Relator fails to

identify even one such “instance” in his Complaint. Relator does not claim to have ever seen or heard about any document reflecting forgiven “catastrophic coverage” debt. Nor does he offer any explanation for his leap from his (unsupported) speculation that the Manufacturer Defendants are forgiving debts “in many instances,” *id.* ¶¶ 309, 424, to his conclusion that they have forgiven debt owed by PBM Defendants in connection with the specific drugs at issue here. Without such particularized allegations to connect his amorphous hypotheses to the claims he is actually pursuing, he cannot satisfy Rule 9(b).

Second, Relator has not identified any instances in which debt forgiveness actually occurred but was not properly reported to CMS under the Part D program. As with his service fee theory, particularized pleading of those facts is necessary because—as he acknowledges—there is nothing wrong with debt-forgiveness so long as it is properly reported to CMS on the designated forms as a rebate or discount. *See id.* ¶ 431 (“If the Manufacturer Defendants are commonly ‘forgiving’ the PBM Defendants from their Part D catastrophic exposure, these amounts should be properly reported as discounts via Direct and Indirect Remuneration (“DIR”) reports to CMS . . .”). The most Relator can say is that “*we expect discovery will indicate* wide-ranging reporting and financial fraud for Avonex and the other Defendant MS drugs.” *Id.* ¶ 432 (emphasis added). Simply put, he concedes that he filed his Complaint “in hopes of discovering claims” through a “fishing expedition,” *McCloskey*, 446 F.3d at 271, which Rule 9(b) forbids.

3. Relator Fails to Make Specific Allegations Against Any of the PBM Defendants, in Violation of Rule 9(b).

Relator consistently aggregates entirely separate companies, which have entirely separate interactions with manufacturers and Part D, under the rubric “PBM Defendants.” *See* SAC ¶¶ 1, 130. Relator does not distinguish conduct purportedly attributable to any one of the PBM Defendants (Aetna, Cigna, Humana, CVS Health, Express Scripts, or UnitedHealth Group), each

of which are large corporations with wide-ranging business operations and functions and disparate organizational structures. See SAC ¶¶ 124–29. Relator’s generalized and undifferentiated allegations against all PBM Defendants as a group are neither credible nor legally sufficient and, for that reason too, should be dismissed. *Goebel v. Schmid Bros. Inc.*, 871 F. Supp. 68, 73 (D. Mass. 1994) (“When multiple defendants are involved in cases arising in this circuit, Rule 9(b) requires that fraud be alleged particularly as to each defendant.”); *Kermanshah v. Kermanshah*, 580 F. Supp. 2d 247, 258 (S.D.N.Y. 2008) (“[A] complaint alleging fraud against multiple defendants must state the allegations specifically attributable to each individual defendant.”).

B. Relator’s Anti-Kickback Statute Theory Fails for the Same Reasons as His FCA Theory, and for Several Additional Reasons.

Relator also alleges that the PBM Defendants engaged in criminal conduct in violation of the Anti-Kickback Statute. See 42 U.S.C. § 1320a-7b(b)(2)(A) (hereinafter the “AKS”). While a violation of the AKS can serve as a predicate for an FCA violation, to survive a motion to dismiss, Relator must plausibly and specifically allege the elements of both the AKS and the FCA.¹² Relator alleges that “[t]he PBM Defendants . . . receive fraudulent ‘service fees’, as ‘kickbacks’, for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies” SAC ¶ 81. Relator asserts throughout the Complaint the conclusory mantra that purported “service fee” payments must have been “kickbacks” because they exceeded fair market value for the services rendered. See, e.g., *id.* ¶¶ 290, 520, 525, 532, 534, 559. As a result, according to Relator, “[v]irtually all Part D submissions for reimbursement pertaining to the

¹² The Anti-Kickback Statute makes it a crime to: (1) knowingly and willfully, (2) offer or pay, (3) any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person, (4) to induce such person, (5) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service, (6) for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A). For a further discussion regarding the AKS, see Mem. of Law in Support of Manufacturer Defendants’ Jt. Mot. to Dismiss Borzilleri’s SAC, at 8–11.

Manufacturer Defendant drugs over the past 12 years-plus have been ‘tainted’ by kickbacks and have been false claims.” *Id.* ¶ 89. Relator also appears to allege that manufacturers’ supposed forgiveness of “catastrophic coverage” debts was also exchanged for formulary placement of their drugs. *Id.* ¶¶ 81, 83, 397–435.

The Court should reject Relator’s AKS claim on the same basic grounds that warrant dismissal of his FCA claims. He has failed to allege with particularity: (1) any of the supposed services provided in exchange for “service fees” on which his whole theory of liability is based; (2) why these services were “not necessary” or were a “sham”; (3) the fair market value of the services; (4) the amount actually paid for the services; (5) why the amount paid exceeded fair market value and by how much; or (6) whether service fees should have been or were reported to Medicare Part D. For all or any of these reasons, already discussed above, his AKS theory fails.

Relator’s AKS theory suffers additional fundamental flaws, too. First, the AKS requires proof that the Manufacturer Defendants paid (or were solicited to pay) “service fees” to the PBM Defendants to “induce” illegal referrals of Part D business. 42 U.S.C. § 1320a-7b(b)(1), (b)(2)(A); *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App’x 890, 894 (5th Cir. 2013) (“[A]ctual inducement is an element of the AKS violation . . . and [relator] must provide reliable indicia that there was a kickback provided in turn for the referral of patients.”). All Relator appears to allege is that the service fees (which Relator hypothesizes must have been excessive) must have been intended to secure favorable formulary placement. But he does not allege any particular facts even suggesting that this actually occurred between any Defendants, let alone in the Part D Program. The far more reasonable explanation is that any service fees were paid in exchange for legitimate services provided by PBMs.

Second, even if Relator had alleged that a drug manufacturer paid above-fair-market-value service fees with the intent to sway formulary decisions, Relator makes no plausible allegation that any PBM Defendant “*knowingly and willfully*” participated in any such conduct. *See* 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added). Relator cannot adequately allege knowledge or willfulness under the AKS without plausibly setting forth facts showing that each Defendant knew its conduct was unlawful. *Bryan v. U.S.*, 524 U.S. 184, 196 (1998) (holding that willfulness requires that the defendant had “knowledge that the conduct is unlawful”); *U.S. v. Bishop*, 740 F.3d 927, 932–33 (4th Cir. 2014); *U.S. v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013) (an AKS violation requires proof that the defendant “acted with the intent to do something that the law forbids”) (internal quotation marks omitted). Here, Relator uses the word “willful” just *once* in his 159-page pleading. SAC ¶ 153(2).

C. The Complaint Fails to State a Claim for Conspiracy to Submit False Claims.

To survive a motion to dismiss on a conspiracy claim under the FCA, a relator must allege with particularity that defendants entered into an unlawful agreement to defraud the government and took one or more acts in furtherance of the agreement. *See U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) (“Rule 9(b) requirements apply to conspiracy claims under [the FCA]”). Doing so requires pleading “(1) who the co-conspirators are, (2) when or where they entered into an agreement to defraud the government, or (3) what overt acts they took in furtherance of the conspiracy.” *U.S. ex rel. Leysock v. Forest Labs, Inc.*, 55 F. Supp. 3d 210, 221 (D. Mass. 2014).¹³ Although Count II of the Complaint purports to allege an FCA conspiracy, Relator has failed to meet these essential pleading requirements, in addition to other deficiencies of the Complaint discussed above. There is no particularized allegation of an

¹³ Previously, the FCA imposed liability on anyone who “conspire[d] to defraud the Government by getting a false or fraudulent claim allowed or paid.” 31 U.S.C. § 3729(a)(3) (2006). Now, it imposes liability on anyone who “conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G).” 31 U.S.C. § 3729(a)(1)(C).

agreement between any Defendants (or anyone else, for that matter) to violate the FCA. Relator makes only the conclusory statement that “Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims.” SAC ¶ 700. This is insufficient under both Rule 12(b)(6) and Rule (9)(b). *See, e.g., Leysock*, 55 F. Supp. 3d at 221; *U.S. ex rel. Estate of Cunningham v. Millennium Labs. of California*, No. 09-12209-RWZ, 2014 WL 309374, at *2 (D. Mass. Jan. 27, 2014) (dismissing FCA conspiracy claim under Rule 9(b) where “[t]he Complaint includes no allegations of an agreement between defendant and any physician to defraud the government”).

Relator also does not make any plausible factual allegations of an “overt act” in furtherance of an agreement to violate the FCA, let alone with the particularity demanded by Rule 9(b). As elsewhere in the SAC, Relator relies on a boilerplate allegation—devoid of facts—that defendants “took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.” SAC ¶ 700. This summary allegation cannot stave off dismissal, *see Iqbal*, 556 U.S. at 678, and falls well short of meeting the heightened pleading requirements of Rule 9(b). The Court should dismiss Count II.

D. The Ancillary State Law Claims Fail to Allege Any Plausible Claims Under Any State FCA.

Relator’s state law claims, Counts 5 through 32, are subject to the same Rule 12(b)(6) and (9)(b) pleading standards applicable to his federal claims, *see, e.g., U.S. ex rel. Rost*, 507 F.3d at 731 n.8, and they are premised on the same thin factual allegations he offers to support

his federal FCA counts. Therefore, this Court should dismiss all analogous state FCA counts for the same reasons outlined above.¹⁴

* * * * *

The Court need go no further to resolve this case: Relator's failure to offer the plausible and particularized allegations that the Federal Rules of Civil Procedure demand of a plaintiff in a fraud case mean that the Complaint cannot go forward. Because there is no indication that Relator would ever be able to provide anything other than "extra grist for speculation" to "cure the inferential gaps" in his Complaint, moreover, dismissal with prejudice is warranted. *U.S. ex rel. Kelly v. Novartis Pharmaceuticals Corp.*, 827 F.3d 5, 15 (1st Cir. 2016) (holding that "[w]e need hardly rely upon the abuse-of-discretion standard to affirm the district court's decision to dismiss the federal claims with prejudice" where further attempts at amendment would have been futile). But there is another independent basis for dismissal. As the next section explains, Relator's attempt to conjure a FCA suit by appropriating publicly available information—and adding no "insider" information of his own—runs directly into the FCA's public disclosure bar.

II. RELATOR'S FCA CLAIMS ARE PRECLUDED BY THE PUBLIC DISCLOSURE BAR.

The FCA's "public disclosure" bar precludes suits by "opportunistic plaintiffs who have no significant information to contribute of their own." *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 294 (2010). In other words, it "forecloses qui tam actions in which a relator, instead of plowing new ground, attempts to free-ride" by simply repeating "previously disclosed badges of fraud." *U.S. ex rel. Winkelman v. CVS Caremark*

¹⁴ Relator also purports, in counts 33 and 34 of the Complaint, to assert common law claims for unjust enrichment and common law fraud on behalf of the United States. It is well-settled, however, that "[a] relator in a qui tam FCA action does not have standing to assert common law claims based upon injury sustained by the United States." *U.S. ex rel. Allen v. Alere Home Monitoring, Inc.*, --- F. Supp. 3d ---, 2018 WL 4119667, at *14 (D. Mass. Aug. 29, 2018) (quoting *U.S. ex rel. Rockefeller v. Westinghouse Elec. Co.*, 274 F. Supp. 2d 10, 14 (D.D.C. 2003)). Accordingly, counts 33 and 34 are subject to dismissal for this additional reason as well.

Corp., 827 F.3d 201, 206 (1st Cir. 2016) (quoting *U.S. ex rel. Ondis v. City of Woonsocket, et al.*, 587 F.3d 49, 53 (1st Cir. 2009)); accord *U.S. ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 (1st Cir. 2010). That is precisely what Relator is doing here—indeed, he blatantly pleads that his allegations are based on various public disclosures cited in the Complaint and concedes that he has no inside information from which to draw in pleading these claims. *See, e.g.*, SAC ¶¶ 116, 205, 235–242; First Am. Compl. ¶ 92.

The fundamental question under the public disclosure bar is whether “substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed” in any of the enumerated sources identified in the statute. *Winkelman*, 827 F.3d at 208 (quoting 31 U.S.C. § 3730(e)(4)(A) (2010)).¹⁵ To make that determination, courts analyze: (1) whether the allegations or transactions identified in the relator’s complaint have been publicly disclosed; (2) whether the disclosures occurred through the statutorily-prescribed methods; and (3) whether the relator’s allegations are “based upon”—*i.e.*, are “substantially similar to”—those previously disclosed. *See, e.g., id.* at 208; *Ondis*, 587 F.3d at 53; *cf. Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 407–08 (2011) (noting that § 3730(a)(4)’s use of broad terms like “allegations,” “transactions,” “news media,” and “report[s]” suggest a “wide-reaching public disclosure bar,” with respect to both the substance of prior disclosures and the sources in which they appeared).

¹⁵ The Affordable Care Act (ACA) amended the public disclosure bar effective March 2010. Thus, to the extent the Relator alleges false claims made between 2006 and March 23, 2010, the pre-ACA version governs. *See, e.g., Poteet*, 619 F.3d at 107 n.2 (noting that ACA amendments to public disclosure bar are “not retroactive”). As to post-March 2010 false claims, the amended version controls. And as to allegations that straddle the March 2010 effective date, every federal court of appeals to have considered the question has concluded that the amended version of the statute applies. *See U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 841 F.3d 927, 933 n.1 (11th Cir. 2016); *U.S. ex rel. Bloedow v. Planned Parenthood of the Great Nw. Inc.*, 654 F. App’x 335, 335 n.1 (9th Cir. 2016); *U.S. ex rel. Gage v. Davis S.R. Aviation, LLC*, 658 F. App’x 194, 197 n.1 (5th Cir. 2016); *U.S. ex rel. Zeibell v. Fox Valley Workforce Dev. Bd., Inc.*, 806 F.3d 946, 951–52 (7th Cir. 2015); *U.S. ex rel. Antoon v. Cleveland Clinic Found.*, 788 F.3d 605, 614–15 (6th Cir. 2015); *U.S. ex rel. Judd v. Quest Diagnostics Inc.*, 638 F. App’x 162, 165 (3d Cir. 2015); *U.S. ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 915 (4th Cir. 2013). The First Circuit does not appear to have weighed in on that issue, but it is immaterial here because the analysis under both the pre- and post-ACA versions of the public disclosure bar lead to the same result in this case.

To determine whether a relator's allegations are "substantially similar" to prior public disclosures, the court must "compare the substance of the prior disclosures with the substance of the relator's complaint." *Poteet*, 619 F.3d at 114. At bottom, the "ultimate inquiry" is "whether the government has received fair notice, prior to the suit, about the potential existence of the fraud," *Winkelman*, 827 F.3d at 208-09, which is satisfied wherever "the materials necessary to ground an inference of fraud are generally available to the public," *Poteet*, 619 F.3d at 111. If the test is met, a relator's claims can only proceed if he is an "original source" of his allegations. *E.g.*, *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009); *accord* 31 U.S.C. § 3730(e)(4)(A).

Because prior public disclosures in news media and government reports are substantially similar to the allegations in the Complaint, and Relator is not an original source, the public disclosure bar applies and the Court should dismiss the Complaint with prejudice. *See* 31 U.S.C. § 3730(e)(4)(A).

A. Factual Allegations and Fraud Inferences Substantially Similar to Those in Relator's Complaint Were Publicly Disclosed in Qualifying Sources Before He Filed This *Qui Tam* Action.

Whether a prior disclosure involved allegations "substantially similar" to those made in the operative *qui tam* complaint depends on whether "enough was revealed in the [prior] disclosures to put the government on notice of the potential fraud without the aid of the[] relator[]." *Winkelman*, 827 F.3d at 209; *accord U.S. ex rel. Springfield Term. Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994). Claims that are even partly based on public disclosures are deficient under the statute. *U.S. ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 237 (3rd Cir. 2013). Indeed, the public disclosure bar prohibits claims where a relator has simply "memorializ[ed] . . . easily inferable deductions" from public disclosures, *Winkelman*, 827 F.3d at 210, or added "greater detail about the underlying conduct" involved in a scheme that already

was “previously revealed through public disclosures.” *Id.* A public disclosure need not “use magic words or specifically label disclosed conduct as fraudulent” in order to bar a similar *qui tam* claim. *Id.* at 209. The public disclosure bar applies so long as the public sources, taken together, allow for an “inference of fraud [to be] drawn.” *Ondis*, 587 F.3d at 54.

The same is true where the relator’s “independent investigation” or analysis of publicly-disclosed material forms the basis for his allegations. For example, in *Ondis* the First Circuit dismissed the relator’s FCA claims on public-disclosure grounds, even though the relator had conducted his own investigation of public records, including conducting non-public interviews with local developers and others with knowledge of the city’s housing policies and obtaining documents from HUD. *Id.* at 52, 60–61. Notwithstanding the relator’s investigatory efforts there, his *qui tam* claims were doomed by the fact that his alleged facts and inferences of fraud mirrored those reflected in local news media and HUD materials obtained through FOIA requests. *See, e.g., id.* at 58; *accord, e.g., Schindler Elevator*, 563 U.S. at 413 (applying public disclosure bar to relator who relied upon his own “suspicio[ns]” and government information gathered through FOIA requests and thus presented “classic example of ‘opportunistic’ litigat[or] that the public disclosure bar is designed to discourage”); *U.S. ex rel. Alcohol Found. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 461–62 (S.D.N.Y. 2002) (applying public disclosure bar where relator gathered information from articles published by third parties and obtained a unique “perspective” by “spending hundreds of hours compiling facts into a ‘mosaic’”).

As demonstrated below, drug manufacturer service fees to PBMs are well-known and are based on a long-disclosed subject of public discussion and government focus.

2011 OIG Report. In March 2011—nearly three years before Relator filed this *qui tam* action—the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) released a report entitled, “Concerns with Rebates in Medicare Part D.” *See* Ex. G, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, REPORT OEI 02-08-00050, CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, (2011). In all material respects, Relator’s Complaint contemplates the same potential for fraud as the OIG recognized in its report. Indeed, Relator cites that very OIG report as support for his suspicions. *See* SAC ¶¶ 227–30. The OIG Report described the results of OIG’s examination of administrative fees received by PBMs, noting that: (a) PBMs were receiving “fees from drug manufacturers,” (b) in exchange for “services that the PBM provided to the manufacturer, such as negotiating rebates, calculating rebate amounts, and distributing rebates to sponsors,” and (c) the fees “were generally based on a fixed percentage of [Wholesale Acquisition Cost].” Ex. G at ii, 18–19. A majority of the PBMs receiving such fees “did not pass them on to the sponsors” and, “[a]s a result, the sponsors did not report the fees to CMS and therefore they were not passed on to the [Medicare Part D] program,” all because the “PBMs considered these fees to be bona fide service fees, which CMS does not consider price concessions if they are at fair market value.” *Id.* at 19. OIG concluded that reporting of such fees to CMS “may be inaccurate[]” and *recommended an assessment of “whether these fees should be considered rebates.” Id.* (emphasis added). That same spring, OIG’s Semiannual Report to Congress noted that some PBMs “collected fees from drug manufacturers that were not always passed on to the Part D program.” Ex. H, OIG, Semiannual Report to Congress, Oct. 1, 2010–Mar. 31, 2011, at I-16. Two years later, in OIG’s Fall 2013 Semiannual Report to Congress, OIG publicly disclosed that it had

begun undertaking reviews of bona fide service fees. Ex. I, OIG, Semiannual Report to Congress, Apr. 2013–Sep. 2013, at 95–96 (App’x B).

These OIG reports, which squarely qualify as administrative “report[s], . . . audit[s], or investigation[s],” and which are enumerated sources in the statute, 31 U.S.C. § 3730(e)(4)(A), publicly disclosed the inference of fraud that Relator postulates, *i.e.*, that the PBM Defendants received service fees based on a percentage of sales price (namely, WAC), did not pass those fees on to Medicare Part D, and that that conduct amounted to inaccurate reporting and wrongful retention of those funds if they did not constitute bona fide service fees. Ex. D at 7. These OIG reports vividly demonstrate the government’s awareness of the potential fraud alleged by Relator and are quintessential public disclosures that bar Relator’s claims. *See* 31 U.S.C. § 3730(e)(4)(A).

Other Pre-2014 Public Disclosures. OIG’s reports were not the first or only public disclosures that contemplated whether service fees paid by drug manufacturers to PBMs might be improperly reported. Both Relator’s conclusory inferences and the raw materials from which he draws them were a subject of open discussion dating back to the early 2000s.¹⁶

- September 1, 2002, Managed Care, *When Success Sours: PBMs Under Scrutiny* (Ex. J), at 4: “PBMs receive other payments from manufacturers that are not rebates and which are paid separately. These include *administrative fees for services rendered in connection with rebate agreements*. . . . Halbert told analysts that administrative fees don’t exceed 3 percent of the *amount spent for the branded drugs covered by the fees*. . . . *The company retains . . . the administrative fees paid by the drug makers.*” (emphasis added)
- Spring 2003, Journal of Health Law, *The Spotlight on PBMs: Federal Enforcement of the Anti-Kickback Statute on the Pharmaceutical Benefit Management Industry*, 36 J. HEALTH L. 213, 218 (Ex. K): “PBMs . . . typically receive both an administrative fee

¹⁶ The sources referenced here properly may be considered by the Court on this Motion. *See, e.g., Winkelman*, 827 F.3d at 207–08 (noting that a “press release, news articles, CRS report, and record of congressional testimony” were properly before the court regardless of whether the public disclosure inquiry was jurisdictional because “even within the Rule 12(b)(6) framework, a court may consider matters of public record and facts susceptible to judicial notice”).

and a rebate from drug manufacturers. . . . As noted in a HCFA report, “[r]ebates and administrative fees are commonly paid as a percent of the drug’s wholesale acquisition cost (WAC)—which represents the manufacturer’s sale price.” (emphasis added)

- January 28, 2005, 70 Fed. Reg. 4194, 4308–4309 (Medicare Prescription Drug Benefit Final Rule) (Ex. L): “In the preamble to the proposed rule, we said that to the extent the administrative fees paid to Part D plans (or their subcontractors, such as PBMs) are above the fair market value of the services rendered, this differential will be considered a price concession. . . . [A]s fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not *masked as administrative fees*.” (emphasis added)
- September 8, 2005, News Release, U.S. Attorney’s Office, *AdvancePCS to Pay \$137.5 Million to Resolve Civil Fraud and Kickback Allegations* (Ex. M), at 1: “The civil settlement resolves claims under the False Claims Act . . . arising from (1) *payments made by pharmaceutical manufacturers to AdvancePCS in the form of excessive administrative fees and over-priced products and services agreements as an improper reward for favorable treatment of the manufacturers’ drugs in connection with the contracts . . .*” (emphasis added). *See also* Dep’t of Health & Human Servs. & Dep’t of Justice, Health Care Fraud & Abuse Control Program, Annual Report for FY 2005 (Aug. 2006), at 7–8 (describing AdvancePCS settlement) (Ex. N).
- January 2007, Congressional Budget Office (CBO), *Prescription Drug Pricing in the Private Sector* (Ex. O), at 12: “Manufacturers also make other types of payments to PBMs in addition to rebate payments. For example, *manufacturers commonly pay a fee to PBMs for the service of administering formularies. Such fees are frequently equal to about 3 percent of wholesale list prices*.” (emphasis added)
- March 6, 2009, Business Wire, *State of Maryland’s CVS Caremark Contract Audit Reveals More than \$10 Million in Potential Overpayments, Undisclosed Rebates, Improper Drug Switching, According to CtW* (Ex. P), at 1: “In 2006, the United States Office of Personnel Management . . . [determined CVS’s predecessor, AdvancePCS,] kept \$13 million in administrative fees that should have been considered drug rebates and returned to the federal agency.”
- January-February 2013, Specialty Pharmacy Times, *Why We Care About Bona Fide Service Fees* (Ex. Q), at 1–2: “Bona Fide Service Fees (BFSFs) is one of the most important industry terms today, with a dramatic impact across pharmaceutical manufacturers, . . . specialty pharmacy and specialty distributors, and GPOs, as well as CMS and oversight agencies such as the [OIG] and [DOJ]. . . . *The price that the government reimburses for pharmaceutical products under . . . Medicare . . . is impacted by the fees the manufacturer pays to trading partners and how those fees are treated. If a fee is considered a legitimate administrative fee, or a BFSF, it is excluded from statutory pricing calculations that the manufacturer submits to the government, which in turn defines the ‘Government Price.’ If the price is a price incentive (not an excluded BFSF), it also affects pricing. Therefore, the treatment of*

fees moves pricing and reimbursement up or down. . . . If the government pays more than it thinks it should for pharmaceutical products under these programs, it can apply the False Claims Act, which is legal action related to the pharmaceutical manufacturer submitting incorrect data which causes the government to pay more than it should. . . . [T]he treatment of fees impacts all of the statutory pricing. . . .” (emphasis added)

- October 7–8, 2013, CBI Conference, Fair Market Value of Bona Fide Service Fees: Ensure Accuracy of Reported Government Pricing and Compliant Documentation Practices: An industry conference conducted by CBI on the subject of “[a]pproaches to determining fair market value (FMV) and bona fide service fees (BFSF),” which “continue to be a challenge due to limited guidance . . . [and] heavy governing scrutiny,” was open to anyone who paid the registration fee. (Ex. R) All presenters’ presentation materials were subsequently available online for purchase as a “Compendia.” (Exs. S, T). According to Relator, “[a]ll key components of the fraud were verified via presentations . . . at the conference.” SAC ¶ 458.

CBO reports, DOJ press releases, and articles published in Business Wire and various healthcare industry and academic publications clearly constitute “news media.” *See, e.g., Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 291, 297–98 (S.D.N.Y. 2013) (“news media” extends “to ‘smaller’ or ‘professionally specialized’ reader bases”); *cf., e.g., Alcohol Found.*, 186 F. Supp. 2d at 463 (“news media” encompasses published information in “scholarly or scientific periodicals”). Likewise, a written presentation, advertised and available online (even for a fee), counts as a public disclosure under the broad definition of “news media.” *See, e.g., U.S. ex rel. Ondis v. City of Woonsocket, R.I.*, 582 F. Supp. 2d 212, 217 (D.R.I. 2008) (concluding that information published in legal notices or classified advertisements, rather than “substantive news stories,” nevertheless constituted “news media”), *aff’d*, *Ondis*, 587 F.3d 49; *U.S. ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (collecting cases finding that public or promotional websites, legal notices, and advertisements count as “news media”); *cf., e.g., Patriarca*, 295 F. Supp. 3d at 200 (public disclosure not impacted by required “annual subscription fee” to access journal); *U.S. ex rel. Brown v. BankUnited Trust 2005-1*, 235 F. Supp. 3d 1343, 1354–56 (S.D. Fla. 2017) (public disclosure not impacted by procedural

necessity of filing formal requests to obtain materials). Thus, notwithstanding Relator's dramatic characterizations of a conference that he attended organized by CBI as a conspiratorial meeting solely of "industry expert[s]" and "insider[s]," SAC ¶¶ 446, 452, the written presentations from that conference (which Relator describes in SAC ¶¶ 452–89) are public disclosures that were provided to dozens of members of the public and available for sale to the general public. *See Patriarca*, 295 F. Supp. 3d at 200; *accord U.S. ex rel. Rost*, 507 F.3d at 728 n.6 (noting that a disclosure need not be made to *all* members of the general public for the public disclosure bar to apply). Taken together, these sources provided sufficient facts from which an inference could be drawn that at least some PBMs were basing their administrative fees on drug price and retaining some of those fees, rather than reporting them as remuneration for purposes of Medicare Part D reimbursement. Those are precisely the components of the PBMs' supposed fraud alleged in Relator's complaint.

It is irrelevant that these public sources did not identify each of the specific PBM Defendants because, as Relator contends, PBMs are a relatively small and easily identifiable group. SAC ¶ 16. Where the methodology of the supposed fraud and the types of entities involved have been generally aired in prior disclosures, a relator cannot reap a *qui tam* recovery merely by performing the straightforward task of using public information to name particular defendants. *See, e.g., In re Natural Gas Royalties*, 562 F.3d 1032, 1043 (10th Cir. 2009); *U.S. v. Emergency Med. Assocs. of Ill., Inc.*, 436 F.3d 726, 728–29 (7th Cir. 2006) (application of the public disclosure bar was "not [even] a close question" where "since the mid-1990s" there had been "public allegations that Medicare was being billed for services provided by residents as if attending physicians had actually performed the services" and the relator had merely asserted that false-claims theory against specific defendants).

This principle is particularly applicable when the government itself has ready access to documents from which it could identify particular participants in an industry-wide practice. *See, e.g., U.S. v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999) (barring FCA claims when prior complaint alleged the same general scheme against different defendants because the government “presumably would have ready access to documents identifying [the] contractors” and “could easily identify the contractors at issue” itself); *U.S. ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 569–72 (10th Cir. 1995) (dismissing FCA claims when prior disclosures necessarily implicated a group of unnamed laboratories because “the government has already identified the problem and has an easily identifiable group of probable offenders”).

The public documents identified disclose the possibility of PBMs receiving service fees that might have exceeded the fair market value of the services provided, and failing to pass them along as price concessions to plan sponsors and ultimately CMS. Further, there are a relatively small number of easily identifiable PBMs, and the government—not Relator—was well positioned to consult Medicare Part D submissions already in its possession to identify any particular PBMs that may have engaged in the service fee-related practices described in the public disclosures between 2002 and 2013. Relator’s allegations are plainly “based upon” conduct described in numerous public sources years before he filed this *qui tam* suit. Therefore, Relator’s claims are barred unless he is an “original source” of his allegations. 31 U.S.C. § 3730(e)(4). He is not.

B. Relator Is Not an “Original Source.”

With respect to Relator’s pre-2010 claims, Relator is only an “original source” if he had “direct and independent knowledge” of the information underpinning his claims. 31 U.S.C. § 3730(e)(4) (2006). As to post-2010 claims, relator must have had “knowledge that is independent of and *materially adds to* the publicly disclosed allegations or transactions.” 31

U.S.C. § 3730(e)(4)(B) (2010) (emphasis added). Knowledge is “direct,” if it is “immediate,” as “marked by [the] absence of an intervening agency, instrumentality, or influence.” *Ondis*, 587 F.3d at 59. On the other hand, knowledge is not “direct” if it is “based on research into public records, review of publicly disclosed materials, or some combination of these techniques.” *Id.* The “original source” rule differentiates “between those individuals who . . . simply stumble upon a seemingly lucrative nugget and those actually involved in the process of unearthing important information about a false and fraudulent claim.” *Ping Chen*, 966 F. Supp. 2d at 299. Additionally, under both the pre- and post-ACA versions of the statute, Relator must also have voluntarily “provide[d] his . . . information [to the Government] prior to the filing of the qui tam suit.” *Duxbury*, 579 F.3d at 28; *see also* 31 U.S.C. § 3730(e)(4)(B).

Relator is not an original source for three reasons.

First, the Complaint gives no indication that Relator voluntarily shared his information with the government *before* filing this *qui tam* suit under seal in January 2014, which dooms his FCA claims. *See, e.g., Duxbury*, 579 F.3d at 28; *AI Procurement, LLC v. Hendry Corp.*, No. 11-cv-23582, 2013 WL 12061864, at *8 (S.D. Fla. June 24, 2013) (rejecting “original source” solely on this basis).

Second, Relator here falls well short of possessing the “independent” knowledge necessary to qualify as an “original source” under either version of the statute, precisely because the knowledge underpinning his allegations necessarily “depend[ed] on the public disclosure[s].” *U.S. v. Millennium Labs. of Cal.*, 713 F.3d 662, 673 (1st Cir. 2013). Relator is an “investment fund manager and physician” who has worked as a “professional healthcare industry investment analyst for 25+ years.” SAC ¶ 116. He concedes that he “is *not an insider* at any of the Defendants, but rather an industry expert who has filed this case based upon extensive expertise,

investigation and supporting factual evidence.” First Am. Compl. ¶ 92, ECF No. 6. But it is black letter law in this Circuit that “discovery and synthesis of information from different public sources during the course of an independent investigation [cannot] result in original sourcing.” *Millennium Labs.*, 713 F.3d at 674–75. This is true even when a relator applies some “unique expertise or training” to draw conclusions from the “material elements already in the public domain.” *Ondis*, 587 F.3d at 59–60 (quoting *U.S. ex rel. Findlay v. FPC-Boron Employees Club*, 105 F.3d 675, 688 (D.C. Cir. 1997))). Relator’s job entailed collecting and evaluating publicly available information about healthcare companies. By his own admissions, that is all he has done in this case.¹⁷

Third, under the current version of the statute, Relator’s Complaint does not “materially add” to the existing public record. Stitching together facts and reiterating inferences already set out in publicly available documents adds nothing to the state of knowledge preceding Relator’s *qui tam*. Relator’s allegations that he had limited *oral* and supposedly *private* conversations and conferences with “insiders” do not save him because they reveal that even his non-published information was still patently second-hand. *See, e.g.*, SAC ¶¶ 112(a)–(c), 450–87. At best, the facts Relator learned in those conferences and conversations merely confirmed what the OIG and others already had noted years earlier: a significant number of PBMs were (a) calculating their administrative service fees based on drugs’ list prices and (b) keeping the fees for themselves. *See supra* Part II.A. Not only is that practice proper, but also these are hardly facts that materially add to the prior public record. *See, e.g., Winkelman*, 827 F.3d at 212 (“Offering specific examples of . . . conduct does not provide any significant new information where the underlying conduct already has been publicly disclosed.”).

¹⁷ This is exactly what he asserted in his ongoing Massachusetts lawsuit with his employer; his FCA claims are not based on any “insider information” but rather “public information.” (Borzilleri Answer & Countercl. ¶ 32).

Relator's own suspicion does not satisfy the "original source" requirement for him to proceed with a *qui tam* action notwithstanding prior public disclosures. *See Ondis*, 587 F.3d at 59. Instead, Relator epitomizes the tag-along, parasitic litigant whom Congress intended to discourage when it established the original source doctrine. *See Duxbury*, 579 F.3d at 26.

CONCLUSION

This Court should dismiss Relator's claims with prejudice as inadequately pled under Rules 12(b)(6) and 9(b), and incurably barred by prior public disclosures. Given Relator's status as a short-seller outsider, who does not—and cannot—rely on anything other than publicly available information, any prospective amendment would be futile to cure *any* of the dispositive defects raised in this Motion. *See, e.g., Kelly*, 827 F.3d at 15. Relator filed his initial complaint on January 1, 2014, and has already amended his complaint on two separate occasions over a two-year period. ECF Nos. 6, 57. Accordingly, the Court should dismiss all Relator's claims with prejudice.

Dated: November 19, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of November 2018, the undersigned has caused the within Motion to Dismiss to be filed with the Court via the ECF filing system. As such, this document will be electronically sent to the parties through their registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Michael P. Robinson

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA, THE
STATE OF CALIFORNIA, THE STATE
OF COLORADO, THE STATE OF
CONNECTICUT, THE STATE OF
DELAWARE, THE STATE OF FLORIDA,
THE STATE OF GEORGIA, THE STATE
OF HAWAII, THE STATE OF ILLINOIS,
THE STATE OF INDIANA, THE STATE
OF IOWA, THE STATE OF LOUISIANA,
THE COMMONWEALTH OF
MASSACHUSETTS, THE STATE OF
MICHIGAN, THE STATE OF
MINNESOTA, THE STATE OF
MONTANA, THE STATE OF NEVADA,
THE STATE OF NEW JERSEY, THE
STATE OF NEW MEXICO, THE STATE
OF NEW YORK, THE STATE OF
NORTH CAROLINA, THE STATE OF
OKLAHOMA, THE STATE OF RHODE
ISLAND, THE STATE OF TENNESSEE,
THE STATE OF TEXAS, THE
COMMONWEALTH OF VIRGINIA, THE
STATE OF WASHINGTON, THE STATE
OF WISCONSIN AND THE DISTRICT
OF COLUMBIA, *ex rel.* JOHN R.
BORZILLERI, M.D.

Plaintiffs,

BAYER HEALTHCARE
PHARMACEUTICALS, INC., BIOGEN,
INC., EMD SERONO, INC.,
NOVARTIS PHARMACEUTICALS
CORPORATION, PFIZER, INC.,
TEVA NEUROSCIENCE, INC., TEVA
PHARMACEUTICALS USA, INC.,
AETNA, INC., CIGNA
CORPORATION,
CVS HEALTH CORPORATION,
EXPRESS SCRIPTS HOLDING CO.,
HUMANA, INC.,
UNITEDHEALTH GROUP, INC.

Defendants.

CIVIL ACTION NO. CV-14-031-WES

RELATOR'S SECOND AMENDED
COMPLAINT PURSUANT TO THE
FEDERAL FALSE CLAIMS ACT [31
U.S.C. §3729 *et seq.*]; AND
SUPPLEMENTAL
STATE FALSE CLAIMS ACTS

JURY TRIAL DEMANDED

NATURE OF THE ACTION

1. John R. Borzilleri, M.D. ("Relator"), a physician and professional healthcare investment fund manager, brings this Qui Tam action on behalf of the United States, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, the State of Washington and the District of Columbia (the "Plaintiff States" and collectively with the United States, the "Government Plaintiffs"), for violations of the Federal False Claims Act, 31 U.S.C. §3729-33 ("FCA") et seq., as well as for violations of the following State False Claims Acts: the California False Claims Act, Cal Government Code §§12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310; the Connecticut False Claims Act, Conn. Gen. Stat. §17b-301b; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201 et seq.; the Florida False Claims Act, Fla. Stat. §§ 68,081 et seq.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §§49-4-168 et seq.; Hawaii False Claims Act, Haw. Rev. Stat. §§661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1 et seq.; the Indiana Whistleblower Reward and Protection Act, Indiana Code §5-11-5.5; the Iowa False Claims Act, Iowa Code §§ 685.1 through 685.7; the Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 et seq.; the Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§5A et seq.; the Michigan Medicaid False Claims Act, MCLS §§400.601 et seq.; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 through 15C.16; the Montana False Claims Act, Mont. Code Anno. §§17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. §§357.010 et seq.; the

New Jersey False Claims Act, N.J. Stat. §2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§27-14-1 et seq.; the New York False Claims Act, NY CLS St. Fin. §§187 et seq.; the North Carolina False Claims Act, 2009-554 N.C. Sess. Laws §§1-606 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws §§9-1.1-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-171 et seq.; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1 et seq.; the Washington Medicaid Fraud False Claims Act, Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214; the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§20.931; and the District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03 et seq. (hereafter referred to as the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts against the following Defendants, and their affiliates, subsidiaries, agents, successors and assigns: Bayer Healthcare Pharmaceuticals, Inc., Biogen, Inc; EMD Serono, Inc., Novartis Pharmaceuticals Corporation; Pfizer, Inc; Teva Neuroscience, Inc.; and, Teva Pharmaceuticals USA, Inc.; (referred to collectively as the "Manufacturer Defendants"); as well as, Aetna, Inc.; Cigna Corporation; CVS Health Corporation; Express Scripts Holding Co; Humana, Inc.; and, UnitedHealth Group, Inc. (referred to collectively as the "Pharmacy Benefit Manager (PBM) Defendants").

INTRODUCTION

2. The United States now faces a national crisis regarding the cost of pharmaceuticals. The cost of treating the most severe and life-threatening medical conditions in the US, such as cancer, multiple sclerosis, rheumatoid arthritis and many others, with brand name drugs is now typically 4-6 fold higher than it was twelve years ago. The cost increases coincide with the passage of Medicare Part D in 2003 and its enactment in 2006.

3. Pharmaceutical spending has been the fastest growing segment of US healthcare sector, which now consumes about 17% of the US economy, double the share of most other developed economies.

4. The skyrocketing US drug costs are placing a severe burden across our society. On a personal level, with therapies, particularly of the “specialty” variety, routinely now costing \$70,000-\$200,000 or more a year per person, many patients and their families face heartbreaking choices or financial ruin, as they struggle to pay for life-saving drugs. Physicians and other dedicated health professionals strive to help their sickest and most vulnerable patients access life-saving therapies, as beneficiary out-of-pocket “cost-sharing” exposure rises along with the escalating drug prices.

5. The rising drug costs are placing a severe financial burden on American private industry and taxpayers. US businesses are forced to decrease benefits and/or increase premiums/cost-sharing for their employees to remain competitive with foreign competitors who have access to the same drugs at a fraction of the US cost.

6. Furthermore, US taxpayers are funding an ever-increasing portion of these escalating drug costs through government drug programs, especially Medicare Part D.

7. The majority of the vast increase in US drug costs over the past decade has not occurred due to a wave of innovative new drugs reaching the US market. Rather, the primary driver has been the “inexplicable” massive price increases for numerous “old” blockbuster drugs, many of which have faced plummeting clinical use and market share due to severe competition.

8. The pricing abuse among “old” blockbuster and new drugs has been particularly severe in the US multiple sclerosis (MS) therapeutic category, the target of this Qui Tam action.

9. The US “list” prices for the four “old” leading US MS drugs in this case, Biogen’s Avonex (FDA-approved 1996), Teva’s Copaxone (1996), EMD Serono’s Rebif (2002) and Bayer’s Betaseron (1993), have increased in unison from about \$15,000 patient/year in 2005 to

the \$100,000 range/year in mid-2018, as prescriptions written by doctors and usage by patients has plummeted 40-70%.

10. The arrival of numerous new clinically-similar US brand MS drugs, and even generic products, astoundingly has only led to further severe uniform price increases across the category.

11. The Manufacturer and PBM Defendants in this case continue to promulgate the “complexity” surrounding extreme US brand drug pricing.

12. In reality, the cause of escalating US drug pricing is a straightforward price collusion scheme between certain US pharmaceutical companies (who set US drug prices) and the uniquely-American, dominant US Pharmacy Benefit Managers (PBMs, who administer access to prescription drugs for the vast majority of Americans).

13. The “Rosetta Stone” behind the US brand drug pricing crisis is a secret and seismic shift in the financial compensation model between drug manufacturers and the leading PBMs, which has its origins in the Medicare Part D program.

14. Simply put, the PBM Defendants now make most of their compensation via “service fees” from drug manufacturers, not “rebates”, as is still widely-presumed. Legitimate “service fees” are called Bona Fide Service Fees (BFSFs) in Medicare Part D and other government drug programs.

15. As with the Defendants’ MS drugs in this case, the “service fees” paid by the drug manufacturers are often linked to massive drug prices and fraudulent collusive price increases, with no relation to legitimate “services” provided by the PBM Defendants and their specialty pharmacy subsidiaries.

16. The four largest PBM Defendants in this case (Express Scripts, CVS Health, UnitedHealth Group and Humana) control drug access for more than 80% of Americans, including the Medicare Part D program where this scheme originated.

17. Two of the dominant PBMs, CVS Health and UnitedHealth Group, have secretive partnerships with two of the smaller US PBM operators, Defendants Aetna and Cigna, respectively. Both parties in these secretive arrangements are benefitting significantly from the “service fee” price collusion scheme outlined in this Complaint.

18. The PBM industry is a uniquely-American business, with a minimal presence outside this country. When Medicare Part D began, the US prices for the Defendant drugs in this case were at parity with the costs in major European countries. Now twelve years later, US prices for these “old”, competitively-challenged Defendant MS drugs are routinely 4-8 fold higher domestically, due to massive unilateral US price increases.

19. European drug markets appear to be operating properly, while the US has been greatly distorted by this systemic, collusive “service fee” scheme.

20. In recent years, as the public outcry regarding US drug pricing has escalated, both the pharmaceutical and PBM industries have been increasingly “blaming” each other for egregiously profiting from high US drug prices. The deceitful rhetoric has included all sorts of unverifiable claims regarding rebates, discounts, gross/net drug prices, drug coupons, patient assistance programs, etc.

21. Noticeably absent from the discussion are any significant mention of “manufacturer service fees” or the Medicare Part D program, the true epicenter of massive US brand drug price inflation.

22. The one topic both the pharmaceutical and PBM industries agree on is that Medicare Part D has been an astounding “success” and that its “private competition” model should be a template for all government drug programs. In fact, corporate interests are now pushing for Centers for Medicare and Medicaid (CMS) to expand the Part D “model” into the Part B program. We find this ironic because CMS’ own public data clearly indicates that drug price inflation in the Part D program has been far greater than in the Part B program.

23. This ongoing scheme represents among the most severe corporate violations of the public trust in the history of this nation. Many Americans have lost their lives, have lost access to life-savings drugs and have faced financial ruin due to this intentional wide-ranging fraud. The resulting harm has been particularly severe for the most vulnerable elderly and disabled Americans who depend upon the Medicare Part D program.

24. On the broader scale, the financial harm to the public is staggering. Just for the eight (8) Defendant MS drugs in this case, we estimate fraudulent US drug sales of more than \$59 billion over the past decade (with about 30% attributable to Medicare Part D), with the scheme ongoing and escalating.

25. The scheme has placed the financial viability of both the Medicare Part D program and our overall health insurance market at risk of insolvency.

26. We remain staunch supporters of the pharmaceutical industry and the need for innovative new drug therapies. This Qui Tam case has nothing to do with that important issue. The primary offenders of this centralized scheme have been a select group of Defendant senior executives, not the dedicated scientists, researchers and other employees, working at these companies.

SUMMARY OF THE FRAUDULENT "SERVICE FEE" SCHEME

27. John R. Borzilleri, M.D. ("Relator") has ascertained that the Manufacturer Defendants of multiple sclerosis (MS) "specialty" drugs have and continue to make fraudulent overpayments of illegitimate "Bona Fide Service Fees" (BFSFs) far in excess of legally-required "Fair Market Value" (FMV) to the PBM Defendants, as part of a nationwide collusive price inflation scheme in the Medicare Part D program.

28. In Medicare Part D, PBMs were expected to negotiate in good faith with drug manufacturers to obtain "rebates" and lower drug costs for beneficiaries and taxpayers.

29. Instead, the Manufacturer and PBM Defendants entered into an intentional,

secretive and fraudulent price inflation scheme, based upon “service fee” contracts, in gross violation of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS).

30. In sharp contrast to drug rebates, BFSFs are the only major financial item excluded from Part D “negotiated price” calculations, thereby leading to higher drug reimbursement prices and greater revenues/profits for the Defendants.

31. As per Center for Medicare and Medicaid Services (CMS) regulations, “service fees” in excess of FMV should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D. In turn, the plan sponsor (almost always via its contracted PBM) should report “service fees” in excess of FMV to CMS in Direct and Indirect Remuneration (“DIR”) reports as “discounts”, leading to lower Part D “negotiated” drug prices. The Defendants are intentionally not doing so in order to advance the “service fee” scheme, to fraudulently increase Part D MS drug prices and maximize their fraudulent profits.

32. Arm’s-length negotiations between the Manufacturer and PBM Defendants would have prevented virtually all of the massive 4-6 fold US price inflation for the 8 Manufacturer Defendant MS brand drugs in this case over the past decade-plus.

33. In recent years, as US “specialty” MS drug prices have become more extreme and numerous, fraudulent abuse of plan sponsor Part D “catastrophic” cost-sharing requirements has become widespread to advance the “service fee” price inflation scheme.

34. The Manufacturer Defendants (and other biopharmaceutical companies) are routinely “forgiving” the 15% unlimited “catastrophic” exposure of the PBM Defendants’, in their dominant roles as Part D plan sponsors. We will discuss this issue in more detail later in the complaint.

35. BFSFs are payments from drug manufacturers to PBMs and other service vendors in Part D (and other government drug programs) for a wide array of “support services”, such as rebate administration, inventory management, drug shipping/delivery, reimbursement/financial

assistance, patient education/clinical programs, drug adherence programs, phone support, data reports, etc.

36. The fraudulent Manufacturer Defendant “service fee” payments to the PBM Defendants are standardly calculated via secretive “percent of revenue” contracts, based upon inflated brand drug “list” prices and massive price increases, primarily using Average Wholesale Price (AWP) or the related Wholesale Acquisition Cost (WAC) from public databases.

37. AWP is also the basis for reimbursement for brand drugs in Medicare Part D. As per the US Department of Health and Human Services (HHS), the “negotiated price that the sponsors and beneficiaries pay pharmacies for the ingredient cost of the drug is usually based upon Average Wholesale Price (AWP) discounted by a specified percentage...” Office of Inspector General (OIG), OEI-03-7-00350, Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid, February 2009.

38. These “service fee” payments from the Manufacturer Defendants are linked contractually to massive US MS drug prices, with no relationship to bona fide “support services” being provided by the PBM Defendants and their specialty pharmacy subsidiaries.

39. In these “service fee” contracts, both Defendant parties are fraudulently inflating US MS drug “list” prices, Part D reimbursement levels and their profits, with the additional drug costs largely passed on to taxpayers and patients in Medicare Part D.

40. Massive increases in “service fee” payments to the PBM Defendants have occurred despite a significant decline in actual “support services” being provided for the “old” Defendant “blockbuster” MS drugs, commensurate with their sharply declining clinical use and prescription volume.

41. According to the Part D regulations, legitimate BFSFs paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D should:

- a. Be paid only for legitimate “support” services, based upon clinical usage of the

drug;

- b. Represent “reasonable compensation”, based upon the actual cost of providing the “service”;
- c. Be “commercially reasonable” and not be “distorted” by anticompetitive market factors;
- d. Be consistent with the “efficient distribution of drugs”, at affordable prices for patients.

42. All of these legal requirements for BFSFs are encompassed in the long-established Federal “Four-Part Test”, which all BFSFs must “pass” to be considered “bona fide” or “legitimate” in Medicare Part D and other government drug programs. 71 Fed. Reg. 69624, 69667-9.

43. All the Defendants in this Qui Tam case knew or should have known of the clear legal requirements for “legitimate” BFSFs.

44. The “Four-Part Test” requires that:

- a. The “itemized” service is actually performed for the manufacturer;
- b. The manufacturer actually needs the “service” and is not performing the service itself;
- c. The “service fee” is kept by the PBM (or other service providers, such as specialty pharmacies) and not shared with the payer client (otherwise the payment would simply be another form of drug discount); and,
- d. The “service fee” payment is paid at “Fair Market Value” (FMV), commensurate with an “arm’s length” transaction between unaffiliated parties.

45. In Part D and other government drug programs, drug manufacturers have the legal responsibility to ensure that BFSFs are legitimate and paid at FMV. However, both Defendant parties have extensive legal liability under both the Anti-Kickback Statute (AKS) and the False Claims Acts (FCA).

46. All of the above four components of the “Four Part Test” are commonly being

fraudulently violated in the Part D contractual and financial arrangements between the Manufacturer and PBM Defendants.

47. However, the central focus of this case is the wide-ranging evidence of ongoing violations of the “Fair Market Value” (FMV) requirements regarding BFSFs.

48. The abuse has been most severe for the “old” Manufacturer Defendant MS drugs in sharply declining clinical use, namely Biogen’s Avonex (FDA-approved 1996), Teva’s Copaxone (1996), EMD Serono’s Rebif (2002) and Bayer’s Betaseron (1993).

49. As the scheme has expanded in the US MS category, BFSF abuse has also become severe with newer, extreme-priced “oral” MS drugs, including Novartis’ Gilenya (FDA-approved 2010) and Biogen’s Tecfidera (2013). These two Manufacturer Defendant MS products have been added to the case since the last Complaint in May of 2014.

50. The Relator has also filed a separate Qui Tam action, in the Southern District of New York (15-Civ. 7881 (JMF)), alleging Part D “service fee” pricing fraud pertaining to drugs in the US rheumatoid arthritis, diabetes, cancer and other markets.

51. Following the government’s non-intervention decision, the Relator filed a First Amended Complaint in the Southern District of New York. The public health and fiscal harm is distinct for each Defendant drug product in both of these Qui Tam actions.

52. BFSFs were employed in other government drug programs, prior to the enactment of Part D. However, Part D was the catalyst for severe BFSF fraud for several key reasons.

53. First, as the first “private competition” federal drug program, Congress placed no limits on brand drug price increases in the program (in sharp contrast to Medicaid), presuming arm’s-length negotiation by the PBM Defendants who control the program.

54. Second, assuming “manufacturer rebate” negotiations would remain the key target for “cost-savings” and PBM profits, Medicare requires their deduction from Part D “negotiated” prices and requires full disclosure.

55. Third, assuming BFSFs would be for legitimate “support services”, CMS excludes these payments from Part D “negotiated” prices.

56. Compounding the situation, CMS placed few reporting requirements and no financial limits on the amounts of BFSFs in the Medicare Part D program.

57. Part D insulates most beneficiaries from massive price increases because the majority of drug costs associated with high prices are covered by taxpayers, via the program’s subsidies. Most importantly, the Low-Income Subsidies (LIS) cover almost all routine costs for low income beneficiaries, while the Reinsurance Subsidies cover 80% of all extreme drug costs for all Part D beneficiaries above a modest annual limit (only \$5,000 in 2018).

58. Finally, the liberal use of financial assistance programs by drug manufacturers (often with the assistance of PBMs) has limited beneficiary out-of-pocket exposure for much of the past decade and aided in deflecting public scrutiny.

59. Driven by these factors, Part D led to a seismic and secretive shift in the US pharmaceutical market and the financial transactions between drug manufacturers and the dominant PBMs.

60. Prior to Medicare Part D, the PBM Defendants made virtually all their profits from the portion of rebates they “retained” in their negotiations with manufacturers.

61. After the arrival of Part D, the PBM Defendants began secretly making the vast majority of their profits from “service fee” payments from drug manufacturers, both in Medicare Part D and the private insurance market.

62. Wide-ranging US brand drug patent expirations (leading to lower brand drug sales and fewer rebate opportunities), have been a key factor propelling the “service fee” scheme to its current stratospheric heights, now more than 15 years after Part D was enacted as part of the Medicare Modernization Act (MMA) of 2003.

63. With generic prescriptions now accounting for more than 90% of US drug volume

(up from about 50% when Part D began), both the Manufacturer and PBM Defendants became increasingly dependent on a narrower group of remaining brand drugs for revenues and profits.

64. Further violating the public trust and the law, the financial scheme has intentionally been kept secret by the Defendants from virtually all affected and influential constituents, including patients and their families, physicians and other healthcare providers, taxpayers, client corporations, insurance plan clients, unions, pension funds, independent pharmacies, patient support organizations, regulators, Congress, investors and the Securities and Exchange Commission (SEC).

65. In April 2018, following the unsealing of our Qui Tam actions, the Relator filed a Whistleblower Complaint (via TCR) with the SEC regarding all the Defendants in both the Rhode Island and Southern District of New York (SDNY) Qui Tam actions. Separate from our Medicare Part D fraud allegations, failure to provide any significant financial disclosures regarding these “service fee” arrangements and their dominant profit contribution represents a gross violation of the SEC “materiality” requirements.

66. The Part D program has been compromised by the near complete control of all key functional roles by the PBM Defendants. In Part D, the PBM Defendants, and their wholly-owned subsidiaries, provide all three of the key Part D functions (plan sponsor, PBM and specialty pharmacy functions) for the majority of Part D plans and beneficiaries.

67. Because CMS depends upon plan sponsors for Part D program oversight, combined ownership and vertical integration has been a key factor enabling this scheme, due to severe conflicts of interest, limited transparency and lax oversight.

68. Based upon the biopharmaceutical industry’s own recent incriminating public data, the Manufacturer Defendants are typically contractually paying the PBM Defendants (and their specialty pharmacy subsidiaries) about 8% of US brand MS “specialty” drug sales, based upon the massive “list” prices and 4-6 fold price increases. Pharmaceutical Research and

Management Association (PhRMA) report, “Follow the Dollar”, November 2017.

69. In these contracts, after years of massive drug price inflation (to the \$100,000 cost/year range for all US MS drugs in mid-2018), the PBM Defendants are receiving astounding “service fees” in the \$8,000 range for each US patient treated with US MS “specialty” drugs, including the Defendant products in sharply declining use.

70. The PBM Defendants themselves have publicly admitted a near complete dependence on “services fees” for US MS drug profits. As per a June 2017 report from the lobbying group closely controlled by the PBM Defendants, the Pharmaceutical Care Management Association (PCMA), US “manufacturer rebates” for US MS drugs were only in the “7% of sales” range from 2011 thru 2016, despite ongoing massive price increases.

71. The PCMA report confirmed prior PBM Defendant executive public commentary that the PBM Defendants typically only keep about 10% “manufacturer rebates”.

72. Using the Defendant’s own data from the November 2017 PhRMA and the June 2017 PCMA Reports, the PBM Defendants are receiving approximately 11-fold greater compensation, for high-cost MS “specialty” drugs, via “service fees” from the Manufacturer Defendants compared to their “retained” portion of “manufacturer rebates”.

73. For the individual declining-use MS Defendant products in this case, we estimate that “service fee” payments from the Manufacturer Defendants to the PBM Defendants have increased approximately 5-fold over the decade for each Defendant drug prescription, driven solely by the massive price increases.

74. Our investigation found no legitimate justification for massive increases in “service fees” paid for MS drugs products with sharply eroding clinical usage.

75. We did not identify any legitimate PBM Defendant “support services” attributable to massive price increases, other than potential abusive patient financial support programs required to advance the scheme.

76. According to the PhRMA December 2017 data, these manufacturer “service fees” now account for 90-100% of PBM Defendant profits from “specialty” MS drugs.

77. To this day, the majority of independent pharmaceutical and PBM experts still cite “manufacturer rebates” as the primary source of PBM Defendant profits, despite it being invalid now for more than a decade.

78. The gross violation of the Part D regulations, as well as the FCA and the AKS, is even starker when considering “service fee” payments at the aggregate level and the plummeting prescription volume for key Defendant MS drugs in this case.

79. For the declining-use MS products, we estimate that the Manufacturer Defendants are commonly paying the PBM Defendants approximately four times as much in aggregate annual “service fees” for supporting half or less as many prescriptions and patients compared to a decade ago. In layman’s terms pertaining to “services”, think of paying someone four times as much money to paint half of your house.

80. With the low level of “manufacturer rebates”, the vast majority of the financial gains from the price increases accrue to the Manufacturer Defendants, as indicated by their SEC-reported US sales.

81. The PBM Defendants, in turn, receive fraudulent “service fees”, as “kickbacks”, for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies and the avoidance of long-established, effective, PBM cost-saving strategies (aggressive rebate negotiations, brand drug “therapeutic substitution” and “formulary restriction” programs, etc.).

82. PBM brand drug “therapeutic substitution” and “formulary restriction” programs are the long-standing mechanisms for the PBM Defendants to obtain brand drug price concessions from drug manufacturers during negotiations.

83. In these standard negotiating practices, the PBM Defendants demand significant price concessions for placing a brand drug on its formulary and not implementing/enforcing

additional restrictions on access, such as prior authorization requirements, high co-pays, high co-insurance, etc.

84. In a normal operating market, had standard PBM Defendant formulary and cost-savings practices been legitimately implemented, the vast majority of price increases for the Defendant MS drugs would not have occurred over the past twelve years. For drugs in declining use, price decreases might have been expected.

85. The PBM Defendant negotiating leverage for cost savings should be particularly strong for the “old” Manufacturer Defendant “blockbusters” in declining clinical use in the crowded US MS category. The US MS market is now populated with about 12 clinically-similar MS drugs, compared to only 4 when Medicare Part D began.

86. Furthermore, cost-savings negotiating tactics should be particularly effective in Part D, where the vast majority of the plans and beneficiaries utilize the PBM Defendants’ “national formularies”.

87. Under the False Claim Act, “kickbacks” in federal programs are, by law, also false claims for reimbursement. While “kickbacks” are a criminal offense, under the FCA, liability only has to be proved by a preponderance of the evidence. 31 U.S.C. § 3731(d) US ex. rel. Pasqua v. Kan-Di-Ki, LLC, 2:10-cv-00965 C.D. CA. (March 8, 2013).

88. Furthermore, both the Manufacturer and PBM Defendants have caused or directly submitted a myriad of false claims via the array of submissions required for reimbursement in the Medicare Part D program, including Prescription Drug Event (PDE) reports, Direct and Indirect Remuneration (“DIR”) reports, Part D annual plan bids, as well as financial data required for Part D subsidy reconciliation. (Direct, Low-Income and Catastrophic subsidies).

89. Virtually all Part D submissions for reimbursement pertaining to the Manufacturer Defendant drugs over the past 12 years or so have been “tainted” by kickbacks and have been false claims.

90. Both Defendant parties, as well as their subsidiaries and their senior executives (Chief Executive Officer and Chief Financial Officer), must “expressly certify” compliance with the Anti-Kickback Statute (AKS) and the False Claim Act (FCA) to participate in Medicare Part D.

91. The wide-ranging legal liability for the PBM Defendants in Part D contrasts sharply with their historic limited exposure in the private insurance sector. Due to lack of fiduciary responsibilities under the Employment Retirement Income Security Act (ERISA), the PBM Defendants have successfully deflected a wide array of private lawsuits alleging abusive business practices over the past several decades.

92. Prior US Department of Justice PBM Defendant case settlements have already established negligence in the FMV of BFSFs as a basis for false claims and kickbacks. United States Settlement Agreement with Advanced PCS (now part of CVS Health), September 7, 2005. United States Settlement Agreement with Medco Health Solutions, October 23, 2006.

93. The States have been named as plaintiffs in this case, due to severe harm caused by the scheme. States are required to fund about a third of the cost of their high-consuming “dual-eligible” population in the Medicare Part D program. Prior to Part D, these State beneficiaries received their drug benefits via state Medicaid programs. Due to price inflation protections on brand drugs in Medicaid, states are paying fraudulently higher drug costs (4-6 fold higher) for the Defendant products due to the Part D pricing scheme.

94. The cumulative and compounding harm to the public fisc from this decade-plus systemic, ongoing pricing scheme is staggering. Overall, we estimate cumulative fraudulent US sales of about \$59 billion between 2006 and 2017 for the 8 Defendant MS “specialty” drugs in this case, with about 30% attributable to the Part D program.

95. Our US MS category sales fraud estimates have nearly quadrupled since our last Rhode Island filing in May 2014, due to the cumulative impact of ongoing massive and uniform

price increases, as well as the inclusion of two additional brand drugs in the case.

96. To enable the collusive pricing scheme, we estimate that the Manufacturer Defendants have paid the PBM Defendants fraudulent “service fees” of approximately \$4 billion between 2006 and 2017, with about 30% attributable to the Part D program.

97. Our direct “service fees” fraud estimates have vastly increased since our last Rhode Island filing, due to the Defendant public disclosure of a higher “service fee” contract rate for “specialty” drugs (8% rather than the 4% rate used in our prior filings), a lower MS “rebate” rate and the inclusion of two additional brand drugs in the case.

98. When this scheme is applied across numerous massively-inflating “blockbuster” US brand drugs and major therapeutic categories (beyond just the MS category), the overall profits for the PBM Defendants are truly astounding.

99. The staggering profit benefit for the PBM Defendants is reflected in the SEC-reported financial statements of Express Scripts, the largest US PBM and the only major public stand-alone PBM.

100. Despite declining revenues and prescription volume over the past 5 years, Express Scripts’ annual profits have nearly tripled. In 2013, Express Script’s reported revenues of \$104 billion and net income of \$1.8 billion. In 2017, Express Scripts reported revenues of \$100 billion and net income of \$4.5 billion.

101. Escalating manufacturer “service fee” payments, tied to massive brand drug prices and price increases, have been the primary driver of Express Script’s remarkable profit growth in recent years, despite severe competition from and market share losses to other leading PBM Defendants.

102. A substantial 30% decrease in Express Scripts’ Selling, General and Administrative (S,G&A) spending over the 5 years, from \$4.6 billion in 2013 to \$3.3 billion in 2017, has been a major contributor to the company’s profit growth.

103. Express Scripts' sharply declining S,G&A spending trends indicate that escalating "support services" have not been provided to drug manufacturers as the "fee" payments have accelerated in recent years.

104. In fact, Express Scripts S,G&A trends indicate that the PBM is getting paid a lot more money by the drug manufacturers, in aggregate, for doing considerably less legitimate "support" work.

105. Besides Express Scripts, all the other PBM Defendants have also reported remarkable profit growth over the past 5 years. However, because of their more diversified business models, and their limited financial disclosures, we are unable to assign profits specifically to their PBM/specialty pharmacy subsidiaries.

106. For all the PBM Defendants, we expect discovery to determine that the manufacturer "service fee" scheme has been a primary driver of both their PBM and overall corporate profit growth over the past decade.

107. The evidence of this systemic "service fee" scheme is overwhelming. In fact, this pharmaceutical/PBM collusive "service fee" scheme is the "Rosetta Stone" behind virtually all instances of "inexplicable" massive US brand drug price inflation over the past decade. Furthermore, this scheme, with its origins in Medicare Part D, is the only viable explanation.

108. The systemic scheme, which began with the large biopharmaceutical and PBM companies, has also been aggressively employed by an array of smaller companies. Notable examples include Mallinckrodt's Acthar Gel, Mylan's Epipen, Turig's Daraprim, as well as the broad product portfolios of Valeant and Horizon Pharmaceuticals.

109. The major pharmaceutical and PBM corporations have done a remarkable job of keeping media and other investigative efforts focused on these few small "bad actors".

110. Notably, the aggregate US patient and financial harm of one of the "blockbuster" MS drugs in this case, driven by the same scheme, dwarfs that of these combined small

companies.

111. For example, even after its 5,000% price increase, the annual US sales of Turig's Daraprim were only approximately \$10 million.

112. The Relator's first hand and investigative evidence of the "service fee" scheme is extensive and conclusive. The evidence includes:

- a. In October 2013, the Relator attended a conference at which 50-60 directly-involved "corporate insiders" discussed the scheme openly. Representative "insider" quotes from the conference include: a) compensation for service providers from manufacturers had "shifted from rebates to fees"; b) "fees were the key to government pricing"; c) service fee agreements were the "main source of income"; d) service vendors "all want percent of revenue deals"; e) the contracts are not being "refreshed" for price increases; and f) manufacturers need to "consider whether percent of sales can be consistent with FMV as prices rise".
- b. In December 2014, a pharmaceutical CEO discussed the details of the scheme with the Relator in a private investor meeting. Key quotes include: a) "well, PBMs don't make their money off rebates anymore, PBMs make their money through service fees"; b) to put through big price increases, you just have to "play ball with them", via service fee contracts.
- c. The Relator has verified the scheme in private discussions with several highly-experienced independent PBM consultants.
- d. Public disclosure of PBM Defendant client contracts, and related public commentary, verify the scheme. Several instructive Express Scripts and CVS Health client contracts are discussed later in this Complaint.
- e. Recent public commentary from PBM Defendant senior executives verify the industry's reliance on the "service fees", rather than rebates, for profits.

- f. For the first time, the pharmaceutical industry itself, via its closely-controlled lobbying organization, the Pharmaceutical Research and Management Association (PhRMA), publicly corroborated the scheme in a November 2017 report.
- g. The PBM Defendants corroborated the “service fee” scheme in the US MS drug category, in the June 2017 report from the PCMA, the PBM industry’s closely-controlled lobbying organization.

JURISDICTION AND VENUE

113. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. 3730(e), there has been no statutorily relevant public disclosure of the “allegations or transactions” in this Complaint. Relator is the original source of the facts and information alleged in this Complaint.

114. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in this District and /or transact business in this District.

115. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

PARTIES

116. Plaintiff/Relator John R. Borzilleri, MD (“Relator”), an investment fund manager and physician, is a resident of Cutchogue, New York. He has been a professional healthcare

industry investment analyst for 25+ years. The Relator is a licensed physician in the State of New York, with an MBA degree from Columbia University.

117. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer") manufactures, markets and/or distributes more than 19 drugs in the United States. Bayer Healthcare Pharmaceuticals, Inc. is a subsidiary of Bayer AG, a Germany-based pharmaceutical company, located at 51368 Leverkusen, Germany. Bayer is among the leading worldwide pharmaceutical companies, with worldwide reported revenues of 35 billion Euros in 2017. In its pharmaceutical segment, Bayer focuses on cardiovascular, women's health, men's health, ophthalmic and oncology therapies. Related to this case, Bayer markets Betaseron in the United States for the treatment of multiple sclerosis. Betaseron was FDA-approved in the US in 1993.

118. Defendant Biogen, Inc. ("Biogen") is a Delaware corporation, headquartered at 225 Binney Street, Cambridge, MA 02142. Biogen discovers, develops, manufactures, and markets therapies in multiple sclerosis, Alzheimer's disease and other neurodegenerative conditions. Biogen reported worldwide revenues of \$12.3 billion in 2017. Related to this case, Biogen markets Avonex, Pledigry and Tecfidera in the United States for the treatment of multiple sclerosis, which were FDA-approved in 1996, 2014 and 2013, respectively. Avonex, Pledigry and Tecfidera accounted for 74% of Biogen's US product sales in 2017.

119. Defendant EMD Serono, Inc. ("EMD Serono") is a biopharmaceutical subsidiary of Merck KGaA, a Darmstadt, Germany-based global pharmaceutical and chemical group. EMD Serono's US subsidiary is headquartered at One Technology Place, Rockland MA 02370. EMD Serono's key products include treatments for neurologic, fertility and metabolic disorders. Related to this case, EMD Serono has co-markets, with Pfizer, Rebif in the United States for the treatment of multiple sclerosis. Rebif was FDA-approved in 2002 and remains one of EMD Serono's top-selling pharmaceutical products in the United States.

120. Defendant Novartis Pharmaceuticals Corporation ("Novartis") researches,

develops, manufactures and distributes medications. Novartis is owned, through a United States holding company, by Novartis International AG, a pharmaceutical manufacturer headquartered in Basel, Switzerland. Novartis' corporate headquarters in the United States are in East Hanover, New Jersey. Novartis AG reported worldwide sales of \$49.1 billion in 2017. Related to this case, Novartis markets Gilenya and Extavia in the United States for the treatment of multiple sclerosis. Gilenya and Extavia were FDA-approved in 2010 and 2009, respectively. In 2017, Gilenya was Novartis' top-selling pharmaceutical product, with US and global sales of \$1.7 billion and \$3.2 billion, respectively.

121. Defendant Pfizer, Inc. ("Pfizer"), a Delaware corporation, is headquartered in New York City at 235 East 42nd Street, New York, New York 10017. Pfizer is the world's largest pharmaceutical company with a focus on cardiovascular/metabolic disease, immunology, inflammation, oncology and neuroscience. Pfizer sells its products throughout the world and reported worldwide revenues of \$52.5 billion in 2017. Related to this case, Pfizer has co-promoted Rebif in the United States with EMD Serono. Rebif was FDA approved in the United States for the treatment of multiple sclerosis in 2002.

122. Defendants Teva Neuroscience, Inc. and Teva Pharmaceuticals USA, Inc. ("Teva") are subsidiaries of Teva Pharmaceutical Industries, Ltd., a worldwide pharmaceutical company engaged in the development, manufacture, marketing and sale of pharmaceutical products, including specialty medicines, generic and over-the-counter ("OTC") products, active pharmaceutical ingredients, and novel new therapeutic entities. Teva Pharmaceutical Industries, Ltd. is headquartered at 5 Basel Street, Petach Tikva 49131, Israel. Teva reported worldwide revenues of \$22.4 billion in 2017. Related to this case, Teva Neuroscience, Inc., based in Overland Park, Kansas, markets Copaxone in the United States for the treatment of multiple sclerosis. Teva Pharmaceuticals USA, Inc., based in North Wales, Pennsylvania is responsible for the US distribution of Copaxone. Copaxone was initially FDA-approved in 1996 and the franchise

remains Teva's top-selling brand drug franchise, with US and worldwide sales of \$3.0 billion and \$3.8 billion, respectively, in 2017.

123. Defendants Bayer Healthcare Pharmaceuticals, Inc., Biogen, Inc., EMD Serono, Inc., Novartis Pharmaceuticals Corporation, Pfizer, Inc., Teva Neuroscience, Inc. and Teva Pharmaceuticals USA, Inc. are collectively identified as the "Manufacturer Defendants" in this Complaint.

124. Defendant Aetna, Inc. ("Aetna"), headquartered in Hartford, CT, and its subsidiaries, is one of the nation's leading diversified health care benefits companies. Aetna's headquarters are located at 151 Farmington Ave, Hartford, CT 06156. Through annual contracts with CMS, Aetna offers HMO and PPO products for eligible individuals in certain geographic areas through the Medicare Advantage program. Aetna is a national provider of the Medicare Part D Prescription Drug Program ("PDP") in all 50 states and Washington, D.C. to both individuals and employer groups. Aetna offers pharmacy benefit management services and specialty and mail order pharmacy services to its members. Aetna's pharmacy fulfillment services are delivered by Aetna Specialty Pharmacy ("ASP") and Aetna Rx Home Delivery®. ASP compounds and dispenses specialty medications and offers certain support services associated with specialty medications. In 2017, Aetna reported revenues of \$60.5 billion. In 2011, CVS Health began to perform the administration of selected functions for Aetna's retail pharmacy network contracting and claims administration; mail order and specialty pharmacy order fulfillment and inventory purchasing and management; and certain administrative services for Aetna. In December 2017, Defendant CVS Health announced an agreement to acquire Aetna, Inc.

125. Defendant Cigna Corporation ("Cigna"), headquartered in Bloomfield, CT, and its subsidiaries, is a global health services provider of medical, dental, disability, life and accident insurance and related products and services. Cigna's headquarters are located at 900 Cottage Grove Road, Bloomfield, CT 06002. Cigna's Medicare Part D plans are available in all 50 states

and the District of Columbia. With a network of over 65,000 contracted pharmacies, Cigna Pharmacy Management is a comprehensive pharmacy benefits manager ("PBM") offering clinical integration programs and specialty pharmacy solutions. Cigna Pharmacy Management offers fast, cost-effective mail order, telephone and on-line pharmaceutical fulfillment services through our home delivery operation. Under a 2013 agreement, Catamaran Corporation (now part of Defendant UnitedHealth Group) provides Cigna with access to their technology and service platforms, prescription drug procurement and inventory management capabilities, retail network contracting and claims processing services. Cigna reported revenues and net income of \$41.6 billion and \$2.23 billion, respectively, in 2017. In March 2018, Cigna announced an agreement to acquire Defendant Express Scripts.

126. Defendant CVS Health Corporation ("CVS Health" or "CVS"), headquartered in Woonsocket, RI, and its subsidiaries, is the largest integrated pharmacy health care provider in the United States. CVS Health's headquarters are located at One CVS Drive, Woonsocket, RI 02895. CVS Health's Pharmacy Services Segment provides a full range of PBM services to our clients consisting primarily of employers, insurance companies, unions, government employee groups, managed care organizations ("MCOs") and other sponsors of health benefit plans and individuals throughout the United States. In addition, through our SilverScript Insurance Company ("SilverScript") subsidiary, CVS Health is a national provider of drug benefits to eligible beneficiaries under the Federal Government's Medicare Part D program. The Pharmacy Services Segment operates under the CVS Caremark® Pharmacy Services, Caremark®, CVS Caremark®, CarePlus CVS/pharmacy®, RxAmerica®, Accordant®, SilverScript® and Novologix® names. CVS Caremark participates in the administration of the drug benefit added to the Medicare program under Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA, Medicare Part D") through the provision of PBM services to its health plan clients and other clients that have qualified as Medicare Part D prescription drug

plans ("PDP"). CVS Caremark reported revenues and net income of \$184.8 billion and \$6.6 billion, respectively, in 2017. In December 2017, CVS Health announced an agreement to acquire Defendant Aetna, Inc.

127. Defendant Express Scripts Holding Company ("Express Scripts"), headquartered in St. Louis, MO, and its subsidiaries, is the largest PBM company in the United States, offering a full range of services to our clients, which include managed care organizations, health insurers, third-party administrators, employers, union-sponsored benefit plans, workers' compensation plans and government health programs. Express Scripts headquarters are located at One Express Way, St. Louis, MO 63121. Through its licensed insurance subsidiaries (i.e., Express Scripts Insurance Company ("ESIC"), Medco Containment Life Insurance Company and Medco Containment Insurance Company of New York), Express Scripts operates as Part D PDP sponsors offering PDP coverage and services to clients and Part D beneficiaries. Express Scripts, through our core PBM business, provide Part D-related products and services to other PDP sponsors, MA-PDPs and other employers and clients offering Part D benefits to Part D eligible beneficiaries. Express Script's specialty pharmacy subsidiary, Accredo Health Group ("Accredo®"), is focused on dispensing infused, injectable, inhaled and oral drugs that require a higher level of clinical services and support compared to what typically is available from traditional pharmacies. Express Scripts reported revenues and net income of \$100 billion and \$4.5 billion, respectively, in 2017.

128. Defendant Humana, Inc. ("Humana"), headquartered in Louisville, KY, and its subsidiaries, is a leading health care company that offers a wide range of insurance products and health and wellness services. Humana's headquarters are located at 500 West Main Street, Louisville, KY 40202. During 2017, 79% of Humana's total premiums and services revenue were derived from contracts with the federal government. Most Humana Medicare Advantage plans offer the prescription drug benefit under Part D as part of the basic plan, subject to cost sharing and other limitations. Humana offers stand-alone prescription drug plans, or PDPs, under

Medicare Part D, including a PDP plan co-branded with Wal-Mart Stores, Inc., or the Humana-Walmart plan. Humana, Inc. reported revenues and net income of \$52.8 billion and \$2.45 billion, respectively, in 2017.

129. Defendant UnitedHealth Group, Inc., ("UnitedHealth" or "UnitedHealth Group") headquartered in Minnetonka, MN, and its subsidiaries, is a diversified health and well-being company. UnitedHealth provides health care benefits to a full spectrum of customers and markets. UnitedHealth Group's headquarters are located at 9900 Bren Road East, Minnetonka, MN 55343. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits for Medicare beneficiaries and retirees. UnitedHealthcare Community & State manages health care benefit programs on behalf of state Medicaid and community programs and their participants. UnitedHealth's Optum division is a health services business serving the broad health care marketplace, including payers, care providers, employers, government, life sciences companies and consumers, through its OptumHealth, OptumInsight and OptumRx businesses. UnitedHealthcare Medicare & Retirement provides Medicare Part D benefits to beneficiaries throughout the United States and its territories through its Medicare Advantage and stand-alone Medicare Part D plans. OptumRx is UnitedHealth's full service Pharmacy Benefit Manager (PBM) subsidiary. UnitedHealthcare Medicare & Retirement offers two standalone Medicare Part D plans: the AARP Medicare Rx Preferred and the AARP Medicare Rx Saver plans. In 2015, UnitedHealth acquired the PBM Catamaran Corporation. UnitedHealth Group, Inc. reported revenues and net income of \$201.2 billion and \$10.6 billion, respectively, in 2017.

130. Defendants Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc. and UnitedHealth Group, Inc., are collectively identified as the "PBM Defendants" in this Complaint.

BACKGROUND INFORMATION

A. The Medicare Program

131. Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. The Department of Health and Human Services (“HHS”) administers the Medicare program through the Centers for Medicare and Medicaid Services (“CMS”). There are four major components to the Medicare program:

- a) Part A, the hospital insurance benefits program.
- b) Part B, the supplemental medical insurance benefits program, which generally pays for a percentage of certain medical and other health services, including physician services.
- c) Part C, the Medicare Advantage program, which allows CMS to contract with public and private entities to provide, at a minimum, Medicare Part A and B benefits to certain Medicare beneficiaries.
- d) Part D, the voluntary prescription drug benefit program.⁴² U.S.C. § 1395w-101, et seq.

B. The Medicare Part D Program

132. Part D was established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, which set up a voluntary prescription benefits program for Medicare enrollees. Part D became effective January 1, 2006. Unlike Parts A and B, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D “sponsors” to administer prescription drug plans. Part D benefits are provided by a Part D plan sponsor, which is either a prescription drug plan (“PDP”), a Medicare Advantage organization plan (“MA-PD”), or a Program of All-Inclusive Care for the Elderly (“PACE”).

133. A Part D sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month (“PMPM”) cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. From the bids, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. If the Part D plan sponsor’s bid exceeds the benchmark, the

enrolled beneficiary must pay the difference as part of a monthly premium.

134. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the amount paid to the pharmacy.

135. As a condition for receiving its monthly payment from CMS, a Part D Plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. 42 C.F.R. § 423.505(k)(1). If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must "similarly certify" that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. 42 C.F.R. § 452.505(k)(3).

136. Part D Plan sponsors must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

137. Part D Plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with PBMs and specialty pharmacies. PBMs can provide a variety of services to sponsors to help manage their prescription drug benefit. These services include processing prescription drug claims, contracting with pharmacies, managing formularies, as well as negotiating rebates with drug manufacturers. PBMs can be compensated for these services in a variety of ways, including receiving a fixed

payment per claim or retaining a percentage of sponsors' rebates.

138. PBMs can also be directly compensated by drug manufacturers via designated "bona fide service fees" (BFSFs) for a wide array of product-related "services", such as inventory management, patient education, phone support, shipping, reimbursement assistance, data reports, etc., which would have otherwise been performed by the manufacturer. Legitimate BFSFs, paid at FMV, are excluded from government "negotiated price" calculations.

139. CMS has established a unique bid and reimbursement process in the administration of Part D with plan sponsors. Under Medicare Part D, plan sponsors are required to submit bids to CMS in the first week of June for the following calendar plan year. The bids are based upon the sponsor's estimate of its anticipated monthly drug costs for Part D beneficiaries in the plan, as well as administrative costs and expected profit. *OIG Report, Medicare Part D Reconciliation Payments for 2006 and 2007*, OEI-02-08-00460, September 2009. CMS uses the submitted data to determine individual plan premium rates and monthly subsidy payments made to plan sponsors for the following calendar plan year. The monthly subsidy payment schedule of Part D is designed to help plans effectively manage "cash flow" during a plan year as actual drug costs accrue.

140. The plan sponsor bid cost estimates and related monthly subsidy payments consist of four distinct tranches. First, the sponsor must provide a cost estimate for the "basic" Part D benefit for a beneficiary of "average" health in the plan, for which it receives monthly "Regular Subsidy" payments. According to CMS, the "Regular Subsidy" monthly payments for Part D plans across the US are relatively similar since the amounts are based upon national beneficiary cost averages, with modest adjustments for age and health status in each particular plan.

141. Second, the plan sponsor must provide an estimate of the benefit cost for low-income (LIS) beneficiaries (approximately 30% of overall Part D enrollment) in the plan for the following calendar year, for which CMS provides monthly "Low-Income (LIS) Subsidy"

payments. LIS beneficiaries are low-income elderly and disabled people, who commonly are afflicted with severe chronic medical conditions that often necessitate treatment with high-priced specialty drugs. Other than small copayments, CMS covers virtually all routine cost-sharing requirements for LIS beneficiaries in Medicare Part D.

142. Third, the sponsor must estimate the cost of providing “catastrophic” drug coverage for Part D beneficiaries whose annual out-of-pocket spending exceeds the annual maximum threshold (\$3,600 in 2006, rising to \$5,000 in 2018). For “catastrophic” drug costs, CMS covers 80% of the estimated costs via monthly “Reinsurance Subsidy” payments; with plan sponsors and non-LIS beneficiaries responsible for 15% and 5% of spending over the threshold, respectively. In Part D, the use of high-priced “specialty” drugs is the primary driver of crossing the annual catastrophic spending threshold. In contrast to “Regular Subsidy” payments, monthly “LIS Subsidy” and “Reinsurance Subsidy” payments among plans can vary widely, depending upon the enrollment and health status characteristics of a particular plan.

143. Starting in 2011, CMS added the “Gap Discount Subsidy” as part of the ACA legislation, which requires drug manufacturers to provide price discounts to all Part D beneficiaries in the so-called “donut hole” coverage window. In plan bid submissions, plan sponsors must estimate the amount of manufacturer “donut hole” discounts for the following calendar year, for which CMS provides monthly “Gap Discount Subsidy” payments. Since CMS hired a Third Party Administrator (TPA), Palmetto GBA, to administer the Gap Discount program, the “Gap Discount Subsidy” payments appear to be “pass through” amounts from manufacturers to plans sponsors.

144. Part D plan sponsors must provide detailed information to CMS in order to track performance, reconcile subsidy payments and to aid in the detection/prevention of fraud. In administering Part D, plan sponsors are required to submit a “Prescription Drug Event” (“PDE”) record for each prescription for all covered drugs dispensed to enrollees. The PDE includes more

than 50 different fields of data, including end-user pharmacy drug cost data. Notably, the PDE does not provide drug costs paid by PBMs to drug manufacturers.

145. In addition, sponsors must submit quarterly and year-end DIR ("Direct and Indirect Remuneration") reports to CMS to disclose any rebates or price concessions, which almost entirely come from manufacturers via PBM negotiations for the vast majority of plans.

146. Both the PDE and DIR data are "self-reported", with apparently limited CMS oversight or verification. Medicare Part D - Prescription Drug Event Reconciliation Process, A-18-08-30102, June 1, 2010. For the vast majority of Part D plans, the PDE and DIR reports are prepared by contracted PBMs, with limited controls by either CMS or unaffiliated plan sponsors.

147. Both "Low-Income Subsidy" and "Reinsurance Subsidy" plan sponsor payments undergo a reconciliation process after each plan year. In the case of "Low-Income Subsidy" payments, CMS guarantees full reimbursement of any unforeseen LIS cost-sharing requirements. In reconciliation, the cost-sharing responsibilities for excess "catastrophic" drug spending are the same as during the bid process. Namely, CMS covers 80% of unlimited excess costs, with the plan sponsor and beneficiary responsible for 15% and 5% (for non-LIS beneficiaries only), respectively.

148. As part of the 2003 MMA legislation, the drug benefit for many of the highest cost, most-severely ill beneficiaries "dual eligibles" beneficiaries were transferred, without recourse, from state Medicaid programs to Medicare Part D. "Dual eligibles" are low-income elderly and disabled beneficiaries eligible for both Medicaid and Medicare benefits. Former State "dual eligibles" account for about two-thirds of Part D LIS beneficiaries which, in turn, have historically accounted for the majority (up to 70% in early program years) of Part D premium-priced "specialty" drug spending.

149. By law, each State is required to fund a significant portion of Medicare Part D spending for their respective "dual eligible" beneficiaries via "phased-down contribution" or

"clawback" payments to CMS paid on a monthly basis. In the program years 2006 through 2014, State "clawback" payments accounted for 32-37% of Part D LIS Subsidy costs each year. Furthermore, the State Part D financial responsibilities are legally tied to Federal Medicaid matching transfers. As such, if any State fails or refuses to pay its CMS-determined "clawback" payments, the same amount will be deducted from its scheduled Federal Medicaid matching funds. Overall, States made cumulative "clawback" payments to CMS of \$80.7 billion for the years 2006 through 2016.

150. Prior to Medicare Part D, State "dual eligible" beneficiaries received their outpatient drug benefit via State Medicaid programs. Medicaid requires additional manufacturer rebates for brand price increases greater than inflation (CPI-Urban), whereas Medicare Part D provides no such protection.

151. The Part D regulations clearly indicate that plan sponsors, as well as PBM/specialty pharmacy subcontractors ("First Tier, Downstream and Related Entities", FDRs), are liable under the False Claims Act for fraudulent data submissions to CMS due to their express requirement to "certify" compliance with regulations as a prerequisite for participation and payment. In addition, the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO) must individually expressly "certify" compliance. The provision of C.F.R. § 423.505, entitled "Certification of data that determines payment" states:

- a) General rule. *"As a condition of receiving a monthly payment under subpart G of this part (or fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies."*

- b) Certification of claims data. *"The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based upon best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of Federal reimbursement."*
- c) Certification of bid submission data. *"The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and assumptions related to projected reinsurance and low-income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265."*
- d) Certification of allowable costs for risk corridor and reinsurance information. *"The Chief Executive Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement."*

DETAILS OF THE FALSE CLAIMS/KICKBACK VIOLATION PATHWAY

152. For the Manufacturer Defendants:

- 1) The Manufacturer Defendants knowingly made fraudulent overpayments of *"Bona Fide Service Fees"* (*"BFSFs"*) far in excess of the legally-required *"Fair Market Value"*

("FMV") to the PBM Defendants, as well as their subsidiaries and partners, in the Medicare Part D program.

- 2) These fraudulent FMV BFSF payments are straightforward "kickbacks" by Manufacturer Defendants to the PBM Defendants to enable the massive price increases, to gain formulary access and to obviate standard PBM cost-savings practices that would lead to far lower Defendant drug prices in a crowded, intensely competitive US MS drug market.
- 3) By statute and law, "kickbacks" are also direct false claims according to the False Claims Act.
- 4) According to 31 U.S. code 3729, anyone who "*knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval*" faces liability. The Manufacturer Defendants have "*caused*" the PBM Defendants to submit a wide array of false claims to federal and state governments for reimbursement, including PDE reports, DIR reports, annual plan sponsor bids, and data required for annual reconciliation of Part D subsidies.
- 5) As per the regulations, "*service fees*" in excess of FMV should be reported by the Drug Manufacturer to the plan sponsor. In turn, the plan sponsor (usually via its contracted PBM) should report the excessive "*service fees*" to CMS in its DIR report as a "*discount*", leading to lower Part D drug prices. The Defendants are intentionally not doing so in order to advance the "*service fee*" scheme, to fraudulently increase Part D drug prices and maximize their fraudulent profits.
- 6) The minimal direct Part D reporting requirements regarding BFSFs for the Manufacturer Defendants has been a central factor abetting the fraudulent scheme. As such, we view this fraud as primarily as "*fraud of exclusion*", especially pertaining to Direct and Indirect Remuneration ("*DIR*") reports.

- 7) As per the law, the Manufacturer Defendant legal liability regarding BFSFs is independent of its Part D reporting requirements, or lack thereof.
- 8) The "*express certification*" requirements of the Manufacturer Defendants, as well as their participating subsidiaries, against violation of the AKS and the FCA also clearly establishes liability. For each Defendant, the CEO and CFO must also "*expressly certify*" compliance with applicable laws, including the AKS and the FCA.

153. For the PBM Defendants:

- 1) The fraudulent Manufacturer Defendants FMV BFSF overpayments to the PBM Defendants are "kickbacks" (i.e., "payments for referral") and a violation of the Anti-Kickback Statute ("AKS"). The fraudulent payments were made by the Manufacturer Defendants to the PBM Defendants in a quid pro quo exchange for favorable formulary positioning which enabled mutually-beneficial, massive and collusive, price increases reimbursed by CMS and taxpayers.
- 2) The willful receipt of these "*kickbacks*" is a criminal offense by all Defendant parties because the Part D regulations require all participants, including manufacturers, plan sponsors, PBMs, specialty pharmacies, and other First Tier, Downstream and Related Entities (FDRs), to "*expressly certify*" compliance with all relevant laws, including the AKS and FCA.
- 3) The PBM Defendants, in their role as PBMs, specialty pharmacies and plan sponsors, have directly submitted a wide array of false claims for reimbursement, including PDE reports, DIR reports, annual plan sponsor bids, and data required for annual reconciliation of Part D subsidies.
- 4) Virtually all Part D submissions impacting reimbursement for the Defendant MS drugs, for most of the past 12 years, are fraudulent and tainted by the systemic scheme.

- 5) Due their “*express certification*” requirements and coordination of the scheme, the Defendant CEOs and CFOs of these corporations may be accountable for the AKS and FCA violations.

DETAILS REGARDING THE STATE FALSE CLAIMS VIOLATIONS

154. In Medicare Part D, each State is responsible for funding a significant portion of the drug costs of their “dual eligible” beneficiaries (i.e., low-income elderly and disabled individuals who qualify for both Medicaid and Medicare benefits) whose drug benefit was transferred from Medicaid to Medicare Part D as part of the MMA legislation.

155. The States pay their mandatory portion of Part D drug spending via monthly transfers, known as “Phase Down” or “Clawback” payments. By law, these State “Clawback” payments cover 35-40% of Part D LIS Subsidy costs each year of the Part D program.

156. Driven by the massive Part D drug price inflation for “specialty” drugs, directly resulting from this “service fee” scheme, State annual Clawback” payments have increased sharply since the start of Medicare Part D. As per the Medicare Trustee reports, State “Clawback” payments have increased from \$5.5 billion in 2006 to \$10.0 billion in 2016, with cumulative State payments of \$80.7 billion through the latter year. State “Clawback” payments are forecasted to be \$12.0 billion in 2018 and \$22.5 billion by 2026. 2017 Medicare Trustees Report, July 2017.

157. Due to the brand price inflation statutes in Medicaid, theses State “dual-eligibles” would have access to “old” Manufacturer Defendant drugs at a fraction of the cost, if not for the Part D pricing scheme.

158. The “old” Manufacturer Defendants MS drugs in this case, including Biogen’s Avonex and Pfizer/Serono’s Rebif, are currently available at 80-90% discounts to the prices in Medicare Part D.

159. As such, the “kickbacks” and federal false claims submissions related to the Manufacturer Defendant drugs have led directly to widespread financial fraud at the State level.

THE RECENT INCRIMINATING PhRMA INDUSTRY REPORT

160. In a November 2017, nearly four years after our initial Qui tam filing, the Pharmaceutical Research and Manufacturers Association (PhRMA), the leading pharmaceutical lobbying organization, released a report, entitled “Follow the Dollar”.

161. While the purpose of the report was to shift blame for severe US drug prices towards its collusive PBM Defendant partners, the document definitively incriminates both Defendant parties in the systemic “service fee” scheme.

162. In the report, PhRMA, for the first time, disclosed average contract terms for “service fees” between biopharmaceutical manufacturers and the dominant PBM Defendants. Of note, the individual “service fee” contracts between the Manufacturer and PBM Defendants remain a closely guarded secret, obtainable by the non-insider Relator only via discovery.

163. PhRMA is funded and controlled by the major biopharmaceutical companies. Current board members of PhRMA include Michael Vounatsos (CEO of Defendant Biogen), Kare Schultz (CEO of Defendant Teva), Vasante Narasimhan (CEO of Defendant Novartis), Dieter Weinand (Head of Pharmaceuticals & Member of Board of Management for Defendant Bayer) and Belen Garijo (member of the Executive Board & CEO, Defendant EMD Serono/Merck KGaA).

164. In the November 2017 report, PhRMA disclosed that the PBM Defendants and their specialty pharmacy subsidiaries receive an average of 8% of the “list” (WAC) drug price, inclusive of all price increases, for each US private insurance patient treated with a high-cost “specialty” drug, such as the Manufacturer Defendant MS drugs.

165. In the report, PhRMA estimated that the PBM/specialty pharmacy typically keeps about 20% of “manufacturer rebates” for “specialty” drugs. However, recent public commentary, the senior management of both Express Scripts and CVS Health, as well as the PCMA lobbying organization indicates the PBM Defendants only keep 10% or less of overall “manufacturer

rebates.”

166. For large private insurance clients, the PBM Defendants often don’t keep any rebates, leaving manufacturer “service fees” as virtually the sole profit source.

167. As stated by Express Script’s CEO, Tim Wentworth: “It’s important to understand how rebates flow. We retain 10% of rebates for our services and administrative fees, and 90% flows straight through to the plans.” Forbes Healthcare Summit, New York City, November 30, 2017.

168. Straightforward calculations using the data from this report indicate that the PBM Defendants currently garner about 90-100% of their profits for the Defendant “specialty” MS brand drugs from these manufacturer “service fees”, with almost all of the small remainder from “retained” manufacturer “rebates”.

169. To this day, the majority of independent pharmaceutical and PBM experts still publicly cite “manufacturer rebates” as the primary source of PBM Defendant profits, despite the claim being false for more than a decade.

170. As per the report, overall compensation from drug manufacturers, from combined “fees” and “rebates”, accounts for 98% of PBM Defendant profits for each “specialty” drug treated patient in the US private insurance market.

171. Notably, the “8% of sales” “specialty” contract rate, disclosed by PhRMA, is double the conservative 4% contract terms estimate in our prior Qui Tam Complaints.

172. Based upon this disclosure, and ongoing massive Defendant drug price inflation, we have greatly escalated our estimates for the direct “service fee” fraud payments to the PBM Defendants related to the “specialty” MS drugs in this case.

173. These private insurance calculations from the PhRMA report likely significantly understate the contribution of manufacturer “service fees” to PBM Defendant profits, especially regarding Medicare Part D.

174. In the report, PhRMA claimed that 20% of the “manufacturer fees” are “passed on” to private insurance clients. However, our discussions with experience independent PBM consultants uniformly indicate that these “manufacturer service fees” are virtually never shared with private insurance clients.

175. In fact, the PBM consultants stated that they had never negotiated a client contract with a leading PBM, in which ANY “manufacturer fees” were shared with one of their private insurance clients. Furthermore, the PBM consultants stated that they had never seen or reviewed a single “service fee” contract between a PBM and a drug manufacturer.

176. This PBM consultant feedback is consistent with PBM Defendant CVS Health’s public disclosures. Regarding a Maryland state contract discussed in detail later in the Complaint, CVS Health publicly admitted that it “does not disclose to its clients detailed information regarding service fees (from manufacturers) received and does not share those fees with its clients.” Before the Maryland State Board of Contract Appeals, Docket Nos. MSBCA 2544, 2548 & 2565, March 2007.

177. Since BFSFs cannot be “passed on” in government drug programs, the PhRMA report’s claim of sharing 20% of “legitimate” fees with private clients is irrelevant in the Part D program.

THE RECENT INCRIMINATING PCMA INDUSTRY REPORT

178. In June 2017, the Pharmaceutical Care Management Association (CMA), the leading PBM industry lobbying organization, released a report, entitled “Increasing Prices Set by Drugmakers Not Correlated with Rebates”.

179. The purpose of the report was to shift blame for severe US drug prices towards the biopharmaceutical industry. However, combined with the above PhRMA report, the PCMA report definitively incriminates both Defendant parties in the “service fee” scheme pertaining to MS drugs.

180. PCMA is funded and controlled by the dominant PBM Defendants. Current board members of PCMA include Tim Wentworth (CEO of Defendant Express Scripts), William Fleming (President, Health Services for Defendant Humana), Chris Hocesvar (President, Strategy, Segments and Solutions for Defendant Cigna), Randy Hyun (President Pharmacy Management for Defendant Aetna), John Prince (Chief Executive Officer of the OptumRx PBM subsidiary of Defendant UnitedHealth Group) and Jon Roberts (Executive Vice President and Chief Operating Officer of Defendant CVS Health).

181. First, the report corroborated that the PBM Defendants standardly “retain” a small portion of “manufacturer rebates”; only in the 10% range, and none for many larger private insurance clients.

182. As per Mark Merritt, the President and CEO of the Pharmaceutical Care Management Association (PCMA), in the press release accompanying the report: “PBMs are hired by America’s largest, most sophisticated, health purchasers to reduce costs by, among other things, promoting generics and negotiating rebates and discounts on brand-name drugs. Typically, PBMs pass along 90 percent or more of these savings to plans, which use them to cut premiums, out-of-pocket costs and other expenses. Many health purchasers require PBMs to pass through 100 percent of rebates.” PCMA Press Release, June 12, 2017.

183. In their analysis of the “Top 200 Brand Drugs”, the PCMA found no correlation between increasing drug prices and the magnitude of “manufacturer rebates”

184. In fact, PCMA reported that “Drugmakers raise prices even when rebates are low in major drug categories”.

185. Specific to this case, PCMA reported that “multiple sclerosis (MS) drugs have had high price increases yet rebates on MS drugs are low.”

186. As per PCMA, between 2011 and 2016, despite a 125% increase in WAC cost, “rebate levels for these drugs was only 7%” throughout the six year period.

187. In concluding the report, PCMA proposed a rationale for the vast manufacturer price increases: “Perhaps to counter shrinking prescription volume for brand drugs”.

188. The PCMA report makes no mention of PBM Defendant compensation from MS drug manufacturers related to the vast price increases, especially pertaining to “service fees”.

189. The straightforward math from the PhRMA and PCMA reports verifies the fraudulent participation of both Defendant parties in the “service fee” scheme in the US MS marketplace.

190. With the PBM Defendant only keeping about 10% of minimal (7%) manufacturer MS discounts, PBM Defendant compensation from rebates has remained very low despite massive price increases.

191. On the other hand, PBM Defendant compensation from “service fees”, which are typically all kept by the PBM, has secretly and intentionally skyrocketed along with the massive price increases.

SECRETIVE PBM DEFENDANT PARTNERSHIPS

192. Inter-relationships of the PBM Defendants also increase complexity and decrease transparency. The PBM Defendants UnitedHealth, Humana, Express Scripts and CVS Health have full ownership of the PBMs/specialty pharmacies servicing the Part D plans. However, various secretive arrangements among the PBM Defendants further increase concentration and limit disclosure regarding PBM practices in both Part D and the private insurance sector.

193. In plans sponsored by Defendants Aetna and Cigna, pharmacy benefits are provided via long-term arrangements with CVS Health, and UnitedHealth Group, respectively. UnitedHealth Group took over the Cigna partnership upon its acquisition of the PBM Catamaran in 2015.

194. Recent merger announcements will further increase the concentration, and decrease transparency, in the US PBM/specialty pharmacy marketplace. In December 2017, CVS

Health announced its intention to acquire Aetna, Inc. In March 2018, Cigna announced its intention to acquire Express Scripts. These transactions will only escalate already severe systemic "service fee" and US drug pricing abuse.

195. According to SEC filings and management commentary, Aetna and Cigna appear to have maintained a significant amount of control over PBM functions in their arrangements with larger PBM Defendants, especially regarding key formulary decisions and manufacturer contract negotiations.

196. As such, Defendants Aetna and Cigna are knowingly participating in and benefiting from the "service fee" scheme. However, public disclosure regarding the contractual arrangements for these PBM Defendant partnerships has been minimal. Close scrutiny of the financial terms and transactions related to these secretive arrangements will be a key part of case discovery. Following is a review of the limited public disclosure regarding the PBM Defendant partnerships.

197. According to the July 27, 2010 press release, Aetna stated: "Aetna and CVS Health today announced they have entered into a 12-year contract to provide Pharmacy Benefit Management (PBM) services that will further enhance value and services for Aetna's customers and members. Aetna will retain its PBM and manage clinical programs, protocols and oversight of its pharmacy benefit operations...In addition, CVS Caremark will manage purchasing, inventory management and prescription fulfillment for Aetna's mail-order and specialty pharmacy operations." The impact on this contract of the proposed CVS Health acquisition of Aetna remains unclear.

198. As per its 2014 10-K filing, Cigna states: "In June 2013, we entered into a ten-year pharmacy benefit management services agreement with Catamaran Corporation. Under this agreement, we utilize Catamaran's technology and services platforms, retail network contracting and claims processing."

199. Catamaran's 2014 10-K further states: "The two organizations are partnering on sourcing, fulfillment and clinical services. The partnership combines Cigna's significant clinical management and customer engagement capabilities with Catamaran's innovative technology solutions, while seeking to leverage the two companies' scale of network choice and efficient procurement to deliver value to Cigna's clients and members."

200. Catamaran stated: "The gross profit percentage related to the Cigna contract is significantly lower than historical gross profit percentages due to the related transaction volume." The lower profits for UnitedHealth/Catamaran suggest that Cigna is actively participating in the "service fee" scheme, the primary source of PBM Defendant profits.

201. In contrast, the long-term contract between Express Scripts and Anthem is apparently financially unfavorable for the latter. We suspect that Express Scripts is gaining most of the financial benefit from manufacturer "service fees" in this contract. At present, Express Scripts and Anthem are in litigation and the latter has already announced its intention not to renew the partnership. Due to these developments, we have removed Anthem as a Defendant in this Qui Tam case.

202. Catamaran was acquired by PBM Defendant UnitedHealth Group in 2015, with minimal disclosure regarding any impact on the prior Cigna partnership. With no transparency, the impact of the proposed acquisition of Express Scripts by Cigna on the existing UnitedHealth PBM contract remains unclear.

PBM PART D PROFITS: SECRET MANUFACTURER FEES, NOT REBATES

203. The secretive reliance of the PBM Defendants on the "service fee" scheme, rather than "manufacturer rebates", for profits has been verified by data from both the federal government and the Defendants themselves.

204. In fact, this key, still secretive, financial discovery was the starting point of the Relator's fraud investigation more than five years ago. We summarize here and provide more

details later in the document.

205. First, a 2011 Office of Inspector General (OIG) report documented that PBMs “retained” minimal “manufacturer rebates” in Medicare Part D in the program’s first three years of operation (2006-2008), despite the onset of severe systemic brand drug price increases. “Concerns with Rebates in the Medicare Part D Program”. OIG HHS Report, OEI-02-08-00050, March 2011.

206. As per the OIG report, in Medicare Part D for the year 2008, PBMs “retained” only \$24 million (less than 1%) of overall \$6.5 billion of drug manufacturer rebates. (Emphasis added)

207. As such, by definition, the PBMs were being compensated in Part D via a pathway other than “manufacturer rebates”, which was the intent of the legislation and remains the current public presumption.

208. Besides “rebates”, BFSFs are the only other mechanisms for large financial payments from drug manufacturers to the PBM Defendants in Medicare Part D.

209. With minimal retention of Part D rebates, “services fees” became secretly and knowingly the primary source of profits for the PBM Defendants in the program.

210. Second, more recently both Express Scripts and CVS Health have disclosed that they keep only about 10% of aggregate “manufacturer rebates”, which, like “service fees”, are standardly contractually-based on AWP or WAC prices.

211. Third, CMS’ own data documents that Medicare Part D “manufacturer rebates” have averaged about 10-15% of AWP “list” prices annually since the inception of the program. Medicare Trustee Reports. The modest actual Part D rebates contrast with the unverifiable large rebate claims of the Manufacturer and PBM Defendants in recent years.

212. As per another government report, the “manufacturer rebate rate” for high-cost “specialty” drugs (including the Defendant rheumatoid arthritis and cancer drugs in this case) has

commonly been far less than the 10-15% aggregate rate in Medicare Part D. GAO-10-242, 2010; Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier”.

213. As per the previous section, the PBM Defendants themselves, via the PCMA report, verified the ongoing low level (only 7%) of “manufacturer rebates” for US MS drugs in recent years, despite ongoing massive price increases.

214. Indicative of the systemic “service fee” scheme, in addition to the MS category, the PCMA report verified the low level of “manufacturer rebates” in the US rheumatoid arthritis category, despite ongoing massive price increases.

215. According to PCMA, for rheumatoid arthritis drugs, including AbbVie’s Humira and Amgen’s Enbrel, “the weighted average rebate level for these drugs for the 2011-2016 period was 11%” despite 125% price inflation.

216. The AWP cost per patient per year for Humira and Enbrel has increased in unison from about \$15,000 in 2005 (just prior to Part D) to the \$70,000 range in mid-2018.

217. AbbVie’s Humira is the top-selling US and worldwide brand drug with reported US sales of \$12.4 billion 2017. We estimate that about two-thirds of Humira’s vast US growth over the past decade-plus can be attributed to the fraudulent “service fee” scheme.

218. Amgen’s Enbrel is a top-spending drug in the vast majority of Part D and private insurance plans. Amgen has reported robust US revenue growth for Enbrel over the past decade-plus, despite about a 20% decrease in annual prescription volume and treated patients.

219. Amgen’s US Enbrel sales increased from \$2.5 billion in 2005 to \$5.2 billion in 2017. All of Enbrel’s cumulative sales growth over this period can be attributed to the fraudulent scheme.

220. Both Humira and Enbrel are targeted in our Qui Tam action in the Southern District of New York.

221. Based upon government data and the PBM Defendants' own public disclosures, the PBM Defendants are making very little profit from "manufacturer rebates"

222. Assuming an average 10% "manufacturer rebate" and the PBM Defendant publicly-stated 10% rebate "retention rate", the PBM Defendants are keeping only about 1% of AWP-based drug product sales, on average, as "rebate" compensation.

223. In sharp contrast, the PBM Defendants are secretly obtaining far greater compensation (and the vast majority of their profits) in Part D via manufacturer "service fees", routinely linked to massive, anti-competitive drug prices and price increases.

224. Using the straightforward math, based upon the PhRMA's November 2017 report, the PBM Defendants now secretly receive, on average, 8-to-11 times as much compensation from manufacturer "service fees" compared to "retained manufacturer rebates" for MS "specialty" drugs.

225. Of course, the PBM Defendant compensation for any particular "specialty" brand drug will depend upon specific contractual terms.

226. Furthermore, with ongoing massive US price increases, the absolute PBM "service fee" compensation for the MS drugs has skyrocketed relative to "rebates".

227. We will use a single "specialty" MS drug, Biogen's Avonex, to illustrate the astounding economics for both Defendant parties in this collusive "service fee" scheme. Similar financial dynamics exist for the other Defendant MS products in this case, especially the long-marketed, declining-use drugs, Pfizer/Serono's Rebif, Bayer's Betaseron and Teva's Copaxone.

228. The annual US patient AWP cost for Biogen's Avonex (and all the older products) has increased from about \$15,000 at the start of Part D in 2005 to the \$100,000 range in mid-2018, despite plummeting clinical usage of the drug.

229. Assuming the PCMA 7% manufacturer rebate rate, the full Avonex "rebate" from Biogen increased from \$1,050/patient in 2005 to \$5,860/patient in 2018.

230. The PBM Defendant keeps 10% of the full rebate each year, or about \$105/Avonex patient in 2005 and \$586/patient in 2018, a \$481 absolute increase and nearly 6-fold increase. See **Exhibit 1**.

231. The absolute increase in PBM compensation via “service fees” relative to “retained rebates” has been many magnitudes greater since the start of Part D.

232. Using the “8% of sales” PhRMA average contract rate, the PBM/specialty pharmacy “service fee” payment would be \$1,200/Avonex patient in 2006, rising to \$7,840/patient in early 2018, a far greater \$6,640 absolute and nearly 7-fold increase.

233. Based upon these estimates, the PBM/specialty pharmacy compensation from “manufacturer service fees” for each US Avonex-treated MS patient is 11-to-13-fold higher than from “retained “manufacturer rebates”, both in 2005 and 2018. See **Exhibit 1**.

234. Of course, the financial benefit for the PBM Defendants from the scheme pales in comparison to the gains for Biogen from the massive price increases. The net revenues/patient to Biogen (after rebates and fees) rises from about \$12,750 in 2005 to the \$83,300 range in 2018. See **Exhibit 1**.

Exhibit 1**Medicare Part D: PBM Defendant "Service Fee" vs. "Rebate" Compensation
Biogen's Avonex**

	<u>2005</u>	<u>2018</u>	<u>Change 2005-2018</u>
AWP Cost/Patient/Year	\$15,000	\$98,000	\$83,000
Estimated Manufacturer Rebate Rate	7%	7%	-
Estimated Manufacturer Rebate Rate	\$1,050	\$6,860	
Est. PBM Rebate Retention Rate	10%	10%	-
PBM "Retained Rebates"	\$105	\$686	\$481
Estimated PBM "Service Fee" Rate	8%	8%	-
PBM "Fee" Retention Rate	100%	100%	-
PBM "Retained Service Fees"	\$1,200	\$7,840	\$6,640
Biogen US Revenues/Patient (\$)¹	\$12,750	\$83,300	

1 Excludes some other potential revenue offsets, especially drug financial assistance programs.

Source: Redbook, PhRMA, PCMA.

DETAILS OF THE FRAUDULENT "SERVICE FEE" SCHEME

235. This long-standing, centralized fraudulent pricing scheme, which began from the outset of Medicare Part D, originated from the unique financial incentives regarding rebates and BFSFs incorporated into the program.

236. In Part D, all rebates and discounts provided by drug manufacturer are deducted from "negotiated prices" and serve to lower program and beneficiary drug costs. In sharp contrast, BFSFs are the only major financial item excluded from "negotiated price" determinations in Part D.

237. These shifting disclosure and financial incentives in Part D, which began now more than 15 years ago, were seismic for both the pharmaceutical and PBM industries. However,

prior to our Qui Tam Complaints, the public and most health care experts remained unaware.

238. Compounding the abuse, CMS places no restrictions on the amount of BFSFs in Part D and initially placed minimal BFSF direct reporting requirements on manufacturers and PBMs, despite documented government concern regarding potential fraudulent abuse.

239. As stated by CMS in 2012: “We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at ‘fair market value’ for bona fide services.” Federal Register, Vol 77, No 22, February 2, 2012.

240. Without sufficient regulatory controls or oversight, nor Part D protection from brand drug price inflation (unlike with Medicaid), the Defendant parties have advanced this BFSF scheme to a staggering magnitude in the first 12-plus years of the program’s existence.

241. Further indicative of long-standing collusion and intent, the Defendants quickly and secretly first began transitioning to the “service fee” model in the private health insurance market, starting in 2003 with the legislative passage of Medicare Part D, three years before it started in January 2006.

242. This seismic profit model transition is reflected in the 2003-2011 10-K filings of Medco Health Solutions, the largest US PBM prior to its 2012 merger with PBM Defendant Express Scripts. The Medco filings are discussed in greater detail later in the Complaint.

243. According to the Part D regulations, legitimate patient and product support-related BFSFs paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D should be based upon drug and patient utilization.

244. As per the Code of Federal Regulations (CFR) at Sections §423.514 and §423.514 entitled “Reporting requirements for pharmacy benefit manager data”: “Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as

defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan". (Emphasis added)

245. Rather than linking BFSF payments to drug/patient utilization and legitimate FMV assessment, both the Manufacturer and PBM Defendant parties have violated the FCA and the AKS, with illegitimate BFSF payments in Part D based primarily upon massive, anti-competitive price increases.

246. There are few, if any, "legitimate" or "bona fide" services solely related to a drug's price or massive drug price increases, with the possible exception of patient financial assistance programs (PAPs). Of course, the meteoric increase in financial assistance programs has been essential for advancing this price inflation scheme and deflecting public scrutiny.

247. Part D regulations and legal case precedents have established that all BFSF payments must be paid at "fair market value" (FMV) commensurate with an "arm's length transaction between unrelated parties".

248. By law, drug manufacturers bear the primary legal responsibility for the legitimacy of BFSFs, based upon the "Four-Part Test", 71 Fed. Reg. 69624, 69667-9.

249. In Part D, any "service fee" amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in "excess" of FMV must be reported to CMS as "price concessions/discounts" in DIR (i.e., "Direct and Indirect Remuneration") reports. When doing so, CMS will apply the "discount" to Part D "negotiated prices", thereby lowering drug prices for beneficiaries and taxpayers.

250. As stated by CMS in 2011: "In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4." Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated

June 6, 2011.

251. A lack of direct BFSF reporting requirements for drug manufacturers, PBMs and specialty pharmacies in Part D has played a key part in maintaining the secrecy of this long-standing scheme.

252. As such, we anticipate that a review of Defendant CMS Part D financial filings may not be of much value in the investigation of these allegations. For instance, with an array of inter-related subsidiaries, the PBM Defendants have many paths to obscure “service fee” fraud from regulators.

253. The regulatory reporting deficiencies regarding BFSFs, especially pertaining to drug manufacturers, do not diminish the clear legal liability of the Defendant parties in this case. According to the Part D regulations, manufacturer liability regarding the FMV determination of BFSFs is unrelated to any CMS reporting or direct disclosure responsibilities.

254. Upon request from government authorities, particularly in a fraud investigation, drug manufacturers must provide detailed information about BFSFs, including the “itemized” services provided for individual drug product, the related payments and a legitimate FMV determination.

255. As a condition of both participation and reimbursement in Medicare Part D, the Defendant corporations, their subsidiaries (“First Tier, Downstream and Related Entities”, FDRs), as well as Chief Executive Officer (CEO) and Chief Financial Officer (CFO), must “expressly certify” against violation of both the FCA and the AKS.

256. In addition to direct “kickback” and false claims allegations, broad “express certification” adds an additional and substantial layer of liability for all the Defendants.

257. The CFR at § 423.505 (4) states: “The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and

assumptions related to projected reinsurance and low-income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265."

258. In § 423.505 (4), the CFR further states: "The Chief Executive Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this is information will be used for the purposes of obtaining Federal reimbursement."

259. The legal liability of the PBM Defendants, either in their Part D role as plan sponsors or FDRs, has already been established by a prior Qui Tam case, the United States of America, ex. rel. Anthony Spay v. CVS Caremark Corporation.

260. The Spay case definitively established PDE submissions as a "claim for payment". Civil Action 09-4672, US District Court Eastern District of Pennsylvania.

261. As per the Spay Court Order: "The defendants' contracts with the sponsor required them to submit PDEs directly to CMS. Relying on CMS program instructions that stated that PDEs "will enable CMS to make payment," the court held that when the defendants submitted PDEs to CMS they 'clearly' were submitting 'claims' under § 3729(a)(2)."

262. Per the Spay Court Order: "the court ruled that these false statements rendered the claims false because defendants were required by 42 C.F.R. § 423.505(k)(3) to certify that the PDEs submitted to CMS were accurate, complete and truthful, and to acknowledge that the data in the PDEs would be used to obtain federal reimbursement."

263. The Defendant "percent of revenue" BFSF contracts, linked to massive price

increases, fall outside the protection provided by either the "Group Purchasing Organization (GPO)" or the "Personal Services and Management Contracts" Safe Harbors. §1001.952.

264. These Safe Harbors require both FMV compensation and detailed disclosure to both CMS and private payers. Neither requirement has been met in these typically "secretive" BFSF manufacturer/PBM contract arrangements.

265. The BFSF fraud among high-cost "specialty" drugs has been exacerbated by the increasing dominance of PBM Defendant centralized mail order specialty pharmacies. While the "Any Willing Pharmacy" (CFR at §423.120 (a) (8)) provision prohibits rote exclusion of independent pharmacies from Part D networks, CMS regulations allow the PBM Defendants to offer "preferred" financial terms to their wholly-owned specialty pharmacies.

266. The PBM Defendants claim the rise of their "narrow networks" lead to lower drug prices for beneficiaries. However, the real PBM incentive for "narrow networks" is to capture the tremendous profit stream from the "service fees" associated with extreme-priced "specialty" drugs.

267. The dominance of the PBM Defendant mail order pharmacies has led to increased concentration of US "specialty" drug volume, further decreasing transparency regarding Manufacturer/PBM Defendant financial transactions.

268. Within these wholly-owned specialty pharmacies, the PBM Defendants have proprietary visibility/discretion over all pharmaceutical transactions, while limiting transparency for CMS and private payers. This unique position provides the PBM Defendants with numerous pathways to obscure the fraudulent "services fees" and other financial transactions with the Manufacturer Defendants.

269. Centralized specialty pharmacies, dominated by the PBM Defendants, now account for most of the prescription volume for the large-spending "specialty" drug categories targeted for severe BFSF fraud in the Relator's Qui Tam filings.

270. According to IMS, 86% of US multiple sclerosis drug prescriptions were dispensed by specialty pharmacies in 2014, up from 73% in 2010. In the anti-TNF inflammatory drug category, 76% of US prescriptions were dispensed by specialty pharmacies in early 2015, up from 54% in 2009.

271. Driven by massive price inflation and “service fee” incentives, manufacturers and their PBM partners have little, if any, incentive to compete on price and/or aggressive rebates for market share.

272. Instead, the true battle behind the scenes is for the terms of “service fee” agreements between manufacturers and PBMs/specialty pharmacies as ALL products in major US brand drug therapeutic categories vastly-inflate in lockstep.

273. The dominant PBM/specialty pharmacies have considerable negotiating leverage with manufacturers, to obtain rebates and prevent price increases, in the wide-distribution, long-standing, top-spending and crowded US MS drug category. Other US therapeutic categories, with an array of clinically-similar brand drugs, thereby affording considerable PBM negotiating leverage, include the rheumatoid arthritis, diabetes, certain cancer segments and others.

274. Rather than using their leverage to garner savings for taxpayers and beneficiaries in Part D, the PBM Defendants have employed it to gain egregious “service fee” payments.

275. Beyond these crowded drug categories, an increasingly intense battle regarding “service fees” between manufacturers and PBMs/specialty pharmacies has also been underway in recent years regarding more unique “specialty” drugs, which typically face less competition.

276. Notable unique, extreme-priced, high revenue-generation, “specialty” drugs include AbbVie’s Imbruvica (leukemia), Roche’s Esbriet (pulmonary hypertension) and various other small population, extreme-cost “specialty” drugs.

277. For these “unique” products, manufacturers increasingly seek “limited distribution” specialty pharmacy networks. In some instances, the manufacturer may use an

“exclusive” specialty pharmacy.

278. In these situations, the manufacturers have strong negotiating leverage with the PBM Defendants and smaller PBM/specialty pharmacy operators, such as Diplomat Pharmacy. To maximize profits, manufacturers seek to pay “service fees” to only a limited number of PBM/specialty pharmacies.

279. Prior to Part D, “limited distribution” drug arrangements were primarily and legitimately only employed for drugs that carry major safety risks, as per the FDA’s Risk Evaluation and Mitigation Strategy (REMS) program. However, without any regulatory restrictions and the aberrant “service fee” incentives, “limited distribution” arrangements are now increasingly employed primarily for financial reasons.

280. Both the manufacturers and PBM/specialty pharmacies in these arrangements have a strong incentive to aggressively increase prices at the expense of their payer clients.

281. Certain “limited distribution” arrangements suggest a potential for severe “service fee”-related pricing abuse, especially for products of little clinical value and/or those dependent upon severe price increases for US-centric growth. Both partners in this arrangement may be perversely motivated to vastly increase drug prices and drug usage, rather than to prevent inappropriate spending for clients.

282. Over the past decade, the sole distribution arrangement with Express Scripts for Mallinckrodt/Questcor’s Acthar suggests a high likelihood of severe “service fee” abuse. The arrangement between Questcor and Express Scripts was signed coincidentally with an announced massive Acthar price increase in 2007, just after the start of Part D.

283. Acthar is an unusual product which gained a broad “grandfathered” label from the FDA, for a wide array of autoimmune indications, prior to the 1960’s when the agency began requiring clinical trial proof for approval. Most expert physicians see little clinical utility for Acthar beyond a rare pediatric seizure condition.

284. Regardless, Questcor (later acquired by Mallinckrodt), with help from a dedicated “marketing” team from Express Scripts, turned the product into a billion dollar blockbuster by serially promoting Acthar for a variety of these clinically-unproven medical uses.

285. Other older “unique” specialty products that offer the potential for “service fee” abuse include Jazz Pharmaceutical’s Xyrem (narcolepsy) and Mylan’s Epipen (emergency allergic treatment). The primarily US-based revenue growth for both of these products has also been driven, in large part, by massive price increases.

286. Prior US Department of Justice PBM Defendant case settlements have already established negligence in the FMV of BFSFs as a basis for false claims and kickbacks.

287. On September 7, 2005, a Settlement Agreement was entered between the United States, Advanced PCS (now part of PBM Defendant CVS Health) and three Relators. In the Settlement, AdvancePCS paid the sum of \$137.5 million to resolve allegations brought forth by the US government.

288. As per the Advance PCS Settlement document: “The United States alleges that...AdvancePCS allegedly solicited and/or received payments of (a) administrative fees from pharmaceutical manufacturers for services related to the negotiation and administration of rebate contracts with those manufacturers, and (b) fees for products and services agreements from pharmaceutical manufacturers...”

289. The Advanced PCS settlement document further states: “The United States also alleges that to the extent that the payments exceeded the value of the above-referenced services and products, AdvancePCS knowingly caused false claims to be made to OPM and false Medicare claims to be made to HHS. In addition, the United States alleges that AdvancePCS knowingly caused false Medicare claims to be made to HHS in connection with soliciting and/or receiving kickbacks in the nature of payments exceeding the value of the above-referenced services and products.”

290. Our investigation indicates a high likelihood of “sham” BFSF payments (i.e. FMV equal to zero) from the Manufacturer Defendants to the PBM Defendants for services that are not actually being provided.

291. All the PBM Defendants make extensive claims regarding “clinical support” they are providing to physicians and patients, especially regarding “specialty” drugs. Common clinical support services highlighted by the PBM Defendants include injection training, patient consultations regarding drug efficacy/safety, input regarding drug selection and drug adherence programs.

292. However, extensive Relator interviews with specialist MS physicians uniformly indicate that the vast majority of clinical “support services” are actually being provided by office medical staff or directly by drug manufacturers, not the PBM Defendants or their affiliated specialty pharmacies.

293. The dominant role of centralized mail order pharmacies for the distribution of “specialty” drugs indicates that the PBM Defendants are greatly overstating their “clinical support services”. Simply put, even for patients newly-started on “specialty” drugs, the PBM Defendants typically have minimal, if any, in-person contact.

294. Furthermore, for the vast majority of MS patients that are stable on chronic drug therapy, potential PBM/specialty pharmacy “services”, beyond simply mailing the prescription, are scant. Our discussions with both expert physicians and “specialty” drug-treated patients verify these findings.

295. The potential for “sham” “service fee” payments may be even greater for oral MS drugs, including Defendant Novartis’ Gilenya and Defendant Biogen’s Tecfidera. For many MS patients chronically-administered oral drugs, few legitimate “support services” are being provided by the PBM Defendants, beyond simply re-filling and mailing the prescription.

296. While the majority of the fraudulent drug costs enabled by the Part D BFSF

scheme have been borne by US taxpayers at the federal level, State drug spending fraud has also been severe.

297. Prior to 2006, low-income seniors and disabled individuals who qualified for both Medicare and Medicaid received outpatient drug benefits through state Medicaid programs. When Medicare Part D was implemented in 2006, these "dual eligible" beneficiaries began receiving drug coverage under Medicare Part D, without recourse.

298. Due to their compromised health, these "dual eligibles" accounted for 50% of Medicaid drug costs and the majority of extreme-priced "specialty" drug spending prior to the transfer, despite only comprising 13% of the Medicaid enrollment in 2005. OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.

299. By law, each state is required to fund about a third of Medicare Part D spending for their respective "dual eligibles" via "clawback payments" to CMS. From 2006 through 2016, States made cumulative "clawback" payments of \$80.7 billion to CMS. 2017 Medicare Trustees Annual Report, July 2017.

300. Medicaid requires additional manufacturer rebates for all annual brand price increases greater than inflation (CPI-Urban) whereas Medicare Part D provides no such protection. After many years of severe price increases, the Medicaid net cost for many brand drugs, especially older "specialty" drugs, is now a fraction of the Part D price.

301. The Relator obtained propriety information indicating that the Medicaid 2013 net cost for four long-marketed MS specialty therapies (Avonex, Rebif, Betaseron and Copaxone) was 80-90% below the \$40,000-50,000 annual patient cost range in Part D at that time. The pricing disparity between Medicaid and Medicare Part D has widened considerably further since 2013. Similar dynamics now prevail for many other "old" blockbuster brand "traditional" and "specialty" drugs in other therapeutic categories.

302. In its most recent comparison of Medicaid and Medicare Part D rebates, the Office of Inspector General (OIG) concluded that "the inflation-based additional rebate, meant to protect Medicaid from large drug increases in drug prices, was the primary reason that Medicaid rebates were higher than Part D rebates". OIE-03-10-00650, Medicaid Rebates For Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.

303. From the same report: "for the 200 brand-name drugs with the highest Part D expenditures in 2012, rebates accounted for 47 percent of Medicaid expenditures, whereas rebates totaled 15 percent of Part D expenditures."

304. If state "dual eligibles" had remained within Medicaid, their brand drug costs would now be a fraction of the cost in Medicare Part D. A significant portion of State "clawback" payments since the start of Part D have been driven by the "service fee" fraudulent pricing scheme.

305. Our investigation indicates fraudulent abuse of the essential Part D plan sponsor "catastrophic" cost-sharing requirements. In Part D, plan sponsors (i.e., the insurance entities) are required to pay 15% of all drug costs above a very modest annual threshold (\$3,600 in 2006, rising to \$5,000 in 2018).

306. This "cost-sharing" exposure was expected to motivate plan sponsors to negotiate aggressively with manufacturers to get favorable prices for high-cost "specialty" drugs. However, this essential cost-control mechanism has broken down because, in practice, the PBM Defendants (and their wholly-owned subsidiaries) surprisingly serve as the plan sponsor, PBM and specialty pharmacy for the majority of Part D plans and beneficiaries.

307. After more than a decade of massive price inflation, the PBM Defendants (in their function as plan sponsor) are responsible for about \$14,000-16,000 of "catastrophic" annual drug costs for each US MS patient treated with the Defendant drugs.

308. The dominant PBM Defendants could have similar or even greater “catastrophic” cost-sharing exposure for many other Part D beneficiaries treated with high cost “specialty” drugs, including top-spending Part D rheumatoid arthritis, cancer and hepatitis C therapies.

309. We concluded that the Manufacturer Defendants, in many instances, are “forgiving” the PBM Defendants for this “catastrophic” exposure in order to further the “service fee” pricing scheme.

310. Without this cost-sharing “forgiveness”, massive plan sponsor catastrophic exposure for the PBM Defendants would have led to legitimate price negotiation with the Manufacturer Defendants, preventing most, if not all, of the Defendant MS drug price inflation. The potential abuse of Part D “catastrophic” cost-sharing requirements appears aided by minimal Defendant CMS reporting requirements.

STAGGERING FRAUD FOR 7 MAJOR DEFENDANT MS DRUGS

311. While the “service fee” business model is now employed systemically, this case focuses on a US MS therapeutic category in which the fraudulent scheme has been advanced to a staggering degree.

312. For the “old” MS drugs in this case (Avonex, Rebif, Betaseron and Copaxone), the decade-plus long “service fee” scheme has yielded an astounding 5-6 fold increase in US prices, despite plummeting clinical use, prescription volume and market share.

313. Driven solely by massive price increases, the Manufacturer Defendants have reported, in their SEC filings, robust US sales growth for the MS drug products.

314. Due to severe competition, legitimate PBM negotiations would have prevented virtually all of these price and US sales gains over the past decade.

315. While this price collusion scheme began with the older long-marketed MS drugs, the scheme has now apparently been employed across the entire US MS drug category.

316. The eight MS drugs targeted in this case are: Biogen IDEC’s Avonex (FDA-

approved 1996); Biogen's Tecfidera (2013); Biogen's Pledigry (2014); Teva's Copaxone (1996); Pfizer/Serono's Rebif (2002); Bayer's Betaseron (1993); Novartis' Extavia (2009) and Novartis' Gilenya (2010).

317. Massive, uniform and fraudulent price inflation has occurred across the entire US MS drug marketplace over the past decade. See **Exhibit 2**.

318. Despite severe competition from an array of new, clinically-similar MS therapies, including several generic products, the "list" price for all drugs in the category has increased in unison from the \$20,000 range in 2006 to the \$85-115,000 range in mid-2018. The evidence of pricing fraud has markedly accelerated since our initial January 2014 Qui Tam filing when US MS pricing were uniformly in the \$50-65,000 patient/year range.

Exhibit 2**US Multiple Sclerosis Market**

Uniform, Massive Price Inflation

\$AWP

<u>Drug/Manufacturer/Launch Yr</u>	<u>US Annual Cost Per Patient (\$AWP)</u>					
	<u>2006</u>	<u>2010</u>	<u>2013</u>	<u>2015</u>	<u>2017</u>	<u>2018</u>
Avonex (Biogen, 1996)	\$20,066	\$41,587	\$65,448	\$79,834	\$90,533	\$97,775
Pledigry (Biogen, 2014)	-	-	-	79,834	90,533	97,775
Rebif (Pfizer/Serono, 2002)	22,221	37,465	69,644	82,940	98,992	98,992
Betaseron (Bayer, 1993)	20,012	41,311	64,541	81,330	95,728	102,334
Extavia (Novartis, 2009)	-	<u>38,250</u>	<u>57,794</u>	<u>72,694</u>	<u>85,644</u>	<u>90,783</u>
Average Interferon	\$20,766	\$39,653	\$64,357	\$79,326	\$92,286	\$97,532
Copaxone 20 mg (Teva, 1996)	-	\$44,166	\$67,226	\$89,213	\$103,864	\$103,864
Copaxone 40 mg (Teva, 2014)	-	-	-	72,115	83,981	83,981
Glatopa (Sandoz, 2015)	-	-	-	<u>78,991</u>	<u>78,991</u>	<u>78,991</u>
Average Glatiramer		\$44,166	\$67,226	\$80,106	\$88,945	\$88,945
Gilenya (Novartis, 2010)	-	\$56,909	\$71,514	\$89,008	\$106,738	\$113,142
Tecfidera (Biogen, 2013)	-	-	64,800	83,347	98,208	106,064
Aubagio (Sanofi, 2012)	-	-	<u>64,505</u>	<u>83,051</u>	<u>95,209</u>	<u>95,209</u>
Average Oral MS		\$56,909	\$66,940	\$85,135	\$100,051	\$104,805
Average US MS Drug (\$)	\$20,766	\$41,910	\$66,174	\$81,523	\$93,761	\$97,094

Source: Truven/Red Book.

319. The FDA-approved drug labels, as well as the treatment guidelines from major medical organizations, clearly indicate that ALL the US brand MS drugs are clinically-similar and largely interchangeable.

320. In a properly functioning US marketplace, the PBM Defendants should have tremendous negotiating leverage regarding all the US MS drugs, but especially pertaining to products with eroding prescription volume and market share. Unfortunately, legitimate price negotiation has not occurred due to the systemic “service fee” price inflation scheme.

321. As per the FDA-approved labels, ALL marketed MS drugs are approved primarily

for the same relapsing/remitting MS patients, which account for the majority of the marketplace. While a few of the drugs can claim modest potential efficacy advantages (e.g., Rebif and Gilenya) based upon comparative clinical trials, the clinical role of all the drugs is virtually interchangeable.

322. ALL the available MS drugs are approved as viable first, second or third line therapies, as per the recently updated April 2018 treatment guideline from the American Academy of Neurology. Practice Guidelines: Disease-modifying Therapies for Adults with Multiple Sclerosis, AAN, April 2008.

323. ALL the available relapsing/remitting MS drugs have been approved based upon the same 20+ year-old standard clinical trial measures, namely the drug's impact on "disability", "multiple sclerosis exacerbations" and "brain lesions as measured by MRI (magnetic resonance imaging)."

324. The clinical choice of a particular drug for any patients depends upon numerous factors, including the drug's mode of administration, its side effect profile, modest differences in relative efficacy, physician/patient preference, and perhaps most importantly, formulary access.

325. The stark divergence between pricing and clinical usage/prescription volume trends for the four long-marketed US MS therapies, Avonex, Copaxone, Rebif and Betaseron is clearly indicated in **Exhibit 3**.

326. Further indicative of severe anti-competitive pricing activity, the price inflation for these four "old" MS drugs has continued unabated in the most recent years as prescription volume and market share erosion has accelerated.

Exhibit 3**Massive Uniform US Multiple Sclerosis Drug Price Inflation****Despite Eroding Clinical Use/Intense Competition**

	2006 Annual Patient Cost	2013 Annual Patient Cost	2018 Annual Patient Cost	2006-18 Change in AWP	Percent Change in US Treated Patients ³	
<u>Product (US Approval)</u>	<u>AWP (\$) ^{1, 2}</u>	<u>AWP (\$) ^{1, 2}</u>	<u>AWP (\$) ^{1, 2}</u>		<u>2006-17</u>	<u>2010-17</u>
Avonex (Biogen, 1996)	\$20,066	\$65,448	\$97,775	4.9X	-63%	-46%
Copaxone (Teva, 1996)	\$20,100	\$67,226	\$86,963	4.3X	-32%	-39%
Rebif (Serono, 2002)	\$22,221	\$69,644	\$98,992	4.5X	-50%	-58%
Betaseron (Bayer, 1993)	\$20,012	\$64,541	\$102,334	5.1X	-70%	-65%
Extavia (Novartis, 2009)	-	\$57,794	\$90,783	-	-	-
Tecfidera (Biogen 2013)	-	\$64,800	\$106,064	-	-	-
Gilenya (Novartis, 2010)	-	\$71,514	\$113,142	-	-	-

¹ From Redbook/Truven Analytics Pricing Database.

² Patient cost estimates based upon average FDA-approved maintenance dose.

³ IMS Health National Prescription Audit (NPA) database and our estimates.

327. As per **Exhibit 3**, the clinical usage for 3 of the 4 “old” Defendant injectable MS drugs (Avonex, Rebif and Betaseron) has decreased by about 50-70% each over the past decade as massive uniform US price increases have continued.

328. Over the same time frame, the clinical use of Teva’s Copaxone has decreased approximately 40%. The prescription volume erosion for Teva’s Copaxone, the long-standing US MS market share leader, has accelerated in recent years due to the arrival of several generic versions. Counter to legitimate market dynamics, Copaxone brand “list” prices have continued to escalate, even after generic arrivals.

329. These “old” US brand MS drugs have faced severe competition from an array of new clinically-similar MS drug that have reached the market over the past decade, including

Novartis' Extavia (2009, a brand equivalent of Betaseron), Novartis' Gilenya (2010), Sanofi's Aubagio (2012), Biogen's Tecfidera (2013), and Roche's Ocrevus (2017).

330. Over the past decade, the prescription volume and market share of "old" injectable MS drugs has plummeted primarily due to the broad shift to more convenient new "oral" MS therapies, namely Gilenya, Tecfidera and Aubagio. Overall, the market share of the four "old" injectable MS drugs has decreased from 100% in 2006 (at the start of Part D and this scheme) to about 35% in mid-2018.

331. Furthermore, over the past 6-8 months, all self-administered injectable and oral MS therapies have been negatively impacted by the gains for Roche's Ocrevus, leading to volume declines for the entire market. Ocrevus is an injectable product administered in the office by physicians that offers strong efficacy and requires dosing only twice a year. Ocrevus is standardly reimbursed via Medicare Part B, rather than via Medicare Part D for the self-administered Defendant drugs.

332. In a normal competitive system, the arrival of an array of clinically-similar products to an already mature market would be expected to yield intense price competition. In reality, the exact opposite has happened in the US MS drug market.

333. New drugs reaching the market are launched near the prevailing fraudulently-inflated category price levels, then quickly join the price inflation "fee" scheme.

334. The divergent pricing trends for MS and other "specialty" drugs in the US and Europe clearly indicates the role of both Medicare Part D and PBMs in this domestic price inflation scheme. The PBM industry is a uniquely American industry, with a minimal presence outside of this country.

335. Prior to the arrival of Medicare Part D, the cost of the four "old" blockbuster MS drugs at the center of this case, Biogen's Avonex, Teva's Copaxone, Pfizer/EMD Serono's Rebif and Bayer's Betaseron, were approximately at parity among the US and major European

countries, at about \$10,000/patient/year.

336. Now, more than 12 years after the arrival of Part D (administered by PBMs), the cost of these four drugs is in the \$100,000 range in the US, while prices have increased minimally in Europe. Noteworthy is the initial divergence in pricing trends around 2003 when Part D was enacted, with accelerating disparity starting in 2006 when the program began. See **Exhibit 4**.

337. US MS drug price inflation resulting from the scheme, along with the patient and taxpayer harm, have markedly accelerated since our initial Qui Tam filing in January 2014. US MS drug prices have nearly doubled from the \$50,000 patient/range in early 2014 to the \$100,000 range in mid-2018.

338. At the individual Defendant drug level, the geographic pricing diversity is even starker, for both long-marketed and newer MS therapies.

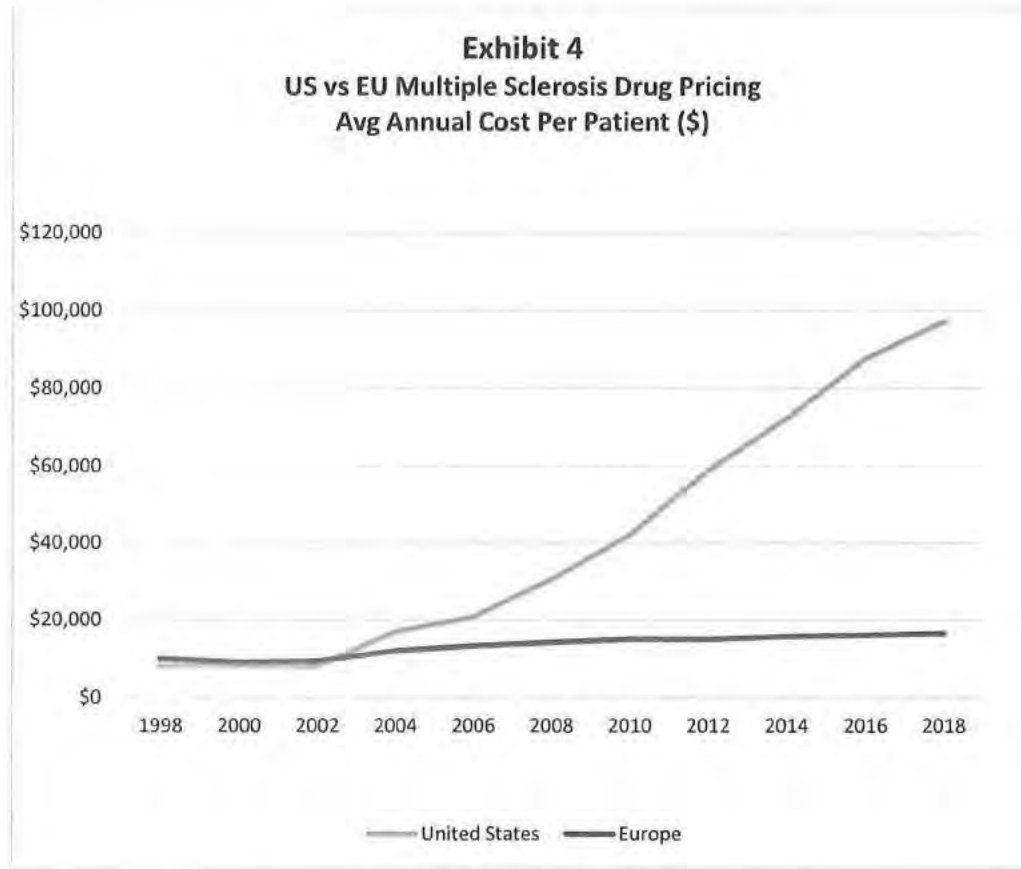
339. For the “old” MS Defendant drugs, patient costs in Europe have changed minimally over the past decade, consistent with their deteriorating usage and market share.

340. With vast fraudulent domestic price inflation, Avonex, Copaxone, Rebif and Extavia US prices were 6-8 fold higher compared to the five major European countries in early 2017. The disparity has widened considerably further since then. See **Exhibit 5**.

341. Furthermore, the newer “oral” drugs, Novartis’ Gilenya and Biogen’s Tecfidera, are priced nearly 4-fold higher in the US compared to the EU. In Europe, both Gilenya and Tecfidera are priced at approximately double the cost of the older MS drugs. See **Exhibit 5**.

342. The EU MS pricing dynamics indicate a normal competitive environment, with robust pricing for “innovation”. In contrast, the US MS market has been greatly “distorted” by the “service fee” price collusion scheme.

343. Indicative of the systemic US pricing and fee scheme, similar geographic divergence in pricing has occurred for many other “old” blockbuster “specialty” and “traditional” drugs in other therapeutic areas, including cancer, diabetes, rheumatoid arthritis and others.



Source: Truven/Redbook, CSFB.

Exhibit 5**US vs. EU MS Drug Price: Defendant Products**

March 2017

<u>Product</u>	<u>Est. Annual Cost of Treatment</u>		<u>US Multiple of EU Price</u>
	<u>US</u>	<u>EU¹</u>	
Avonex	\$58,000	\$10,000	5.8X
Pledigry	\$58,000	\$9,000	6.4X
Rebif	\$71,000	\$11,000	6.5X
Copaxone	\$70,000	\$9,000	7.8X
Extavia	\$58,000	\$9,000	6.4X
Gilenya	\$71,000	\$19,000	3.7X
Tecfidera	\$66,000	\$17,000	3.9X

¹ Average of 5
major EU countries.

Source: Biostrategy Analytics, March 18, 2017

344. The primary purpose of the contractual negotiations between the manufacturer and PBM defendants is to maximize drug prices for ALL drugs in the MS category, leading to higher revenues and profits for both collusive parties via the “service fee” scheme.

345. In addition to undermining legitimate brand drug price competition, the “service fee” scheme has greatly impeded the expected cost savings from recent generic launches for the market-leading MS therapy, Teva’s Copaxone. Of note, in the marketplace, PBMs are not typically paid “service fees” for generic drug products.

346. In 2014, the first generic version of the long-marketed 20mg daily version of Copaxone became available. A year prior to the generic arrival, Teva’s daily version of Copaxone commanded approximately a 40% share of the overall US MS market.

347. However, despite the potential for considerable generic cost savings, Teva quickly

transferred (in less than a year) more 75% of its Copaxone franchise to its newer 40mg, thrice weekly version of the product just prior the generic launch.

348. This unprecedented quick transition was accomplished despite no clinical advantages, other than minor dosing convenience, for the new Copaxone formulation. As a result, only 25% of the US Copaxone market was directly amenable to switching when the generic arrived.

349. Legitimate PBM negotiations on the behalf of patients would have restricted Teva's switching program to enable future generic cost savings. We expect discovery will determine that the PBM Defendants aggressively assisted Teva in this fast transition to the new formulation in order to preserve their vast "service fee" payments from the market-leading brand Copaxone franchise.

350. In a normally operating marketplace, the PBM Defendants would aggressively promote a cheaper generic version of Copaxone, leading to lower drug costs for Part D and private beneficiaries.

351. It is notable that the Sandoz generic division of Novartis launched the initial generic version of 20mg Copaxone at a very high price, in the \$79,000/patient/year range, which was astoundingly higher price than Teva's new 40mg brand formulation at that time. Novartis' likely motive was to maximize pricing and sales for Gilenya, its far more financially-important oral MS therapy.

352. More recently, the "service fee" scheme has undermined the impact of broader availability of both the 20 and 40 mg versions of Copaxone. Mylan launched a 20mg and 40 mg generic version of Copaxone in late 2017. Novartis/Sandoz also recently launched its formulation of the 40mg version.

353. In a normal competitive market, we would expect broad availability of a generic to lead to intense pricing pressure for both Teva's Copaxone and other clinically-similar brands

in the US category.

354. However, the impact of generic Copaxone remains very modest. In early 2018, generic Copaxone still only accounted for about 25% of the US Copaxone market and about 6-7% of the overall US MS market.

355. Indicative of the ongoing collusive “fee” scheme, uniform aggressive price increases have continued for numerous other brand US MS drugs, despite wider generic Copaxone availability.

356. In **Exhibit 6**, we provide the contribution of price increases and utilization to SEC-reported US sales for the 7 major Defendant MS products for the 2005 to 2017 period.

357. The revenue impact of price increases has been greatest for the long-marketed MS drugs in declining use since the start of Medicare Part D. However, ongoing massive price increases have also been a key growth driver for the newer US MS therapies, Biogen’s Tecfidera and Novartis’ Gilenya.

Exhibit 6**Manufacturer Defendant US Product Sales: 2005-2017****Driven by Massive Price Increases**

	2005 Reported US Sales (\$mil)	2017 Reported US Sales (\$mil)	2017 US Sales at 2005 Prices (\$mil)	Reported Growth 2005-2017	Growth Without Price 2005-2017
Avonex/Pledigry (Biogen)	\$939	\$1,889	\$322	101%	-66%
Copaxone (Teva)	782	3,000	530	284%	-32%
Rebif (PFE/Serono)	390	1,257	216	222%	-45%
Betaseron (Bayer)	584	482	77	-17%	-80%
Subtotal	\$2,695	\$6,628	\$1,145	146%	-58%
Tecfidera (Biogen)	-	\$3,294	\$845	-	-
Gilenya (Novartis) ¹	-	1,709	403	-	-
Total Revenues	\$2,695	\$11,631	\$2,394	332%	-11%

¹ Assumes strong premium pricing of \$30,000/patient/year for Tecfidera and Gilenya.

Source: Company reports, Redbook, IMS and our estimates.

358. Based upon SEC-reported US sales, public pricing data and documented utilization trends, we calculate that all the growth and more in the US MS category, between 2005 and 2016, has been driven by massive price increases enabled by the “service fee” scheme.

359. First, with plummeting usage, none of the price increases for the four long-marketed MS drugs, Avonex, Copaxone, Rebif and Betaseron, would have occurred in a legitimate competitive market. In fact, price decreases would have been expected for these eroding drug products.

360. Second, the launch prices of newer US MS drugs were fraudulently elevated by the abusive inflation of these older therapies. Without the “service fee” scheme, new MS therapies would have been launched only at a modest premium to the older drugs in the mature and crowded

US market.

361. In our view, US MS new drug launch prices in the 2010-2013 timeframe would have optimistically been in the \$30,000 patient/year range, still a large premium to the “old” drugs, but far below the actual launch prices.

362. Given the intense battle for market share, all subsequent price increases for all the drugs in the category would have been prevented with legitimate negotiation between MS drug manufacturers and the dominant PBM Defendants.

363. Without the pricing scheme, we estimate that overall combined US sales for the 7 Defendant MS drugs would have remained flat in the \$2.5 billion range between 2005 and 2017. We assumed a US launch prices of \$30,000 patient/year for Gilenya and Tecfidera, far higher than the \$17-19,000 range in Europe.

364. In reality, driven by massive uniform price inflation, the revenues generated by the 8 Defendant MS drugs have more than quadrupled since the start of Part D, with SEC-reported US sales of nearly \$12 billion in 2017. See **Exhibit 6**.

365. Our estimate of stagnant overall Defendant US MS drug sales over the past decade is consistent with the legitimate competitive dynamics in the US MS market.

366. The US MS market has long been mature, with only modest annual overall prescription growth for the past several decades. The market was already highly-competitive a decade ago when only the four “old”, clinically-interchangeable Defendant MS drugs were on the market. Over the past decade, the number of clinically-similar US MS drugs competing for this mature patient population has tripled.

367. Our estimate of stagnant US sales for the 7 Defendant drugs does not include additional patients treated with other US MS drugs that are not part of this case, including Tysabri (Biogen), Aubagio (Sanofi), Ocrevus (Roche) and the new generic versions of Copaxone.

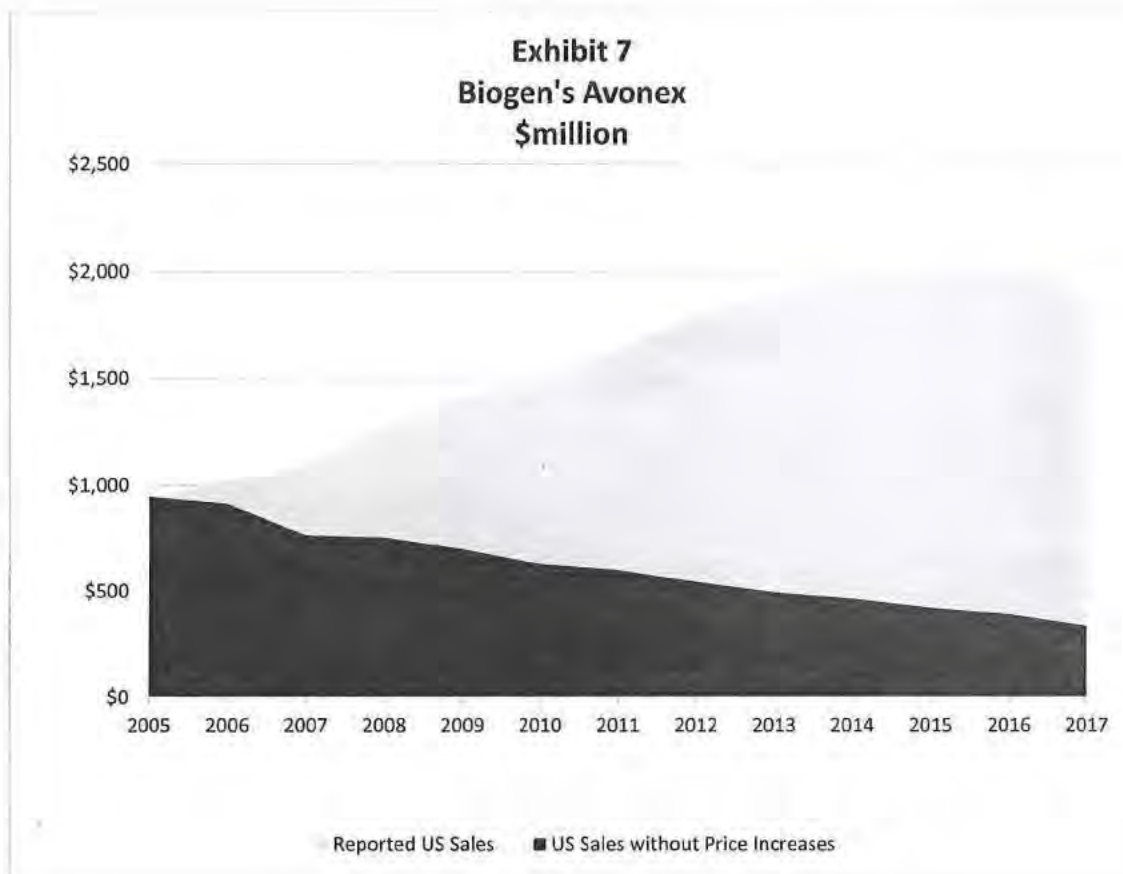
368. According the PBM Defendant Express Script’s own data, the US MS market has

been the largest spending (and among the fastest growing) “specialty” drug categories in both Medicare Part D and the commercial insurance market for numerous years over the past decade.

369. Furthermore, as per the same Express Scripts data, the US MS category has been among the top three “specialty” drug spending categories for virtually every year since the arrival of Medicare Part D, with price increases as the primary driver. Express Scripts Drug Trend Reports.

370. The staggering, cumulative public harm caused by this scheme over the past decade is well-illustrated by the graphic contribution of price and volume to SEC-reported US sales for the major MS drugs in this case.

371. For Biogen’s Avonex/Pledigry, SEC-reported US sales increased from \$939 million in 2005 to \$1.9 billion in 2017, with all the growth due to massive, relentless price increases. The AWP annual US patient cost of Avonex has risen from about \$15,000/patient in 2005 to the \$98,000 range in early 2018. Without price increases, we estimate US Avonex sales would have fallen to the \$330 range in 2017, as clinical use of the drug plummeted more than 50% over the past decade. See **Exhibit 7**.

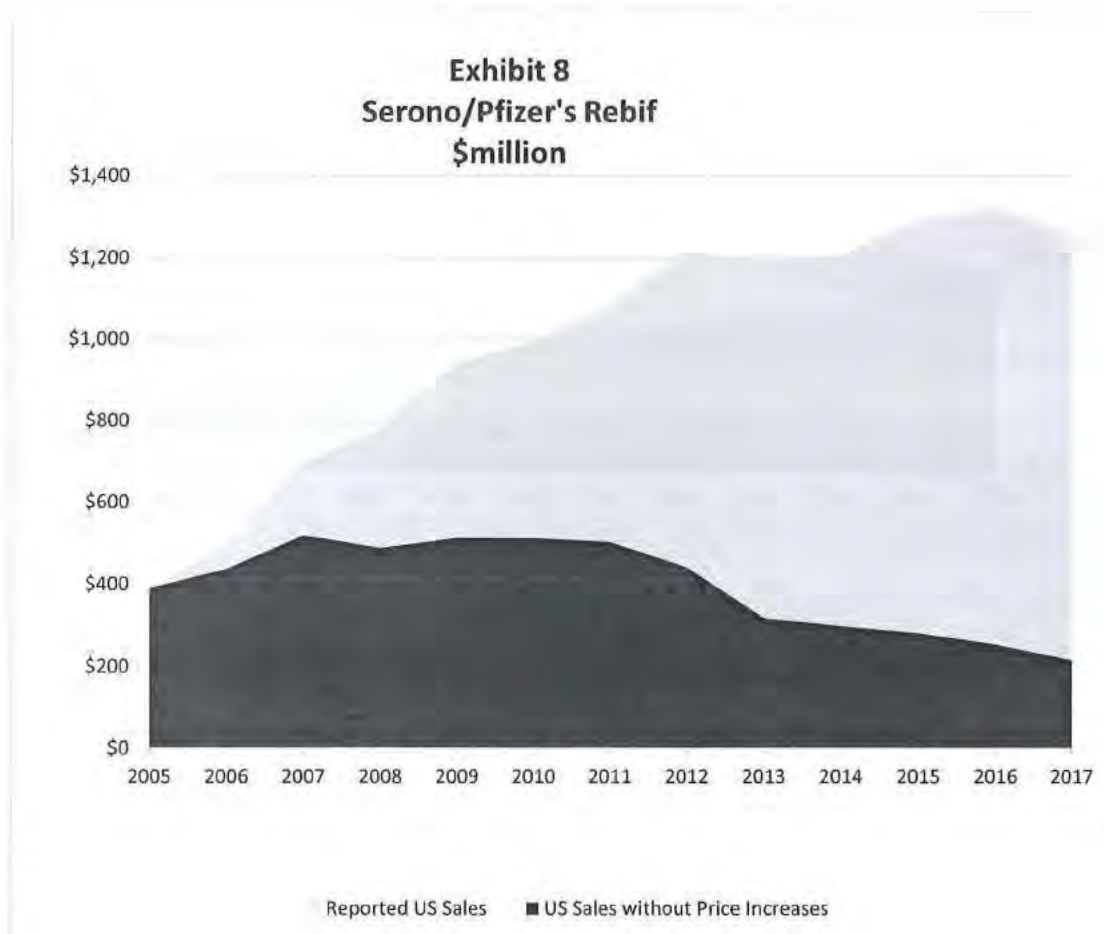


372. The graphic depiction for Pfizer/Serono's Rebif and Bayer's Betaseron are just as severe compared to Avonex. Rebif and Betaseron, price increases have been in lockstep with Avonex, while prescription volume erosion has been similar or greater (down about 50-70% over the past decade). IMS, National Prescription Audit database.

373. The AWP cost of Rebif has increased from about \$17,000/patient/year in 2005 to approximately \$99,000/patient/year in early 2018. The AWP cost of Betaseron has increased from about \$16,000/patient/year in 2005 to about \$102,000/patient/year in early 2018.

374. Despite the vast prescription erosion, Rebif has remained one of EMD Serono's largest US brand drug products, driven entirely by fraudulent price increases. We estimate that EMD Serono achieved US Rebif sales of \$390 million in 2005, growing to the \$1.2 billion range in 2017. Without vast price increases, based upon sharply eroding clinical usage (down about

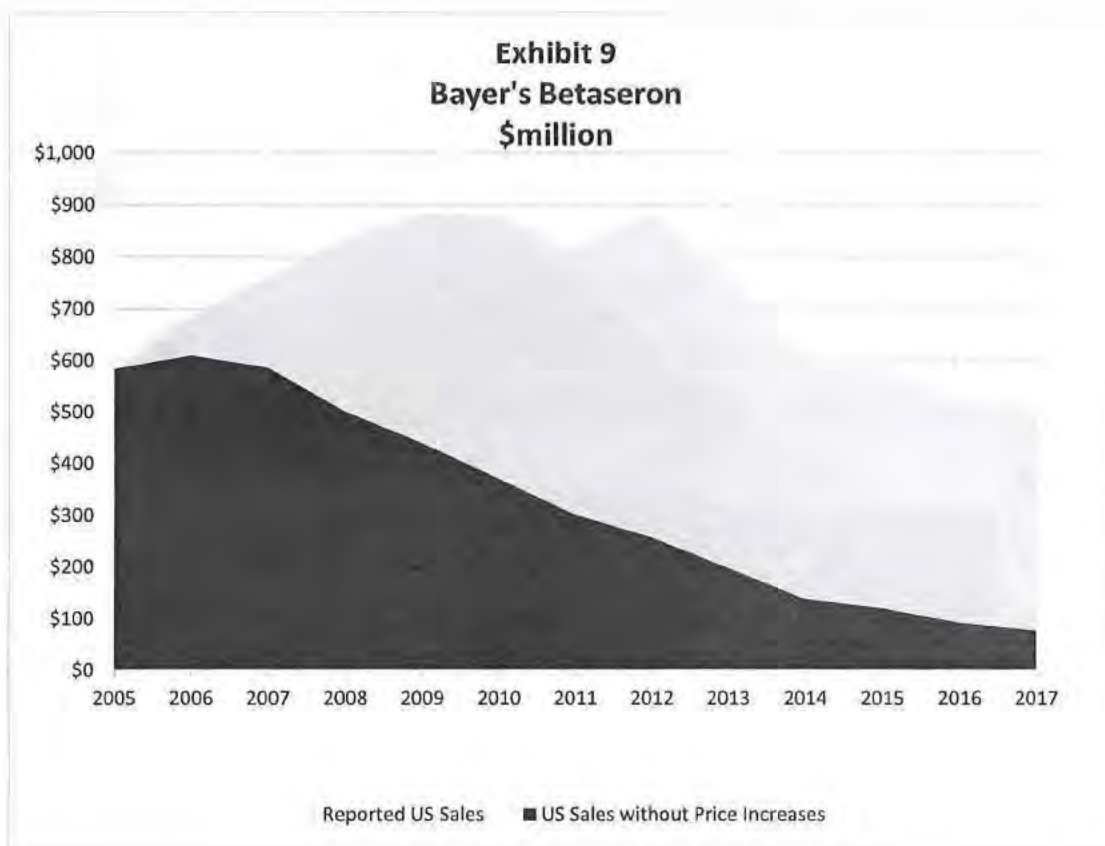
50%), we estimate US Rebif sales would have fallen to the \$220 million range in 2017. See **Exhibit 8**.



375. The US sales performance of Bayer's Betaseron has been strong for much of the past decade, also driven solely by massive fraudulent US price increases. Our US sales estimates for Betaseron are somewhat less accurate than for other Defendant products, because Bayer has not consistently reported a geographic breakdown of the product's sales over the past decade. We estimate that Bayer achieved US Betaseron sales of \$585 million in 2005, rising to the \$900 million range in 2012. Thereafter, reported US Betaseron sales have apparently been in decline,

impacted by severe erosion in clinical usage and market share, offset by ongoing massive price increases.

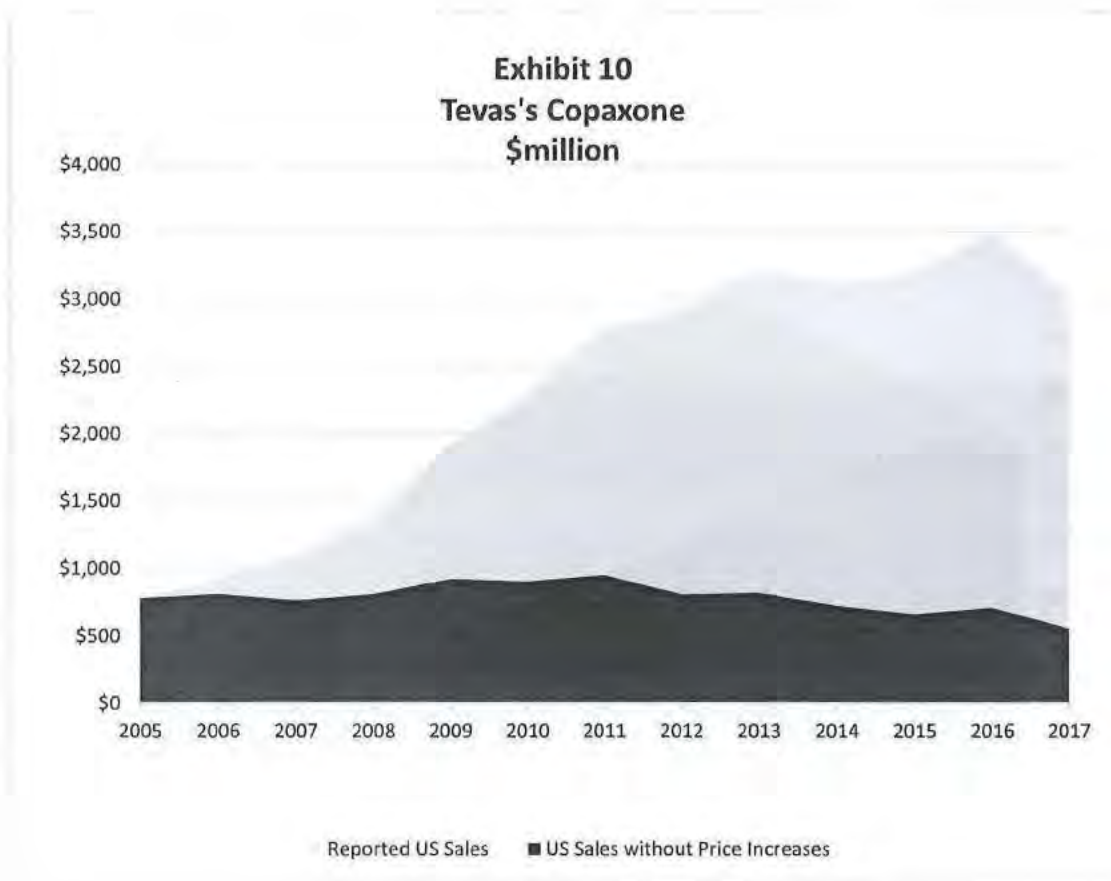
376. We estimate that Bayer achieved US Betaseron sales of about \$480 million in 2017. Without vast price increases, we estimate US Betaseron sales would have been about \$80 million, with clinical usage down in the 70% range over the past decade. See **Exhibit 9**.



377. Teva's Copaxone, SEC-reported US sales rose from about \$782 million in 2005 to \$3.0 billion in 2017. The AWP cost of the 20mg daily version of Copaxone has risen from about \$20,000/patient/year in 2005 to about \$104,000 patient/year in early 2018. The newer thrice weekly 40 mg formulation of Copaxone carries an AWP "list" price of about \$84,000 patient/year

in mid-2018, up from the \$72,000 range when launched a few years ago.

378. Without price increases, we estimate that US Copaxone sales would have fallen to the \$530 million range in 2017. As indicated above, the US revenues have held up remarkably well over the past several years, despite the arrival of generic versions. See **Exhibit 10**.

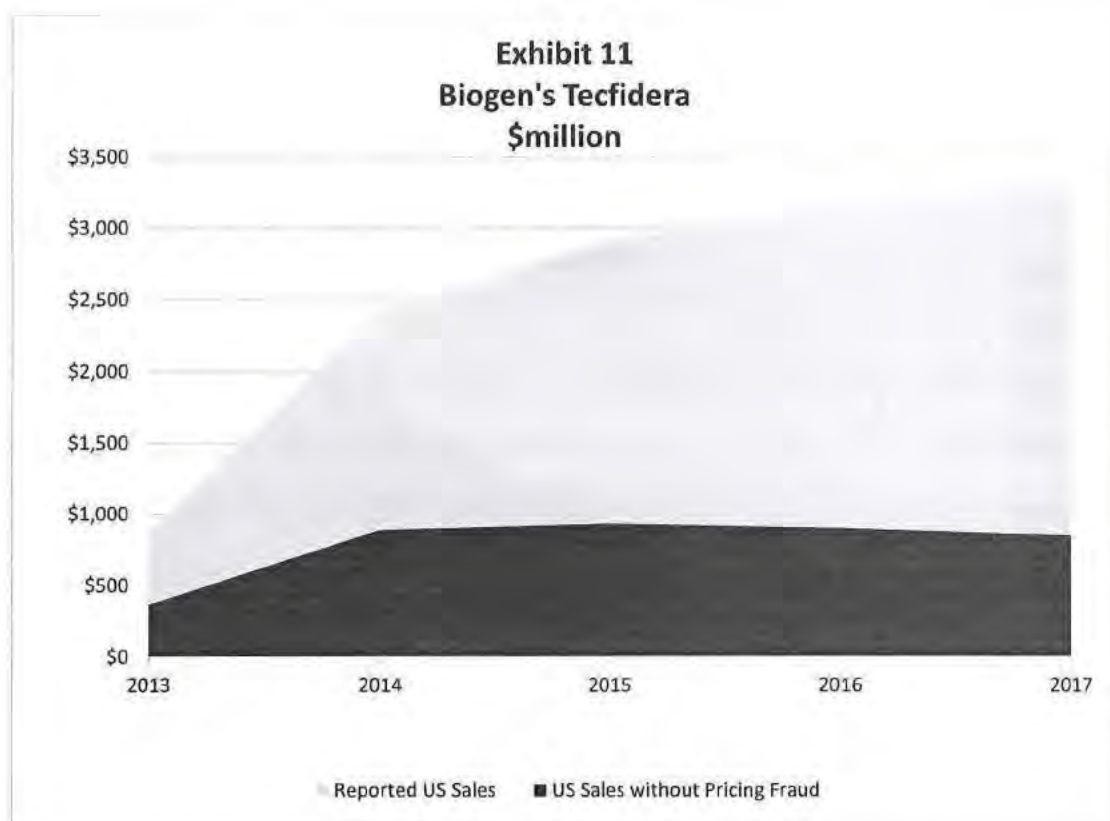


379. For Biogen's Tecfidera, SEC-reported US sales increased from \$864 million in 2013 (its year of launch) to \$3.3 billion in 2017. Driven by fraudulent price escalation of Biogen's Avonex, we estimate that nearly half of Tecfidera's \$55,000 cost/patient/year launch price was driven by the "fee" scheme.

380. Further, we believe the majority of subsequent massive Tecfidera price increases

would not have occurred in a legitimate market. The AWP annual US patient cost of Tecfidera has risen to \$106,000 in early 2018.

381. As indicated graphically, in recent years Tecfidera has increasingly become reliant on price increases for US growth as volume gains have lessened. Without the “fee” scheme, we estimate that US Tecfidera sales would have been significantly lower; about \$370 million in 2013, rising to \$850 million in 2017. See **Exhibit 11**.

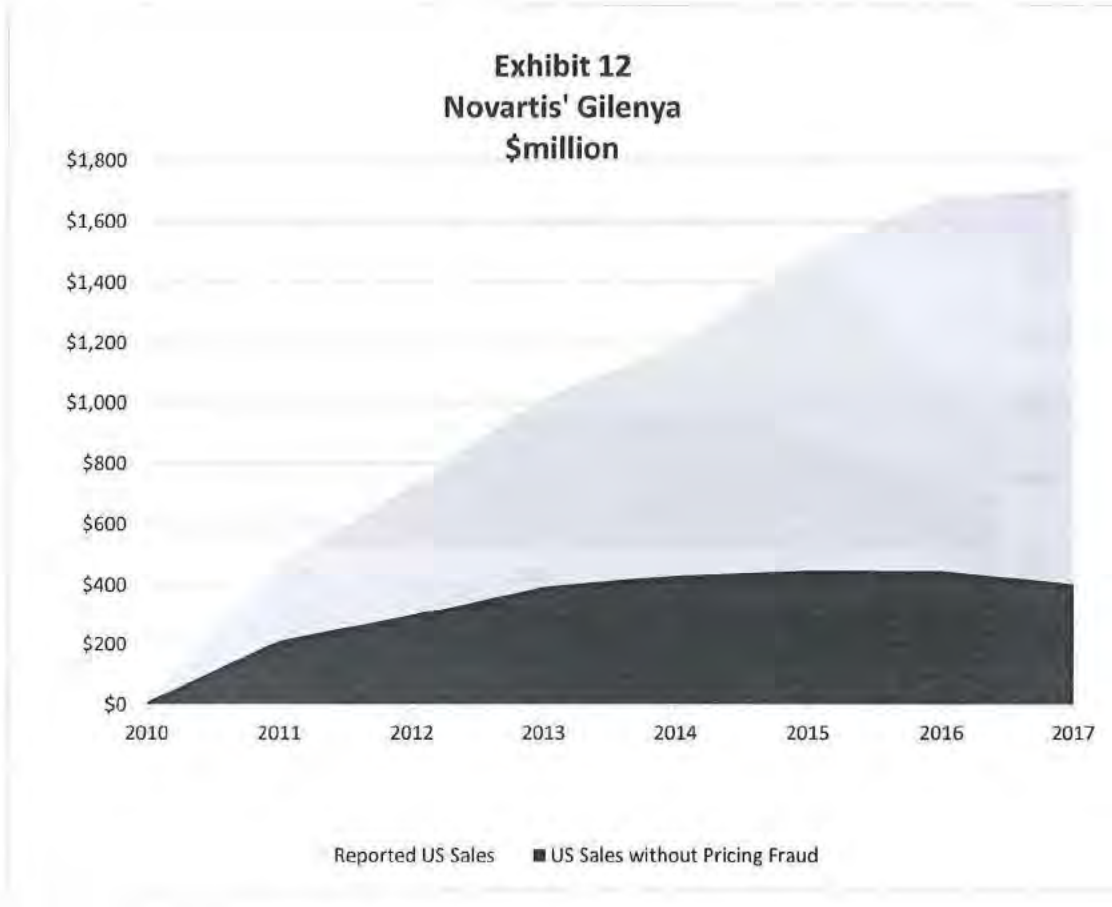


382. For Novartis' Gilenya, SEC-reported US sales increased from \$468 million in 2011 (its first full year on the US market) to \$1.7 billion in 2017. Gilenya is now Novartis' top-selling US and worldwide brand drug product. Similar to Tecfidera, we estimate that much of Gilenya's approximately \$48,000 cost/patient/year launch price can be attributed to the “fee”

scheme.

383. Further, we allege that the majority of subsequent massive Gilenya price increases would not have occurred in a legitimate market. The AWP annual US patient cost of Gilenya has risen to about \$113,000 in early 2018.

384. Without the “service fee” scheme, we estimate that US Gilenya sales would have been significantly lower; about \$215 million in 2011, rising to about \$405 million in 2017. See **Exhibit 12**.



385. In **Exhibit 13**, we summarize the cumulative estimated “service fee” and US sales fraud, by Defendant MS product for the 2006-2017 period. The fraud estimates are truly

staggering due to the magnitude of massive price increases and cumulative/compounding impact of this systemic scheme.

386. For the 7 major Manufacturer Defendant MS products targeted in this Complaint, we estimate that more than \$59 billion of cumulative fraudulent US drug sales have been enabled by the scheme between 2006 and 2017, with the scheme ongoing and escalating. We estimate that 30% of this fraud, or nearly \$18 billion has occurred in Part D.

387. Our fraudulent sales estimates in the US MS category have nearly quadrupled since our last Qui Tam filing in May 2014, due to ongoing massive and uniform price inflation and the addition of two Defendant products (Novartis' Gilenya and Biogen's Tecfidera) to the case.

Exhibit 13

Staggering Cumulative Financial Harm: 2006-2017

Direct "Service Fee" and US Sales Fraud (\$ million)

	Direct "Service Fee" Fraud (\$mil) ¹	US Sales Fraud (\$mil)	Estimated Part D Market Share (%)
Avonex (Biogen)	\$839	\$12,487	30%
Copaxone (Teva)	1,348	19,866	30%
Rebif (PFE/Serono)	553	8,356	30%
Betaseron (Bayer)	305	4,552	30%
Tecfidera (Biogen)	\$581	\$8,613	30%
Gilenya (Novartis)	381	5,607	30%
Total	\$4,006	\$59,480	30%
Part D	\$1,202	\$17,844	

¹ Using the PhRMA 8% average contract rate for "specialty" drugs.

Source: Corporate reports, PhRMA, PCMA, Redbook, our estimates.

388. Our cumulative estimates of US sales fraud for the individual Manufacturer Defendant MS drugs are similarly staggering and have greatly increased since our last Qui Tam filing.

389. Due to its position at the market share leader for much of the past decade, the US sales fraud estimate is greatest for Teva's Copaxone, at nearly \$20 billion between 2006 and 2017.

390. For the other "old", declining US MS drugs, Biogen's Avonex, EMD Serono/Pfizer's Rebif and Bayer's Betaseron, we estimate cumulative US sales fraud of \$12.5 billion, \$8.4 billion and \$4.5 billion, respectively, between 2006 and 2017, with the scheme ongoing. See **Exhibit 13**.

391. Our US sales fraud estimates for the two newer "oral" MS therapies, Biogen's Tecfidera and Novartis' Gilenya, are also considerable. We estimate cumulative fraudulent Tecfidera and Gilenya US fraudulent sales of \$8.6 billion and \$5.6 billion from their launch through the end of 2017, with the scheme ongoing. See **Exhibit 13**.

392. We estimate that this US MS drug sales fraud has been enabled by approximately \$4.0 billion in fraudulent "service fee" payments from the Manufacturer Defendants to the PBM Defendants across the entire domestic health insurance market between 2006 and 2017.

393. We estimate that 30% or \$1.2 billion of this direct "service fee" fraud (the majority of which has been paid to the dominant PBM Defendants) has occurred in the Medicare Part D program. See **Exhibit 13**.

394. Our estimates for direct fraudulent "service fee" payments by the Manufacturer Defendants to the PBM Defendants has more than quadrupled since our last Qui Tam filing. The vast increase is due to ongoing massive price inflation, the addition of two additional Defendant products and, most importantly, a higher "specialty" drug "service fee" contract rate.

395. Our current direct "service fee" fraud estimate is calculated using the standard

“8% of revenue” fee contract rate for “specialty” drugs provided by the pharmaceutical lobbying organization, the PhRMA, in its November 2017 report. This recent PhRMA contract rate disclosure is twice that of the “4% of revenue” conservative assumption in our prior Qui Tam Complaints.

396. In this action, we seek restitution for the massive overpayment of Part D drug costs and “service fees” generated by this systemic price collusion scheme, plus treble damages.

EVIDENCE OF SEVERE PART D CATASTROPHIC “COST-SHARING” FRAUD

397. The escalating “service fee” scheme for extreme-priced “specialty” drugs has fueled severe financial fraud regarding essential Part D plan sponsor “catastrophic” cost-sharing requirements.

398. The evidence of “catastrophic” abuse has particularly escalated in the recent years, with the annual AWP patient cost of MS “specialty” drugs now uniformly in the \$100,000 range.

399. In Part D, taxpayers (via the Part D “Reinsurance Subsidies”) cover 80% of all drug costs for any beneficiary crossing a modest annual “catastrophic threshold”, which was \$3,600 in 2006 and rose to \$5,000 in 2018.

400. For extreme-priced “specialty” drugs, typically with an annual treatment cost now in the \$70-200,000 range (\$5,000-16,700 or more per month), most treated Part D patients now cross the “catastrophic threshold” in the first 1-2 months of each calendar year.

401. In order to incentivize aggressive price negotiation with manufacturers, Part D requires plan sponsors to cover an unlimited 15% of all “catastrophic” spending for beneficiaries.

402. This “cost sharing” requirement is the central Part D mechanism to incentivize cost control and legitimate negotiation with drug manufacturers regarding extreme-priced “specialty” drugs in the program.

403. However, as noted previously, since the PBM Defendants serve all three key functions (plan sponsor, PBM and specialty pharmacy) for the majority of Part D plans and

beneficiaries, this “independent” plan sponsor function has been compromised.

404. The failure of this essential cost-control mechanism is indicated by the vast increase in Part D “catastrophic” spending in recent years.

405. Massive unanticipated “catastrophic” over-spending has been the primary driver of accelerating Part D spending in recent years. In 2016, Part D “catastrophic” spending was \$34.8 billion, up more than 3-fold just since 2010 and from only \$6 million in 2006.

406. “Catastrophic” spending accounted for less than 15% of Part D spending in 2006, rising to 38% of program spending in 2016. According the 2017 Medicare Trustees Report, “catastrophic” spending is forecasted to be \$42.1 in 2018 and more than \$80 billion by 2026, remaining the primary driver of Part D spending growth.

407. This “catastrophic” overspending in recent years has been fueled by the massive inflation of older “specialty” drugs, as well as the broad Part D use of new hepatitis C therapies and extreme-priced cancer drugs.

408. In a properly-functioning marketplace, this excess spending should have placed an extreme financial burden on Part D plan sponsors, including the dominant PBM Defendants.

409. A MedPAC report from June 2015 indicated that plan sponsors had under-forecasted Part D “catastrophic” spending by more than \$6 billion in 2013 (or by more 50%) of the actual “catastrophic” spending of \$19 billion for the year. MedPAC Report to Congress: Medicare and the Health Care Delivery System, June 2015, Chapter 6, “Sharing Risk in Medicare Part D”.

410. Consistent with their dominant plan sponsor role in the Part D program, 70% of the unforeseen spending was attributed to the four largest PBM Defendants, Express Scripts, CVS Health, UnitedHealth Group and Humana.

411. At the 15% cost-sharing rate, the \$6 billion in excess Part D “catastrophic” spending in 2013 corresponds to unforeseen plan sponsor additional “cost-sharing” exposures of

more than \$900 million just for that single year for all plan sponsors and about \$630 million for the four largest PBM Defendants.

412. Furthermore, the bid, premium and actual “catastrophic” spending data suggest a further marked acceleration in unforeseen plan sponsor “cost-sharing” for 2014 and 2015.

413. Aggregate plan sponsors forecasted a 40% increase in Part D “catastrophic” spending between 2013 and 2015. The actual 2015 “catastrophic” spending came in at \$33.2 billion, 73% higher than 2013.

414. We estimate Part D plan sponsors (i.e., primarily the PBM Defendants) underestimated combined 2014 and 2015 “catastrophic” spending by another \$10 to \$20 billion.

415. This additional program spending leads to an estimated \$1.5 to \$3.0 billion in unforeseen “cost sharing” expenses for aggregate Part D plan sponsors for 2014 and 2015 combined, with the four largest PBM Defendants responsible for about \$1.1 to \$2.1 billion.

416. Despite this large unforeseen “cost-sharing” burden, all the PBM Defendants have reported robust financial results for 2013-2015 and none has indicated significant financial challenges in Part D.

417. This fact is inconsistent with both the huge financial burden faced by the PBM Defendants from the “catastrophic” over-spending and the typically low operating profit margins (5-6% range) for Part D plan sponsors in their annual bids submitted to CMS.

418. In reality, the massive “catastrophic” cost over-runs should have reeked financial havoc among PBM Defendants in Part D, but it never materialized.

419. To put the magnitude of this unforeseen plan sponsor cost-sharing burden in perspective, the Part D plan bids for all sponsors across the nation in 2007 included “expected profits” of only \$1.07 billion. GAO Report OEI-02-08-00460, Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.

420. Based upon the 2015 plan bids (average \$130/beneficiary) and annual enrollment

(39.2 million people), we estimate aggregate Part D profits in the \$3.0-3.5 billion range for aggregate US Part D plan sponsors for 2015.

421. There is no mathematical possibility that the dominant PBM Defendants could handle these massive unforeseen 2013-2015 “catastrophic” cost-sharing requirements (approximately \$2.4 to \$3.9 billion), without severe disruption to their financial performance and the overall Medicare Part D program.

422. This amount of unforeseen “catastrophic” cost-sharing would have negated virtually all Part D plan sponsor profits for the three year period.

423. The only way the PBM Defendants could avoid the tremendous dislocation from this unforeseen “cost sharing” exposure is through another secretive fraudulent financial arrangement with drug manufacturers.

424. We concluded that, in many instances, manufacturers are fraudulently excusing the PBM Defendants from their 15% “catastrophic” cost-sharing exposure (in their role as plan sponsors), in order to advance the now pervasive “service fee” pricing scheme.

425. We will again use Biogen’s Avonex to illustrate the scale of potential plan sponsor “cost-sharing” fraud. See **Exhibit 14**.

426. The annual AWP cost/patient of Avonex has increased from about \$20,000 in 2006 to the \$98,000 range in early 2018.

427. In Part D, in 2006, the plan sponsor would be responsible for 15% of all Avonex costs above the \$3,600 threshold, or about \$2,460 in annual costs, payable to the manufacturer, Biogen.

428. After the massive price increases, the plan sponsor would be responsible in 2018 for nearly \$14,000 in “cost-sharing” for each Part D Avonex-treated patient above the modest \$5,000 threshold that year.

429. With these dynamics, it would appear mathematically impossible for the PBM

Defendants to pay the escalating plan sponsor Avonex “cost-sharing” exposure (in their role as plan sponsors), in order to advance the now pervasive “service fee” scheme.

430. The 15% plan sponsor “cost-sharing” burden for each Avonex-treated patient would be nearly twice as much as the “service fees” received via a standard “8% of revenue” “specialty” drug contract, leading to considerable losses for the PBM Defendants.

Exhibit 14

Medicare Part D: Severe Catastrophic "Cost-Sharing" Fraud Biogen's Avonex

	<u>2006</u>	<u>2018</u>	<u>Change</u> <u>2006-2018</u>
AWP Cost/Patient/Year (\$)¹	\$20,000	\$98,000	\$78,000
Annual Part Catastrophic Threshold (\$)	\$3,600	\$5,000	
Drug Costs Above Catastrophic Threshold (\$)	\$16,400	\$93,000	\$76,600
Plan Sponsor "Cost Sharing" Rate (%)	15%	15%	-
Plan Sponsor Catastrophic "Cost Sharing" (\$)	\$2,460	\$13,950	\$11,490
PBM "Service Fees"/Avonex Patient (\$ @ 8%)	\$1,600	\$7,840	\$6,240

1 Excludes some other potential revenue offsets, especially drug financial assistance programs.

Source: CMS, Truven Analytics, PhRMA.

431. If the Manufacturer Defendants are commonly “forgiving” the PBM Defendants from their Part D catastrophic exposure, these amounts should be properly reported as discounts via Direct and Indirect Remuneration (“DIR”) reports to CMS, serving to lower program “negotiated” drug prices.

432. However, with Part D reimbursements based on high AWP “list” prices, we expect discovery will indicate wide-ranging reporting violations for Avonex and the other Defendant MS drugs.

433. These “forgiven” costs are another form of “kickbacks” and false claims required to advance the pervasive “service fee” pricing scheme.

434. Due to very limited public disclosure by either CMS or the Defendants, we have not attempted to estimate the magnitude of potential Part D plan sponsor “catastrophic” cost-sharing fraud. However, in recent years, the Part D “cost-sharing” financial fraud likely exceeds that from direct “service fee” payments for many extreme-priced “specialty” drugs.

435. The underestimation of “catastrophic” spending in annual plan sponsor bids leads to artificially low Part D beneficiary premiums, which are beneficial to the both the PBM and Manufacturer Defendants.

436. Low Part D premiums are a key marketing tool for the PBM Defendants and have contributed to accelerating enrollment in recent years.

437. Both Defendant parties gain political capital from low Part D premiums. The Defendants, politicians and related parties frequently cite the low premium levels as indicative of Part D’s success in controlling spending, while largely ignoring the exploding “catastrophic” Part D cost increases in recent years.

438. Of course, in a properly-functioning program, the Defendant strategy falls apart if the Part D plan sponsors were actually bearing their share of the vast “catastrophic” excess spending.

439. Key Part D regulatory shortfalls have contributed to fraudulent abuse of the Part D plan sponsor “cost-sharing” cost-control mechanism. If Part D plan sponsors were truly independent entities, “catastrophic” risk-sharing would force legitimate, aggressive price negotiations with manufacturers by the PBM Defendants.

440. Second and surprising to us, Medicare Part D does not require separate reporting and accounting (in PDE or any other CMS submissions) of the plan sponsor 15% “catastrophic” cost-sharing requirement, despite it being the primary mechanism for controlling high-cost “specialty” drug spending.

441. These regulatory shortfalls regarding plan sponsor “catastrophic” cost-sharing shrouds this important issue in secrecy that requires full investigation in the public interest.

442. With “specialty” drugs now the primary driver of both the biopharmaceutical and PBM industries, the apparent failure of the plan sponsor “catastrophic” cost-sharing mechanism now threatens the long-term viability of the Part D program.

EVIDENCE OF THE “FEE” SCHEME – DIRECT INSIDER COMMENTARY

443. Dr. Borzilleri obtained confirmation of Defendant intentional participation in the fraudulent systemic “service fee” scheme from his attendance at a one-of-kind conference specifically focused on the topic. On October 7-8, 2013 in Philadelphia, PA, Dr. Borzilleri attended a two-day conference entitled, “Fair Market Value of Bona Fide Service Fees”.

444. Consistent insider commentary over the two-day conference verified all key aspects of the fraudulent “service fee” arrangements between the Manufacturer and PBM Defendants.

445. The conference presenters and attendees were acutely aware that “service fee” contracts were routinely structured as a “percent of revenues”, inclusive of massive price increases. Furthermore, manufacturers and PBMs continue to structure contracts in this manner despite clear legal FMV risks and repeated legal/consultant advice against the practice. Detailed commentary from the conference is provided in the next section.

446. In December 2014, Dr. Borzilleri obtained corroboration of the BFSF scheme during a “one-on-one” meeting at an investor conference with James Schoeneck, the former CEO of Depomed, a mid-capitalization biopharmaceutical company. Depomed marketed Gralise for

the treatment of neurologic pain, which competed directly with Defendant Pfizer's Lyrica.

447. When asked about the competitive justification for coincident severe Gralise and Lyrica price increases, Mr. Schoeneck casually stated "well, PBMs don't make their money off of rebates anymore". He said, the "PBMs make their money off of service fees" and you just have to "play ball with them" to get a contract. He then stated that the typical contract required paying "3-4% of revenues", which would include the price increases".

448. Depomed had just recently announced the successful negotiation of contracts with the three-leading stand-alone PBMs at the time, Express Scripts, CVS Health and Catamaran for both private insurance and Part D formulary access for Gralise. Catamaran was acquired by Defendant UnitedHealth Group in 2015.

449. Both Pfizer's Lyrica and Depomed's Gralise are characterized as "traditional" pill drugs in PBM drug formularies, not high-cost "specialty" therapies. The "3-4% of sales" "service fee" contract rate (inclusive of price increases), quoted by Mr. Schoeneck, is consistent with the "traditional" drug rate disclosed by the PhRMA in its November 2017 report.

DETAILED COMMENTARY FROM "FMV OF BFSF INDUSTRY CONFERENCE"

450. Dr. Borzilleri obtained definitive confirmation of the "service fee" scheme from his attendance at an industry expert conference focused specifically on the topic. The two-day conference, sponsored by CBI, was entitled "Fair Market Value of Bona Fide Service Fees". The event was held in Philadelphia on October 7-8, 2013.

451. CBI describes itself as "the leading provider of market-driven, unbiased conferences for the pharmaceutical, biotechnology, medical device and healthcare industries."

452. The conference was attended by senior corporate government program staff from the biopharmaceutical and drug distribution industries, as well as representatives from leading consulting and law firms that advise industry regarding BFSFs and FMV. Of particular note was the absence of CMS or any other government agencies at the conference.

453. Key staff from the Defendants were in attendance, including Amgen, AbbVie, Bristol-Myers Squibb, Pfizer, Sanofi and Express Scripts. Also present were representatives from other leading drug manufacturers and service providers, including Johnson and Johnson, Glaxo, Astellas, Gilead, Mylan, Otsuka and Diplomat Specialty Pharmacy.

454. The legal and consulting firms, which gave most of the presentations and led discussions, are the leading firms among a narrow group of pharmaceutical and PBM industry advisors with dedicated BFSF and FMV healthcare practices. As per their corporate websites, these firms advise the majority of top pharmaceutical and biotechnology companies regarding compliance with government regulations.

455. Besides CIS, consultant firm presenters included representatives from Huron Consulting and Navigant Consulting.

456. On the legal front, presenters included representatives from King & Spalding, Reed Smith, Hogan Lovells and Sidley Austin. See **Exhibit 15** for a list of conference presenters and attendees.

Exhibit 15**"First Ever" Fair Market Value of Bona Fide Service Fees Conference****October 7-8, 2013, Philadelphia, PA*****Presenter/Attendee List***

<u>Name</u>	<u>Title</u>
<i>Presenters (in chronological order)</i>	
Tom Evigan	Senior Director, Commercial Contracting at Compliance Implementation Systems (CIS)
John Shakow	Partner, King & Spalding
Mark Linver ¹	Managing Director, Huron Consulting Group
Stephanie Gilson	Assistant General Counsel, Johnson & Johnson
Christopher Jackson	Corporate Attorney, Otsuka American Pharmaceuticals, Inc.
Donna White	Senior Director, Contracts and Compliance at Cornerstone Therapeutics
Joseph Metro	Partner, Reed Smith LLP
Mark Dewyngaert, Ph.D.	Managing Director, Huron Consulting Group
Michael Hepburn ²	Senior Director, Government Contract Compliance at Janssen Pharmaceuticals, Inc.
Doris Chern ²	Senior Manager, Pricing Strategy and FMV at Janssen Pharmaceuticals, Inc.
Jim Abrams	Director, Government Pricing and Reporting at Mylan Pharmaceuticals
Trevor L. Wear	Senior Associate, Sidley Austin, LLP
Julie DeLong, CFA	Director, Valuation and Financial Risk Management at Navigant Consulting, Inc.
Isabel P. Dunst	Partner, Hogan Lovells US LLP
John Moose, MBA, CPA, ABV	Project Leader, Huron Consulting Group
<i>Other Attendees</i>	
Sajid Saeed	Director Fee-for-Service, GlaxoSmithKline
Greg Haverkamp	Senior Manager of Government Contracts and Compliance, Novo Nordisk
Mitzi Cole	Strategic Pharmaceutical/Biotechnology Legal Counsel, Pfizer
Cynthia Bass	Associate General Counsel, Sanofi US
Cheryl Allen	VP Development/Industry Relations, Diplomat Specialty Pharmacy
Allyson Behm	Senior Corporate Attorney - Regulatory, Astellas
Jason Carter	Senior Manager, Government Analytics & Compliance, Roche/Genentech
Josh Parker	Director, Product Marketing, Express Scripts/Accredo Health

Lyndsay Nahf	Director, Central Consultancy Group, AbbVie
Linda Ozark	STAR Project Manager, Marketing Operations Systems, AbbVie
Jill Thompson	Senior Counsel and Assistant Secretary, NPSP Pharmaceuticals
John Walsh	Director Trade Account Management, Pfizer
Christine Morse	Senior Attorney, Novo Nordisk
Jamie Rowe	Senior Category Manager, Amgen

¹ Mark Linver did not attend the conference; his presentation was given by his colleague, Mark Dewyngaert.

² Janssen Pharmaceuticals is a division of Johnson & Johnson.

Source: CBI conference agenda and attendee poster from conference, Corporate websites.

457. At the conference, Dr. Borzilleri directly heard extensive commentary from the “insider” conference presenters, which fully corroborated the “service fee” allegations outlined in this Complaint. Dr. Borzilleri noted considerable trepidation among the presenters and audience regarding legal exposure throughout the two-day conference.

458. All key components of the fraud were verified via presentations, candid discussions and direct quotes at the conference, namely:

- a. “Service fees”, rather than manufacturer rebates/discounts, have become the primary vehicle for manufacturer compensation of PBMs/specialty pharmacies;
- b. The standard contract terms between manufacturers and service vendors utilize “percent of revenue” terms; without adjustment even for severe price increases, despite broad awareness of FMV fraud risk.
- c. The experts recognize that the majority of “service fees” should legitimately be valued via the straightforward “Cost Approach” to FMV assessment, but it is rarely being done;
- d. The large service vendors, including the PBMs, are using their considerable negotiating leverage to preserve “percent of revenue” service contracts with

manufacturers.

459. In the first few minutes of his opening statements, Tom Evegane of CIS, the Chairman of the conference, stated that "fees were the key to government pricing" and the majority of compensation to service providers from manufacturers had "shifted from rebates to fees".

460. On the second day, Mr. Dewyngaert, a senior consultant from Huron Consulting, stated that "service fee agreements" accounted for a "substantial pool of money" and were the "main source of income" for service vendors.

461. A key presenter was John Shakow, from the law firm King & Spalding. Mr. Shakow disclosed that he was a defense lawyer in the *Streck Qui Tam* case, which included allegations of "service fee" abuse in the Medicaid program.

462. After providing background on the history of BFSFs and potential legal risks, Mr. Shakow stated that he was "not a fan" of "percent of revenue" contracts and that manufacturers need to "consider whether percent of sales can be consistent with FMV as prices rise". He stated it was "a lot easier to have a fixed fee per unit of service", which would make him "less worried regarding the impact of price increases".

463. Mr. Shakow went on to say that "percent of revenue" arrangements "may bear no relation to the value of service unless (the service is) price-based". He expected that "percent of revenue" deals will be "challenged in the future".

464. Mr. Shakow emphasized that the manufacturer's handling of fees must be able to "withstand review/auditing by an independent party, which can determine the same FMV", as well as "justify the FMV to an outside party brought in by the government". He stated that the government will "look beyond the agreement and evaluate the true nature of the fees, via emails, communications, interviews and sworn testimony", in its search for "intent".

465. In their joint presentation, Isabel P. Dunst, a partner at Hogan Lovells and Julie

DeLong, the Director of Valuation and Financial Risk Management at Navigant Consulting, offered somewhat contrasting viewpoints regarding valuation methodologies. Ms. Dunst stated that she "did not recommend percent of sales" contracts to her manufacturer clients, while Ms. DeLong indicated more flexibility.

466. Ms. DeLong stated that she "can value anything" and was comfortable "translating per unit fees to percentage of revenue". Ms. DeLong elaborated, stating that "some want to be paid in different ways" and that she could "translate FMV into a dollar amount per month or year, as well as a percent of revenues". During this discussion, Ms. Dunst stated that she hoped "the conference was not being recorded".

467. Ms. DeLong further stated that the FMV was a "snapshot in time" and "percent of revenue" deals had greater risk when linked to fast-rising "list" prices.

468. An audience member then asked about the proper FMV handling of fees for a \$100 versus a \$1,000 prescription with the same number of pills. Ms. Dunst, of Hogan and Lovells, replied that a "real problem was developing with percent of revenue" contracts. We view this commentary as particularly relevant for fast-inflating, extreme-priced oral "specialty" drugs, which may not require significant legitimate support services.

469. Numerous presenters stated the "Cost Approach" is the most legally-justifiable FMV methodology for the vast majority of services provided for manufacturers by service vendors. In the "Cost Approach", the payment is determined by a straightforward determination based upon the staffing, time and resources required to provide a specific service.

470. In his discussion of contracting processes, John Moose of Huron Consulting stated that the negotiating parties must recognize that "most of the value of services comes from the connection with the patient" and that a "dollar amount per activity is the easiest to justify".

471. Julie DeLong and Isabel P. Dunst specifically discussed the topic of FMV for services provided for "specialty" drugs. Ms. Dunst stated that she "does not view the specialty

channel any differently from other channels" regarding the handling of fees and FMV.

472. If a particular "specialty" service is "core" to the business model of the specialty pharmacy and "they are already doing it", the manufacturer "should not be paying for it". Ms. Dunst and Ms. DeLong indicated that virtually all the specialty pharmacy services are patient/unit based and should be valued using the "Cost Approach".

473. Despite the uniform recommendation of the "Cost Approach" for FMV "fee" determinations, conference presenters repeatedly admitted that this methodology is rarely used in practice. Rather, "percent of revenue" contracts, inclusive of all price increases, remain the industry standard.

474. A definitive moment in the two-day conference came during the final presentation of the first day given by Jim Abrams, the former Director of Government Pricing and Reporting at Mylan Pharmaceuticals. Mylan's leading brand drug, Epipen (epinephrine for severe allergic reactions) has been a controversial product, with its vast US sales growth over the past decade driven by massive price increases.

475. Mr. Abrams took a simple poll of the audience. He asked attendees to raise their hands "if they were using a rigorous cost-plus approach to qualify fees" - only one person, among the 50-60 conference attendees, raised his hand.

476. John Moose of Huron Consulting specifically discussed the need for contract adjustments for rising drug prices. He stated that unless manufacturers put "adjustments in contracts for price changes", they "run the risk of paying too much". He stated that manufacturers need to "refresh" contracts for price increases and service changes, in order to maintain reasonable FMV determinations. Despite his expert recommendation, Mr. Moose admitted that "he had not done any refreshes for service contracts".

477. In her presentation, Stephanie Gilson, the Chief Counsel at Johnson & Johnson, admitted that "percent of WAC (Wholesale Acquisition Cost), deals are often not updated by

manufacturers".

478. The considerable negotiating leverage of large service vendors, especially the PBM Defendants, pertaining to "service fee" contracts was apparent at the conference.

479. Jim Abrams of Mylan polled the audience of largely manufacturers and consulting/legal advisors, asking for an indication of who had "engaged vendors to assess fee structure". Out of the 50-60 attendees, only 2 raised their hands.

480. Tom Evegán of CIS then commented that "very few vendors were willing to provide the data" and were "worried" about doing so. Mr. Evegán expressed concern since "manufacturers were looking for documentation since manufacturers were responsible if ever challenged".

481. Mr. Shakow further stated that "up to a few years ago, few contracts gave specifics regarding fees" and this "could be trouble".

482. Numerous expert presenters emphasized the need for manufacturers to insist on broad "audit rights" in their contracts with large service vendors, while admitting little success with these requests.

483. Mr. Shakow stated that shifting away from "percent of revenue" service contracts was difficult for manufacturers because vendors "all want percent of revenue deals" and change required "getting partners to agree".

484. Mark Dewyngaert from Huron stated that "often partners (i.e. service vendors) will not allow cost plus" fee determinations.

485. Ms. Gilson stated Johnson & Johnson was "trying to work with intermediaries" in order to decrease their reliance on "percent of WAC" contracts, but were getting "strong pushback from service providers". She stated that to change these business practices may require either a "manufacturer industry initiative" or a "CMS mandate".

486. Finally, expert commentary indicated that the federal government has been

struggling to address industry "service fee" practices. Ms. Gilson stated that the Office of the Inspector General (OIG) "has been looking at these practices", but really had little knowledge" and the "learning curve takes time". She further stated that the OIG auditors had only just "engaged" with J&J directly on this issue recently in the "second quarter of 2013".

487. An attendee agreed that the OIG was "behind industry" and asked Ms. Gilson when the government would be "dangerous enough to understand how industry works". Ms. Gilson responded that she thought "CMS was getting burned out because a lot of stakeholders were in their ear".

LONG-STANDING PATTERN OF DEFENDANT SECRECY AND DECEIT

488. Avoiding the detection of a scheme of this magnitude and duration requires extreme secrecy and lack of transparency, which must be stringently coordinated at the executive suite level.

489. Both the Manufacturer and PBM Defendants uniformly refuse to disclose any information in their SEC filings regarding their mutual financial arrangements, including contracts, rebates, "service fees" or any other transactions.

490. Specific to this scheme, we have found no discussion of BFSFs in any of the Defendants' SEC filings over the past decade, since the arrival of Medicare Part D. Failure to disclose this material information has enabled this scheme and led to severe financial and medical harm.

491. The extreme lack of financial disclosure in the PBM industry is legendary in the investment world and central to the pricing scheme. The PBM SEC disclosures regarding their source of profits are scant and often misleading.

492. For instance, the following is the only comment from Express Scripts in its 2015 10-K regarding its drivers of gross profit growth: "This increase is also due to better management of ingredient costs and formulary, as well as cost savings from the increase in the aggregate

generic fill rate, partially offset by lower claims volume”.

493. Similar to Express Scripts, none of the other three dominant PBMs, CVS Health, UnitedHealth Group and Humana, provides detailed disclosure of its sources of profits from prescription drugs.

494. Furthermore, the PBM Defendants provide minimal, if any, disclosure of the profit contribution of “specialty” drugs and Medicare Part D, the key growth driver in recent years.

495. With little verifiable financial information in the public domain, the senior executives from the Manufacturer and PBM Defendant intentionally disseminate a wide array of deceitful, misleading and inaccurate information in order to deflect attention from their collusive scheme. Key topics of deceit include drug rebates, price increases, Medicare Part D, patient assistance programs (PAPs) and drug coupons.

496. Both drug manufacturers and PBMs effectively utilize their closely-controlled trade organizations, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Pharmaceutical Care Management Association (PCMA). These organizations are funded by the industry, with numerous senior executives from the Defendants serving as board members.

497. We will highlight a couple examples of coordinated misinformation, which are indicative of the long-standing, nationwide collusive scheme.

498. A repeated strategy is the use of spurious and unverifiable internal or “paid consultant” research. For instance, in April 2016, the PhRMA and manufacturers aggressively utilized “research” from IMS that indicated that net price increases realized by US drug manufacturers declined sharply in 2015 to only 2.8%, despite average AWP price increases of 12% for the year. IMS Institute for Health Informatics, March 2016.

499. The pharmaceutical manufacturers, including executives of the Defendants, have widely attributed this net pricing decline to aggressive “rebate/discount” negotiations by PBMs, despite the data being inconsistent with a wide array of data indicating far higher pricing and lower

manufacturer rebate trends (including the CMS data for Medicare Part D).

500. However, the footnotes of the IMS report indicate that their “cost savings” calculations also included manufacturer patient assistance programs (PAPs) and “service fees”, thereby intentionally exaggerating the “calculated discounts” to payers and beneficiaries.

501. The PAP impact was included at “retail” prices, rather than the far lower true manufacturing cost of the drugs.

502. Since PBM “service fees” are nearly universally not shared with payer clients, their inclusion in the “discount” calculations is intentional deceit.

503. The PBM industry and the PCMA routinely use similar deceitful tactics. In November 2011, the PCMA paid a consulting firm, Visante, to generate a report regarding drug coupons, an increasingly controversial topic. Many experts report that drug coupons cause patients to inappropriately use expensive brand drugs. How Copay Coupons Could Raise Prescription Drug Costs by \$32 Billion Over the Next Decade. November 2011.

504. Not surprisingly, the “paid” research concluded that drug manufacturers were fully to blame for the abuse of drug coupons and that PBMs could do little about it since they did not have access to the prescription claims data. This conclusion is inaccurate and deceitful for extreme-priced “specialty” drugs, which now account for the majority of money spent on coupon programs.

505. The PBM Defendants dominate the specialty mail order pharmacy market, which now accounts for 80% of US “specialty” drug prescription volume. As such, the PBMs have full access to all claims data for their administered “specialty” prescriptions and could stop the use of coupons at any time in the interest of their private insurance clients.

506. Over the past several years, as US pricing scrutiny has escalated, the collusive pharmaceutical and PBM industries are increasingly “blaming” each other for drug massive drug price increases that have resulted from their mutual scheme. The manufacturers claim that they

are keeping only small portion of price increases, while the PBMs are taking extraordinary profits through their “murky” and nontransparent business practices.

507. The PBMs, in turn, state that they have no control over drug pricing. Both Defendant parties continue to focus on “rebates” as the key issue, while assiduously avoiding discussion of “service fees”.

508. Regardless of the recent escalation in the deceitful “adversary” rhetoric, manufacturers and PBMs have been in actuality working closely together for the past two decades. In the decade before Part D, PBMs made the majority of their profits from manufacturer rebates. Since Part D, PBMs have made the largest portion of their profits in collusive pricing scheme regarding manufacturer “service fees”.

PART D REQUIREMENTS FOR “BONA FIDE SERVICE FEES (BFSFs)”

509. Indicative of the secrecy of this scheme, we have been unable to locate any public record of legislative discussion of BFSFs prior to Congressional passage of Part D into law. In fact, BFSFs are not even mentioned in the 416-page Medicare Modernization Act (MMA) of 2003, which enacted the Part D program. PUBLIC LAW 108-173, DEC. 8, 2003.

510. In addition, BFSFs are only cursorily mentioned in the subsequent Code Federal Regulations (CFR) governing the Part D program, in Sections §423.514 and §423.501.

511. Section §423.514 of the CFR establishes the exclusion of BFSFs, in sharp contrast to manufacturer rebates, from Part D “negotiated price” calculations.

512. In Section §423.514, among other reporting requirements, the regulations state: “Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan”.(Emphasis added)

513. Section §423.501 of the CFR states: "Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug".

514. According to CMS, all BFSFs must pass the "Four-Part Test" in order to "qualify" for exclusion from Medicare Part D "negotiated price" calculations. 71 Fed. Reg. 69624, 69667-9. The first three parts of the test are:

515. the "itemized" service is actually performed;

516. the manufacturer would otherwise perform or contract for the service in the absence of the service contract, and;

517. the fee is not passed on in whole or in part to a client (i.e., it is kept by the PBM Defendant or other service providers).

518. However, the "Achilles Heel" facing both the Manufacturer and PBM Defendant in this scheme is the final criteria of the "Four-Part Test", which requires that all BFSFs be paid at "Fair Market Value" ("FMV") commensurate with an "arm's length" transaction between unaffiliated parties.

519. The CMS regulations regarding the handling of BFSFs and the legal requirements of FMV in Medicare Part D have been unequivocally in place since the start of the program in 2006. Since at least 2007, the handling of BFSFs and FMV has been virtually identical in the Medicaid, Medicare Part B and Medicare Part D drug programs.

520. In the Part D regulations, CMS places the legal onus on the drug manufacturers to justify that the fees represent "fair market value" ("FMV") for the services rendered. However, as mentioned previously, both the Manufacturer and PBM Defendant are liable under the FCA and the AKS for the fraudulent BFSFs and excessive drug costs in Medicare Part D.

521. CMS states: "manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination." (Emphasis added) 77 Fed. Reg. at 5332.

522. CMS has purposely kept its guidance regarding FMV vague due to concerns about potential fraud. CMS reiterated its position in its February 2012 proposed rule: "We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define 'fair market value' at this time." Federal Register, Vol 77, No 22, February 2, 2012.

523. CMS has made it clear that it considers all payments to service vendors, other than BFSFs, to be price discounts/concessions that must be included in Part D "negotiated price" calculations.

524. Per the Medicare Part D DIR ("Direct and Indirect Remunerations") Reporting Requirements for 2010 Payment Reconciliation, dated June 6, 2011: "CMS considers all remunerations received directly or indirectly from pharmaceutical manufacturers, with the exception of bona fide service fees (BFSFs), to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor."

525. By law, any "service fee" amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in "excess" of FMV must be reported to CMS as price concessions (i.e., "Direct and Indirect Remuneration") which serve to lower drug costs in Medicare Part D.

526. As per CMS in 2011: "In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other

amount and fair market value must be reported as DIR in column DIR #4." Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated June 6, 2011.

527. Legal precedent (*American Lithotripsy Society v. Thompson*, 215 F Supp. 2d 23 (200), US District Court, District of Columbia) has established that payments in excess of FMV are "payments for referral" and a violation of the Anti-Kickback Statute (AKS).

528. In 2006, CMS enacted regulations clarifying BFSFs. The regulations expressly re-affirmed that "service fee" payments must be for legitimate services rendered and thus not related to the price of the drug. (Emphasis added) Fed. Reg. 69624, 69668 (Dec 1, 2006) (relevant sections codified at 42. C.F.R. 414.802, 414.804).

529. In its 2007 final rule, CMS added that BFSFs should be "associated with the efficient delivery of drugs". In the rule, CMS interprets this standard to "encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69667-6.

530. The AKS requires that transactions be "commercially reasonable". 69 Fed. reg. 16,093 (March 26, 2004) According to the statute's theory, most business transactions must be "commercially reasonable" or there would be no reason for them to occur.

531. The AKS considers "commercial reasonableness" of a financial transaction to be a separate and distinct determination compared to FMV. The AKS states: "If compensation is based upon comparables, assurance is required that the markets are not "distorted" and that compensation is "commensurate with the skill level and experience reasonably necessary to perform the contracted service". *OIG Supplemental Compliance Program for Hospitals*, p 4866-67.

532. In this scheme, the broad use of "percent of revenue" contracts, linked to massive price increases has corrupted and "distorted" the US pharmaceutical market. As per the AKS, a

Defendant following these practices simply because others are doing it is not a viable defense. Each Defendant is individually responsible for ensuring, separately and distinctly, the appropriate levels of “commercial reasonableness” and FMV in its business transactions.

533. The AKS separately requires that, in any compensation arrangement, the payment must represent “reasonable compensation”. 26 C.F.R. 1.162-7 (b) (3) (2004). In this case, the typical 7 to 8-fold increase in “service fee” compensation per patient for the “old” Defendant drugs, driven by massive price increases, fails this requirement by a wide margin.

534. We have determined that the large “service fees” paid, per patient per year, by the Defendant Manufacturers to the PBM Defendants for both oral “specialty” and “traditional” drug products represents excessive compensation far outside of FMV.

535. Although CMS has increased BFSF reporting requirements in recent years, the data still has important limitations. First, virtually all BFSF and DIR reporting is still done by the plan sponsor “insurance” legal entity in Part D and are only reported at the “aggregate” level (not by individual product).

536. To this day, CMS does not require direct reporting of BFSFs, or their FMV justification, by drug manufacturers. Furthermore, CMS apparently also does not require direct reporting of BFSFs by PBM or specialty pharmacy legal entities operating in Part D. As such, the PBM Defendants could potentially conceal fraudulent BFSFs in their legally-separate, but wholly-controlled PBM and specialty pharmacy subsidiaries.

537. Given the varied opportunities to obscure illegal “service fee” payments, we anticipate a thorough investigation of these fraud allegations must include a review of all economic transfers between the Manufacturer and PBM Defendant, starting with their contractual arrangements. We would seek to obtain all forms of economic transfer from the manufacturers to the PBMs and their affiliates, including BFSFs, discounts, free goods, cost-sharing offsets, etc.

538. The CMS “Four-Part Test” requirement for manufacturers to “itemize” BFSFs by

individual product and service is also an important consideration in this case. Upon request by the government, such as in a fraud investigation, the Manufacturer Defendants must produce documentation of individual services actually provided by PBM Defendants for specific products and the FMV assessment methodology used to assign appropriate value.

REVIEW OF FAIR MARKET VALUE (FMV)

539. With CMS purposely not defining methods for BFSF FMV assessment in the Part D program, each drug manufacturer must determine its own process based upon acceptable practices in the private marketplace.

540. Although FMV assessment in the business world is designed to provide flexibility, a review of the topic reveals remarkable consistency in recommended approaches across both private and government entities.

541. The definition of FMV provided by the American Society of Appraisers has been generally accepted by both private industry and government agencies: "The price expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts". American Society of Appraisers Business Valuation Standard Glossary, Approved June 2005, Copyright 2005, American Society of Appraisers.

542. In the private sector, generally accepted valuation principles employ three primary approaches to FMV assessment: the "Income", "Market" or "Cost" Approaches.

543. Using the "Income Approach", the FMV payment would be based upon the amount and timing of cash flows generated by the business, asset or service.

544. The "Income Approach" is typically not relevant for "services" provided by healthcare professionals (i.e., including PBM "service fee" agreements with manufacturers) because "these services cannot, and should not be, directly associated with cash flow." Helman,

Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.

545. In the "Market Approach", FMV is determined by looking at the market prices of similar services. As such, a manufacturer may decide to determine the FMV of a "service fee" arrangement with a PBM/specialty pharmacy based upon the financial terms of competitor manufacturer/vendor relationships.

546. A "percent of revenue" arrangement is the most common form of "Market Approach" FMV methodology. However, some Manufacturer and PBM Defendant may utilize other contract terms, such as flat fees and lump sum payments, in abusive "service fee" arrangements, particularly if they seeking to avoid legal issues pertaining to "percent of revenue" arrangements.

547. The "Market Approach", including "percent of revenue" constructs, carries significant risk under the AKS.

548. These concerns were summed up in a 1992 letter from the OIG to the IRS: "Merely because another buyer may be willing to pay a particular price is not sufficient to render the price to be paid fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to result from the purchase." Letter from D. McCarty Thorton, Associate General Counsel, Office of Inspector General (HHS) to T. J. Sullivan, Technical Assistant, off of the Associate Chief Counsel, Employee Benefits and Exempt Organizations, December 22, 1992.

549. In the "Cost Approach", the FMV of the service is based upon the specific cost of providing the service, plus a reasonable profit. In this methodology, the FMV should not exceed the cost to obtain substitute service from a third-party in an "arm's-length" transaction.

550. Expert commentary clearly indicates that the straightforward "Cost Approach" is the most appropriate and accurate way to assess the FMV of "service fees" paid by manufacturers

to PBMs and specialty pharmacies. First, FMV experts clearly state that FMV payments should be determined for a "service and not a person". Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.

551. In a September 2012 presentation, consultants from Huron Associates stated: "Once a fair market value range for an activity is determined, the amount should be multiplied by the volume of that activity for each type of service and added together to arrive at a fair market value range for the contract." Huron Life Sciences Presentation, "Determining the Bona Fide Nature of Fee-for-Service Arrangements", 9/27/12.

552. In the same presentation, Huron Life Sciences described the particulars of the appropriate "Cost Approach" for "bona fide" services. The "price for a bona fide service" can be thought of as an amount that covers:

- a) *"the direct cost of the service;*
- b) *the overhead associated with delivering that service;*
- c) *the cost of assets used up in the delivery of the service; and,*
- d) *a reasonable return on the assets employed in the delivery of that service".*

553. The appropriateness of the "Cost Approach" was verified by a wide array of industry experts at FMV of BFSF conference attended by Dr. Borzilleri in October 2013.

DIPLOMAT PHARMACY SEC FILINGS: TRUE LOW FMV OF "SERVICE FEES"

554. The SEC filings of the largest remaining independent specialty pharmacy, Diplomat Pharmacy, Inc., verify that the appropriate "arm's length" compensation to the PBM Defendants for providing manufacturer services should be very modest, even for "complex" specialty drugs.

555. According its public disclosures, Diplomat provides services for all the Defendant "specialty" drugs in this case. However, in comparison to the larger PBM Defendants, Diplomat

has apparently historically lacked the negotiating leverage with drug manufacturers that would enable favorable "percent of revenue" service contract arrangements.

556. Despite offering specialty pharmacy services to manufacturers which they claim to be equal to, if not superior to, the PBM Defendants, Diplomat disclosed, in its Form S-1 filed with the SEC in July 2014 for its Initial Public Offering (IPO) that the company received minimal compensation from manufacturers for these "services".

557. As per page 18 of the S-1, Diplomat states: "We also provide a significant amount of direct and indirect services for the benefit of our pharmaceutical manufacturer customers and our patients in order to get access to specialty drugs, and our failure to provide services at optimal quality could result in losing access to existing and future drugs. In addition, we incur significant costs in providing these services and receive minimal service fees in return." (Emphasis added)

558. While Diplomat and likely other smaller specialty pharmacies, receive minimal compensation, the larger PBM Defendants are receiving large and escalating "percent of revenue" "fee" payments, tied to massive price increases, for the same Manufacturer Defendant "specialty" drugs.

559. This wide discrepancy, between the PBM Defendants and smaller "arm's length" operators, indicates that the appropriate FMV "service fee" payments to the PBM Defendants should be a fraction of what they are currently receiving.

"PERCENT OF REVENUE" CONTRACTS NOT PROTECTED BY SAFE HARBORS

560. The "percent of revenue" Part D BFSF contractual arrangements between the Manufacturer and PBM Defendant are not protected by Office of Inspector General (OIG) Safe Harbors regarding "kickbacks".

561. The relevant OIG Safe Harbors in this matter pertain to Personal Services and Group Purchasing Organizations (GPOs).

562. On April 18, 2003, the OIG issued a document in the Federal Register entitled

“OIG Compliance Program Guidance for Pharmaceutical Manufacturers” In the document, OIG states: “In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value, for legitimate, reasonable, and necessary services” (Emphasis added). Further details are provided in the “Personal Services and Management Contracts Safe Harbor”. §1001.952.

563. The April 2003 OIG Pharmaceutical Manufacturer guidance states: “Any rebates or other payments by drug manufacturers to PBMs that are based on or otherwise related to, the PBM’s customers’ purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO Safe Harbor at 42 CFR 1001.952(j).” By definition, “service fee” payments contractually-linked to massive price increases are “related to the PBM customers’ purchases”.

564. GPOs are organizations that act as purchasing intermediaries that negotiate contracts between health care providers (primarily hospitals) and vendors of medical products and services, including manufacturers, distributors and other suppliers.

565. The GPO Safe Harbor appears to be the only federal mechanism potentially affording specific protection for “service fee” contracts structured as a “percent of manufacturer revenues”, albeit with significant limitations.

566. According to the April 2003 guidance, “That safe harbor (GPO) requires, among other things, that the payments be authorized in advance by the PBM’s customer and that all amounts actually paid to the PBM on account of the customer’s purchases be disclosed in writing at least annually to the customer.” This information must be disclosed to the Secretary of Health and Human Services (HHS), upon request.

567. With consent of the entity (i.e., payer client), the GPO Safe Harbor states:

“participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.”

568. In violation of the GPO Safe Harbor, in most instances, neither the manufacturer nor PBM Defendant is disclosing the contracts or amounts of “service fees” to either private insurance clients or CMS.

569. In addition, in many contractual arrangements, the PBM Defendants garner manufacturer “service fees” far in excess of the 3% GPO limit.

570. The Safe Harbor states that the GPO can neither be “wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity.” Since the PBM Defendants wholly-own the PBM, specialty pharmacy and plan sponsor subsidiaries in most instances in Part D, the GPO Safe Harbor cannot apply in these predominant situations.

571. In February 2016, with the release of the AMP final rule and its related public commentary, CMS definitively stated that BFSFs are not protected by the GPO Safe Harbor. 42 CFR Part 447. While the AMP rule pertains to Medicaid, the regulatory requirements for BFSFs are identical in all government drug programs, including Part B and Part D.

572. As per the government reply below, drug manufacturers must determine the legitimacy of “service fee” arrangements via the Four-Part test, including a FMV determination.

573. As per page 5180 of the February 2016 AMP rule document: “Comment: A few commenters urged CMS to rely on the GPO safe harbor associated with the federal anti-kickback statute as it defines which fees would qualify as bona fide. The commenter stated that the final rule should state that a fee satisfying the anti-kickback statute safe harbor requirement meets the fair market value prerequisite and is a bona fide service fee”.

574. CMS Response: “We believe that to adopt a categorical exclusion of

administrative fees if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination as to whether or not the fee is bona fide because it would mean that the manufacturer has not evaluated the details of the specific arrangements regarding the services being performed. Additionally, we do not agree that we should adopt the safe harbor provisions associated with the federal anti-kickback statute as part of this rule as it does not address bona fide service fee determinations for purposes of determining included and excluded transactions related to a manufacturer's determination of AMP and best price.” (Emphasis added)

PBM CLIENT CONTRACT INDICATE ‘SERVICE FEE’ FRAUD

1) EXPRESS SCRIPTS:

575. While manufacturer/PBM “service fee” contracts remain closely guarded by the Defendants and outside the public domain, we have located several PBM/payer client relationships that indicate the fraudulent drug pricing scheme between the Defendant parties.

576. PBM/payer client contract terms are highly standardized across the PBM industry, both in the private insurance market and Medicare Part D.

577. A good example is the April 2012 PBM contract between Express Scripts and the Oklahoma City Municipal Facilities Authority. Express Scripts, Inc., Pharmacy Benefit Management Agreement, signed December 10, 2012.

578. The Oklahoma City contract states: “In addition, ESI (Express Scripts) provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on

the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price (AWP) or (ii) 5.5% of the wholesale acquisition cost (WAC) of the products.”

579. Express goes on to highlight other fee opportunities from manufacturers in the Oklahoma City contract. The PBM contract further states: "In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These services are not part of the formulary rebate and associated administrative fees."

580. As such, the actual service fee payments from some manufacturers to Express Scripts may be considerably higher than the "4.5-5.5% of sales" range stated in the previous paragraph.

581. Further increasing Express Scripts' manufacturer "service fee" opportunity, the Oklahoma contract excludes both "specialty" drugs and its own specialty pharmacies from general contract terms.

582. Exhibit A-1 of the contract states: "Specialty products will be excluded from any price guarantees set forth in the Agreement. In no event will the Mail Service Pharmacy or Participating Pharmacy pricing terms specified in the Agreement, including, but not limited to, the annual average ingredient cost discount guarantees, apply to Specialty Products dispensed by Curascript". (i.e., a wholly-owned specialty pharmacy subsidiary of Express Scripts)

583. The contract further states that Express Scripts' wholly-owned specialty pharmacy subsidiaries can make separate "service fee" arrangements with manufacturers. As per the Oklahoma contract: "ESI has several licensed pharmacy subsidiaries, including our specialty pharmacies. These entities may maintain product purchase discount arrangements and/or fee-for-

service arrangements with pharmaceutical manufacturers and wholesale distributors. These subsidiary pharmacies contract for these arrangements on their own account in support of their various pharmacy operations. Many of these subsidiary arrangements relate to services provided outside the PBM arrangement and may be entered irrespective of whether the particular drug is on one of ESI's national formularies. Discounts and fee-for-service payments received by ESI's subsidiary pharmacies are not part of the PBM formulary rebates or associated administrative fees paid to ESI in connection with ESI's PBM formulary rebate programs."

584. With these numerous potential manufacturer "service fee" revenue streams, the PBM Defendants have the opportunity for vast, non-transparent compensation from manufacturers in both Part D and the private sector, especially for "specialty" drugs exhibiting severe price inflation.

585. In the Oklahoma City contract, Express Scripts directly admits its culpability to the "service fee" scheme. First, the contract states: "ESI and Sponsor shall comply with all applicable and existing federal, state and local laws, standards, codes, ordinances, administrative regulations and all amendments and additions thereto, pertaining in any manner to the work and/or services provided by this Agreement."

586. Second, under section 7.13 of the contract, entitled "Alignment of Interests", the agreement states: "ESI acknowledges and agrees (as represented by ESI's response to Sponsor's RFP (i.e., Request for Proposal) that its business model is to align its interests with those of Sponsor. ESI does not engage in any business with a pharmaceutical manufacturer that is designed to manipulate the price or cost of any Brand Drug or Generic Drug in a manner that adversely impacts the cost to Sponsor of providing pharmacy benefits to Members under this Agreement. In this regard, "adversely impacts" is intended to mean that Sponsor would be required to pay a higher price for a Brand Drug or Generic Drug than the market would otherwise provide if it were not for ESI's business arrangement with such pharmaceutical manufacturer."

587. In stark violation of this contract language, the client and CMS drug costs for a wide array of brand drugs have been exorbitantly escalated by the collusive "service fee" arrangements between Express Scripts and drug manufacturers, linked to massive price increases.

588. As stated previously, the wide-ranging Part D liability for the PBM Defendants contrasts sharply with the situation in the private insurance market. Due to lack of ERISA fiduciary responsibilities, the PBM Defendants have successfully fought off a wide array of private payer lawsuits over the past several decades.

2) **CVS HEALTH:**

589. CVS Health/client contracts also indicate fraudulent "service fee" arrangements with manufacturers based upon severe price inflation.

590. A clear example is CVS Health's May 15, 2008 agreement with the National Association of Counties. In a section entitled "Disclosure of Manufacturer Fees", this contract states: "Caremark may receive fees or other compensation from Manufacturers, including, without limitation, administrative fees not exceeding three percent of the aggregate cost of the pharmaceutical products dispensed to participants, and fees for property provided or services rendered to a Manufacturer (which may include providing physicians clinical messages consistent with the Performance Drug List, as defined below). Caremark's specialty pharmacies may also receive fees from the Manufacturers for products and services provided ...The term Rebate as used in this Agreement does not include these fees and discounts which belong exclusively to Caremark or Caremark's mail order or specialty pharmacies, respectively."

591. All reimbursement in the Nation Association of Counties contract was based upon discounts to the Average Wholesale Price (AWP), with no protection from price increases.

592. Caremark provided definitive commentary regarding its handling of manufacturer fees during the 2007 bidding process for a contract to manage pharmacy benefits for the Maryland State Employee and Retiree Health and Welfare Program.

593. In this contract, Maryland sought full "pass-through" to the State for all manufacturer compensation to the PBM, including rebates and "service fees".

594. During the Maryland negotiations, the State asked CVS Health to confirm the following contract provision: "The Contractor (i.e., PBM) selected shall not retain any revenue (attributable to the State's business) from pharmaceutical manufacturers or wholesalers, including, but not limited to data fees, access fees, market share fees, rebates, formulary access fees, administrative fees or marketing grants." Before the Maryland State Board of Contract Appeals, Docket Nos. MSBCA 2544, 2548, & 2565, March 2007.

595. Caremark replied in writing as follows: "Caremark agrees to the retail, mail, specialty, market share and rebated components. The following further explains Caremark's positioning on passing through service and data fees: Service fees that Caremark receive from pharmaceutical manufacturers include fees that Caremark may receive in connection with programs offered by Caremark, such as physician or participant education programs; compliance and persistency programs; and communications to healthcare professionals. These fees that are paid to Caremark are not paid to or allocated by Caremark on a client-specific basis. Rather, these fees are paid to reimburse Caremark for its service program offerings. For these reasons, Caremark does not disclose to its clients detailed information regarding service fees received and does not share those with its clients." (Emphasis added)

596. The Maryland Procurement Officer wrote that he "did not understand Caremark's response". He also stated that he found the response to be "purposely confusing" and interpreted Caremark's response to mean that "Caremark was holding back money that he wanted to get for the State".

597. Caremark did not provide greater clarity on these statements despite several requests. Maryland, in turn, awarded the Maryland contract to another vendor despite Caremark's being the lowest bid.

598. These CVS Health disclosures indicate that manufacturer "percent of revenue" service fee contracts are set at a national level and not determined by the specific service needs of clients.

599. In the "County" contract, CVS Health certified that it "shall not violate the federal anti-kickback statute...with respect to the performance of its obligations under this agreement."

PHYSICIAN INTERVIEWS: MINIMAL PBM DEFENDANT CLINICAL ROLE

600. Our discussions with physicians indicate that the clinical claims of the PBM Defendants greatly overstates their limited role in day-to-day patient care. As part of this investigation, Dr. Borzilleri conducted interview with 20-25 leading physicians in the multiple sclerosis, rheumatoid arthritis and cancer therapeutic areas.

601. In virtually all instances, the physicians indicated that the PBM Defendants primary role was to fill/deliver prescriptions and sometimes coordinate financial assistance. The need for patient financial assistance is now ubiquitous for "specialty" drugs after years of vast price inflation.

602. According to the physicians, for a patient newly-started on an injectable MS or anti-inflammatory "specialty" drug, their medical staff provides virtually all clinical support.

603. For the majority of stable patients chronically taking the long-marketed "specialty" drugs at the center of this case, the physicians reported minimal clinical involvement of PBMs/specialty pharmacies. One physician described the clinical claims of PBM/specialty pharmacies as a "gimmick to justify themselves."

604. In fact, numerous physicians stated that attempts at clinical intervention by centralized PBM/specialty pharmacy staff is often harmful, since the organizations typically have no in-person contact with these complex patients. One physician tersely stated, "If patients have a problem with their CML (chronic myeloid leukemia) drug, they call me, not an 800 number at

a PBM or a specialty pharmacy”.

605. Conversations with physician experts uniformly indicated that PBM/specialty clinical services were even more scant for most oral “specialty” drugs.

PART D ORIGINS OF THE “SERVICE FEE” SCHEME

606. Before Medicare Part D, the dominant PBMs made virtually all their profits from the portion of “rebates” they “retained” from their negotiations with manufacturers on behalf of their private insurance clients.

607. In the private sector, aggressive PBM “rebate” negotiations with manufacturers were essential for controlling drug costs and preventing severe price increases. As compensation, the PBM kept (i.e., “retained”) a significant, but often secretive, portion of these rebates.

608. Concerns regarding potential manufacturer/PBM collusion regarding “rebates” led to several major PBM lawsuits and settlements just as Medicare Part D was coming to fruition. On September 7, 2005, a Settlement Agreement was entered into between the United States, the PBM Advanced PCS and three Relators (Brown, Waite and Schulmann). In the settlement, AdvancePCS paid the sum of \$137.5 million to resolve allegations brought forth by the US government.

609. On March 24, 2004, Advance PCS became a wholly-owned subsidiary of Caremark Rx, Inc. Subsequently, on March 22, 2007, Caremark Rx merged with CVS to form CVS Caremark (now renamed as CVS Health), one of the largest PBM Defendants in this case.

610. The Justice Department made a similar Settlement Agreement in 2006 with another PBM, Medco Health Solutions. Medco merged with PBM Defendant Express Scripts in April 2012.

611. Despite these and other legal matters, as well as widespread concerns about their business practices, last decade PBMs were charged with the central role of “negotiating” in good faith with drug manufacturers on behalf of beneficiaries and taxpayers in the then new Medicare

Part D program.

612. Cognizant of the central role of “manufacturer rebates” in the private insurance sector, Congress legislated assuming similar dynamics in the Part D program. Congress expected PBMs to aggressively negotiate with manufacturers for rebates/discounts on behalf of Part D beneficiaries and to be compensated by “retaining” a portion of the savings.

613. Congress required full disclosure of “rebates”, including the portion kept by the PBMs, and their deduction from Part D “negotiated” prices in order lower drug costs for beneficiaries and the program. As such, compensation of PBMs by manufacturers via “rebates” in Part D would lead to lower drug prices and lower future industry profits, particularly regarding the competitively-challenged MS Defendant products in this case.

614. Part D requires full disclosure of brand drug pharmacy “price spreads”, thereby limiting another prior key source of revenues/profits for the dominant PBMs. The abuse of brand drug “price spreads” was the central focus of the wide-ranging Average Wholesale Price (AWP) litigation, which resulted in more than \$3 billion in pharmaceutical industry Qui Tam and RICO settlements.

615. In sharp contrast to rebates, legitimate BFSFs from manufacturer to PBMs (and other service providers) are the only major financial item excluded from government drug price calculations, including from Part D “negotiated” prices.

616. PBM compensation via BFSFs would lead to lower rebates and higher drug prices for both collusive partners. In fact, BFSFs became the only pathway for significant non-transparent payments between manufacturers and PBMs/specialty pharmacies in the Part D program.

617. By linking the “service fee” model to vast drug price increases, both manufacturers and PBMs could garner staggering profits. The vast majority of the rising drug costs would be borne primarily by taxpayers in Part D (via the program’s various subsidies) and by largely

unaware clients in the private sector.

618. Obviously, this new business model is counter to the intent of the Part D program, which sought legitimate negotiation between PBMs and manufacturers and affordable drugs costs for beneficiaries and taxpayers.

619. It is not surprising that the Defendants quickly pursued their own self-interest by secretly switching from the “rebates” to the “service fee” business model with the arrival of Medicare Part D. What is surprising is the astounding magnitude to which they have advanced the scheme.

620. Both the design of Part D and industry competitive threats contributed to the Defendants’ aggressive pursuit of this fraudulent pricing scheme.

621. Most importantly, massive US brand drug patent expirations over the past decade decimated the prior largely secretive PBM “rebate”-based compensation model.

622. Starting around the time of Part D’s arrival, virtually all the top brand drugs in the former top-spending primary care therapeutic categories lost patent protection, including the cholesterol lowering, anti-hypertensive, antidepressants, anti-ulcer and antihistamines drug segments. As a result, generics now account for 90+% of US prescription volume, compared to about 50% a decade ago.

623. These patent expirations left the biopharmaceutical industry, but especially the Manufacturer Defendants in this case, increasingly dependent upon a small number of remaining brand drugs, many of which also faced severe competition from new entrants.

624. The PBM financial opportunity from manufacturer brand drug rebates, their prior primary source of profits, also plummeted along with the widespread patent expirations.

625. Unfortunately, to the extreme detriment of the American public, rather than accepting the sharply deteriorating competitive market reality, the senior executives at these Defendant companies intentionally chose a fraudulent path for their corporate and personal

financial gain.

626. We suspect that the astounding stock-based compensation packages for these senior executives, most of whom have been employed for the duration of the scheme, has been a key factor driving the abuse to the current stratospheric heights.

627. The increasing reliance of the Defendants upon high-cost “specialty” drugs for revenue and profit growth has been a key driver of the escalating scheme. After the massive wave of traditional US patent expirations over the past decade, many of the few remaining brand drugs are extreme-priced and highly-profitable “specialty” drugs, such as the Defendant MS therapies.

628. Furthermore, the lax Part D definition of “specialty” drugs, based solely on price without any criteria for complexity or legitimate support needs, helped advance the scheme.

629. The long-marketed MS drug products in this case were widely and chronically self-administered successfully, at far lower prices, by patients long before the illicit shift to the “service fee” based PBM compensation model.

630. As such, the purpose of this shift in “compensation model” was clearly to generate profits for the collusive partners, not to provide better care for US MS patients or to lower drug costs for Part D and its beneficiaries.

631. Primarily driven by massive price increases on older drugs, “specialty” drugs now account for about 35-40% of US drug spending (up from about 10-15% at the start of Part D), while accounting for only 1-2% of overall US prescription volume (but about 10-20% of the shrinking US brand drug volume).

632. This price collusion scheme has masked and offset a tremendous drug cost-savings opportunity over the past ten years for American taxpayers and private employers, but especially in the Medicare Part D program.

633. If not for the massive price increases for the relatively few remaining US brand drugs, especially of the “specialty” variety, American taxpayers, employers and employees would

have benefited from a sharp erosion in drug costs over the past decade due to massive patent expirations.

634. These dynamics are clearly reflected in the spending trends for the Medicare Part D program itself. According to CMS's own data, the average drug costs for the majority of relatively healthy Part D beneficiaries (i.e., those not needing extreme-priced "specialty" drugs) decreased by an astounding 43% (i.e., annual "Direct Subsidies" per beneficiary) between 2006 and 2014. Medicare Trustees Report, 2015.

635. Ironically, both the pharmaceutical and PBM industries frequently cite the Part D program as a glowing example of "free market" success and have recommended it as a "model" for controlling drug spending in other segments of the US market.

PART D LEGISLATIVE HISTORY AND KEY GOVERNMENT DATA

636. When the Medicare Part D program began, both legislators and CMS expected private competition to generate significant cost savings for seniors and to hold down drug prices.

637. In October 2003, as Congress was debating the Medicare Part D legislation, President George W. Bush claimed: "The best way to provide seniors with modern medicine, including prescription drugs coverage...is to give them better choices under Medicare. If seniors have choices, health plans will compete for their business by offering better coverage at more affordable prices." The White House, President Calls on Congress to Complete Work on Medicare Bill (Oct. 29, 2003).

638. In November 2003, Secretary of Health and Human Services, Tommy Thompson, stated: "Health insurance companies are going to get into this market...The pharmaceutical benefit managers (PBMs) who will be taking over purchasing of the drugs are going to be able to purchase in bulk with the pharmaceutical companies and hold down prices." (Emphasis added) The Big Story with John Gibson, Fox News Network (Nov. 26, 2003).

639. Key government officials actually suggested Medicare Part D drug cost savings would be even greater than in other federal drug programs, such as Medicaid.

640. While awaiting implementation of the program, in September 2004, Medicare Administrator Mark McClellan claimed that the private insurers would be able to obtain "the best" prices for seniors. He stated: "Our approach is expected to provide the best discounts on drugs, discounts as good or better than could be achieved through direct government negotiation." (Emphasis added) Testimony of Dr. Mark McClellan, Senate Finance Committee, Hearing on The Medicare Prescription Drug Benefit, 109th Cong. (Sept. 14, 2005).

641. Legislative proponents and CMS clearly expected significant "negotiated" rebates/price concessions from drug manufacturers to be the primary method to limit elderly drug costs, to prevent severe brand drug price inflation and to compensate PBMs and other service vendors for their efforts in the Medicare Part D program.

642. We found no public evidence of legislative debate regarding the role of "Bona Fide Service Fees" ("BFSFs") in Medicare Part D, with the issue remaining largely out of the public eye even now, nearly 15 years since the program's inception.

643. Counter to these expectations, considerable brand drug inflation in Medicare Part D commenced as soon as the program was implemented in January 2006.

644. According to CMS's own data reported in comments to a January 2010 General Accounting Office (GAO) report (GAO-10-242): "An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both specialty and non-specialty tier) between January 2006 and October 2009."

645. In addition, counter to the CMS expectations, the percentage rate of rebates in Medicare Part D have been modest compared to other federal drug programs. Since inception, manufacturer rebates have averaged about 10%, with an increase in the last few years as the public outcry has escalated. Medicare Trustee Annual Reports.

646. Compared to Part D, manufacturer rebates in the Medicaid program have been far larger, averaging 34% of program spending for the years 2006 through 2009. OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.

647. The far larger rebate proportion in Medicaid is because its statutes, in sharp contrast to Medicare Part D, require that manufacturers provide additional rebates to CMS for any revenues generated by brand drug price increases on marketed products greater than general inflation (CPI-U, Consumer Price Index-Urban).

648. With ongoing severe Part D price inflation, OIG's most recent comparison of Medicaid and Medicare Part D indicated further divergence in rebate trends. For the year, 2012, rebates for the top-spending 200 brand drugs in Medicare D were 15% of the program's spending versus 47% for Medicaid. OIE-03-10-00650, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.

649. In March 2011, the Office of Inspector General (OIG) of the Department of Health and Human Services released a report entitled "Concerns with Rebates in the Medicare Part D Program". OIG HHS Report, OEI-02-08-00050, March 2011. The OIG analysis was based on all Part D sponsor rebate reports and plan bid data for 2008, as well as an in depth review of six selected sponsors.

650. The OIG report disclosed that Medicare Part D sponsors reported receiving \$6.5 billion in drug manufacturer rebates in 2008, corresponding to approximately 10% of total gross Part D drugs costs of \$63 billion for the year.

651. However, central to these fraud allegations and contrary to legislative expectations, PBMs "retained" less than 1% or only \$24 million of the \$6.5 billion (Emphasis added) in total manufacturer rebates reported to CMS in plan sponsor "Direct and Indirect

Remuneration" ("DIR") reports for 2008.

652. In addition, 61% of plan sponsors reported that PBMs retained no Part D rebates in 2008.

653. As such, counter to legislative and public expectations, PBMs received minimal rebate compensation from drug manufacturers in 2008. This OIG report is the only federal document we have been able to locate which discusses manufacturer rebates "retained" by PBMs in the Part D program.

654. Since BFSFs were, by law, the only significant payments excluded from Part D sponsor DIR reports in 2008, virtually all PBM compensation for that year, beyond the minimal reported "retained" rebates, came in the form of BFSFs from manufacturers.

655. Additional direct CMS data confirms both extreme price increases and very low level of rebates for many high-cost "specialty" drugs in Part D.

656. In January 2010, the General Accounting Office (GAO) released a report (GAO-10-242), entitled: Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier". The study analyzed "specialty" drug pricing and manufacturer price concession trends in the first three years of Part D, 2006 through 2008.

657. In the analysis, the GAO obtained "specialty" drug pricing and price concession data for 20 key specialty drugs from 7 large plan sponsors, which represented 51% of all Medicare Advantage Part D enrollment and 67% of standalone Part D enrollment in 2008.

658. In the report, the GAO identified ten chronic conditions commonly treated with "specialty" drugs; then selected two therapies for evaluation from each therapeutic category.

659. For all reviewed "specialty" drugs, the GAO found the level of discounts/rebates was below the 9-11% average in the Medicare Part D program throughout the 2006-2008 period. In addition, the Medicare Part D costs per patient had risen considerably for major "specialty"

drugs, due to severe price inflation.

660. In the multiple sclerosis category, negotiated discounts for Biogen's Avonex were only 1.1-2.6% of list price, despite a 35% price increase over the two years. Discounts for Teva's MS therapy were modestly higher, at 6.2-8.0% of list price during the period, with a 26% increase in cost of therapy over the two years.

661. In the anti-TNF category, negotiated discounts for AbbVie's Humira were in the 6.1-8.2% of list price range, with 9% price inflation over the two years. For Amgen's Enbrel, negotiated discounts were lower, at 2.0-3.7% of list price, with 7% price inflation between 2006 and 2008.

662. In the cancer space, no negotiated discounts were provided in any year for Novartis' Gleevec and Roche's Tarceva (an oral drug for lung cancer), despite 24% and 13% price escalation, respectively, between 2006 and 2008.

663. The magnitude of price increases for the above noted "specialty" drugs and many other brand products has greatly accelerated since this dated GAO study.

MEDCO SEC FILINGS: LONG-STANDING, INTENTIONAL "SERVICE FEE" FRAUD

664. Prior to its 2012 merger with PBM Defendant Express Scripts, Medco Health Solutions was the largest independent PBM operating in the US.

665. As part of a 2004 settlement of a prior Qui Tam case and a related (OIG) Corporate Integrity Agreement, Medco provided unique and instructive financial disclosures in its 2003-2011 SEC 10-K filings regarding the burgeoning "service fee" scheme.

666. For the fiscal years 2003 through 2011, Medco disclosed both overall brand manufacturer rebates, as well as the amount of rebates the PBM "retained". Furthermore, Medco provided disclosures regarding its "service fee" contractual arrangements with drug manufacturers.

667. The 10-K disclosures indicate that Medco quickly and secretly began shifting away from a “manufacturer rebate”-based compensation model towards a primarily “service fee”-based model in the private insurance market upon the 2003 passage of the Medicare Part D legislation. Furthermore, the vast majority of the transition was complete by 2006 when Part D was started.

668. In 2003, Medco “retained” \$1.6 billion, or 54% of all brand rebates from manufacturers, which accounted for more than 100% of Medco’s gross profits for the year.

669. By 2006, Medco “retained” only \$670 million, or 20% of all brand rebates, which accounted for only 28% of surging gross profits for the year.

670. In 2011, Medco’s retained a similar magnitude of rebates (\$757 million), which represented only 16% of exploding operating profits for the year.

671. For Medco overall, gross profits rose 60% from \$1.5 billion in 2003 to \$2.4 billion in 2006 and then nearly doubled in the next five years to \$4.6 billion in 2011, despite a sharp drop in the contribution from “retained” manufacturer rebates.

672. These financial disclosures bluntly indicate that Medco was completely dependent upon manufacturer rebates for its profits at the time of Part D's legislative passage. In fact, in 2003, with “retained” manufacturer rebates, the remainder of Medco's operation, inclusive of its generic business, was unprofitable in 2003.

673. As the largest PBM in the US in 2003 by a wide margin, these Medco financials infer that manufacturer rebates were the dominant profit driver throughout the PBM industry in 2003.

674. In 2003, as the market leader, Medco had by far greatest generic procurement negotiating leverage and the most efficient mail order operations.

675. If Medco's operations in 2003, excluding “retained” brand rebates, were unprofitable, smaller PBMs were either similarly dependent on manufacture brand rebates for

profits or were minimally profitable at best.

676. Medco attributed its remarkable business transformation and profit growth between 2003 and 2011 to gains in its generic business.

677. Medco stated in its 2004 10-K: "the impact on profitability from the increase in generic utilization, particularly in mail order, more than offsets the impact from lower rebate retention on brand name prescriptions."

678. Medco suggested a wider range of profit contributors in its 2006 10-K, stating: "the gross margin effect of overall higher rebate sharing levels is partially mitigated by other elements of pricing including higher claims processing, administrative and other client service fees, higher generic dispensing rates, and increased specialty volumes."

679. In its final 2011 10-K prior to the Express Scripts merger, Medco reiterated its ongoing dependence on generics for profits: "Our future success will be largely dependent on our ability to drive mail-order volume and increased generic penetration rates in light of the significant brand-name drug patent expirations expected to occur over the next several years."

680. Medco never mentioned in its SEC filings a shift in compensation mechanisms for brand drugs from manufacturers towards "service fees" or any impact from Medicare Part D.

681. Based upon its own financial disclosures, Medco's claims regarding accelerating generic profitability between 2003 and 2011 would appear to be mathematically impossible.

682. Excluding "retained" brand drug rebates, Medco reported an astounding increase in its annual gross profits from a -\$71 million loss in 2003 to a \$3.9 billion profit in 2011.

683. With Medco's generic segment apparently unprofitable in 2003, the implied vast transformation in this business segment would appear unfeasible.

684. In reality, the only viable explanation for this profit transformation is the clandestine shift from a PBM compensation model based on brand manufacturer rebates to one based upon "service fees", as a direct result of the Medicare Part D financial incentives.

685. With the increased brand “spread” and “rebate” transparency requirements in Part D, “service fees” became the only mechanism for large-scale “hidden” payments between drug manufacturers and PBMs. Medco secretly began the transition in the private insurance sector prior to the 2006 enactment of Part D, without any public disclosure.

686. There can be little doubt that other PBMs followed the lead of the market leader, Medco, in this secretive profit transition.

687. The Medco financial disclosures indicate a well-orchestrated, intentional systemic collusive scheme that has caused unimaginable public harm, now more than 13 years in duration.

688. Medco disclosed that its manufacturer “service fee” contracts with drug manufacturers were calculated as a “percent of revenues”, inclusive of price increases.

689. Several of Medco's 10-Ks, including the 2006 document states: “Our contracts with manufacturers provide us with rebates and fees for prescription drugs through our mail-order and retail pharmacy networks, discounts for prescription drugs we purchase and dispense from our mail-order pharmacies, and performance-based fees associated with certain biopharmaceutical drugs. Rebates and fees are generally calculated as a percentage of the aggregate dollar value of a particular drug that we dispensed, based upon the manufacturer’s published wholesale price for that drug”.

690. In closing, the information in this Complaint all points to a singular conclusion. Namely, that the vast “inexplicable” price inflation for the Defendant brand MS drugs, and many others in the US marketplace, has been caused by this intentional, long-standing, secretive and collusive “service fee” scheme. After five-plus years of intensive investigation, we conclude that there is no other viable explanation.

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE

False Claims Act

31 U.S.C. §§3729(a)(1) and (a)(2)

(Against All Defendants)

691. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

692. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

693. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval, within the meaning of 31 U.S.C. §3729(a)(1).

694. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2).

695. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

696. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

697. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT TWO

False Claims Act

31 U.S.C. §3729(a)(3)

(Against All Defendants)

698. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

699. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

700. By virtue of the acts described above, Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims, within the meaning of 31 U.S.C. §3729(a)(3). Defendants, moreover, took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

701. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

702. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every violation of 31 U.S.C. §3729(a)(3) as described herein.

COUNT THREE

Federal False Claims Act

31 U.S.C. §3729(a)(7)

(Against All Defendants)

703. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

704. This is a claim for penalties and treble damages under the Federal False Claims

Act.

705. By virtue of the acts described above, including without limitation Defendants' overpayment of BFSFs in lieu of rebates, which would have reduced the ultimate cost reimbursed by the federal government under Medicare Part D, to Service Vendors, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

706. As a result, money was lost to the United States through the non-payment or non-transmittal of money from foregone discounts and rebates to which the United States was entitled and owed by the Defendants, and other costs were sustained by the United States.

707. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

708. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

COUNT FOUR

Federal False Claims Act

31 U.S.C. §§3729(a)(1) and (a)(2)

(Against All Defendants)

709. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

710. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

711. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States

Government for payment and/or approval, within the meaning of 31 U.S.C. §3729(a)(1) by paying BFSFs as illegal remuneration to Service Vendors (primarily PBMs and their specialty pharmacy subsidiaries in Medicare Part D) in order to induce purchase of Defendants' MS drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

712. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid and/or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2) by paying BFSFs as illegal remuneration to induce Service Vendors to purchase MS drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

713. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

714. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

715. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT FIVE

California False Claims Act

Cal Gov't. Code §12651(a)(7)

(Against All Defendants)

716. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

717. During the Relevant Time Period, the Manufacturer Defendants and the PBM

Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of California via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

718. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California, within the meaning of Cal Gov’t. Code §12651(a)(7). The State of California has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIX

Colorado Medicaid False Claims Act

Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310

(Against All Defendants)

719. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

720. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Colorado via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

721. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation

to pay or transmit money or property to the State of Colorado. The State of Colorado has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVEN

Connecticut False Claims Act

Conn. Gen. Stat. § 17b-301b(a)(7)

(Against All Defendants)

722. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

723. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Connecticut via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

724. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Connecticut, within the meaning of Conn. Gen. Stat. § 17b-301b(a)(7). The State of Connecticut has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHT

Delaware False Claims And Reporting Act

6 Del Code §1201(a)(7)

(Against All Defendants)

725. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

726. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Delaware via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

727. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Delaware, within the meaning of 6 Del. Code §1201(a)(7). The State of Delaware has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINE

Florida False Claims Act

Fla. Stat. Ann. §68.082(2)(g)

(Against All Defendants)

728. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

729. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Florida via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

730. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Florida, within the meaning of Fla. Stat. Ann. §68.082(2)(g). The State of Florida has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TEN

Georgia False Medicaid Claims Act

Ga. Code Ann. §49-4-168.1(7)

(Against All Defendants)

731. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

732. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Georgia via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

733. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Georgia, within the meaning of Ga. Code Ann. §49-4-168.1 (7). The State of Georgia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT ELEVEN

Hawaii False Claims Act

Haw. Rev. Stat. §661-21(a)(7)

(Against All Defendants)

734. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

735. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Hawaii via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

736. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Hawaii, within the meaning of Haw. Rev. Stat. §661-21(a)(7). The State of Hawaii has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWELVE

Illinois Whistleblower Reward

And Protection Act

740 Ill. Comp. Stat. §175/3(a)(7)

(Against All Defendants)

737. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

738. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements

regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Illinois via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

739. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Illinois, within the meaning of 740 Ill. Comp. Stat. §175/3(a)(7). The State of Illinois has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTEEN
Indiana False Claims and
Whistleblower Protection Act
IC 5-11-5.5-2(b)(6)
(Against All Defendants)

740. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

741. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

742. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation

to pay or transmit money or property to the State of Indiana, within the meaning of IC 5-11-5.5-2(b)(6). The State of Indiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FOURTEEN

Iowa False Claims Act

Iowa Code §§ 685.1 through 685.7

(Against All Defendants)

743. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

744. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

745. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Iowa. The State of Iowa has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FIFTEEN

Louisiana Medical Assistance Programs Integrity Law

La. Rev. Stat. § 46:438.3(C)

(Against All Defendants)

746. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

747. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Louisiana via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

748. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Louisiana, within the meaning of La. Rev. Stat. § 46:438.3(C). The State of Louisiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIXTEEN

Massachusetts False Claims Law

Mass. Gen. Laws ch. 12 §5B(8)

(Against All Defendants)

749. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

750. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Massachusetts via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

751. By virtue of the acts described above, Defendants knowingly made, used, or

caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts, within the meaning of Mass. Gen. Laws ch. 12 §5B(8). The Commonwealth of Massachusetts has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVENTEEN

Michigan Medicaid False Claims Act

§400.607(3)

(Against All Defendants)

752. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

753. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Michigan via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

754. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Michigan, within the meaning of §400.607(3). The State of Michigan has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHTEEN

Minnesota False Claims Act

Minn. Stat. §§ 15C.01 through 15C.16

(Against All Defendants)

755. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

756. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Minnesota via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

757. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Minnesota. The State of Minnesota has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINETEEN

Montana False Claims Act

Mont. Code Ann. 17-8-403(1)(g)

(Against All Defendants)

758. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

759. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements

regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Montana via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

760. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Montana, within the meaning of Mont. Code Ann. 17-8-403(1)(g). The State of Montana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY

**Nevada Submission of False Claims to State or Local
Government Act**

**Nev. Rev. Stat. Ann. §357.040(1)(g)
(Against All Defendants)**

761. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

762. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Nevada via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

763. By virtue of the acts described above, Defendants knowingly made, used, or

caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Nevada, within the meaning of Nev. Rev. Stat. Ann. §357.040(1)(g). The State of Nevada has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-ONE

New Jersey False Claims Act

N.J. Stat. §2A:32C-3(g)

(Against All Defendants)

764. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

765. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Jersey via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

766. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Jersey, within the meaning of N.J. Stat. §2A:32C-3(g). The State of New Jersey has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-TWO

New Mexico Medicaid False Claims Act

N.M. Stat. Ann. § 27-14-3(a)(7)

(Against All Defendants)

767. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

768. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Mexico via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

769. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Mexico, within the meaning of N.M. Stat. Ann. § 27-14-3(a)(7). The State of New Mexico has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-THREE

New York False Claims Act

NY CLS St. Fin. §189(g)

(Against All Defendants)

770. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

771. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements

regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New York via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

772. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New York, within the meaning of NY CLS St. Fin. §189(g). The State of New York has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FOUR

North Carolina False Claims Act

2009-554 N.C. Sess. Laws §1-607(a)(7)

(Against All Defendants)

773. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

774. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of North Carolina via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

775. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of North Carolina, within the meaning of 2009-

554 N.C. Sess. Laws §1-607(a)(7). The State of North Carolina has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FIVE

Oklahoma Medicaid False Claims Act

Okla. Stat. tit. 63, §5053.1B (7)

(Against All Defendants)

776. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

777. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Oklahoma via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

778. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Oklahoma, within the meaning of Okla. Stat. tit. 63, §5053.1B (7). The State of Oklahoma has thereby suffered actual damages and is entitled to recover treble Oklahoma damages and a civil penalty for each false claim.

COUNT TWENTY-SIX

Rhode Island State False Claims Act

R.I. Gen. Laws §9-1.1-3(7)

(Against All Defendants)

779. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

780. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Rhode Island via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

781. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Rhode Island, within the meaning of R.I. Gen. Laws §9-1.1-3(7). The State of Rhode Island has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-SEVEN

Tennessee False Claims Act and

Medicaid False Claims Act

Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(1)(D)

(Against All Defendants)

782. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

783. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Tennessee via Federally-

mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

784. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Tennessee, within the meaning of Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(1)(D). The State of Tennessee has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-EIGHT

**Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. §36.002(12)
(Against All Defendants)**

785. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

786. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Texas via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

787. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Texas, within the meaning of Tex. Hum. Res. Code Ann. §36.002(12). The State of Texas has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-NINE

Virginia Fraud Against Taxpayers Act

Va. Code Ann. §8.01-216.3(a)(7)

(Against All Defendants)

788. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

789. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Virginia via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

790. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Virginia, within the meaning of Va. Code Ann. §8.01-216.3(a)(7). The Commonwealth of Virginia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY

Washington Medicaid Fraud False Claims Act

Wash. Sess. Laws, Laws of 2012

Ch. 241 §§ 201 through 214

(Against All Defendants)

791. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

792. During the Relevant Time Period, the Manufacturer Defendants and the PBM

Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Washington via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

793. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Washington. The State of Washington has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-ONE

Wisconsin False Claims For Medical Assistance Act

Wis. Stat. §20.931(2)(g)

(Against All Defendants)

794. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

795. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Wisconsin via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

796. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation

to pay or transmit money or property to the State of Wisconsin, within the meaning of Wis. Stat. §20.931(2)(g). The State of Wisconsin has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-TWO

District of Columbia False Claims Act D.C.

Code Ann. §2-308.14(a)(7)

(Against All Defendants)

797. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

798. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the District of Columbia via Federally-mandated, non-recourse “Clawback” payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

799. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia, within the meaning of D.C. Code Ann. §2-308.14(a)(7). The District of Columbia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-THREE

Unjust Enrichment

800. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

801. By virtue of their conduct, Defendants have been unjustly enriched at the expense of the United States. By obtaining money as a result of their violations of federal law, Defendants were unjustly enriched, and are liable to account and pay such amounts to be determined at trial.

802. By this claim, Relator demands a full accounting of all BFSFs (and interest thereon) incurred and/or paid by the Manufacturer Defendants to the PBM Defendants for services and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States.

COUNT THIRTY-FOUR

Common Law Fraud

803. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

804. Manufacturer Defendants made or caused to be made material and false representations concerning the calculation, for which they are responsible, of the BFSFs that were paid to the PBM Defendants for services that CMS requires be provided at FMV, which representations were made by Service Vendors for Services that CMS requires be provided at FMV, with knowledge of their falsity or with reckless disregard for the truth. The PBM Defendants then knowingly submitted false claims for payment to the United States to act upon those misrepresentations to the United States' detriment. The United States acted in justifiable reliance upon both the Manufacturer Defendants and the PBM Defendants misrepresentations by making payments on the false claims.

805. Had the Manufacturer Defendants and the PBM Defendants made truthful statements, the United States would not have made payments for excessive prices for the Manufacturer Defendants' multiple sclerosis drugs in Medicare Part D.

806. As a direct and proximate cause of Defendants' conduct, the United States has

been damaged in an amount to be determined at trial.

PRAYERS FOR RELIEF

807. WHEREFORE, the Relator acting on behalf of and in the name of the United States of America, and on his own behalf, demands and prays that judgment be entered as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.*, and the Anti-Kickback Statute as set forth above;

B. That this Court enter judgment in favor of the United States against the Defendants jointly and severally in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not Eleven Thousand Dollars (\$11,000) for each false claim;

C. In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

D. In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to 31 U.S.C. § 3730(d) and in favor of the Relator against Defendants for reasonable expenses, attorneys' fees and costs incurred by the Relator;

E. In favor of the Relator and the United States and against the Defendants for all costs of this action;

F. In favor of the Relator and the United States and against the Defendants for such other and further relief as this Court deems to be just and equitable.

G. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Cal. Govt. Code §1651(a);

H. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310;

I. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Conn. Gen. Stat. § 17b-301b;

J. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of 6 Del. C. § 1201(a);

K. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of Fla. Stat. Ann. § 68.082(2);

L. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of Ga. Code Ann. § 49-4-168.1.

M. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Haw. Rev. Stat. § 661-21(a);

N. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

O. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least \$5,000 for each violation of IC 5-11-55;

P. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil penalty of at least \$10,000 for each violation of Iowa Code §§ 685.1 through 685.7;

R. That at this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of La. Rev. Stat. § 437 et. seq.;

S. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B;

T. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of MI Public Act 337;

U. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Minn. Stat. §§ 15C.01 through 15C.16;

V. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Mont. Stat. Ann. 17-8-401;

W. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

X. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of N.J. Stat. §2A:32C-3;

Y. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

Z. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of \$12,000 for each violation of NY CLS St. Fin. §189;

AA. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty or \$11,000 for each violation of 2009-554 N.C. Sess. Laws §1- 607(a);

BB. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Okla. Stat. tit. 63, §5053.1B;

CC. That this Court enter judgment against Defendants in an amount equal to

three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of R.I. Gen. Laws §9-1.1-3;

DD. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(I);

EE. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

FF. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of Va. Code Ann. §8.01-216.3(a);

GG. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Wis. Stat. §20.931(2);

HH. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Washington has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214;

II. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of D.C. Code Ann. §2-308.14(a);

JJ. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

KK. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

LL. That Relator recovers such other relief as the Court deems just and proper.

JURY DEMAND

808. Plaintiff/Relator demands a trial by jury on all counts.

Dated: June 26, 2018

Respectfully Submitted,
RELATOR John R. Borzilleri, M.D.

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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,
ex rel. JOHN R BORZILLERI, M.D. et al.,

Plaintiffs,

vs.

ABBVIE, INC., et al.,

Defendants.

Case No. 15-cv-7881(JMF)

**MEMORANDUM OF LAW IN SUPPORT OF
RELATOR'S OPPOSITION TO
THE DEFENDANTS' MOTIONS TO DISMISS
RELATOR'S SECOND AMENDED COMPLAINT**

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In accordance with the Court's August 10, 2018 Order (Docket 201), Relator John R. Borzilleri, M.D., respectfully submits this memorandum of law in opposition to the Pharmaceutical Defendants' ("PhMD") and the PBM Defendants' ("PBMMD") motions to dismiss. For the reasons set forth below, both the Pharmaceutical Defendants' and the PBM Defendants' motions should be denied.

PRELIMINARY STATEMENT

The Relator, John R. Borzilleri, M.D. respectfully requests that the Court deny both the Pharmaceutical and PBM Defendants Motions to Dismiss in their entirety. In this Opposition, the Relator provides sufficient legal authority to overcome the Defendants' challenges to public disclosure, original source and particularity requirements of the False Claims Act (FCA) and Anti-Kickback Statute (AKS). The Relator further avers that his allegations regarding most targeted drugs in the SDNY action, namely "traditional" drugs, provided unique investigative "notice" to the government, thereby avoiding the first-to-file bar. Dr. Borzilleri is an original source regarding the SDNY action's vast expansion of the systemic "service fee" scheme beyond the narrow US "specialty" drug market (only 1-2% of US prescriptions, and the sole focus of his prior District of Rhode Island (RI) *qui tam* filing) into the far larger "traditional" brand pharmaceutical market (the primary focus of this SDNY action). The Relator plans to file a Motion requesting an evidentiary hearing regarding first-to-file issues, particularly regarding "specialty" drugs in the SDNY case.

BACKGROUND

In this *qui tam* action, John Borzilleri, M.D., MBA, a non-insider healthcare investment analyst, has alleged, in extensive factual detail and specificity, that the Pharmaceutical and PBM Defendants have knowingly and secretly conspired over the past 15+ years to commit perhaps the largest healthcare fraud in the history of this nation, SAC ¶ 22. With its origins in the Medicare Part D program, the Manufacturer and PBM Defendants have "partnered" in a collusive fraudulent scheme to massively

raise the U.S. brand drug prices for all Americans. SAC ¶ 12.

While the Relator's Complaint contains a wide array of contributing factors and evidence, the fraudulent scheme is remarkably straightforward. Due the financial incentives and disclosure requirements in Medicare Part D, the Defendants secretly and intentionally switched from a manufacturer "rebate-based" profit model to one based upon illegitimate "service fees." SAC ¶¶ 12-13, 99-100, 128,283. Legitimate "service fees" in Medicare Part D and other programs are called "bona fide service fees (BFSFs)." SAC ¶ 13. Fraudulent "service fees" payments from the Manufacturer Defendants to the PBM Defendants have been contractually-driven by inflated "list"¹ drug prices (virtually always via percent of revenue contracts), rather than legitimate volume-based "service" needs as is clearly required by the Medicare Part D statutes and the law. SAC ¶¶ 35, 128, 315, 447. These massive "service fee" payments are "kickbacks" that are greatly in excess of legally-required fair market value (FMV), as required by the standard "four-part test" for "bona fide service fees" in Medicare Part D and all government drug programs. SAC ¶¶ 41-43.

Prior to Medicare Part D, the PBM Defendants made virtually all their profits from the portion of rebates/discounts they "retained" from their negotiations with drug manufacturers on behalf of payer clients. SAC ¶¶ 12, 201. Until very recently, independent PBM and pharmaceutical industry experts still universally held that manufacturer rebates were the PBM Defendants' primary source of profits. In reality, since the 2006 arrival of Medicare Part D, the PBM Defendants have secretly and knowingly (with virtually no public disclosure) made the large majority of their PBM profits from U.S. brand drugs via manufacturer "service fees". SAC ¶¶ 13, 102, 460-1, 736, 779-805. For many U.S. brand drugs, especially the drugs targeted in this case, the meteoric increase in fraudulent "service fee" payments have been driven solely by similarly massive and fraudulent "list" price increases.

¹ AWP means "Average Wholesale Price"; WAC means "Wholesale Acquisition Cost", which is standardly about 17-18% less than AWP; both are set by drug manufacturers in public databases, including Medispan, First Databank and Micromedex Redbook; AWP is the benchmark for Part D drug reimbursement; both AWP and WAC are standardly used in manufacturer/PBM "service fee" and "rebate" contracts.

Very recently, for the first time, the PBM Defendants CVS Health and Express Scripts finally publicly admitted what the Relator has long known; namely that brand drug “manufacturer rebates” now account for little PBM Defendant profits, leaving secretive “manufacturer services fees” as their primary income source.

On its August 8, 2018 earnings conference call with Wall Street analysts, CVS CEO Larry Merlo stated: *“And while some have speculated that our retained rebates represent as much as \$2 billion, the simple fact is that over the last number of years, we have positioned the Caremark model and its broader value proposition to the point where in 2018, we expect retained rebates to be about \$300 million, or about 3% of our annual adjusted earnings per share.”* (emphasis added).

In its own quarterly earnings report just two days prior, on August 1, 2018, Express Scripts disclosed: *“Rebates are applicable to less than 10% of Express Scripts’ claims; Express Scripts retains approximately \$400 million of rebates.”* With Express Scripts reported net income of \$4.5 billion in 2017, retained “manufacturer rebates” accounted for a maximum of 9% of their overall profits, and potentially far less. See *CVS Health and Express Scripts 2Q 2018 SEC filings and earnings conference call transcripts*.

Despite the prior widely held view that “manufacturer rebates” account for a large proportion of PBM profits, no Wall Street analyst asked the senior managements of either CVS or Express Scripts on the earnings conference calls about the major source of company profits. Of course, as set forth in the Second Amended Complaint, the long-standing “dark secret” is “manufacturer service fees”, commonly linked to massive US drug prices and price increase. See *SAC generally. See CVS Health and Express Scripts 2Q earnings conference call transcripts*.

Astoundingly, even following these PBM Defendant disclosures, the press still refers to manufacturer “rebates” and “discounts” as the primary profit source for the PBM Defendants. Just the other day, on November 15, 2018, Express Scripts announced plans for a “new formulary” that “upends

the status quo by creating a path to preferred status for drugs that have lower list prices.” The Bloomberg article begins: “Express Scripts Holding Co. and other pharmacy-benefit managers make money by negotiating drug prices on behalf of health-plan providers. The list prices that pharmaceutical companies set for their drugs diverge wildly from their real cost, and PBMs widen and feast on the gap, which helps make them some of the principal beneficiaries of America’s byzantine pricing system.” Ironically, putting lower price drugs on their formularies is exactly what the PBM Defendants have been deceitfully claiming to be doing for the past decade-plus, while they are actually fraudulently making most of their profits via secretive “manufacturer service fees” linked to massive “list” prices. *Lower Drug Prices Get an Assist from a Big Player, Bloomberg, November 15, 2018.*

As the already high prices of “specialty” drugs have reached stratospheric levels in recent years, fraudulent abuse of the Part D plan sponsor Catastrophic cost-sharing requirements has been essential for advancing the “service fee” scheme. An explosion in Part D Catastrophic spending, in large part driven by this scheme, has been the primary driver of program spending in recent years. SAC ¶¶ 403-404. Without abuse of the Part D Catastrophic cost-sharing provisions, the highly-profitable PBM Defendants would otherwise be sustaining severe financial losses on each and every high-cost Part D “specialty” prescription they ship to patients via their dominant wholly-owned specialty pharmacies. SAC ¶¶ 395-444. The PBM Defendants’ own numerous public disclosures verify that “specialty” drugs and Medicare Part D have been major drivers of revenue and profit growth over the past decade.

By intentionally engaging in this collusive price inflation scheme, Defendants have violated the Anti-Kickback Statute (AKS) and the False Claims Act (FCA). Furthermore, the ongoing scheme now threatens the sustainability of the Medicare Part D program itself. SAC ¶ 24

This ongoing and escalating scheme has yielded five-to-seven-fold price increases over the past decade for the fourteen (14) carefully-selected Defendant cancer, insulin, rheumatoid arthritis and other “blockbuster” drugs targeted in this case. The scheme has been responsible for approximately

\$114 billion in overpriced U.S. drug sales in the broader U.S. pharmaceutical market over the past decade-plus – more than \$35 billion in Medicare Part D alone. SAC ¶ 23. For the same Defendant drugs, the PBM Defendants have garnered an estimated \$7 billion in fraudulent “service fees” in the broader U.S. pharmaceutical market over the past decade-plus - about \$2.1 billion directly attributable to Medicare Part D. SAC ¶ 94.

At the individual drug level, the Manufacturers Defendants are now routinely paying the PBM Defendants about five-fold greater aggregate “service fee” compensation, while providing “services” for half or less as many prescriptions and treated patients compared to a decade ago. SAC ¶ 104 At the individual prescription level, for these old “blockbuster” chronic therapies, the Manufacturer Defendants are paying the PBM Defendants hundreds and even thousands of dollars for each monthly prescription, often for simply mailing the medicine to a patient’s home. SAC ¶¶ 99, 105, 259, 263-75, 332, 337, 719. To describe these egregious “service fee” payments as exceeding the Manufacturer Defendants’ irrefutable liability for Fair Market Value (FMV) compensation in Part D is an understatement.

On the personal level, directly resulting from this scheme, millions of the most vulnerable American patients (especially the elderly and disabled that depend upon Medicare Part D) and their families have lost their lives, lost access to life-saving drugs or faced bankruptcy/financial ruin. The media is rife with stories of cancer patients destitute in their final months of life, diabetics losing limbs or going into comas as they ration unaffordable insulin, and rheumatoid arthritis patients begging for financial assistance.

A Washington Post article from March 2016, attached hereto as Exhibit 1, discusses the patient consequences of massive price inflation of Novartis’ Gleevec from about \$26,000 patient/year in 2001 to “more than \$120,000.” As per a Gleevec patient in the article: “within a year the drug she needs to stay alive was costing her more than \$800 (per month in co-pays). She and her husband considered

divorce, hoping her single income was low enough to qualify for financial aid.” *This drug is defying a rare form of leukemia – and it keeps getting pricier.* Washington Post, March 9, 2016.

Similarly, an article dated November 10, 2017, attached hereto as Exhibit 2, discusses the severe patient health and financial consequences of the massive Catastrophic cost-sharing exposure for severely-ill and disabled Part D beneficiaries. “For 23 years, Diane Whitcraft injected herself every other day with Betaseron, a drug that helps prevent flare-ups from multiple sclerosis. But as her 65th birthday approached last September, she made a scary decision: to halt the medication altogether. With health insurance through her job, Whitcraft had paid a \$50 or \$100 monthly co-pay for the drug; she hadn't even realized that the price of Betaseron had soared to more than \$86,000 a year. Shopping around for drug coverage through Medicare, the out-of-pocket costs were mind-boggling: close to \$7,000 annually...But Whitcraft still doesn't understand why her drug, which launched with a list price of about \$11,500 more than two decades ago, costs so much today – a question she raised in her letter.” (to the manufacturer, Bayer AG) ...Each prescription drug plan is structured a little differently, but people with very high drug costs almost inevitably enter what's called the “catastrophic” phase of coverage. Then, they pay 5 percent of the list price of their drug — no small sum in an age of \$10,000-a-month cancer drugs or, in Whitcraft's case, a more than \$7,000-a-month multiple sclerosis therapy. The number of seniors who reach the catastrophic phase has almost doubled over a four-year period, to more than 1 million people in 2015, according to a new analysis by the Kaiser Family Foundation.” *Expensive specialty drugs are forcing seniors to make hard choices*, November 10, 2017).

Likewise, an article from STAT dated November 12, 2018, attached as Exhibit 3, discusses a mother's protest at Eli Lilly's headquarters, following the death of her son due to unaffordable insulin. “He died on June 27, 2017 — less than a month after his 26th birthday, when he could no longer stay on his mother's health insurance plan. Without insurance, the restaurant manager was facing about \$1,300 a month in out-of-pocket costs...Lilly spokesman's reply: “We take this issue seriously and

continue to explore innovative ways to find long-term solutions to help eliminate or significantly reduce the out-of-pocket expenses for patients.” *Protesters take anger over insulin prices to drug makers, some bearing children’s ashes*, STAT, November 12, 2018.

Another article from STAT, dated November 14, 2018, attached as Exhibit 4, discusses the patient impact from the uniform and massive price inflation for AbbVie’s Humira and Amgen’s Enbrel. “Jess Caron, a 32-year-old New Hampshire mother of two with Crohn’s disease, said she has watched with alarm as her annual deductible and copays have risen along with Humira’s list price. She said Humira has saved her from gastrointestinal problems that had previously made it difficult to leave the house but paying for it is becoming a challenge. She said her drug costs eat up her annual \$3,500 deductible in a single month, forcing her to pay it all at once. “It’s frustrating as hell,” Caron said, noting that chronically ill patients are often faulted for failing to make cost-efficient treatment choices. “And here we are looking at a perfect example of the system being rigged against patients being able to make the best financial decision. Basically a scam is happening, and patients are left footing the bill, and the blame.” *Extraordinary tactics, perverse incentives: Makers of the top-selling drugs hike prices in lockstep, and patients bear the cost*, STAT, November 14, 2018.

Finally, an article from CNBC just from this past Friday, November 16, 2018, attached as Exhibit 5, reports that Defendant Pfizer announced plans to resume aggressively raising US brand drug prices. “Pfizer will raise prices on 41 of its prescription drugs in January after initially putting off those plans this summer amid pressure from President Trump.” “Read (Pfizer CEO Ian Read) said by the end of the year, the company’s strategy on price increases would be back to ‘business as normal’.” *Pfizer to raise prices on 41 prescription drugs next year despite pressure from Trump*, CNBC, November 16, 2018.

THE DEFENDANTS' AD HOMINEM MOTIONS TO DISMISS

A. Hyperbole, Without Challenging Alleged Facts

Having long anticipated many possibilities in the Defendants' approach, Dr. Borzilleri was heartened by their remarkably standard Motions to Dismiss, which he believes only further incriminate both broad Defendant groups, and perhaps more importantly, the individual corporate Defendants.

Both Pharmaceutical and PBM Defendant Motions are filled with irrelevant personal attacks against Dr. Borzilleri, along with hyperbole and distortions designed to undermine his factual allegations and evidence.

However, once one sifts through the "smoke screen" attempted by the two Defendant groups, their Motions to Dismiss are notable for being devoid of any significant "factual" information beyond what has already been provided to the Court in the Relator's detailed Second Amended Complaint. *See PhRMD and PBMMD generally.*

As the Relator stated in the SAC, this "service fee" scheme is the "'Rosetta Stone' behind virtually all instances of 'inexplicable' massive US brand drug price inflation over the past decade-plus. In fact, this scheme, with its origins in Medicare Part D, is the only viable explanation." SAC ¶ 123. Unsurprisingly, neither Defendant group, nor any individual Defendant, even attempted to provide an alternative "theory" for the massive four-seven-fold price increases for the Manufacturer Defendant drugs.

The few attempts at "factual" challenge by the Defendants appear to only further incriminate them. First, the Pharmaceutical Defendants make a nonsensical argument that a highly-incriminating recent report from their closely-controlled lobbying organization, the Pharmaceutical Research and Manufacturers of America (PhRMA), somehow "contradicts Borzilleri's position" and therefore negates his allegations. *See PhMD, Section II(A)(2)(b).*

In the 2017 report, the PhRMA, for the first time, provided "sample", industry-wide "service

fee” contract rate terms between drug manufacturers and PBM/Specialty Pharmacies, pertaining to both “specialty” and “traditional” drug therapies. As noted in the SAC, the PhRMA-disclosed “sample” overall contract rate for “specialty drugs” with the PBM Defendants (combined 8% overall for the PBM Defendants and their wholly-owned specialty pharmacies) that was twice as high as the 4% rate estimate in the Relator’s initial SDNY Complaint. SAC ¶¶ 177-197. This disclosure caused the Relator to estimate far greater direct “service fee” payment fraud estimates for “specialty” drugs in the SAC, compared to his initial Complaint. The 4% contract rate “sample” in the report was identical to the rate estimate used for “traditional” drugs in the Relator’s initial SDNY Complaint. As per the SAC, many of the Manufacturer Defendant CEOs are current Board of Director members of PhRMA. SAC ¶ 200.

The Pharmaceutical Defendants illogically claim that the “variability” of “service fee” contract terms for individual drugs negates the value of their own “sample” rates provided in the report. The Pharmaceutical Defendants fail to recognize that the exact “service fee” contract rate for any individual Defendant drug is not of major consequence, unless the contract rate is properly decreased to maintain FMV as massive price increases ensue (especially for majority of the Defendant drugs with plummeting clinical use and prescription volume). The Defendants never make that factual argument, and first-hand evidence provided by the Relator clearly indicates that these contract rate adjustments are virtually never being made across the pharmaceutical industry, despite both industries’ broad awareness of fraud exposure and the direct advice of their legal and consultant advisors. SAC ¶ 478.

The Defendants also ask the Court to believe that these “sample” rates, disclosed for private commercial patients, have no relevance to Medicare Part D. This attempt is baseless, since the Relator has already shown that the PBM Defendants are obtaining minimal profits from “manufacturer rebates” in Medicare Part D, which leaves “manufacturer service fees” as the only other option for significant compensation in the program. SAC ¶¶ 59-60, 101-102, 187, 252

As noted previously, both PBM Defendants CVS and Express Scripts very recently publicly disclosed, for the first time, their minimal current overall profit contribution from “manufacturer rebates.” Of course, overall corporate profits would include the Medicare Part D program, which has been the largest growth driver for all the PBM Defendants. SAC ¶ 21, *Express Scripts and CVS 2Q 2018 earnings reports* on August 1 and August 3, 2018, respectively.

Direct Medicare claims data for the specific Manufacturer Defendant drugs, also confirms uniform and massive price inflation for the Defendant drugs in Medicare Part D relative to the broader US healthcare insurance market. *Medicare Part D Drug Spending Dashboard, CMS, May 2018.*

The Defendants also claim that the recent highly incriminating report from the Pharmaceutical Care Management Association (PCMA) (the leading PBM lobbying organization, closely controlled by the large PBM Defendants) provides no support for the “service fee” allegations because the report only discusses rebates and price increases. Again, the Defendants seem to ignore the obvious contribution of the report to Relator’s allegations. The PCMA disclosed that manufacturer rebates for two highest-spending “specialty” drug therapeutic categories in the Relator’s *qui tam* actions, namely autoimmune/arthritis and multiple sclerosis drugs, have uniformly remained very low (only 7-10%) for ALL the PBM Defendants, despite massive “list” price increases. SAC ¶ ¶ 198-213. The CEOs or other senior executives from all the PBM Defendants are current Board of Director members of the PCMA. SAC ¶ 200.

Combined with Relator’s other investigation findings, this disclosure shows that the PBM Defendants are making 90+% or more of their profits (and 10 times more compared to manufacturer rebates) from “manufacturer service fees” for these “specialty” drugs, with these “fee” payments having fraudulently exploded with the massive “list” price increases over the past decade-plus. SAC ¶ ¶ 59-60.

B. The Manufacturer and PBM Defendants' Motions to Dismiss are Virtually Identical – Suggesting they are “Partners”, not “Adversaries”.

As the public outcry pertaining to exorbitant U.S. drug pricing and huge price increases has escalated in recent years, both the biopharmaceutical and the PBM industries, as well as the individual companies within each, have faced escalating scrutiny. In response, the biopharmaceutical and PBM industries, respectively (via individual Defendant senior management and their lobbying organizations), have aggressively been blaming each other for high US brand drug prices. Each industry claims the other is profiteering from the huge U.S. brand drug price increases, while they, of course, are always acting in the best interest of patients and taxpayers. For instance, PBMs say that manufacturers are solely in control of drug prices, Patient Assistance Programs (PAPs), drug coupons and other factors. In turn, the manufacturers claim that PBMs are profiteering by keeping massive manufacturer rebates and patient co-pay/cost-sharing monies. However, as noted in the SAC, noticeably absent from this public rhetoric has been any mention, by either party, of the potential role of “manufacturer service fees” paid to PBMs or the Medicare Part D program in massive U.S. drug prices. SAC ¶ 20.

All the disingenuous and deceitful management rhetoric between these two dominant healthcare industries disappeared in the Pharmaceutical and PBM Defendants' separate Motions to Dismiss. The Motions for both broad Defendant groups are virtually identical, without a single disparaging comment about each other in either document. The Motions appear to be primarily a “cut and paste” of each other, with some modest differences. The Defendant groups even go as far as to reference each other's Motions, suggesting they have consulted each other when drafting the documents. The Motions were filed within minutes of each other with the court on October 1, 2018. In the Relator's view, this strategic choice verifies what the Relator alleges: that the Defendant parties have long been close secretive “partners”, not adversaries, in massively raising U.S. brand drug prices.

“Determining whether a complaint states a plausible claim for relief will, as the Court of

Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) The Relator’s “experience and common sense” as a physician and professional financial analyst were the driving factors behind his initial and ongoing uncovering of this scheme.

The Relator’s investigation began to answer a basic incongruous dilemma: “*How can the US prices of a wide array of old “blockbuster” drugs increase massively, in unison, when their usage by patients and doctors is plummeting?*” Original SDNY Complaint (“C”) ¶ 375. In a free market, in the pharmaceutical or any other industry, product prices do not increase when usage is plummeting – unless there are unusual circumstances (shortages, manufacturing disruption, etc.) or some kind of anti-competitive activity. ¶ 360.

However, in 2013, the Relator’s intensive research uncovered the true and shocking cause – the clandestine shift to the fraudulent “service fee” profit scheme, driven by the abuse of little-known Part D financial incentives. These discoveries, along with all the Relator’s subsequent evidence relayed in the SAC, arose from following the “common sense” creed of any experienced and ethical professional investment analyst – “*Follow the Money.*”

C. Both the Manufacturer and PBM Defendant Motions Largely Ignore the Massive “Kickback” Scheme at the Center of this Case.

Massive “service fee” kickbacks are the centerpiece of this *qui tam* action. There is nothing subtle about the magnitude of the alleged kickbacks. For many of the products, these increased “service fee” payments have coincided with a severe erosion in drug usage and legitimate support needs. As set forth in the Second Amended Complaint, “In layman’s terms pertaining to “services”, think of paying someone four times as much money for painting half of your house” SAC ¶ 104.

The Pharmaceutical Defendants refer to the central kickback allegations in their Motion to Dismiss. “The crux of Borzilleri’s Rhode Island complaint – just like his complaint in this case – is the contention that pharmaceutical manufacturers paid excessive service fees to PBMs that amounted to criminal kickbacks...” *See PhMD, Introduction*. However, the Pharmaceutical Defendants make no

other specific arguments in their Motion against the Relator's kickback allegations.

In their Motion, the PBM Defendants' make a brief, half-hearted attempt to dispel the kickback allegations. *See PBMMMD, Section I (B)*.

In the Relator's view, both Defendant groups chose to minimize the kickback allegations precisely because they are so egregious.

The recent First Circuit *Kester* case, which is on point and was not mentioned by the Defendants, provides important precedents for numerous issues in the instant case. U.S. ex re. *Kester v. Novartis, et.al.*, 1:11-CV-08196-CM-JCF (SDNY, November 2011)

D. NONE of the Individual Pharmaceutical or PBM Defendants filed SEPARATE Motions to Dismiss.

In addition to the two broad Defendant group Motions to Dismiss, all thirteen (13) individual Pharmaceutical and PBM Defendants were given the option to file separate briefs, with consent of the Court. The Relator had expected numerous individual Defendants to file separate briefs due to the wide range of alleged financial fraud in this case.

Among the Manufacturer Defendants, the financial exposure of Bristol Myers Squibb (\$2.5 for a single cancer drug, Sprycel) and Eli Lilly (\$4.1 billion for a single insulin drug, Humulin) pales in comparison to the massive fraud estimates for Abbvie (\$32 billion for Humira), Amgen (\$19 billion for Enbrel), Sanofi (\$21 billion for Lantus), Pfizer (\$25.8 billion for 7 drugs) and Novartis (\$8.4 billion for Gleevec and Tasisign).

Similarly, among the PBM Defendants, the financial fraud exposure of Cigna and Aetna (with modest Part D market shares) pale in comparison to Express Scripts, CVS Health, UnitedHealth and Humana (the four of whom combined control 80+% of the market). The Relator contemplated that individual PBMs might consider "factually" defending their business practice pertaining to

manufacturer “service fees” and the Medicare Part D program.

Despite an array of possibilities, none of the individual Manufacturer or PBM Defendants even petitioned the Court for consideration to file a separate brief. Furthermore, these Defendant corporations made this decision despite each management’s distinct fiduciary responsibility to their shareholders and with the advice of separate, world-class corporate defense counsel. As with the broader Defendant groups, the Relator believes this same decision was made by each individual Defendant because the extensive factual evidence in the SAC is true, accurate and virtually irrefutable.

The lack of any “factual” challenge to the Relator’s allegations supports Relator’s theory of the participation of all the Defendants in this extensively detailed and documented “service fee” scheme. In their unified defense against these allegations, the senior managements of all the Pharmaceutical and PBM Defendants appear to be counting on their assiduously crafted and guarded 15+ year veil of secrecy to avoid non-insider Relator discovery and investigation.

E. The Legal Arguments by the Pharmaceutical and PBM Defendants are the SAME.

The specific legal arguments by both broad Defendant groups, and by extension the individual Defendants, are superimposable. Their arguments target first-to-file concerns (as disclosed to the Court in the SAC) and particularity requirements (given the Relator’s non-insider status). SAC ¶ 49.

In addition, both Defendant groups expend considerable effort to argue general pleading, public disclosure and original source deficiencies.

F. SAC Facts Ignored or Distorted by the Defendants.

Most notably, in their Motion, the Manufacturer Defendants ignore the central basis of this *qui tam* case; namely their irrefutable legal liability to CMS and taxpayers for the “Fair Market Value” (FMV) payment of Bona Fide Service Fees (BFSFs, i.e., “manufacturer service fees”) to the PBM Defendants in Medicare Part D and all government drug programs. *See* 42 C.F.R. § 423.501 With this

glaring omission, the Manufacturer Defendants then seem to imply that their lack of direct Part D reporting requirements for Direct and Indirect Remuneration (DIR) or BFSFs somehow absolves them of any legal liability. *See* 42 C.F.R. § 423.308.

In reality, to avoid fraud, the Manufacturer Defendants are legally responsible to inform the PBM Defendants regarding “service fees” that are in excess of FMV so that the PBM Defendant (either in its Plan Sponsor or PBM role) can properly report these payments to CMS as “discounts” in DIR reports, thereby leading to lower Part D “negotiated prices.” By not doing so, as has been routine, the Manufacturer Defendants are directly causing false claims to be submitted and are providing kickbacks that elevate Part D drug prices and their fraudulent profits.

In the “Regulatory Background” section of their Motion, the PBM Defendants also dodge a central driver of this massive scheme; namely, their functional control over all aspects of the Medicare Part D program. As per the Complaint and public disclosures, these dominant PBM Defendants provide the all-in-one plan sponsor, PBM and specialty pharmacy functions directly for 80-90% of Part D plans and beneficiaries. SAC ¶¶ 65-66, 401. In addition, the PBM Defendants also provide the majority of the contracted PBM and Specialty Pharmacy functions for a large proportion of the shrinking 10-20% of remaining “independent” Part D plan sponsors. 42 C.F.R. § 423.514. The lack of independence of the plan sponsor, which is responsible for almost all Part D reporting and oversight, has perhaps been the greatest factor enabling this abusive systemic scheme. SAC ¶¶ 65, 402, 142 U.S.C. § 1395w-111(b); *See* 42 C.F.R. Part 423. For instance, with independent plan sponsors, severe Catastrophic cost-sharing requirements would force legitimate price negotiation between contracted PBMs and drug manufacturers pertaining to high-cost “specialty” drugs. SAC ¶¶ 406, 440

The Part D dominance of these PBM Defendants is also relevant to the particularity hurdles in this systemic scheme. By definition, these PBM Defendants are also directly submitting almost all Part D PDE reports and all other related Part D required submissions (such as annual plan bids, subsidy

information, data for annual catastrophic reconciliation, etc.) for the specific Defendant drugs to CMS for reimbursement. *See* 42 C.F.R. § 423.308.

G. Defendants' Ad Hominem Attacks on Dr. Borzilleri are Inappropriate, Inaccurate and Irrelevant.

In a choice that indicates the weakness of their arguments on the merits, both Defendant groups include inappropriate, inaccurate and irrelevant attacks on the Relator as a major focus in their Motions to Dismiss.

The Relator, John R. Borzilleri, M.D., MBA has been a successful and ethical healthcare equity analyst/portfolio manager for 25+ years. Prior to his *qui tam* actions, as a professional healthcare investment analyst and portfolio manager, Dr. Borzilleri had long-established, strong professional relationships with the senior managements of most of the Defendant corporations. Following 10+ years of highly-regarded service at major sell-side and mutual fund investment companies, the Relator had been the solo manager of a small (less than \$10 million in client assets) healthcare-focused hedge fund at Boston-based GRT Capital Partners. GRT Capital was acquired by Shepherd Kaplan in November 2017, with the combined firm re-named as Shepherd Kaplan Krochuk, LLP (SKK).

Unfortunately, on April 18, 2018, just a few days after the unsealing of Dr. Borzilleri's nearly 5-year *qui tam* efforts, SKK's senior management informed the Relator that his employment would be terminated, without providing cause. Prior to this sudden notice, the Relator had a 15+ year unblemished, top-performing record at the firm.

When Dr. Borzilleri resisted the sudden termination and highlighted obvious whistleblower retaliation concerns, SKK fired him by serving a lawsuit, immediately demanding he sign an egregious separation agreement absolving the firm of any potential legal liability. When Dr. Borzilleri respectfully declined five days later, SKK forcibly closed his long-standing investment fund, leading to severe financial harm to Dr. Borzilleri and his group of loyal investors. Dr. Borzilleri promptly filed

a Complaint with the Securities and Exchange Commission (SEC) regarding SKK's violation of its SEC-registered fiduciary duties against the fund investors. Dr. Borzilleri has been contacted by the SEC and is now fully cooperating with their investigation.

In addition, Dr. Borzilleri promptly filed a countersuit against SKK in Massachusetts Superior Court, alleging violations of Qui Tam and SEC Whistleblower retaliation statutes, breach of contract and breach of SEC fiduciary duty, among other violations. Dr. Borzilleri's countersuit successfully challenged SKK's Motions to Dismiss in September 2018, and the case is now entering discovery. Dr. Borzilleri expects to be fully exonerated.

Instead of focusing on the merits of Relator's claims against them, Defendants chose to bring this irrelevant personal situation into this *qui tam* action, including attaching Court documents to their Motions to Dismiss. The Relator will not add to this behavior by attaching more. If deemed necessary, all legal documents related to this matter will be provided to the Court (and/or the Defendants) by the Relator, or can be obtained through public records in Massachusetts Superior Court.

H. Dr. Borzilleri's Well-Pleaded Allegations "Assumed as True".

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007).

Given the Defendants' lack of factual challenge in their Motions, the Relator believes a summary of his allegations in the SAC is instructive. These allegations are to be assumed as true in this Motion to Dismiss, for the broad Defendant groups, the individual Manufacturer and PBM Defendants, as well as the specific drug products targeted in this action.

Dr. Borzilleri's "Factual" Allegations are as Follows:

- 1) The Manufacturer Defendants have and continue to pay the PBM Defendants massive fraudulent

“service fee” kickbacks contractually-driven (almost universally via percent of revenue terms) almost entirely by massive four-to-seven-fold “list” price increases, not for providing legitimate utilization-based support services. *See SAC generally.*

- 2) These kickbacks have been paid to ensure PBM Defendant Part D formulary access and to avoid standard PBM cost-control practices (formulary exclusion, aggressive price negotiations, prior authorization, etc.), which would otherwise be very effective for lowering the prices, and preventing price increases, for the competitively-challenged Manufacturer Defendant products. SAC ¶¶ 79-82, 169
- 3) These massive “service fee” payments are wildly in excess of any legitimate methodology employed to determine the arm’s length, Fair Market Value (FMV) and reasonable compensation, as is required by statute and law in the Medicare Part D program. *See SAC generally.*
- 4) The Manufacturer Defendants bear the primary legal responsibility for the FMV payment of BFSFs in Medicare Part D. SAC ¶¶ 44, 289
- 5) By not ensuring that the PBM Defendants (in their dominant role as Part D plan sponsors) properly reported these grossly in-excess-of FMV “fees” properly to CMS as “discounts” (via DIR reports), the Manufacturer Defendants have knowingly caused false claims submissions by their collusive PBM Defendant partners, with virtually every Part D prescription (via PDE reports) for these drug products since the scheme began more than a decade ago. SAC ¶¶ 86, 169.
- 6) Due to their Part D express certification requirements, the PBM Defendants, via their dominant plan sponsor subsidiaries, have knowingly and directly submitted false claims with virtually every Manufacturer Defendant Part D PDE report over the last decade-plus. SAC ¶¶ 168-170.
- 7) Due to their distinct Part D express certification requirements, all three-key participating PBM

Defendant subsidiaries, namely the plan sponsor, PBM and the specialty pharmacy (and likely others), are also separately liable for the kickback and false claim scheme. *id.*

- 8) As massive “specialty” drug price inflation accelerated, both Defendant parties escalated a related kickback and false claim scheme pertaining to Part D plan sponsor Catastrophic “cost-sharing” requirements. Without this related scheme, the PBM Defendants would have incurred massive financial losses on each and every Part D “specialty” drug prescription as the massive price increases ensued. Driven by the expanding scheme, explosive taxpayer-funded Catastrophic spending has been the primary driver of Part D program spending growth in recent years. SAC ¶¶ 32-33, 347, 395-444.
- 9) The primary false claims path has been via: 1) Prescription Drug Event (PDE) reports required for each Part D prescription (which include excessive prices due to unreported excessive fees and Catastrophic forgiveness), and 2) Annual Direct and Indirect Remuneration (DIR) reports, where fees in excess of FMV have not been reported by the PBM Defendant plan sponsors. SAC ¶¶ 86, 151, 161, 163, 169-70.
- 10) In addition to these two primary false claims paths, all other PBM Defendant Part D submissions for payment, including annual plan bids and annual data for Catastrophic reconciliation, have also been tainted by this massive kickback scheme. *id.*
- 11) All these PBM Defendant false claims submissions have been directly “caused” by the Manufacturer Defendant’s fraudulent activities pertaining to their direct FMV liability, as well as their service fee and Catastrophic cost-sharing kickback payments. SAC ¶¶ 86, 169
- 12) These massive, secret, intentional and fraudulent “service fee” kickback payments have accounted for almost all US profits (more than 90%) for the PBM Defendants related to the Manufacturer Defendant brand “specialty” drugs in this case, namely Abbvie’s Humira, Amgen’s Enbrel, Novartis’ Gleevec and Tasigna, and Bristol-Myer’s Sprycel. SAC ¶¶ 59-60

- 13) These massive, secret, intentional and fraudulent “service fee” kickback payments have accounted for the majority of profits (in the 70% or more range) for the PBM Defendants related to the Manufacturer Defendant brand “traditional” drugs in this case, namely Sanofi’s Lantus, Eli Lilly’s Humulin, Pfizer’s Lyrica, Pfizer’s Viagra, Pfizer’s Celebrex, Pfizer’s Premarin, Pfizer’s Chantix, Pfizer’s Pristiq, and Pfizer’s Relpax. *id.*
- 14) Due to failure to disclose the “material” profit contribution of this massive “service fee” payment stream, in April 2018, the Relator filed a form TCR (“Tip, Complaint and Referral”) Whistleblower Complaint with Security and Exchange Commission (SEC), regarding all the *qui tam* Defendants in his SDNY and RI actions. On May 2, 2018, the Relator received written notice of receipt from the SEC. To this date, the Relator has not had any further contact with the SEC regarding his TCR Complaint. SAC ¶ 64

ARGUMENT

A. PUBLIC DISCLOSURE: INAPPLICABLE TO RELATOR’S *QUI TAM* CASES.

1) The Legal Standard for the Public Disclosure Bar.

The Second Circuit and virtually all other jurisdictions have established that the public disclosure bar requires specific disclosure of “allegations” that are “substantially similar” to the Relator’s in prior “public disclosures”.

One of the prominent PBM Defendants, CVS Health Corporation (represented by the same counsel as in this matter) also admits the same in *Kester*. “The Second Circuit . . . has repeatedly held that [a] relator’s claim is ‘based upon’ the public disclosure if the allegations (emphasis added) in the complaint are ‘substantially similar’ to the publicly disclosed information.” *Kester*, 1:11-cv-08196-CM-JCF (SDNY, November 2011), 175, page 9, referencing *Ping Chen*, 966 F. Supp. 2d at 297 n.11.

The public disclosure bar requirement of the “allegations” or “fraudulent transactions” is also verified by a closer review of the numerous case references provided by the Defendants themselves in

their Motions to Dismiss, including the following. *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson* 559 U.S. 280 (2010); *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282 (S.D.N.Y. 2013); *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805 (11th Cir. 2015). *erm. Ry. Co. v. Quinn*, 14 F.3d 645 (D.C. Cir.1994).

2) Dr. Borzilleri's Allegations were not Publicly-Disclosed prior to his *Qui Tam* filing; Defendants' Arguments are Meritless.

Simply put, Dr. Borzilleri's highly specific and detailed "allegations" of "fraudulent transactions" were not in the public domain, in any manner, prior to his initial *qui tam* filing in the District of Rhode Island in early January 2014.

In their Motions to Dismiss, the Defendants highlight numerous public reports provided to the Court by Dr. Borzilleri in the SAC (and some others) as evidence of surpassing the public disclosure bar. However, none of these public documents provide any disclosure of Dr. Borzilleri's detailed and highly-specific fraudulent "allegations" against the Defendant groups or the individual Defendants. In fact, none of the public documents even come close.

Regarding the Defendants "public disclosures", a few broad observations are noteworthy. First, many simply discuss the long-standing Medicare regulatory requirements regarding the Fair Market Value (FMV) of bona fide services fees (BFSFs), without any generalized or specific fraud allegations. In the Relator's view, these documents primarily serve to verify scienter of the Defendants in this *qui tam* action.

Second, many of the public documents highlighted by the Defendants were released prior to the arrival of the Medicare Part D legislation in 2003 and the start of the program in 2006. Only a couple of the documents even directly mention Medicare Part D or Pharmacy Benefit Managers (PBMs). The Relator's allegation of large, unjustified "service fees" fraud is unique to Medicare Part D (compared other government drug programs), due to its dependence on private industry and its lack of statutory drug price inflation protections for beneficiaries and taxpayers.

Finally, very few detailed public documents even exist regarding Part D Catastrophic cost-sharing and none even broach the topic of specific fraud allegations.

The Defendants' meritless "public disclosure" claims regarding several of Dr. Borzilleri's key documents from the SAC are worthy of some specific commentary. First, as disclosed in the SAC, Dr. Borzilleri first noted the potential lack of PBM Defendant Part D compensation via "manufacturer rebates" from review of a March 2011 Office of Inspector General report. OIG Report OEI 02-08-00050. SAC ¶¶ 227-8, 764-9. The Defendants, without merit, suggest that some general comments in the OIG report regarding "bona fide service fees" constitutes significant public disclosure of the Relator's allegations. As per the PBM Defendants' Motion to Dismiss, referencing the OIG report, "A majority of the PBMs receiving such fees "did not pass them on to the sponsors" and, "[a]s a result, the sponsors did not report the fees to CMS and therefore they were not passed on to the [Medicare Part D] program," all because the "PBMs considered these fees to be bona fide service fees, which CMS does not consider price concessions if they are at fair market value." OIG concluded that reporting of such fees to CMS "may be inaccurate[]" and *recommended an assessment of "whether these fees should actually be considered rebates."* Obviously, these general statements do not include any general or specific fraud allegations. In fact, Dr. Borzilleri himself did not uncover the fraudulent "service fee" scheme until 4-6 months after initially reviewing this OIG report.

Second, as set forth in the Relator's SDNY Complaint, one of the key public disclosures that put Dr. Borzilleri on the trail to the scheme was a brief article in the January-February 2013 issue of Specialty Pharmacy Times, a trade journal. *Why We Care About Bona Fide Service Fees* C.¶¶ 386-7. The PBM Defendants again attempt to claim that the limited generalized commentary in this article constitutes public disclosure of Dr. Borzilleri's allegations.

As per the PBM Defendants' Motion, quoting the Specialty Pharmacy Times article: "*If the government pays more than it thinks it should for pharmaceutical products under these programs, it*

can apply the False Claims Act, which is legal action related to the pharmaceutical manufacturer submitting incorrect data which causes the government to pay more than it should. . .”

Again, counter to the public disclosure bar, this article merely states the regulatory and accounting requirements for “service fees” in government drug programs, as well as the obvious False Claim remedy for any financial fraud against US taxpayers. The article makes no specific mention of Medicare Part D, Pharmacy Benefit Managers or any specific fraudulent allegations. The Relator recognized the fraudulent practices set forth in detail in the SAC only after overlaying numerous other central factors driving the scheme, including a) massive price increases and US revenue growth, for the specific competitively-challenged and eroding Defendant drugs; and, b) the numerous design and operational factors related to Medicare Part D.

Third, the Defendant attempt to claim that the industry conference attended by Dr. Borzilleri constitutes a barring public disclosure of his allegations. October 7–8, 2013, CBI Conference, *Fair Market Value of Bona Fide Service Fees*. SAC ¶¶ 452-489 As per the PBM Defendants’ Motion to Dismiss, quoting the SAC, “[a]ll key components of the fraud were verified via presentations . . . at the conference.”. As per the PBM Defendants, the conference was “open to anyone who paid the registration fee” and “All the presentation materials were subsequently available online for purchase as a “Compendia.”

Dr. Borzilleri (and another PBM expert colleague) were apparently the only “non-insiders” among the approximately 50 attendees at the conference. No government officials were discernible at the event, either as presenters or attendees. SAC ¶¶ 452-6.

The Defendants’ claim that the presentation slides from the conference surpass the public disclosure bar is baseless. This fact can be ascertained by a quick review of the slides themselves. See Separate Exhibit. The slides simply discuss the regulatory requirements for BFSFs in all government programs. Notably, neither the term Medicare Part D nor the term Pharmacy Benefit Manager (PBM)

ever appear in the slides; nor do any general or specific fraud allegations. Clear indication of likely fraudulent “service fee” activity only arose from the first-hand-witness commentary obtained by Dr. Borzilleri at the two-day conference. SAC ¶¶ 459-89.

Within days of the conference, these notes were compiled into a detailed document by Dr. Borzilleri, and this document was forwarded to the Justice Department when Dr. Borzilleri initiated discussions. Dr. Borzilleri did seek to obtain from conference organizer (CBI) a written or recorded transcript of the event, but none was ever made available to the attendees or to the public. Other than his *qui tam* case and other Relator documents, Dr. Borzilleri remains unaware of any subsequent public disclosure of commentary from this conference. Furthermore, as per the conference brochure, it was billed as “*The one and Only Event That Focuses Solely on the Challenges When Determining Fair Market Value!*”. This conference was never held again. See the conference brochure agenda in a separate Exhibit.

Due to statutes similar to the federal FCA, this case surpasses the public disclosure bar pertaining to all state law claims.²

Of note, the first and as of this date the only media article regarding Dr. Borzilleri’s allegations was published four months after unsealing on August 16, 2018, in STAT+, a healthcare trade and investment publication. See *Never Mind the rebates. Maybe behind-the-scenes fees are boosting drug prices. Ed Silverman, August 16, 2018*. See Attached Exhibit 6. This short article is only available to paid subscribers of STAT, not broadly to the public.

To date, only one of the SDNY Defendants, Pfizer, has mentioned this *qui tam* case in recent

² See Cal. Gov’t Code § 12652(d)(3)(A); Colo. Rev. Stat. § 25.5-4-306(5)(c); Conn. Gen. Stat. § 4-282(b); 6 Del. Code Ann. tit. 6, § 1206(b); D.C. Code § 2-381.03(c-1) (1); Fla. Stat. § 68.087(3); Ga. Code Ann. § 23-3-122(j)(3); Haw. Rev. Stat. Ann. § 661-31(b); 740 Ill. Comp. Stat. 175/4(e)(4)(A); Ind. Code § 5-11-5.5-7(f); Iowa Code § 685.3(5)(c); La. Stat. Ann. § 439.1(D); Mass. Gen. Laws. ch. 12 § 5G(c); Mich. Comp. Laws, § 400.610a (13); Minn. Stat. § 15C.05(f); Mont. Code Ann. § 17-8-403(6)(a); Nev. Rev. Stat. Ann. § 357.100; N.J. Stat. Ann. § 2A:32C-9(c); N.M. Stat. Ann. § 27-14-10(C); N.Y. State Fin. Law § 9(b); N.C. Gen. Stat. § 1-611(e); Okla. Stat. § 5053.5(B); R.I. Gen. Laws § 9-1.1-4(e)(4)(A); Tenn. Code Ann. § 4-18-104(d)(3); Tex. Code Ann. § 36.113(b); Va. Code Ann. § 8.02-218.8; Wash. Rev. Code § 74.66.080(2).

Security and Exchange Commission (SEC) filings; in its 10-Q filed on November 8, 2018. Surprisingly, Cigna, Express Scripts, CVS and Aetna have not publicly disclosed the Relator's potentially highly damaging *qui tam* cases in their SEC filings ahead of imminent merger closures.

The Express Scripts/Cigna merger was approved by the antitrust division of the DOJ on September 18, 2018; according to the companies, the deal is expected to close by the end of 2018. The CVS/Aetna merger was approved by DOJ on October 10, 2018. According to the companies, the deal is expected to close within a few days, by Thanksgiving 2018. *See Express Scripts and CVS Health 3Q 2018 filings with the SEC.*

3) Dr. Borzilleri is the Original Source of Definitive Information in both *Qui Tam* Actions.

Without prior public disclosure of the “allegations” or “fraudulent transactions”, establishing “original source” is not required in this matter. Regardless, the Relator fulfilled this requirement by “voluntarily providing the information to the Government before filing an action.” 31 U.S.C. § 3730(e)(4)(B) (2006).

Within weeks of identifying the “BFSF/service fee” scheme more than 5 years ago, Dr. Borzilleri sent an email to several senior staff at the Federal Trade Commission (FTC) on June 19, 2013, before even considering filing a *qui tam* action. See Attached Exhibit 7. On the next day, the Relator had a previously-scheduled conference call with these same FTC staff, which then included preliminary discussion of potential BFSF abuse between drug manufacturers and PBMs in the Medicare Part D program. Dr. Borzilleri never received a specific FTC reply to the email nor any follow-up after the conference call.

In addition, when the Relator initiated contact with the Justice Department in mid-October 2013, he forwarded a 105-page report, describing his Part D “service fee” allegations in detail. The initial contact emails with DOJ from October-November 2013, three months prior to the initial *qui tam* filing are in Attached Exhibit 8. Dr. Borzilleri's lengthy initial report sent to DOJ is provided as a

Separate Exhibit.

As a non-insider Relator, Dr. Borzilleri filed the initial *qui tam* case due to his inability, despite extensive effort for nearly a year, to engage a wide array of government officials and healthcare experts in investigation. Importantly, once he uncovered the specific “service fee” scheme (about 6 months after starting his investigation), Dr. Borzilleri did not publicize it beyond the government prior to filing the RI *qui tam* action in early January 2014.

Dr. Borzilleri’s first-hand commentary from the one-of-a-kind “insider” conference, “Fair Market Value of Bona Fide Service Fees”, held in October 2013, was “direct and independent knowledge” that added “materially” to his understanding of the scheme. See 31 U.S.C. § 3730(e)(4)(B) (2012). In fact, the consistent and shocking admissions from this conference were the determining factor in Dr. Borzilleri’s decision to file the initial *qui tam* action in RI less than three months later.

The private first-hand admissions of Depomed’s CEO, James Schoeneck, regarding the broader systemic “service fee” scheme was also essential “direct and independent knowledge”, specifically for this SDNY action. SAC ¶ 448-51. Mr. Schoeneck’s commentary was a major factor driving the expansion of Dr. Borzilleri’s ongoing investigation, which enabled him to provide the government unique “notice” of the distinct and severe public harm caused by the SDNY “traditional” Defendant drugs. Furthermore, consistent with his policy of full transparency with the DOJ, Dr. Borzilleri disclosed his commentary from his meeting with Mr. Schoeneck to the RI DOJ soon after it occurred.

As such, regardless of first-to-file or public disclosure issues related to his prior RI filing, Dr. Borzilleri is the original source of definitive information regarding the vast expansion of this scheme beyond the narrow US specialty drug segment (only 1-2% of US prescriptions and the sole focus of his prior RI *qui tam* filing). Drug products in the far larger “traditional” US brand pharmaceutical market accounts for 9 of the 14 Defendant drugs in this SDNY action.

B. DR. BORZILLERI'S ALLEGATIONS MORE THAN MEET THE STANDARD OF FACTUAL PLAUSIBILITY

1) Legal Standard for Rule 12(b)(6).

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007). To survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter ... to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations, citations, and alterations omitted). Thus, unless a plaintiff's well-pleaded allegations have "nudged [its] claims across the line from conceivable to plausible, [the plaintiffs] complaint must be dismissed." *Id.* at 570; *see also Iqbal*, 556 U.S. at 680. This liberal pleading standard is modified by Rule 9(b), which requires a plaintiff asserting fraud claims to meet a heightened pleading standard.

2) Dr. Borzilleri's Fraud Allegations More than Meet the Standard of Factual Plausibility.

Despite the Defendants' protestations of "speculation and conclusions", Dr. Borzilleri's allegations are set forth with remarkable clarity, detail and specificity. In fact, just a few of the brief sentences in the "Summary" section of the SAC provide the Defendants with clear notice of the kickback and false claims allegations.

As per SAC ¶ 26: "John R. Borzilleri, M.D. ("Relator") has ascertained that the Manufacturer

Defendants of brand drugs have and continue to make fraudulent overpayments of illegitimate “Bona Fide Service Fees” (BFSFs) far in excess of legally-required “Fair Market Value” (FMV) to the PBM Defendants, as part of a nationwide collusive price inflation scheme in the Medicare Part D program.”

As per SAC ¶ 27: “In Medicare Part D, PBMs were expected to negotiate in good faith with drug manufacturers to obtain “rebates” and lower drug costs for beneficiaries and taxpayers.”

As per SAC ¶ 28: “Instead, the Manufacturer and PBM Defendants entered into an intentional, secretive and fraudulent price inflation scheme, based upon “service fee” contracts, in gross violation of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS).”

As per SAC ¶ 33: “The Manufacturer Defendants (and other biopharmaceutical companies) are routinely (and fraudulently, emphasis added) “forgiving” the 15% unlimited “catastrophic” cost-sharing exposure of the PBM Defendants, in their dominant roles as Part D plan sponsors.”

As per SAC ¶ 79: “The PBM Defendants, in turn, receive fraudulent “service fees”, as “kickbacks”, for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies and the avoidance of long-established, effective, PBM cost-saving strategies (aggressive rebate negotiations, brand drug “therapeutic substitution” and “formulary restriction” programs, etc.).

In addition to the specificity of the allegations, the magnitude of financial harm has also been documented by the Dr. Borzilleri for each pharmaceutical product targeted in this action. For each Defendant drug, Dr. Borzilleri has carefully estimated both the direct “service fee” kickbacks paid to the PBM Defendants, as well as the far larger fraudulent Manufacturer Defendant US product sales enabled by the scheme. SAC ¶ 354-94

Neither the Pharmaceutical nor the PBM Defendant group even suggest an alternative “theory” in their Motions to Dismiss for their huge price increases for older drugs that have decreasing market share.

3) This *Qui Tam* case is Amenable to Targeted and Efficient Discovery.

In their Motions to Dismiss, the Defendants claim that the Relator hopes to use discovery as a “fishing expedition.” In fact, after nearly 6 years of intensive investigation, the Relator sees no significant deficiencies in his understanding of the broad mechanics of the scheme or the validity of his specific allegations.

The collusive “service fee” scheme is remarkably straightforward and amenable to targeted and efficient discovery. First, this scheme is highly centralized and primarily controlled at the executive suite level of both the Pharmaceutical and PBM Defendant organizations. Central control, secrecy and lack of transparency have been essential for keeping this massive scheme out of the public domain for the nearly 15 years since Medicare Part D began. The highly secretive, product-specific “service fee” contracts between the Manufacturer and PBM Defendants are standardly negotiated at the national level, making them easily accessible in discovery.

Second, Medicare Part D, among the largest profit drivers for all the Defendants, is also highly centralized. As such, this small group of dominant PBM Defendants directly submits 80-90% of Part D prescriptions (via Prescription Drug Event [PDE] reports) for all drugs, including the Defendant products, for reimbursement. SAC ¶ 15. Finally, these PBM Defendants typically negotiate their Part D plan bids, formularies and other Part D requirements directly with CMS at the national level.

The extreme concentration and lack of competition in the Medicare Part D program was recently verified by documents filed by DOJ in U.S. District Court (D.C.D.C.) pertaining to the imminent merger of PBM Defendants CVS Health and Aetna. First, DOJ admits the dominance of the PBM Defendants in Part D. “Neither entry nor expansion is likely to solve the competitive problems created by the merger between CVS and Aetna. Recent entrants into individual PDP markets have been largely unsuccessful, with many subsequently exiting the market or shrinking their geographic footprint.” *DOJ CVS/Aetna Competitive Impact Study*, page 6A, October 10, 2018. Second, in its

investigation, DOJ confirmed both the national, systemic nature of Medicare Part D, which applies as well as to this abusive *qui tam* scheme. In its Consent Decree for the merger, DOJ required the divestiture of Aetna's nationwide PDP Part D business, stating "That is because contracts with pharmacy benefit managers, retail pharmacy networks, and pharmaceutical companies are almost all negotiated on a national basis..." *id.*, page 7 (emphasis added).

With this background, the Relator is confident of confirming his allegations expeditiously in discovery. In the Relator's view, determining the fraudulence of massive increases in "service fees", directly linked to four-to-seven-fold price increases (particularly while patient usage and prescription volume is plummeting) should not be a complicated endeavor for most of the Defendant drugs.

However, as an experienced equity analyst, Dr. Borzilleri is aware that discovery is likely to require persistence, particularly given the extreme secrecy and the lack of Defendant transparency at the heart of this scheme. For instance, the Defendants might seek to shift the accounting for "service fee" payments to non-Part D health plans or esoteric subsidiaries in order to deflect detection. SAC ¶¶ 65, 293, 650, 697. In addition, the minimal Part D reporting requirements regarding Catastrophic cost-sharing may require unique and iterative discovery requests.

The Relator has prepared and will provide to the Court a comprehensive and targeted discovery plan, should this Court deny Defendants' Motions to Dismiss. The plan will include an array of specific document and data requests, as well as an extensive witness list. SAC ¶ 442.

Dr. Borzilleri is confident that just a few pointed questions regarding "service fees" to a handful of senior Pharmaceutical and PBM Defendant executives, under oath, will open the "Pandora's Box" of this scheme and vastly accelerate investigation of this long-standing conspiracy.

In their Motions to Dismiss, the Defendants go to great lengths to highlight the non-insider Relator's lack of access to their highly secretive specific contract terms and rates, specific fee payments and specific services provided. They repeatedly use absolute "qualifiers", such as "Borzilleri knows

nothing about the Manufacturer Defendants actual contracts with PBMs”, “his admitted lack of actual knowledge”, “absolutely no personal knowledge of anything”, “he concedes he does not know the timing or the amount of any payments”, etc.

To an even greater extent the Defendants repeatedly use relative “qualifiers” to sow doubts regarding the Relator’s extensive and uniform evidence of the scheme and severe financial harm. As per the Manufacturer Defendant Motion: “Borzilleri, however, can offer nothing but his conjecture that a contract *might* exist between some Manufacturer Defendant and some PBM Defendant, that under this hypothetical contract some service fee *may* have been paid, that the hypothetical service fee *may* have exceeded the fair market value for the services provided, that the hypothetical amount over fair market value *may* not have been reported to CMS as DIR, and that false claims *may* exist.”

In reality, the Relator has uncovered nearly the full mechanics of the collusive scheme. Discovery will produce additional evidence of the massive financial harm directly attributable to each Defendant and each targeted drug therapy, so that the fiscal harm to patients and to taxpayers can be even more precisely determined. SAC ¶¶ 122, 180, 218, 433, 720.

4) Relator Deflected Defendants’ Efforts to Limit Potential Discovery.

In their Motion to Dismiss, the PBMs claim that the Relator’s carefully considered decision to target their broader “Holding” companies (rather than specific Part D subsidiaries) as Defendants, was driven by his “financial opportunism.” As set forth in the footnote on page 4 of their Motion, “Several of these Defendants have raised this issue with Relator, identified the correct subsidiary, and requested that the correct party be named; however, Relator’s counsel has refused.”

To be specific, two Defendants, CVS Health and Humana, threatened the Relator’s attorney with “Holding Company” dismissal arguments, if the Relator did not change the Defendant names to these subsidiaries. As a professional healthcare equity analyst, the Relator understood immediately that this was an attempt to limit his ability to discover the full financial underpinnings of their payment

schemes.

As discussed in the previous section, these organizations have large numbers of subsidiaries, specific to Part D and otherwise, which provide many avenues to hide payments from drug manufacturers. However, the PBM Defendants universally report their consolidated financial statements at the "Holding" company level only. For all these PBM Defendants, there is minimal, if any, public financial disclosure at the subsidiary level. Pursuant to this scheme, the "service fee" payments are a primary, if not the largest, profit driver for each PBM Defendant "Holding" company.

As such, the Relator's Defendant party selection is correct and appropriate. Dr. Borzilleri was immediately aware that the PBM Defendants were attempting to limit Relator's access to relevant and material information. Of note, other than this comment in the Motion, neither the broad PBM Defendant group, nor any individual PBM Defendants, argued for dismissal due to the lack of "Holding" company liability. The Relator would welcome that challenge.

5) The Relator has Pleaded a Clear and Material Kickback Scheme for ALL Defendants.

Generally, the FCA outlaws the submission of a false or fraudulent "claim" for payment (*i.e.*, a request for reimbursement) to the government. *See* 31 U.S.C. § 3729(a)(1). Such claims may be rendered "false" in a variety of ways. In this case, the Relator's FCA claims are foremost predicated on underlying violations of the Anti-Kickback Statute ("AKS"). Under the AKS, it is illegal to offer a person "remuneration" (*i.e.*, kickbacks) in order to "induce" that person to "recommend" the purchase of a drug covered by a federal health care program. 42 U.S.C. 3§ 1320a-7b(b)(2). It is likewise illegal to receive remuneration "in return for ... recommending purchasing" such drugs. *Id.* at § 1320a-7b(b)(1). This text comes directly from a court opinion in *Kester*. *U.S. ex rel Kester*, CV-08196-CM-JCF, 233, 9/3/2014. This chain of events is exactly what has also happened in the instant *qui tam* action, except at a magnitude many times greater than in *Kester*.

However, in this case, in addition to the central kickback path, the Relator avers that there is

also a very clear direct Part D FCA submission path for all the Defendants, as will be discussed in more detail *infra*. The alleged “service fee” payments greatly exceed required FMV, by any legitimate arms’ length methodologies chosen at the discretion of the Manufacturers Defendants, as per the Part D statutes. The industry standard FMV methodologies, namely the Income, Market or Cost-based approaches, are discussed in detail by the Relator. SAC ¶¶ 653-67.

Across business sectors, the Cost-based approach is the standard mechanism for determining FMV compensation for “services”. In the Cost-based methodology, the FMV payment is a straightforward calculation of the units of service, the required resources, as well as the staff and hours required. *id.*

However, driven by their fraudulent profit goals, the Pharmaceutical and PBM Defendants have instead universally structured their “service fee” contracts and payments based upon massive “list” price increases and “percent of revenue” contracts, with no legitimate relationship to actual services provided.

As the massive cost in US “specialty” drugs has exploded with the “service fee” scheme, the collusive partners also greatly escalated the abuse of the PBM Defendants’ 15% cost-sharing requirements in Part D. This cost-sharing requirement is the primary mechanism for CMS to promote arm’s-length price negotiation between drug manufacturers and Part D plan sponsors. As per the detailed example (Gleevec, SAC ¶¶ 423-43) provided by the Relator, routine “forgiveness” of this cost-sharing requirement is the only mathematical way to prevent massive PBM Defendant losses on each and every high-cost Part D “specialty” prescription, especially those fueled by massive price increases.

The patient health and taxpayer harm in the instant case is far more severe and clear than it was in two of the most recent major FCA kickback cases, namely *Westmoreland* and *Kester*. In *Westmoreland*, Amgen was accused of paying “kickbacks” to physicians for submitting unused

Aranesp (for anemia) vial volume for reimbursement. In *Westmoreland*, no clear patient harm occurred, and the financial fraud was never specifically quantified. *Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 n.4 (D. Mass. 2011)

Similarly, in *Kester*, Novartis was accused of paying “kickbacks” to specialty pharmacies to encourage switching of therapies and the re-filling of unnecessary prescriptions. Before *Kester* was settled after government intervention, the plaintiff and Novartis hotly debated the role of pharmacies and physicians in the scheme, as well potential patient harm. In *Kester* Court documents, the financial harm caused by the Defendants was only roughly estimated in the tens of millions of dollars range. *U.S. ex rel Kester*, CV-08196-CM-JCF (2011).

In comparison to these precedents, the aggregated alleged kickback payments in the instant case are far more massive, leading to wide-ranging severe patient, taxpayer, societal and business harm. In this case, the only beneficiaries of the massive scheme are the Defendants, their close confidants (consultants, investment bankers, etc.) and stock investors; all other constituents are severely harmed, including Part D and commercial insurance patients, taxpayers, physicians, nurses, other health providers, most public corporations, independent health plans, unions, independent pharmacies, etc.

Of course, the greatest financial beneficiaries of fraud are the relatively small handful of Defendant senior executives, who have received massive stock-based compensation from the highly-centralized scheme they have orchestrated.

Due to the straightforward nature of the scheme, the Relator is able to accurately estimate the massive financial fraud, for both the direct “service fee” kickbacks and US sales fraud. Simply put, none of the price increases for the competitively-challenged Defendant drugs should or would have occurred without Defendants’ egregious Part D-centric scheme.

In contrast, the lack of virtually any price inflation is exactly what has occurred for these “old”

Defendant blockbuster drugs across Europe, where PBMs have little or no role and pharmaceutical prices follows normal supply and demand patterns. SAC ¶¶ 17-18, 368-74.

The Relator did not even attempt to estimate the alleged Catastrophic cost-sharing fraud, which would greatly add to the financial fraud estimates for the high-cost “specialty” drugs in this case.

Notably, the Pharmaceutical Defendants did not attempt a direct argument to invalidate the kickback scheme in their Motion to Dismiss. The PBMs do attempt a feeble attack directly at the kickback scheme. As per the PBM Defendant Motion, page 20: “But he does not allege any particular facts even suggesting that this actually occurred between any Defendants, let alone in the Part D Program. It is at least equally plausible that any service fees were paid in exchange for legitimate services provided by PBMs. (emphasis added). By “equally plausible”, the PBM Defendants tacitly admit that the payments also carry a “nearly equal” plausibility of being fraudulent, which would appear to exceed the modest “plausibility” requirement to reach discovery. Regardless, even suggesting that utilization-based “service fee” payments, tied directly to massive four-to-seven-fold publicly-available “list” price increases for sharply eroding products (as measured by publicly-available industry-standard IMS prescription data), could be legitimate, makes no sense.

6) Alleged Part D False Claims: Often Factually and Always Legally False.

a. The Falsity Standard.

As the Second Circuit opined in *Kester, Mikes v. Strauss* is “binding to the Court regarding “falsity.” Specifically, it held, “Thus, *Mikes’s* holding that a claim is ‘false or fraudulent’ if the party submitting the claim falsely certifies that it is in compliance with a law that is a precondition to payment is still controlling law in this Circuit; it binds this Court. As long as the Government’s allegations meet the *Mikes* standard, I cannot dismiss the Government’s Complaint.” *U.S. ex rel Kester*, CV-08196-CM-JCF, 226, 8/7/2014, referencing *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001).

Subsection (a)(1)(A) of the FCA provides for liability where the defendant “knowingly presents,

or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Subsection (a)(1)(B) provides for liability where the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Subsection (a)(1)(C) provides for liability where the defendant "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)"-meaning conspires to commit a substantive FCA violation. 31 U.S.C. § 3729(a)(1)(C). Thus, all three subsections of the FCA at issue in this case require either the existence of "false or fraudulent" claims or a conspiracy involving "false or fraudulent" claims.

There are two types of "falsity"- i.e., two reasons that the government would not pay the claim if it knew the true facts. One is "factual falsity"; the other is "legal falsity".

b. Defendant's Part D Claims are Often Factually False.

A claim is "factually false" where the party submitting the claim supplies "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.*; see also *Pervez*, 736 F. Supp. 2d at 812. In other words, the party "bills for something it did not provide." *US. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94,113 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011).

In this case, the Relator alleges that the PBM Defendants are submitting drug product claims for reimbursement at fraudulently-escalated prices (in PDE reports), driven by excessive "service fees" that are not being properly reported as price concessions/discounts to CMS (in DIR reports). In addition, in many cases, the PBM Defendants are submitting drug claims for reimbursement when minimal or no services are being provided for large "service fee" payments. SAC ¶¶ 255, 335, 556.

The latter situation is most common for chronic use maintenance refill prescriptions, for which the PBM Defendants (and their specialty pharmacy subsidiaries) are receiving massive "service fees" simply for mailing prescriptions to Part D beneficiaries (as per numerous Relator physician interviews)

id.

Of course, the PBM Defendants' "factually false" claims are also directly "caused" by the Manufacturer Defendants, due to the latter's clear FMV liability regarding BFSFs in Medicare Part D and other government drug programs.

c. Defendant's Part D Claims are Always Legally False.

As in *Kester*, Relator properly asserts that ALL the Part D claims submitted by the PBM Defendants (in their roles as Part D plan sponsors) for each targeted drug prescription, since the scheme began from the 2006 start of Part D to the present, are tainted by the AKS violations. SAC ¶¶ 87, 170. Of course, given the compounding impact of ongoing massive price increases, the magnitude of the "kickbacks" for each Part D submission for reimbursement for each Defendant drug has escalated each year in the program. SAC ¶¶ 354-394

Furthermore, *Kester* definitively established that the 2010 Patient Protection and Affordable Care Act (PPACA) amendment made compliance to the AKS a precondition to the reimbursement of claims: "Claims tainted by AKS violations are ineligible for reimbursement and, thus, false." *U.S. ex rel Kester*, CV-08196-CM-JCF, 233, 9/3/2014. *Kester* established that compliance to the AKS was a precondition for payment of claims submitted to federal health programs both before and after the 2010 AKS amendment. "I join the vast majority of the courts that have considered this issue in holding that compliance with the AKS was a precondition to payment of claims submitted to federal health care programs prior to the 2010 AKS amendment. The amendment merely "clarif[ied]" that the AKS was such a precondition." *Kester*, *id.*, referencing *Westmoreland*, 812 F. Supp. 2d at 52.

Also per *Kester*, there is no controversy that Medicare Part D payment requires ongoing and distinct "express certification" by the PBM Defendants and all their contracted subsidiaries (plan sponsor, PBM, specialty pharmacy and others) to comply with "Federal laws and regulations designed to prevent fraud, waste, and abuse". These laws and regulations include but are not limited to applicable

provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et seq.), and the *anti-kickback statute* (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(l). *Kester*, 8/7/14, *id.*

In this case, as with the Government in *Kester*, the Relator alleges that the PBM Defendants made such express certifications, and that these certifications were "false", given that the PBM Defendants were violating the AKS by receiving kickbacks. These kickbacks came in the form of excessive "service fees" and "catastrophic cost forgiveness", in exchange for formulary access and passing massive fraudulent drug price increases on to Part D beneficiaries, CMS and taxpayers.

The Relator would like to apologize to the Court for a misstatement in the Second Amended Complaint. In the SAC, the Relator incorrectly stated that the Manufacturers must also "expressly certify" compliance with the FCA and the AKS, as a precondition to payment in Medicare Part D. However, this fact is immaterial since the Relator alleges that the PBM Defendants made false express certification requirements that encompass all claims, rendering them "false". *Kester*, *id.*

7) Defendants' "Service Fee" Scheme is not Protected by any AKS Safe Harbors.

In their Motion, the Pharmaceutical Defendants state that "payments from manufacturers to PBMs can (emphasis added) be protected by the GPO (Group Purchasing Organization) safe harbor...other safe harbors exist in addition to the GPO harbor, and they may (emphasis added) be applicable to the various PBM-manufacturer relationships. As discussed in the SAC, the other relevant safe harbor regarding "service fees" pertains to Personal Services, SAC ¶ 305. Notably, neither the Pharmaceutical nor the PBM Defendant groups (and therefore no individual Defendant) even attempt to directly argue protection under either of these safe harbors. As set forth in the SAC, this scheme clearly falls outside of these safe harbors, due to the lack of FMV or reasonable compensation, contract rates commonly in excess of the 3% GPO standard and lack of disclosure. 42 U.S.C. § 1320a-7b(b)(3)(A) & 42 U.S.C. § 1320a-7b(b)(3)(E) SAC ¶ 674-88.

C. RELATOR'S ALLEGATIONS ARE SUFFICIENT UNDER RULE 9 (b) FOR EACH DEFENDANT AND EACH TARGETED DRUG.

1) The Standard for Rule 9(b) Sufficiency

As in *Kester*, the Relator has sufficiently pleaded that all Part D submissions for payment for the Defendant drugs in this scheme, from its 2006 start through the present day, violate the AKS and are therefore "false" and ineligible for reimbursement.

However, *Kester* also definitively established in the Second Circuit that Rule 9(b) requires a plaintiff asserting FCA claims under these two subsections (i.e., (A) and (B) of the FCA) to plead the submission of false claims with a high enough degree of particularity that defendants can reasonably "identify particular false claims for payment that were submitted to the government." *US. ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 232 (1st Cir. 2004). The details included in the complaint must fulfill the purposes of Rule 9(b) by both (1) identifying which of the claims that the defendant submitted were "false," and (2) providing a factual basis (as opposed to mere speculation) to support the plaintiffs assertion that claims were actually submitted to a government program. *See Novartis I*, 2014 WL 2324465, at *9-14. Quoting *Wood* in *Kester*, the plaintiff must provide "identifiable record(s) or billing submission(s) they claim to be false or give a single example of when a purportedly false claim was presented for payment by a particular defendant (emphasis added) at a specific time." (emphasis added) *Wood ex rel. United States v. Applied Research Associates, Inc.*, 328 Fed. App'x 744 (2d Cir. 2009).

Applying this rigorous 9(b) standard to this case, the Relator must provide "particular" evidence that specific Part D false claims for each targeted drug can be attributed to both the individual Manufacturer and individual PBM Defendants in the transaction.

However, the *Karvelas* "identification" standard adopted by the Second Circuit "does not mean that an FCA complaint will be dismissed unless the plaintiff identifies by claim number each and every individual claim that it contends was false. In cases where the alleged fraudulent scheme is extensive

and involves "numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct." *Cardiac Devices*, 221 F.R.D. at 333. Pleading the specifics of thousands of claims would be "cumbersome, unwieldy, and would accomplish no purpose." *Id.* at 338. Instead, the complaint must provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue. In cases with extensive schemes, plaintiffs can satisfy this requirement in two ways: (1) providing sufficient identifying information about all the false claims, or (2) providing example false claims. *Kester*, *id.* at 25

As the *Karvelas* court noted, this is not a "checklist of mandatory requirements" for every FCA complaint. 360 F.3d at 233. "Rule 9(b) does not impose a 'one size fits all' list of facts that must be included in every FCA complaint." *Cardiac Devices*, 221 F.R.D. at 337-38. Ultimately, whether a complaint satisfies Rule 9(b) "depends upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." *Wells Fargo*, 2013 WL 5312564, at *16. It is a fact-specific inquiry. *U.S. ex rel Kester*, CV-08196-CM-JCF, 192, 5/29/2014.

2) A Relaxed Pleading Standard is not Required in this Case.

The Second Circuit has stated that Rule 9(b) may be "relaxed" where key facts "are peculiarly within the opposing party's knowledge," and the plaintiff has no access to those facts. *Boykin v. Keycorp*, 521 F.3d 202, 215 (2d Cir. 2008). The potential for a "relaxed standard" might be particularly appropriate in this case, given the non-insider Relator, the well-pleaded specific and systemic alleged scheme, and, most importantly, the ongoing public health and financial harm. However, the Relator avers that his allegations surpass the standard high degree of particularity required by the Court,

without the need for any special consideration.

Most importantly, recent publicly-disclosed Medicare Part D claims data from CMS provides strong support for the Relator's allegations pertaining to all the Defendants and each specific drug targeted in this action.

Due the Defendants' Rule 12 challenge and in the interest of judicial efficiency, the Relator chose to provide this newly-public CMS data in this Opposition Motion, rather than via an amended Complaint. In addition, as is permissible, the Relator will provide to the Court some important supporting information from his prior Complaints in his RI *qui tam* action. As cited in the Manufacturer Defendants' Motion to Dismiss footnote on page 3: "In considering a motion to dismiss, the Court may consider materials referenced in the complaint and matters of public record. *See, e.g., Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 75 (2d Cir. 1998). [M]atters of public record" that may be considered include "pleadings in another action."

First, before discussing the CMS Medicare Part D claims data specifically, Relator seeks to further establish the dominant role of the PBM Defendants in the Medicare Part D program, by providing supporting information from his First Amended Complaint ("RI FAC", filed May 2014) in the RI action.

Second, prior public data from the RI FAC will verify the true concentrated nature of Medicare Part D across geographic regions of the United States. The public data will also verify the massive uniform price inflation of numerous Defendant products in Part D plans across the nation, and the complete lack of Defendant drug price competition among the PBM Defendants.

3) Wide-Ranging Public Data Irrefutably Establishes that the PBM Defendants Submit 80-90% of Claims for Payment for ALL Drugs in Medicare Part D.

Dr. Borzilleri has pleaded (without challenge by either Defendant group or any individual Defendant) that the PBM Defendants directly submit 80-90% or more of all claims for payment for all

drugs in the Medicare Part D program. This factual statement is based upon a wide array of public data. Dr. Borzilleri excluded the details of this public information from his SDNY *qui tam* filings, in the interest of brevity. Far greater data was provided to the RI Court in the Relator's May 2014 filing of his First Amended Complaint (RI FAC). See Separate Exhibit.

As per the RI FAC, in 2012, the top four PBM Defendants (UnitedHealth, Express Scripts, Humana and CVS Health) controlled 76.2% of the Medicare Part D program. Of note, UnitedHealth's share includes its 2015 acquisition of the PBM Catamaran Corp. Due to a long-term PBM partnership with CVS, Defendant Aetna's Part D business is included in CVS' share. Due to a long-term PBM partnership with United Health, Cigna's Part D business is included in United Health's share. RI FAC ¶ 74 and Exhibit 16. In addition, Anthem and other Blue Cross/Blue Shield plans are partnered with Express Scripts and included in the latter's Part D market share.

Public information from other RIC FAC Sections and Exhibits factually establish similar extreme concentration in all aspects of the Medicare D program, including for LIS ("low-income subsidy") beneficiaries, which account for the majority of Part D spending for most extreme-priced "specialty" drugs. RI FAC ¶ 71 and Exhibit 14.

4) Extreme Concentration and Massive Uniform Defendant Drug Price Inflation in Part D Plans Across the Nation.

When Dr. Borzilleri began his investigation of Medicare Part D back in 2013, the planprescriber.com website (administered by a company named eHealth) enabled a comparison of beneficiary costs for individual drugs in PDP Medicare Part D plans in any area across the U.S., by zip code. This analysis was included in the RI FAC, filed in May 2014. Unfortunately, this specific beneficiary cost comparison was no longer available via the website, starting in approximately mid-2014.

In September 2013, Dr. Borzilleri used this database to perform a specific beneficiary cost

analysis for some of the major “specialty” drugs in his *qui tam* cases for PDP Part D plans in three major cities spanning the United States, namely New York, Minneapolis and Los Angeles. From the SDNY case, the analysis included AbbVie’s Humira, Amgen’s Enbrel, Novartis’ Gleevec and Tasigna, as well as Bristol Myer’s Sprycel. From the RI case, the analysis included three multiple sclerosis drugs; Biogen’s Avonex, Teva’s Copaxone, and Pfizer/Serono’s Rebif.

The analysis shockingly showed virtually identical and massive price inflation and beneficiary drug costs for all these “specialty” drugs across all 25-27 available Part D plans in all three major metropolitan areas. RI FAC ¶ 145 and Exhibit 26.

In September 2013, the cost of both AbbVie’s Humira and Amgen’s Enbrel was identical \$25,881 and \$25, 637, respectively, per patient per year for all available plans in all three cities, up from around \$12,000 when Part D began. After ongoing massive inflation driven by the “service fee” scheme, both Humira and Enbrel now carry AWP “list” prices (which are standardly the basis for PBM Defendant “service fee payments) in excess of \$70,000 per Part D patient per year.

In late 2013, the cost of Novartis’ Gleevec, Novartis’ Tasigna and Bristol-Myer’s Sprycel was \$72,783, \$102, 300 and \$102, 329, respectively, per Part D patient per year. Gleevec’s “list” price per patient was in the \$35,000/range per patient when Part D began in 2006. With accelerating fraudulent price increases, Gleevec’s “list” cost per year was in the \$150,000 per patient per year range in 2015, just prior to its early 2016 US patent expiry. Sprycel and Tasigna now have AWP “list” prices in the \$200,000 range per Part D beneficiary, despite wide availability of generic Gleevec.

As per RI FAC Exhibit 26, the same massive uniform inflation also occurred with the multiple sclerosis drugs targeted in the RI *qui tam* case. The Relator’s analysis clearly indicates a complete lack of price competition among Part D plans across the nation for these drugs.

In this analysis, Dr. Borzilleri also took a closer look at the available Part D plans in each geographic region. The PBM Defendant commonly claim that the wide array of Part D plans available

in each area are an indication of healthy competition. However, “true” drug price competition is lacking because the PBM Defendants provide the PBM/specialty pharmacy functions for the majority of plans in virtually ALL geographic regions.

Not surprisingly, in September 2013, in all three of these major cities (New York, Minneapolis and Los Angeles), the top four PBM Defendants (Express Scripts, CVS, United Health and Humana) provided the PBM services for 80-85% of the Part D plans and beneficiaries. The data for Los Angeles in September 2013 is provided in the RI FAC Exhibit 27.

5) Part D Concentration Among the PBM Defendants Now Even More Severe.

According to a May 2018 Kaiser Family Foundation analysis of CMS data, Medicare Part D is now even more concentrated compared to a few years ago. For combined PDP and Medicare Advantage Part D plans across the nation, the market shares in 2018 are: UnitedHealth Group (23%), Humana (18%), CVS Health (14%), Aetna (8%), Express Scripts (6%), Wellcare (4%) and Cigna (3%). Of course, this data understates the PBM and Specialty Pharmacy concentration in Part D due the array of non-transparent partnerships: CVS Health with Aetna and Wellcare; UnitedHealth with Cigna; and Express Scripts with Anthem and other Blue Cross/Blue Shield plans. Adjusting for these arrangements, the PBM/specialty pharmacy horizontal and vertical market share concentration in Medicare Part D is even more extreme: United Health Group (27%), CVS Health (26%), Humana (18%) and Express Scripts (15%), for a combined 86% market share for the four largest PBM Defendants. *Henry J. Kaiser Family Foundation, Data Brief, May 2018.*

6) Recent Publicly-Released CMS Part D Data Definitively Establishes 9 (b) Sufficiency for EACH Defendant & EACH Specific Defendant Drug.

a. Introduction – CMS Part D Database Recently Publicly-Released.

In mid-May 2018, CMS publicly-released a database that, for the first time, provides detailed Part D payment and claims data for each specific drug in the program. The Relator did not become

aware of the new CMS database until after serving the Defendants with the Amended Complaints in his SDNY and RI qui tam cases. For the program years 2012 through 2016, the database provides the following data for the national Part D program for each and every specific drug, including the Defendant products: Total Spending, Total Dosage Units, Total Claims, Total Beneficiaries, Average Spending Per Dosing Unit (weighted), Average Spending per Claim and Average Spending per Beneficiary. The Total Spending and Claims fields for the full compendium of Part D drugs is provided as a Separate Exhibit. The entire searchable database is available and downloadable at the following CMS link: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>

b. CMS Part D Database Provides Specific Claims for Payment for EACH Defendant and EACH Defendant Drug Product.

As patent-protected brand drugs, by definition, every Part D Claim in the CMS database for the individual Defendant drugs can be attributed to each specific Drug Manufacturer Defendant. Each and every Part D prescription/Part D claim for payment (i.e., Prescription Drug Event (PDE) report) for these drugs has been “tainted” by “service fee” kickbacks and/or related Part D Catastrophic “cost-forgiveness” kickbacks (for the Defendant extreme-priced “specialty” drugs).

In addition, with each fraudulently-inflated PDE report required for each drug prescription, each Manufacturer Defendant has directly “caused” a false claim submission by each specific PBM Defendant PDE report. The claims for payment were factually and legally false, due to each Manufacturer Defendant “knowingly” violating its clear FMV responsibility for the payment of “service fees” in Medicare Part D.

With their national dominance of the Part D program irrefutably established, UnitedHealth, CVS, Humana and Express Scripts are directly submitting to CMS about 27%, 26%, 18% and 15%, respectively, of Part D claims for payment for each individual Defendant drug product.

Attached Exhibit 9 provides the 2012-2016 Part D claims for the fourteen Defendant drugs. In

aggregate, Part D claims for all Defendant drugs decreased 4% over the four years, from 19.9 million in 2012 to 19.1 million in 2016. In sharp contrast, overall Part D program claims for payment grew 28% over the four years (driven by strong enrollment gains), from 1.13 billion claims in 2012 to 1.44 billion claims in 2016.

As would be expected, the Part D claims volume is far greater for the widely-used “traditional” Defendant drugs (such as Lantus/Humulin (insulins) and the Pfizer products), compared to smaller population, but high-cost “specialty” drugs (such as the CML cancer drugs, Gleevec, Tasigna and Sprycel). The Part D claims volume for the high-spending arthritis/autoimmune “specialty” therapies, Enbrel and Humira, are intermediate.

On the high-end, annual claims volume for Sanofi’s Lantus (the top-spending Part D drug for several years) were in the 7.8-8.8 million per year range during the four years. On the low end, Bristol-Myers Sprycel’s Part D claims volume rose from only about 14,000 in 2012 to 34,000 in 2016.

c. CMS Data Verifies the “Service Fee” Scheme in Part D for the 2012-2016 Period, and both Before and After.

Based upon detailed analysis of the CMS Part D data, Dr. Borzilleri has verified the “service fee” price collusion scheme for each targeted Defendant drug in the SDNY case.

Nearly identical to his prior SAC analysis, Part D spending for ALL Defendant drugs vastly increased during the 2012-2016 period, driven entirely by severe price increases as volume either plummeted, eroded or slowed for all these “older” competitively-challenged brand drug products. With documented minimal PBM Defendant compensation from “manufacturer rebates”, illegitimate “manufacturer service fees” linked to massive “list” price increases are the only major alternative profit source for the Defendant drugs in the Part D program.

7) Uniform and Massive Part D Defendant Drug Spending Growth - Driven by Fraudulent “Service Fee”-driven Price Increases.

For the Defendant product group in aggregate, Part D spending more than doubled between 2012 and 2016 (+105%), while annual claims filed declined 4% over the period. Overall Part D

spending for the fourteen Defendant drugs grew from \$6.3 billion in 2012 to \$13.0 billion in 2016. The Part D spending for these 14 Defendant drugs accounted for 7.6% of overall Part D spending in 2012, rising to 9.5% in 2016. In contrast, these 14 drugs only accounted for 1.8% of Part D claims volume in 2012, dropping to 1.3% in 2016.

All the Part D spending growth and more for each Defendant drug product was driven entirely by massive price increases. See Attached Exhibit 10. However, adjusting for the expanding Part D enrollment (from 30.9 million in 2012 to 40.4 million in 2016, +31%), the volume deterioration for the Defendant drugs was even more severe, down -27% per Part D enrollee over the four years.

The Part D-specific spending, pricing and volume trends for the individual Defendant drugs are remarkably consistent with Dr. Borzilleri's analysis in the SAC. Each Defendant drug exhibited vast Part D spending growth, driven either entirely or almost entirely via massive price increases.

In Exhibit 11, the Relator provides the summary Part D analysis for 8 of the 14 Defendant drugs in this case. Regarding the top-spending arthritis/autoimmune drugs: annual Part D spending for Amgen's Enbrel more than doubled (+118%) to \$1.6 billion between 2012 and 2016, while Part D claims/enrollee declined -14%; the annual Part D spending for Abbvie's Humira more than tripled (+226%) to \$2.2 billion just in four years, while the claims/enrollee grew only 28%.

Regarding the top-spending insulin therapies: annual Part D spending for Sanofi's Lantus more than doubled (+117%) to \$4.2 billion between 2012 and 2016, while Part D claims/enrolled declined -15%; annual Part D spending for Eli Lilly's Humulin nearly tripled (+160%) to \$733 million over the four years, while Part D claims/enrollee declined -5%.

Among Pfizer's top-selling "traditional" drugs: annual Part D Lyrica spending nearly tripled (+174%) to \$2.1 billion between 2012 and 2016, while claims/enrollee increased only 10%; and most severely, annual Part D spending for Premarin rose 39% over the four years to \$342 million, while Part D claims/enrollee declined -52%.

Finally, regarding the CML cancer therapies: annual Part D spending for Novartis' Gleevec more than doubled (+105%) just in three years to \$1.2 billion in 2015 (before its early 2016 US patent expiry), while Part D claims/enrollee increased only 6%; annual Part D spending for Novartis' Tasigna nearly tripled (+181%) to \$342 million between 2012 and 2016, with price increases accounting for two-thirds of growth; annual Part D spending for Bristol's Sprycel Novartis' Gleevec more than tripled (+226%) to \$322 million between 2012 and 2016, while Part D claims/enrollee increased 81%.

Indicative of the systemic nature of the collusive "service fee" scheme, the Part D prices for All the Defendant drugs (except a couple products) doubled in unison over the four years, regardless of Part D claims volume trends. See Exhibit 12. Consistent with the systemic scheme, for each drug product, each Manufacturer Defendant and each PBM Defendant is secretly and knowingly maximizing the drug's Part D price and its contractually-linked "service fee" profit stream, respectively.

As per public pricing databases, all Manufacturer Defendants has irrefutably instituted additional similar massive US price increases for all the individual drugs driven by the scheme, both before and after the 2012-2016 timeframe of the new CMS Part D database. As such, the 2012-2016 Part D verifies the "service fee" scheme, as well as specific false claims submissions for each Defendant and each targeted drug for each year since the program began in 2006.

8) CMS Data Significantly Increases Dr. Borzilleri's Part D Fraud Estimates for Several Major Defendant Drugs and Overall.

In their Motions to Dismiss, the Defendants challenged the accuracy of Dr. Borzilleri's estimates of the proportion of the US sales for each targeted drug that is attributed to the Medicare Part D program. As a physician, the Relator made his Part D share estimates based upon a clinical review of the demographics for the medical conditions treated by each Defendant drug. For instance, cancer therapies are most commonly used in the elderly; hence the 60% Part D estimate for the Defendant CML drug therapies. With often younger treated patients, Dr. Borzilleri estimated a 35% or lower Part

D share for the other Defendant drug products. Overall, Dr. Borzilleri estimated that 30% of the total Defendant US annual drug sales between 2006 and the present (and the same proportion of fraudulent financial harm) are attributable to Medicare Part D.

However, the actual CMS Part D spending and claims data shows that several of the major Defendant drugs are far more dependent upon Part D for their annual US sales, especially the Defendant insulin therapies, Sanofi's Lantus and Eli Lilly's Humulin. As per the CMS data, Part D accounts for about 65% of the US Lantus and Humulin sales, more than double Dr. Borzilleri's 30% estimate in the SAC. Lantus has been the top-selling single drug in Part D for several recent years. Part D also accounts for about two-thirds of the US sales of Pfizer's top-selling US drug, Lyrica (for neurologic pain), similarly more than double the Relator's estimate in the SAC. See Attached Exhibit 12. Also See SAC ¶¶ 354-94 and its Exhibit 12.

Overall, the 2012-2016 CMS database indicates that Part D accounts for about 40% of overall annual Defendant US drug sales, one-third more than the Relator's prior 30% SAC estimate.

Just for illustration, incorrectly using 2012 drug prices as a legitimate baseline, all the Part D spending growth and about 50% of 2016 Part D spending (\$5.8 billion of \$13 billion) for the aggregate Defendant products has been fraudulently-driven by "service-fee"-driven price increases. Using 2012 baseline pricing, Dr. Borzilleri estimates aggregate cumulative Part D fraudulent sales for the Defendant products at about \$16 billion. See Attached Exhibits 13 and 14. Of course, these illustrations greatly underestimate the actual Part D fraud, since 2012 Defendant drug prices were already severely and fraudulently elevated after prior years of massive price increases.

9) With this CMS Claims data, Relator has also Sufficiently Pleaded Rule 9 (b) Regarding ALL other Defendant Part D Submissions for Payment.

With this Defendant and product-specific Part D claims (i.e., PDE) data, the Relator also

exceeds the Rule 9 (b) requirements pertaining to all other Part D submissions for payment, including Direct and Indirect Remuneration (DIR) reports, annual bid submissions and the data required for Catastrophic reconciliation. By definition, if a given PBM Defendant is submitting PDE reports to CMS for each Defendant product, the PBM Defendant is also required to provide the other submissions (which are also required for payment) to CMS, with information specific to each drug product. All of these various Part D submissions for payment are interrelated and linked to the central PDE report required with each and every Part D prescription.

10) The PDE Reports Include Payment Information specific to Dr. Borzilleri's Severe Catastrophic Cost-Sharing Allegations.

In Medicare the plan sponsor 15% Catastrophic cost-sharing requirement is the primary mechanism to incentivize legitimate price negotiations between Part D plan sponsors (i.e., primarily the PBM Defendants themselves) and drug manufacturers regarding extreme-priced specialty drugs. "Specialty" drug spending has been the primary driver of US pharmaceutical spending in both Part D and private insurance market over the past decade. SAC ¶¶ 159, 244.

The PDE report filed with each Part D program has essential financial payment information for the Catastrophic Subsidy. In the PDE report, the plan sponsor must report to CMS the amount of drug cost above the modest annual Catastrophic spending limit in a single field named "Gross Drug Costs Above Out-of-Pocket Threshold (GDCA). See Exhibit 36 of the RI FAC for a detailed discussion of the various PDE submission fields.

To the extent they are submitting amounts "forgiven" by the Manufacturer Defendants in the GDCA field, the PBM Defendants are filing factually and legally false claims for payment. As such, the specific CMS PDE data also provides specific claims data pertaining to Dr. Borzilleri's Catastrophic fraud allegations for each Defendant and each specific drug product. While the PBM Defendants must also provide additional data to CMS for end-of-year Catastrophic reconciliation, the details of these

payment submission requirements are undisclosed beyond CMS and the Defendants themselves.

Dr. Borzilleri's analysis of the June 2015 MedPAC report in the SAC regarding Part D Catastrophic reconciliation verified its rising role in the fraudulent scheme in recent years, as "specialty" prices have accelerated. Despite vastly under-forecasting annual plan Catastrophic spending (\$6 billion just for 2013) and their related 15% cost-sharing requirements (more than \$900 million for 2013), the dominant PBM Defendants had no financial dislocation. SAC ¶¶ 395-444. Of note, this MedPAC report appears to be the only specific public disclosure of Part D Catastrophic reconciliation data since the program began in 2006. Further investigation of the highly-consequential Catastrophic program is not possible without access to Defendant and/or CMS data.

11) Group Pleading is Appropriate for this Uniform, Systemic and National Scheme.

Group pleading is appropriate in this vast systemic scheme in which all the Defendants are "alleged to have engaged in precisely the same conduct." *U.S. ex rel Swoben v. United Health Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016). As is the pattern throughout their motions, the Defendants falsely state that Dr. Borzilleri's allegations are vague and provide no "specific" notice to the Defendant groups or any individual Defendant.

In reality, each and every Defendant has been given notice of highly specific fraud allegations: regarding the specific product/s, the specific claims (all Part D claims), the specific timeframe (2006 to the present, and ongoing) and the specific financial path (fraudulent "service fee" and "catastrophic cost-sharing). Furthermore, the scheme is centralized, national and systemic in nature. The role and fraudulent actions of each Manufacturer and PBM Defendant in the scheme are superimposable, respectively..

As per *Perry* in this Court, "nothing in Rule 8 prohibits collectively referring to multiple defendants where the complaint alerts defendants that identical claims are asserted against each Defendant." *City of Perry, Iowa v. Procter & Gamble, et.al.* 15-cv-8051 (JMF), SDNY, May 19, 2016, referencing *Hudak v. Berkley Grp., Inc.*, No. 13-CV-89 (WWE), 2014 WL 354676, at *4 (D. Conn. Jan

23, 2014).

More recently, the Ninth Circuit Court of Appeals applied *Swoben* in reversing the dismissal of *U.S. ex rel. Silingo v. Wellpoint, Inc.*, based upon group pleading. “In the taxonomy of conspiracy theories, a “chain conspiracy” is one in which “each person is responsible for a distinct act within the overall plan,” while a “wheel conspiracy” involves “a single member or group (the ‘hub’) separately agreeing with two or more other members or groups (the ‘spokes’).” Broadly speaking, if a fraudulent scheme resembles a chain conspiracy, then a complaint must separately identify which defendant was responsible for what distinct part of the plan. By contrast, if a fraudulent scheme resembles a wheel conspiracy, then any parallel actions of the ‘spokes’ can be addressed by collective allegations.” *U.S. ex rel. Silingo v. Wellpoint, Inc.*, U.S. Court Appeals, 9th Circuit, 8:13-cv-01348-FMO-JC, July 9, 2018.

Notably, both *Swoben* and *Silingo* pertained to the centralized and systemic Medicare Advantage (MA) businesses (by definition, each MA plan includes a Medicare Part D benefit) of United Health and Anthem/Wellpoint. The pharmaceutical/PBM conspiracy in this case is a classic “wheel conspiracy” amenable to group pleading, although it appears unrequired given available specific Medicare Part D claims data.

12) PBM Defendant “Services” are Standardized and Minimally-Disclosed.

The Defendants also argue that the Relator’s allegations fail 9(b) because he cannot provide particular “services” and “service fee” payments for each Defendant and each targeted drug. Again, the Defendants are hoping their extensive veil of secrecy will protect them from investigation. Given the systemic, national and carefully concealed nature of this scheme, alleging specific fraudulent “services” and associated payments for each drug would not be practical or necessary.

As we have said, there is nothing subtle about the massive nature and amount of kickbacks in this case. The PBM Defendants are typically getting huge increases in “service fee” payments based

upon national “percent of revenue” contracts with pharmaceutical companies, while the nationwide clinical use of the drug is eroding, stagnating or moderating.

Furthermore, Relator’s alleges based upon extensive investigation that the “services” offered for the “old” blockbuster drugs are standardized among the PBM Defendants, with no indication of any increased service needs or new services being provided for the drugs or the patients treated with them. SAC ¶ 98. Again, the Defendants themselves make no arguments regarding new services or increased service needs for the Defendant drugs in their Motions to Dismiss.

See Exhibit 55 of the Relator’s RI FAC for a nearly identical “list” of specialty pharmacy services (from their own websites), provided by Express Scripts, CVS Health and Catamaran (now part of UnitedHealth). In the SAC ¶ 34, Relator also provides the list of standard PBM services provided by all the PBM Defendants; this list of potential services has not changed in the decade-plus since uniform massive U.S. brand drug price inflation began at the start of Medicare Part .D.

In addition, the Defendants themselves commonly do not provide details regarding specific “services” and “fees” in their own manufacturer/PBM contracts. At the October 2013, FMV of BFSF conference, John Shakow, a leading FMV legal expert for the pharmaceutical industry stated: “up to a few years ago few contracts gave specifics regarding fees” and this “could be trouble.” SAC ¶ 483. A Relator cannot expected to allege specific “service” fraud for each product if the Defendants are not commonly itemizing the “services” themselves.

Finally, the Relator did extensive interviews with 20-25 physician experts regarding “services” provided by the PBM Defendants for the “complex” patients treated with “specialty” arthritis, cancer and multiple sclerosis drugs. Uniformly the physicians stated that the PBM Defendants provided minimal services, especially for most patients being chronically-treated with any of these Defendant drugs. SAC ¶ ¶ 714-720. The physician Relator avers that conversations with almost any and all US physicians will yield similar results regarding the limited clinical role of the PBM Defendants for the

majority of patients.

13) Relator has Supplied the Court with Clear and Specific Fair Market Value (FMV) Benchmarks.

The Defendants argue that the Relator has not provided the court with a “particular” and specific “benchmark” to enable legitimate FMV determinations for the alleged fraudulent “service fee” payments for each targeted drug. The Defendants’ arguments lack any merit. In fact, in the SAC the Relator has provided the Court with the first detailed analysis of FMV in any *qui tam* action. SAC ¶¶ 623-673. In addition, Dr. Borzilleri has provided an unprecedented array of specific first-hand “insider” FMV commentary corroborating the scheme, from his attendance at a one-of-a-kind industry conference. The SAC also included the names and contact information for these “insider” and “expert” witnesses. SAC ¶¶ 452-489.

The SAC includes three distinct “benchmarks” for evaluating the arms’-length appropriateness of the Manufacturer Defendant “service fee” payment to the PBM Defendants. However, given the massive increases in “fee” payments relative to legitimate utilization-driven “services”, the Relator avers that FMV determination will not be a complex endeavor in most instances in an investigation of these allegations.

The primary FMV “benchmark” for each Defendant product is simply the level and rate of legitimate “service fee” payments for the same product before the massive price increases ensued. Central to the cases, the Relator considers the vast majority of price increases for the targeted products to be fraudulent. Severe competition and legitimate negotiation by the dominant PBM Defendants would have prevented or severely-limited Part D price increases, with price declines likely for the eroding-use drug products. This logical “baseline benchmark” is the basis for the Relator’s detailed direct “service fee” and US sales financial fraud estimates in this case (and the Part D-specific fraud estimates in the prior section of this Motion). SAC ¶¶ 386-394. The financial fraud estimates in this

case are enormous, for each drug product and in aggregate, due to the long-standing nature of the scheme and the compounding impact of the massive Defendant product price increases.

The other major FMV “benchmark” discussed in detail in the SAC is the “Cost-Plus” FMV methodology, the standard actuarial practice for valuing “service” payments across all industries. In the “Cost-Plus” approach, a “service fee” payment is based upon a straightforward calculation of the cost of providing the service (staff, man-hours, needed resources and the volume of a required service), plus an appropriate profit margin. As per the SAC, despite being routinely recommended by their own closely-affiliated legal and consulting experts, the Manufacturer and PBM Defendants are not using the Cost-Plus FMV methodology in virtually all their “service fee” contractual arrangements. Rather they are using “Market Approach” “percent of revenue” arrangements, linked to “list” prices, in virtually all instances. The Defendants notably do not directly challenge the Relator regarding this central contention of the scheme in their Motions to Dismiss. While CMS purposely leave the FMV methodology choice for BFSFs up to the drug manufacturers, this flexibility does not lessen the PBM Defendants clear and specific legal liability.

Finally, the Relator provides a “real-world” “benchmark” for FMV, with his discussion of Diplomat Pharmacy, the only public independent specialty pharmacy. SAC ¶¶ 668-673. Despite providing extensive “services” almost exclusively for “complex” “specialty” drug-treated patients, including many Part D beneficiaries, Diplomat receives minimal “service fee” compensation from drug manufacturers. Diplomat’s lack of significant “service fee” compensation reflects their small market share and lack of negotiating leverage relative to the dominant PBM Defendants. The PBM Defendants speciously argue that Diplomat Pharmacy has no relevance to them because it is “not a PBM” and offers a different “scope and type of services”. In reality, Diplomat receiving minimal “service fee” compensation for supporting the very same “complex” patients that yield massive “fee” profit for the PBM Defendants.

Despite the lack of significant “service fee” payments, Diplomat has been a successful public company. However, not surprisingly, Diplomat’s profit margin (in the 1-2% of sales range) are only about 25% of those for Express Scripts (5-6% of sales range), the only standalone public PBM. Notably, the profit margins of Diplomat Pharmacy are comparable to those of the three dominant public drug wholesalers (Cardinal, Amerisource and McKesson). *SEC filings for Cardinal, Amerisource and McKesson*. The drug wholesalers also provide extensive “services” to drug manufacturers. However, drug wholesalers do not control access to drug formularies, which provides the PBM Defendants with their unique “rent-seeking” abusive fee opportunities.

On a final note, a pending case in the First Circuit provides a valuable precedent regarding the FMV allegation requirements to surpass a Motion to Dismiss. In *Bawduniak v. Biogen IDEC, Inc.*, the plaintiff alleges kickback payments in excess of FMV to physicians. Despite minimal discussion of FMV nor any “benchmarks” in the Complaint, the case survived a motion to dismiss and is currently in discovery. *U.S. ex rel. Michael Bawduniak v. Biogen IDEC, Inc.*, D.C. MA (2012.) In contrast, this case provides unprecedented detailed discussion of FMV and very specific “benchmarks”.

14) The Relator has Sufficiently Pleaded Scienter.

Both Defendant groups argue that Dr. Borzilleri fails to plead scienter. But Rule 9(b) allows scienter to be alleged “generally.” FED. R. Civ. P. 9(b); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 339 (2004). In order to be held liable under the FCA, the defendant must have acted “knowingly,” which the statute defines as “ha[ving] actual knowledge of the information,” “act[ing] in deliberate ignorance of the truth or falsity of the information,” or “act[ing] in reckless disregard of the truth or falsity of the information;” the FCA “require[s] no proof of specific intent to defraud.” 31U.S.C. §3729(b)(1).

In their motions, the Defendants primarily reference a recent SDNY *Grubea* opinion. *U.S. ex*

rel. Grubea v. Rosicki, Rosicki & Assocs., P.C., 318 F. Supp. 3d 680 (S.D.N.Y. 2018). In the case, regarding mortgages, the Court had previously ruled that the plaintiff's allegations "were based on little more than conjecture". Furthermore, the plaintiff failed to sufficiently plead scienter despite being given numerous opportunities by the Court, including Complaint amendments and oral argument.

In sharp contrast, the "knowing", "intentional" and "willful" nature of this current case and scheme has been pleaded with considerable specificity and detail. The Relator's Complaint alleges that the "Manufacturer and PBM Defendants entered into an intentional, secretive and fraudulent price inflation scheme, based upon "service fee" contracts, in gross violation of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS)". SAC ¶ 28. Furthermore, the PBM Defendants must "'expressly certify'" compliance with the Anti-Kickback Statute (AKS) and the False Claim Act (FCA) to participate in Medicare Part D. SAC ¶ 88.

Assuming these allegations true at present, it would seem inconceivable that the Defendant senior executives in this centralized scheme (especially the CEO and CFO of the PBM Defendants who must "expressly certify" in Part D) would not be "knowing" of the massive "service fee" payments that account for large proportion, if not the majority, of their overall corporate profits. SAC ¶ 168.

15) Dr. Borzilleri has Sufficiently Pleaded a False Claim Act Conspiracy.

To state a claim for conspiracy under 31 U.S.C. § 3729(a)(1)(C), a relator must allege that: (1) the defendant conspired with others to get a false claim paid by the government, (2) the conspirators performed an act "to effect the object of the conspiracy," and (3) the government suffered damages as a result of the false claim. All of this must be pleaded with particularity under the heightened pleading requirements of Rule 9(b). *See id.* However, conspiracy claims...do not require proof of the submission of a false claim - no conspiracy needs to succeed in order to be actionable. Thus, the Relator was not required to plead the submission of a false claim with particularity in order for his... conspiracy claims

to survive a Rule 9(b) challenge. *US. ex rel. Kester v. Novartis Pharm. Corp.*, 11 Civ. 8196 (CM), 2014 WL 2619014 (S.D.N.Y. June 10, 2014)

The “overt act” consisted of the Manufacturer and PBM Defendants’ (both collectively and among individual Defendants) contractual “agreements” linking “service fee” payments illegally to massive “list” prices, rather than legitimate utilization as required by statute and law. Furthermore, the Defendants have taken extraordinary measures to conceal their conspiracy from detection. They have also obviously failed to release “material facts” by not disclosing to the SEC the central role of “service fees” in US drug pricing and their profits. SAC ¶ 64.

16) Relator’s State FCA Fraud Allegations are also Sufficiently Pleaded.

The Defendants also argue that the Relator’s state law allegations fail to surpass Rule 12(b)(6) and 9(b) pleading standards. Since the Relator has sufficiently surpassed these standards regarding federal claims, and all states have similar FCA statutes, the Defendants’ state challenges should also be dismissed, in their entirety.

D. SAC’S “TRADITIONAL” DEFENDANT DRUGS SURPASS THE FIRST-TO-FILE BAR AND RELATOR WILL REQUEST EVIDENTIARY HEARINGS REGARDING SDNY “SPECIALTY” DRUGS.

1) Dr. Borzilleri’s Ongoing Investigation: Marked Expansion of the Systemic Scheme.

As a physician and professional healthcare equity analyst, Dr. Borzilleri long knew that the “service fee” model arose from the legitimate and significant “support” needs provided by dedicated specialty pharmacies for truly complex, severely ill “specialty” patients, such as those with hemophilia, pulmonary hypertension and rare orphan diseases. These types of patients often require frequent intravenous injections and considerable pharmacy/nursing support. The PBM Defendants then came to dominate the specialty pharmacy market by acquiring all the major prior independent specialty

pharmacies, not surprisingly right around when Part D began.

In the RI case, Dr. Borzilleri alleged that the PBM Defendants then fraudulently employed the price-driven “service fee” model across the “specialty” drug landscape, especially for long-marketed self-administered Part D “specialty” therapies, with limited legitimate “support” needs. The clandestine PBM Defendant compensation model shift (away from manufacturer rebates to fees) was driven by the poorly-known financial incentives pertaining to manufacturer rebates and BFSFs in the new Medicare Part D program, as well as its lack of regulatory limits on brand drug price increases (in sharp contrast to Medicaid and other federal drug programs). This same secretive profit model has been employed across US private drug insurance market, leading to widespread massive US “specialty” drug price increases. While Dr. Borzilleri mentioned other “specialty” drugs in the RI case, he specifically targeted MS therapies because the evidence of abuse was most severe in early 2014.

After the RI filing, Dr. Borzilleri began uncovering clear evidence that the “service fee” scheme was vastly expanding in several ways. First, Dr. Borzilleri began tracking accelerating anti-competitive price increases in other major US “specialty” drug categories, especially the arthritis/autoimmune therapies (dominated by Amgen’s Enbrel and Abbvie’s Humira) and the CML cancer category (especially Novartis’ Gleevec).

Second, and even more disturbing, in late 2014 Dr. Borzilleri unexpectedly began uncovering evidence that the fraudulent “service fee” scheme was being employed far beyond the narrow “specialty” drug market and potentially across the broader “traditional” US brand drug pharmaceutical landscape.

As per wide-ranging public disclosures, “specialty” drugs account for only 1-2% of US prescription volume, but now account for about 35% of US drug spending and most US drug spending growth. *See many Defendant, as well as pharmaceutical and PBM industry public disclosures.*

Traditional brand and generic drugs account for 98-99% of prescription volume in the country.

Due to massive patent expirations over the past 15 years, generic prescriptions account for more than 90% of this volume now. At the time of the RI filing, Dr. Borzilleri did not even imagine a significant role for PBM Defendant “service fees” with “traditional” drugs since they are typically just picked up at the pharmacy or mailed to patients. To the extent pricing abuse was occurring with “traditional” drugs, Dr. Borzilleri presumed it was related to “rebate”, and/or other long-discussed potential abuses.

Dr. Borzilleri’s new unforeseen discovery regarding “traditional” drugs began with a routine November 2014 investor meeting at a conference with James Schoeneck, the now former CEO of Depomed, a mid-capitalization pharmaceutical company. After a routine question regarding the company’s recent severe price increases for Gralise, its “traditional” pill therapy for neurologic pain, Mr. Schoeneck volunteered clear evidence of broad use of the “service fee” scheme with “traditional” drugs. Depomed’s drug, Gralise, competes directly with Defendant Pfizer’s top-selling US drug, Lyrica. SAC ¶¶ 448-54.

As was Dr. Borzilleri’s standard practice with his ongoing investigation, he communicated his disturbing new findings to the RI DOJ. The RI DOJ never asked for the name of the executive or his contact information.

2) SDNY “Traditional” Defendant Drugs Surpass the First-to-File Bar.

As set forth in *Wood* and related cases, the primary purpose of the first-to-file bar is to provide proper notice to the government and avoid “duplicative claims that “do not help reduce fraud or return funds to the federal fisc...”. As the Second Circuit stated, the first-filed complaint ensures that the Government would be equipped to investigate the fraud alleged in the later-filed complaint...” *Wood*, 899, F. 3d at 169. This Court put it even more succinctly: “notice to the Government is key.” *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 792 (S.D.N.Y. 2017). See 31 U.S.C. § 3730(b)(5), U.S.C. § 3730(e)(4).

However, as discussed above, the “traditional” drugs in this SDNY action are not barred by the Relator’s prior RI filing for a straightforward reason. Prior to his surprising investigative findings after the RI filing, the Relator himself had no idea that the “service fee” scheme was being employed outside the narrow and small volume “specialty” drug segment and into the vastly-larger “traditional” US marketplace. Since the Relator himself had no knowledge of this vast expansion of the scheme, he could not possibly have given “notice” to the government to investigate in his prior RI filing.

Similar to the federal FCA, the allegations against the “traditional” Defendant drugs in the SDNY case surpass all relevant first-to-file state FCA requirements.³

Regardless of first-to-file issues, Dr. Borzilleri is the original source of the investigative information in both of his *qui tam* actions. Dr. Borzilleri further gave prompt notice to the RI DOJ of his initial “direct and independent knowledge”, regarding the employment of the systemic “service fee” scheme in the broad US “traditional” pharmaceutical market, nine months prior to filing his second *qui tam* action in SDNY.

3) Dr. Borzilleri’s RI Action ONLY Targets the Narrow US “Specialty” Drug Market.

In their Motions to Dismiss, the Defendants catalog some references from the Relator’s RI Complaint to suggest prior notice to the government for the wide-ranging scheme and all targeted drugs

³ Cal. Gov’t Code § 12652(c)(10); Colo. Rev. Stat. § 25.5-4-306(2)(e); Conn. Gen. Stat. § 4- 277(d); D.C. Code § 2-381.03(b)(6); Del. Code Ann. tit. 6, § 1203(b)(5); Fla. Stat. § 68.083(7); Ga. Code § 49-4-168.2(c)(6); Haw. Rev. Stat. § 661-25(e); 740 Ill. Comp. Stat. § 175/4(b)(5); Ind. Code § 5-11-5.5-4(g); Iowa Code § 685.3(2)(e); La. Stat. Ann. § 46:439.2(A)(3); Md. Code Ann., Gen. Provis. § 8-104(a)(8); Mass. Gen. Laws ch. 12, § 5C(6); Mich. Comp. Laws § 400.610a(4); Minn. Stat. § 15C.05(b); Mont. Code Ann. § 17-8-406(7); N.H. Rev. Stat. Ann. § 167:61-c(II)(b); Nev. Rev. Stat. § 357.080(2); N.J. Stat. Ann. § 2A:32C-5(i); N.M. Stat. Ann. § 44-9-5(E); N.Y. State Fin. Law § 190(4); N.C. Gen. Stat. § 1-608(4); Okla. Stat. tit. 63, § 5053.2(5); 9 R.I. Gen. Laws § 9-1.1-4(b)(5); Tenn. Code Ann. § 71-5-183(b)(5); Tex. Hum. Res. Code Ann. § 36.106; Va. Code Ann. § 8.01-216.5(E); Wash. Rev. Code § 74.66.050(5); Wis. Stat. § 20.931(5)(e) (repealed July 13, 2015).

in the SDNY action. However, a closer look reveals that all the RI FAC references pertain only to “specialty” drugs. The term “traditional” drug does not even appear in the RI Complaints.

As per the Defendants’ reference to RI FAC ¶ 285: “The Relator sees significant signs of anticompetitive behavior in other specialty (emphasis added) drug therapeutic categories, including treatments for pulmonary hypertension, infectious disease, rheumatoid arthritis, diabetes (emphasis added) and cancer.” *See PhMD, Section I.*

Pertaining to diabetes and the SDNY case, the word “insulin” does not appear even a single time in the RI FAC. Again, that is the case for a clear reason. Because insulin has been on the market for many decades, the PBM Defendants categorize it as a “traditional” drug in their drug formularies and public reports. *Express Scripts Drug Trend Reports, all years.*

The Relator did not even fathom, prior to ongoing investigation after the RI filing, that insulins were involved in the “service fee” scheme. The “specialty” diabetes drugs indicated by the RI Complaint are the newer Glucagon-Like-Peptide-1 (GLP-1) agonists that have reached the US market just in the past decade. See RI FAC Exhibit 26.

Finally, the Defendants allege that simply stating the names of the SDNY Defendants put the government on notice of the far broader fraudulent scheme in the SDNY complaint. In the overall US market and Medicare Part D, all the Manufacturer Defendants sell both “specialty” and “traditional” drugs. As such, the naming of the SDNY Defendants in the RI Complaints has no bearing on the specific SDNY “traditional” drug product allegations.

CONCLUSION

Relator, John R. Borzilleri, M.D. respectfully requests that the Court deny both the Pharmaceutical Manufacturer and PBM Defendant Motions to Dismiss, in their entirety. The Relator plans to file a motion for an evidentiary hearing regarding first-to-file issues, especially pertaining to “specialty” drug in the SDNY case.

November 19, 2018

Respectfully submitted,

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Exhibit 1

This drug is defying a rare form of leukemia — and it keeps getting pricier

By Carolyn Y. Johnson

March 9, 2016



Marge Halford of Taylorville, Ill., holding the last of her Gleevec pills for the month. (Isaac Smith/For the Washington Post)

When the drug company Novartis launched its breakthrough cancer medicine, Gleevec, in 2001, the list price was \$26,400 a year. The company's chief executive acknowledged it was expensive, calling it an "uphill battle to win understanding for our decision."

Today, that hill is a mountain. Since Gleevec was approved to treat a rare form of leukemia, similar drugs have come on the market — and the U.S. wholesale list price for a year's supply of that little orange pill has soared to more than \$120,000.

The pharmaceutical industry has insisted that the competitive market controls the costs of medications and that the overnight price hikes that have sparked public outrage and congressional investigations are outliers.

But Gleevec's arc shows that even for a medicine that is the fruit of years of research — a prime example of what drug companies aspire to do — the market can fail. Instead of rising in sudden surges, Gleevec's price crept inexplicably upward each year. When powerful second-generation drugs began to

give physicians choices, Novartis raised the price even faster.

This price inflation helped turn Gleevec, a drug that was not supposed to make much money, into the biggest drug by revenue at one of the world's largest drug companies.

"They say market forces set the prices reasonably, but there are no market forces," said Hagop Kantarjian, chairman of the leukemia department at the University of Texas MD Anderson Cancer Center. "The drug companies are so few, they have carved out oligopolies."

In a normal competitive market, prices influence what people buy — but not in health care. Brand-name drugs generally do not compete on price, because physicians and patients rarely pick treatments based on price — and often are not even aware what the prices are. Drugs each have a different benefit and side-effect profile, and doctors pick the drug they think will work best for their patients. What competition does take place occurs in secret negotiations between drugmakers and middlemen.

Which all points to a very strange fact about drug prices: They do not really exist. List prices are nothing more than a starting point for bargaining between drugmakers and the companies that provide prescription drug benefits. The cost for patients varies widely, influenced by discounts and rebates developed behind closed doors and applied in secret.

To track how Gleevec became a multibillion-dollar drug, The Washington Post used the median amount paid by privately insured patients and their health plans before discounts and rebates, an analysis prepared by health services researcher Stacie Dusetzina of the University of North Carolina at Chapel Hill using data from Truven Health Analytics.



Marge Halford at her home in Taylorville, Ill. (Isaac Smith/For the Washington Post)

One of those patients is Marge Halford, a 65-year-old nurse who lives in Taylorville, Ill., and has been taking Gleevec since 2009. The amount patients pay can vary widely depending on their insurance plan, and Halford's cost started at \$500 a month, but within a year the drug she needs to stay alive was costing her more than \$800. She and her husband considered divorce, hoping her single income was low enough to qualify for financial aid. But when they did the math, she still made too much money to get help.

About a year ago, sick of watching a whole paycheck disappear to pay for her pills every month and hoping to reduce the nausea and vomiting that are a side effect of the drug, Halford persuaded her doctor to put her on a cheaper, lower dose of Gleevec. Halford likes to say she is blessed — her kids are grown, her house is paid for and she has been able to find the money to pay for her medicine. But she is worried about retirement.

"The drug is so stinking expensive, and I don't know what will happen," Halford said. "The drug is a godsend. The price is not."

A risky start

The odds were stacked against Gleevec from the beginning.

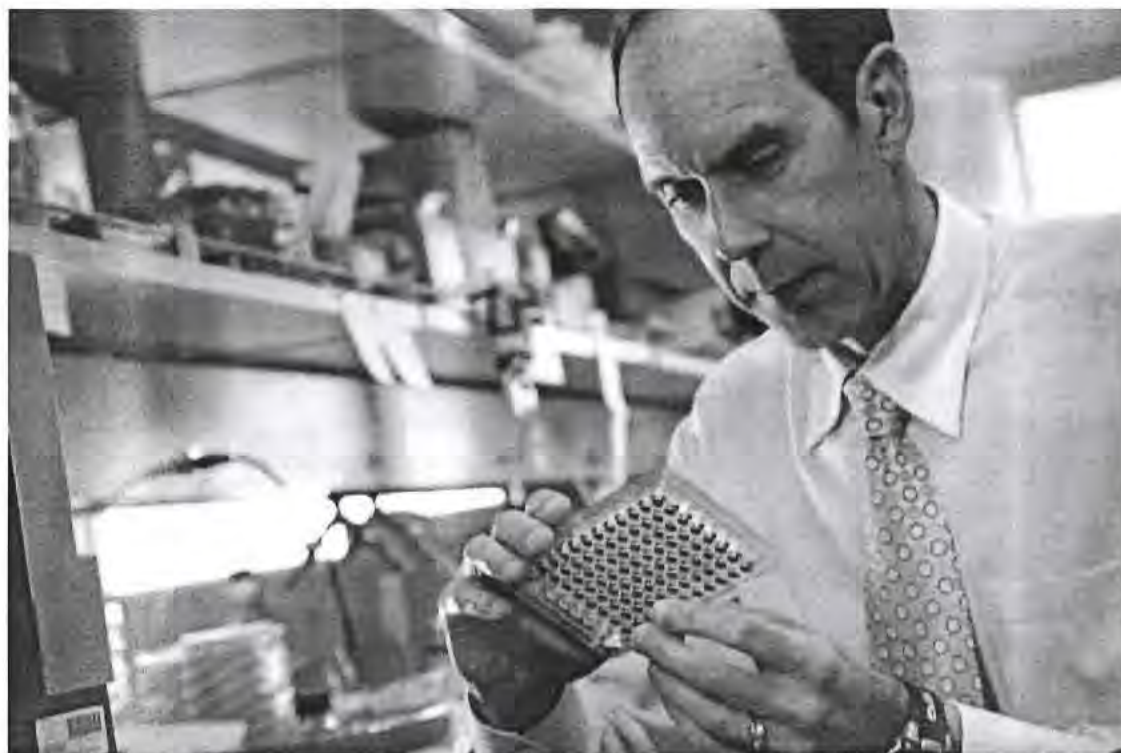
The disease it treats, chronic myeloid leukemia, afflicted a small number of people — about 4,500 new patients each year in the United States. If it worked — a big if in drug development — the numbers suggested it was unlikely to be a big moneymaker.

For major drug companies, a benchmark of success is a blockbuster drug that brings in at least \$1 billion in sales each year. Scientists who worked on Gleevec's early development recalled marketing projections that suggested the drug would peak at \$100 million in annual sales.

"It looked pretty depressing," said Nick Lydon, a scientist who headed the team that developed imatinib — the generic name for Gleevec — in the 1990s. Ciba-Geigy, the company he worked for, was not all that excited about the market for a rare leukemia treatment that used a risky new approach to attack cancer cells, but it decided to take the gamble.

Lydon teamed with Brian Druker, an oncologist and researcher at Oregon Health and Science University who tested the drug on bone marrow samples from his patients.

In 1996, Ciba-Geigy became Novartis in a merger. Two years later, Druker led the first test of the drug in people.



Brian Druker, director of the Knight Cancer Institute at Oregon Health and Science University.
(Michael McDermott/PR Newswire)

The results were dramatic: Many patients experienced a massive reduction in the number of white blood cells, and in some cases cancer cells disappeared altogether.

Under pressure from Druker and patients, Novartis sped up development of imatinib, and in 2001 the drug earned the fastest U.S. cancer drug approval to that date.

That left the company wrestling with the delicate issue of price.

Novartis took “a huge financial risk by scaling up production to a multimillion-dollar level for a drug in early-stage development targeting a small market,” spokesman Eric Althoff said in an email.

In his 2003 book, “Magic Cancer Bullet: How a Tiny Orange Pill is Rewriting Medical History,” Novartis’s then-chief executive, Daniel Vasella, laid out the price considerations: the small patient population, the price of the existing treatment and the need to recoup the significant research and development costs of getting a drug to market. Based on those factors, the company settled on \$2,200 a month.

“The result for Novartis: It would not stand to make a large financial gain,” Vasella wrote.

By the end of 2003, Gleevec was Novartis’s No. 2 drug, a billion-dollar blockbuster. Last year, it generated \$4.7 billion in worldwide revenue, more than half of that from the United States.

The price rises

Novartis nudged Gleevec's price higher slowly, at first. These were not the sudden, steep surges that have been an easy target for politicians but subtle increases that have gone unchecked throughout the industry.

The median amount paid by patients and insurers stayed stable for the first four years, according to Dusetzina's analysis, hovering around \$3,200 a month (in 2014 dollars adjusted for the inflation of medical products). Starting in 2005, the cost ticked upward gradually, at an average of 5 percent above inflation each year, to \$3,757 a month in 2007.

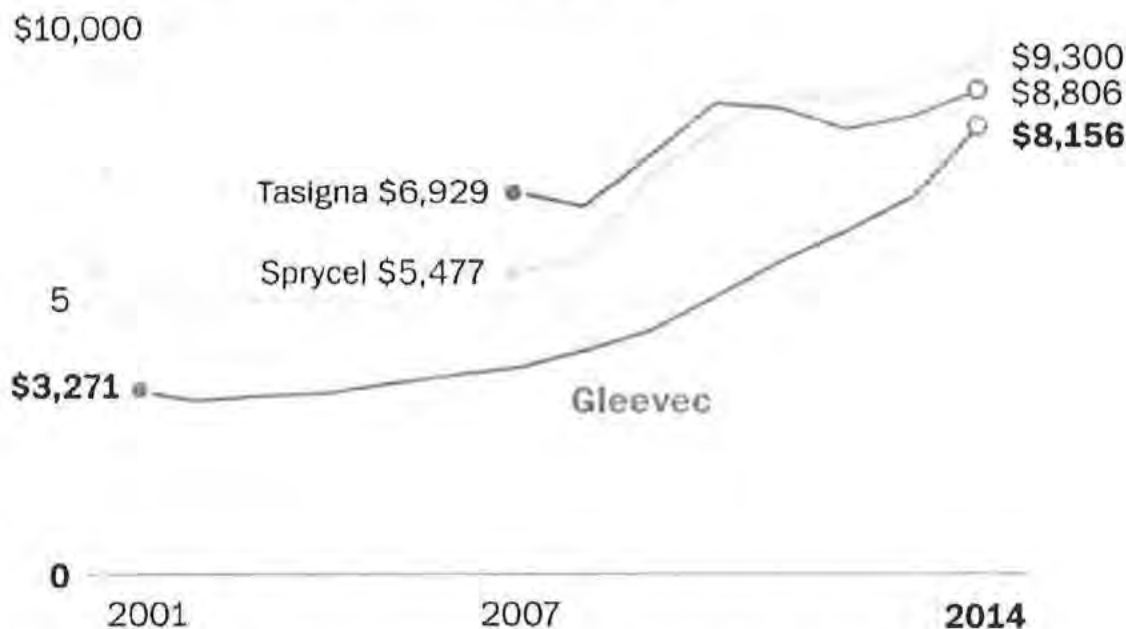
Such incremental drug price hikes have become a defining part of pharmaceutical companies' bottom lines, said Richard Evans, an analyst at SSR Health, an investment research firm. Evans likes to compare drug prices to a balloon without a tether. For the two decades preceding 2013, Evans estimates, annual price hikes of about 4 percent above inflation fueled pharmaceutical growth.

"That is unprecedented," Evans said. "I can't think of any other industry that has had that real pricing power. Structurally, that inflation has obviously been hugely important for the industry."

Rising drug prices

New drugs treating chronic myeloid leukemia were introduced at prices higher than Gleevec's. Their prices have gradually risen since, and Gleevec's price has increased at a greater clip.

Company: ● Novartis ● Bristol-Myers Squibb



Note: Amounts reflect median monthly payments by patients and their private insurance plans. They do not include rebates and discounts. Amounts are adjusted for inflation to 2014 levels.

Source: Truven Health Analytics data analyzed by Stacie Dusetzina

KEVIN UHRMACHER/THE WASHINGTON POST

Competition enters

In 2006, Bristol-Myers Squibb earned approval for a drug called Sprycel, or dasatinib, that would work in the same targeted way as Gleevec. Novartis developed a second-generation drug, too, called Tasigna, or nilotinib, that was approved in 2007.

As is typical, the new drugs entered the market above the price for the existing drug. The drugs were initially approved for a smaller patient population and offered a clear benefit over the existing treatment — people for whom Gleevec had failed now had another option. According to Dusetzina's data, Gleevec's median cost was \$3,757 a month in 2007, compared with \$5,477 for Sprycel and \$6,929 for Tasigna.

The two drugs seemed to exert a magnetic pull on Gleevec's price — upward.

According to Dusetzina's analysis, the amount insurers and patients together paid for Gleevec

accelerated right around the time its competitors were being introduced, as if it were playing catch-up. In 2008, the median cost jumped by 8 percent to \$4,063 a month.

In 2010, Gleevec gained more direct competition from both drugs, which were approved for newly diagnosed leukemia patients. At this point, Gleevec's price increases veered quickly into larger hikes that brought it closer to its competitors. An era of price increases of 10 percent or higher began.

Sales revenue at Novartis followed suit. In 2010, Gleevec's annual global sales soared past \$4 billion.

"What has been hard to justify, as competitor drugs have been developed, is they've entered the market at higher and higher prices and the price of imatinib has continued to go up to match them," said Richard Larson, a hematologist at the University of Chicago. "Ordinarily, you might think with three equally effective drugs on the market, the price should go down through competition, but it's been a failure of the competitive pricing process."

Representatives of Novartis declined an interview request but answered questions by email. Althoff, the Novartis spokesman, said that the ability to raise prices is necessary to reflect not only changing market forces but also the evolving value of the treatment — how much it extends and improves the quality of patients' lives.

He added that "price adjustments" allowed the company to take risks in research and development necessary to fuel innovation, particularly in rare cancers.

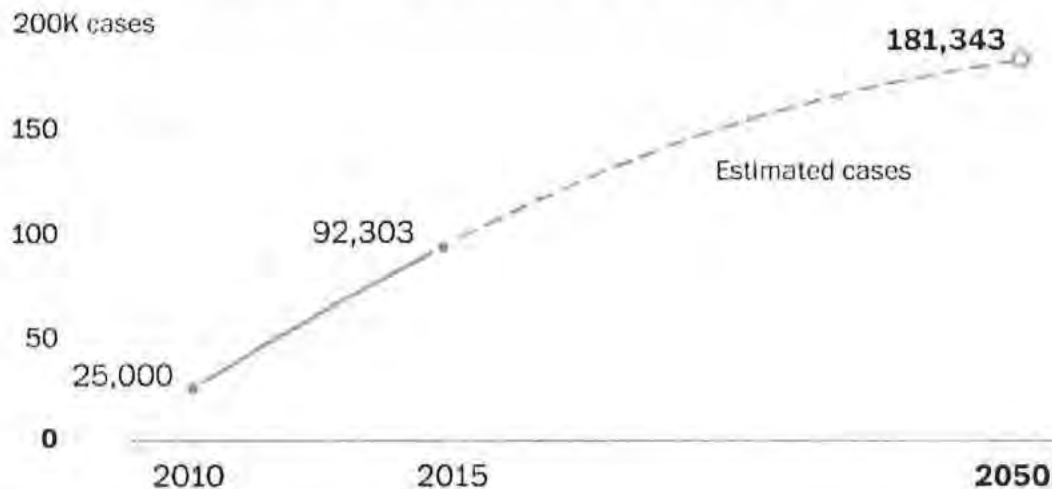
Testing a drug does require additional investment, but at the same time, companies developing drugs for rare diseases, also known as "orphan diseases," can take advantage of federal tax credits.

The Orphan Drug Act offers tax credits for up to half of the cost of clinical testing for each designation — potentially worth tens of millions of dollars. Gleevec has seven orphan-drug designations, including the one for chronic myeloid leukemia.

Althoff would not respond to questions about whether Novartis had used those tax credits, saying the information was proprietary.

Prevalence of chronic myeloid leukemia

The number of people living with the disease in the United States has been growing since 2010, increasing demand for the drugs.



Source: Cancer journal

WEIYI CAI/THE WASHINGTON POST

Rising demand

In 2001, the life expectancy for people with chronic myeloid leukemia was about five or six years. Today, their life spans approach normal.

“I joke, ‘We’re primary care doctors now,’” said Druker, the Oregon oncologist who played a key role in the development of the drug. “When my patients come in, I want to make sure they’re getting their mammograms, their colonoscopies, their cholesterol checked, their blood pressure — because it’s as likely they’re going to die of something else.”

That has meant a steady rise in the number of patients living with the disease and taking Gleevec or its competitors. A 2012 study published in the journal *Cancer* found that, before Gleevec came along, the estimated prevalence of the disease in the United States was between 25,000 and 30,000 people. Because of the drug’s success, that number is projected to have tripled already and to reach 112,000 people in 2020. At the same time, the drug has earned additional approvals for other rare cancers.

“If the expectation was those . . . patients only take the drug for a year or two before it lost its effectiveness, then it seemed reasonable to allow the drug company to profit through its development and marketing,” Larson said. “But in fact most patients do have durable responses. They stay on the drug essentially lifelong.”

In a *patient newsletter* in 2001, Vasella said the small patient population was a key factor that required such a high price and that his company “might be able to lower the price” if more patients began using Gleevec for other cancers.

Although Gleevec never became a drug for a large number of patients, it surpassed expectations and was approved for other rare diseases.

Despite that, the price continued to rise.

Who pays for the drug?

Patients pay a small fraction of the drug's cost. Health plans pay the rest and pass the cost down through higher premiums and deductibles.



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KEVIN UHRMACHER/THE WASHINGTON POST

Access

A lifesaving drug that patients cannot access because it is too expensive would be a public relations nightmare, and pharmaceutical companies take steps to make sure that does not happen.

Althoff noted that the majority of leukemia patients pay no more than \$100 a month for their pills. Novartis has provided the drug free or at reduced cost to an average of 5,000 people in the United States each year for the past 6 1/2 years.

According to Dusetzina's analysis, the median co-pay for privately insured patients has barely budged in the lifetime of the drug, rising from \$16 per month in 2001 to \$33 in 2014. At the same time, the total amount paid for the drug has risen from a median of \$3,271 per month in 2001 to \$8,156 in 2014. Those figures do not take into account discounts or rebates but suggest that insurance is picking up a large amount of the tab.

The rest of that cost is spread across the health-care system, through premiums and deductibles.

Developing innovative drugs costs money, and this may be society's solution to paying for it. But even a relatively small co-pay can affect people's health.

Dusetzina's research, published in the Journal of Clinical Oncology in 2013, found that higher co-pays affect whether people keep taking drugs. In her study of chronic myeloid leukemia patients, nearly 1 in 5 with co-pays above \$53 a month discontinued their drugs in the first six months.

And while Dusetzina's data on co-pays gives a glimpse of how much people with private insurance pay, it does not reflect everyone. According to Medicare data released late last year, total spending on Gleevec rose from less than \$400 million in 2010 to nearly \$1 billion in 2014, not including privately negotiated discounts. People on Medicare's Part D prescription drug plan who do not receive a low-income subsidy pay \$525 a month on average, according to a 2010 Government Accountability Office analysis.

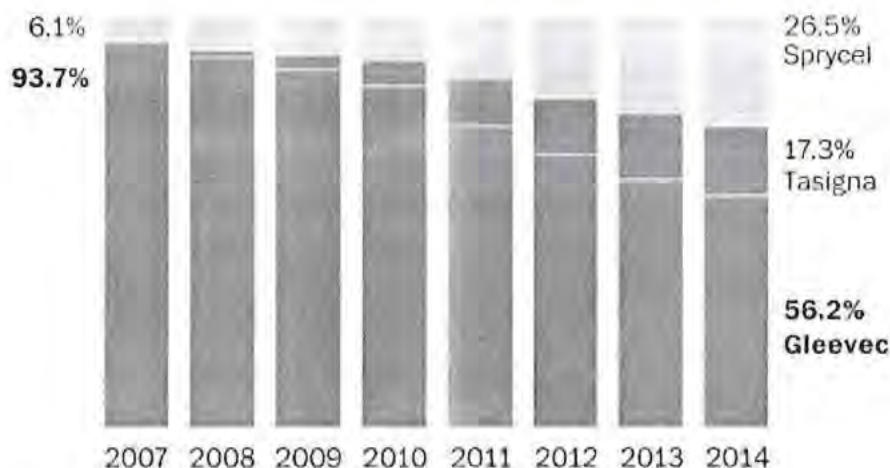
That's Dianne Dale Watson's experience. The 77-year-old retired psychotherapist from Eugene, Ore., said she has saved throughout her life, "like something was chasing me." For the past nine years, she has found herself doling out those savings, \$500 a month, to pay for Gleevec. The drug saps her travel budget to visit her grandchildren in Madison, Wis. She has even made up a song about her prescription drug costs.

"The cost of drugs is a high cost. Where it stops, nobody knows," Watson croons in a high, clear voice. "These drugs that I take are not optional. They help me to go on my way. But Medicare D is dysfunctional, best wishes and have a nice day."

Gleevec's shrinking market share

A growing portion of patients are being treated with a new generation of drugs, including one from Gleevec maker Novartis.

Company: ● Novartis ● Bristol-Myers Squibb



Note: Reflects privately insured patients.

Source: Truven Health Analytics data analyzed by Stacie Dusetzina

WEIYI CAI/THE WASHINGTON POST

Going generic

Gleevec's long, game-changing ride is nearing a new chapter in its story. Its patent exclusivity in the United States ended last month, opening the door for generic competition.

Andrew Hill, a senior research fellow at University of Liverpool, has analyzed how much it costs to make the drug, imatinib, in raw ingredients. A year's worth of drug, made into tablets and bottled, with a 50 percent profit factored in, would cost no more than \$216.

"We have to take away the sort of mystique about this," Hill said. "They're just chemicals."

A patent litigation settlement between Novartis and Sun Pharmaceutical Industries, the first company to produce generic imatinib for the United States, delayed the generic's launch by seven months. Now, Sun Pharma says its price for generic imatinib is 30 to 50 percent less than Gleevec's list price. The company will have six months of exclusivity, and after that the door will be open for other generic competition. The price is expected to fall by 70 to 90 percent off of the brand-name price in the first year, according to University of Chicago health economist Rena Conti.

But Gleevec's last act has been a profitable one. Novartis has hiked Gleevec's price more rapidly in recent years — including a whopping 19 percent increase between 2013 and 2014, from a median of \$6,841 a month to \$8,156, according to Dusetzina's analysis.

"You could replace it with a mental-health or cardiac drug; it would be exactly the same story," Conti said. "They always raise the branded price right before entry."

Novartis's Althoff noted that with discounts, Gleevec is cheaper than other treatments for chronic myeloid leukemia.

Several oncologists said there appears to be a subtle effort by pharmaceutical companies to steer physicians to the next-generation drugs, although there is not yet evidence that they help people live longer. In a 2014 news release, Novartis said that Tasigna, its second-generation drug, had "higher rates of early, deep and sustained molecular responses."

But Vinay Prasad — an oncologist at Oregon Health and Science University who has been critical of cancer drugs that have been approved for stopping cancers from progressing but not saving lives — wonders what that means for patients.

"The question is, 'Does it have anything to do with anything in your life?'" Prasad said.

Halford, the Illinois woman who has for years prayed for a generic, last year found that, after years of trying to get various kinds of financial assistance, something changed. She switched pharmacies and, to her surprise, Novartis offered her a discount. Suddenly she owed only \$10 a month, a steep discount from the \$800 she once paid. Watson recently saw her co-pay fall to zero — for reasons she does not understand but does not want to jinx.



Brian Druker, director of the Knight Cancer Institute at Oregon Health and Science University.
(Michael McDermott/PR Newswire)

The results were dramatic: Many patients experienced a massive reduction in the number of white blood cells, and in some cases cancer cells disappeared altogether.

Under pressure from Druker and patients, Novartis sped up development of imatinib, and in 2001 the drug earned the fastest U.S. cancer drug approval to that date.

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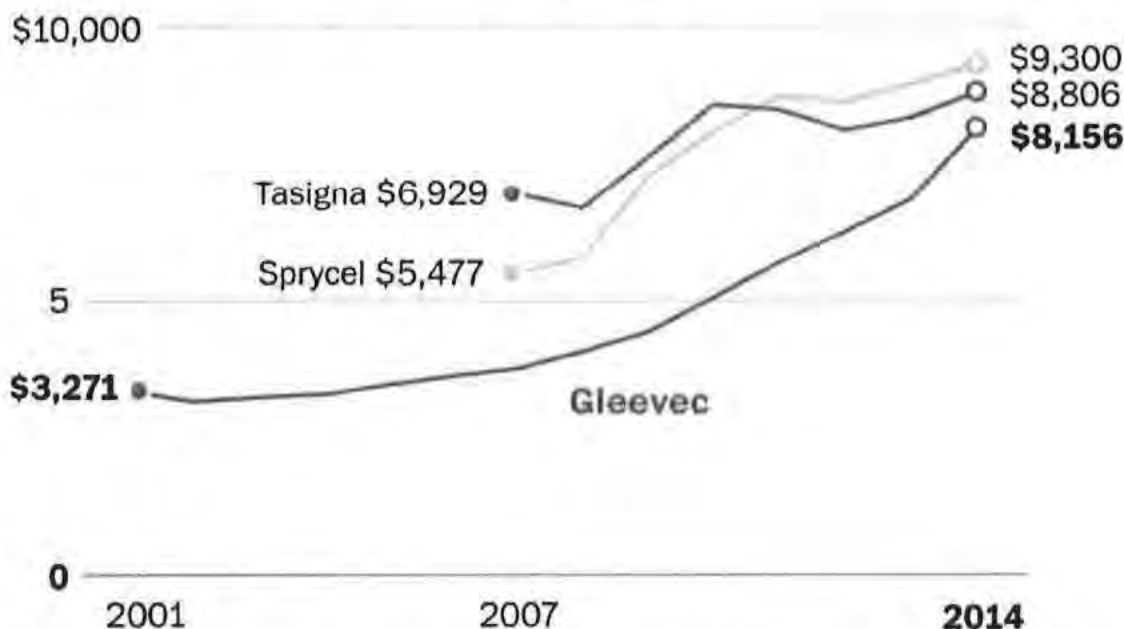
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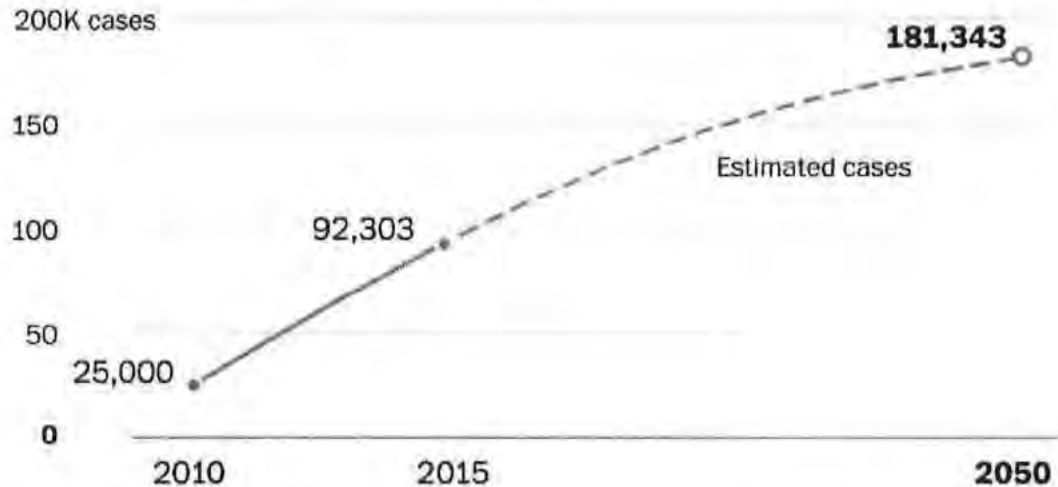
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The rest of that cost is spread across the health-care system, through premiums and deductibles.

Developing innovative drugs costs money, and this may be society's solution to paying for it. But even a relatively small co-pay can affect people's health.

Dusetzina's research, published in the Journal of Clinical Oncology in 2013, found that higher co-pays affect whether people keep taking drugs. In her study of chronic myeloid leukemia patients, nearly 1 in 5 with co-pays above \$53 a month discontinued their drugs in the first six months.

And while Dusetzina's data on co-pays gives a glimpse of how much people with private insurance pay, it does not reflect everyone. According to Medicare data released late last year, total spending on Gleevec rose from less than \$400 million in 2010 to nearly \$1 billion in 2014, not including privately negotiated discounts. People on Medicare's Part D prescription drug plan who do not receive a low-income subsidy pay \$525 a month on average, according to a 2010 Government Accountability Office analysis.

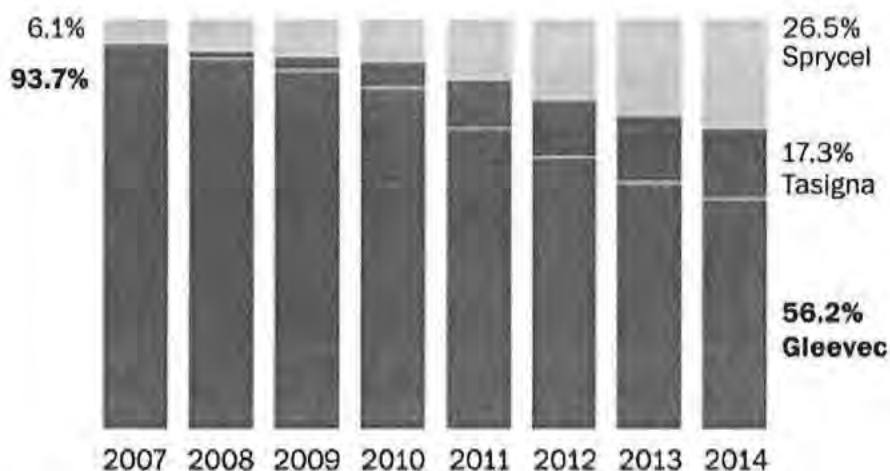
That's Dianne Dale Watson's experience. The 77-year-old retired psychotherapist from Eugene, Ore., said she has saved throughout her life, "like something was chasing me." For the past nine years, she has found herself doling out those savings, \$500 a month, to pay for Gleevec. The drug saps her travel budget to visit her grandchildren in Madison, Wis. She has even made up a song about her prescription drug costs.

"The cost of drugs is a high cost. Where it stops, nobody knows," Watson croons in a high, clear voice. "These drugs that I take are not optional. They help me to go on my way. But Medicare D is dysfunctional, best wishes and have a nice day."

Gleevec's shrinking market share

A growing portion of patients are being treated with a new generation of drugs, including one from Gleevec maker Novartis.

Company: ● Novartis ● Bristol-Myers Squibb



Note: Reflects privately insured patients.

Source: Truven Health Analytics data analyzed by Stacie Dusetzina

WEIYI CAI/THE WASHINGTON POST

Going generic

Gleevec's long, game-changing ride is nearing a new chapter in its story. Its patent exclusivity in the United States ended last month, opening the door for generic competition.

Andrew Hill, a senior research fellow at University of Liverpool, has analyzed how much it costs to make the drug, imatinib, in raw ingredients. A year's worth of drug, made into tablets and bottled, with a 50 percent profit factored in, would cost no more than \$216.

"We have to take away the sort of mystique about this," Hill said. "They're just chemicals."

A patent litigation settlement between Novartis and Sun Pharmaceutical Industries, the first company to produce generic imatinib for the United States, delayed the generic's launch by seven months. Now, Sun Pharma says its price for generic imatinib is 30 to 50 percent less than Gleevec's list price. The company will have six months of exclusivity, and after that the door will be open for other generic competition. The price is expected to fall by 70 to 90 percent off of the brand-name price in the first year, according to University of Chicago health economist Rena Conti.

But Gleevec's last act has been a profitable one. Novartis has hiked Gleevec's price more rapidly in recent years — including a whopping 19 percent increase between 2013 and 2014, from a median of \$6,841 a month to \$8,156, according to Dusetzina's analysis.

"You could replace it with a mental-health or cardiac drug; it would be exactly the same story," Conti said. "They always raise the branded price right before entry."

Novartis's Althoff noted that with discounts, Gleevec is cheaper than other treatments for chronic myeloid leukemia.

Several oncologists said there appears to be a subtle effort by pharmaceutical companies to steer physicians to the next-generation drugs, although there is not yet evidence that they help people live longer. In a 2014 news release, Novartis said that Tasigna, its second-generation drug, had "higher rates of early, deep and sustained molecular responses."

But Vinay Prasad — an oncologist at Oregon Health and Science University who has been critical of cancer drugs that have been approved for stopping cancers from progressing but not saving lives — wonders what that means for patients.

"The question is, 'Does it have anything to do with anything in your life?'" Prasad said.

Halford, the Illinois woman who has for years prayed for a generic, last year found that, after years of trying to get various kinds of financial assistance, something changed. She switched pharmacies and, to her surprise, Novartis offered her a discount. Suddenly she owed only \$10 a month, a steep discount from the \$800 she once paid. Watson recently saw her co-pay fall to zero — for reasons she does not understand but does not want to jinx.



Marge Halford's Gleevec pills. (Isaac Smith/For the Washington Post)

"It was wonderful, but why all of a sudden after six years are you giving me the co-pay?" Halford said.

She does not know why the switch happened, but she can't help but wonder whether it is a ploy to prevent her from switching to a generic.

When Sun Pharma launched its generic, it announced its own \$10 co-pay program. Novartis's competition, it seems, has arrived.

Exhibit 2

Expensive specialty drugs are forcing seniors to make hard choices



Diane and Lee Whitcraft of Webster, Wis. Diane has multiple sclerosis and is forgoing medication because of its cost under her Medicare prescription drug plan. (Courtesy of Diane Whitcraft)

By Carolyn Y. Johnson

November 10, 2017

For 23 years, Diane Whitcraft injected herself every other day with Betaseron, a drug that helps prevent flare-ups from multiple sclerosis. The drug worked well, drastically reducing Whitcraft's trips to the hospital. But as her 65th birthday approached last September, she made a scary decision: to halt the medication altogether.

With health insurance through her job, Whitcraft had paid a \$50 or \$100 monthly co-pay for the drug; she hadn't even realized that the price of Betaseron had soared to more than \$86,000 a year. Shopping around for drug coverage through Medicare, the out-of-pocket costs were mind-boggling: close to \$7,000 annually.

"I was just feeling really bad that my disease was going to affect our retirement budget," Whitcraft said. "You're retired; you're on a fixed income. And it just really was bothersome to me. I was doing this to us. This disease was doing this to us."

Whitcraft's dilemma highlights a growing problem with Medicare prescription drug coverage for seniors who take high-priced specialty drugs: There is no cap on how much they pay. Each prescription drug plan is structured a little differently, but people with very high drug costs almost inevitably enter what's called the "catastrophic" phase of coverage. Then, they pay 5 percent of the list price of their drug — no small sum in an age of \$10,000-a-month cancer drugs or, in Whitcraft's case, a more than \$7,000-a-month multiple sclerosis therapy.

The number of seniors who reach the catastrophic phase has almost doubled over a four-year period, to more than 1 million people in 2015, according to a new analysis by the Kaiser Family Foundation. That trend was driven in part by a new generation of high-priced hepatitis C drugs, but includes high out-of-pocket costs for people taking drugs for cancer, multiple sclerosis, schizophrenia and HIV.

The Affordable Care Act took steps to close the "doughnut hole," the coverage gap where seniors have been on the hook for more of their prescription drug costs. But for a growing number, the doughnut hole barely matters. Their first or second prescription fill of the year might get them out of it, plunging them into a bigger problem — a phase of coverage where there's no upper limit on how much they will pay.

"Once people blow through the doughnut hole and reach the catastrophic threshold, they continue to pay. And these costs are ticking up," said Tricia Neuman, a senior vice president at the Kaiser Family Foundation. "While 5 percent coinsurance doesn't sound like a lot, it can really add up for people who are taking extremely expensive medicines."

[One way Obamacare's plan to cut drug costs for Medicare recipients falls short]

The Kaiser study found that in 2015, the 1 million seniors who reached the catastrophic threshold paid an average of more than \$3,000 out of pocket. One in 10 of them paid at least \$5,200.

Neuman noted that the data, showing a huge increase in the number of people reaching the catastrophic threshold, wouldn't even take into account people such as Whitcraft, who simply opt out and don't fill prescriptions because of the cost. One possible policy solution would be to add a cap for out-of-pocket drug costs beyond a certain threshold — an idea that has been proposed in legislation.

Stacie Dusetzina, a cancer health services researcher at the University of North Carolina at Chapel Hill,

said that the trend probably is driven by a combination of factors: more high-priced specialty drugs coming on to the market, price increases over time for existing drugs and more people taking expensive drugs.

The trend also challenges the pharmaceutical industry's main argument in defending list prices — that those prices are misleading because they do not represent the secret rebates provided to insurers or reflect what patients pay. Seniors are paying coinsurance prices paid based on the list prices, not the secretly negotiated rebated price.

“This is why list prices matter, and rebates aren’t directly helping people needing specialty drugs,” Dusetzina said.

Whitcraft took her last dose of Betaseron on January 5. So far, she hasn't had another attack, but she knows the threat is always there. She said she wouldn't have made the same decision to stop the drug if she were younger, and she wrestled with what to do.

This summer, she did something she thinks she should have done a long time ago. She wrote a letter to the chief executive of Bayer, the company that makes the drug.

Bayer spokeswoman Sasha Damouni said that the company goes through a series of steps before making a decision on how to price a drug, including discussions with doctors and patients. The company also assesses the product's ability to reduce health-care costs by avoiding unnecessary hospitalizations.

But Whitcraft still doesn't understand why her drug, which launched with a list price of about \$11,500 more than two decades ago, costs so much today — a question she raised in her letter.

“It wasn’t filled with anger or anything; I just told him that I had quit the drug, and why. And I suggested someone must be very greedy,” she said. “It's so wrong and so unfair — a drug that was marketed for the first time in 1993 . . . Why did the cost go up so much here?”

Whitcraft said she got a phone call from the company offering the drug at a discounted rate, months after she had come to the difficult decision to stop taking it. She wondered, if the company could offer her a discount on an individual basis, why they couldn't just lower the price for everyone.

Exhibit 3

Protesters take anger over insulin prices to drug makers, some bearing children's ashes

By Megan Thielking @meggophone

November 12, 2018



Nicole Smith-Holt and her son, Alec Smith. Smith died in June 2017 after rationing his insulin. *Courtesy Nicole Smith-Holt*

On Mother's Day, Nicole Smith-Holt, whose son died last year after rationing his insulin, protested insulin prices at a rally at the Minnesota state capitol. That same month, she traveled to Indianapolis to meet with a representative of the insulin maker Eli Lilly.

This week, she and another mother whose child died under similar circumstances plan to travel to the office of insulin maker Sanofi in Cambridge, Mass. They will also be holding their children's ashes.

"It's a visual reminder for them of what's at stake," Smith-Holt said, who will join activists in a "die-in" at the Sanofi office on Friday.

Moving value-based contracting from experimentation to common practice

To move value-based contracts forward, stakeholders must come together around objectives, develop standardized definitions for outcomes measurement, and invest in technology.

Anger over insulin prices in the U.S. has swelled as the nation's largest insulin makers have hiked the price of the drug. Those price increases are now the subject of a class-action lawsuit and have drawn the attention of lawmakers in Washington.

But the price hikes are also fueling public outcry by patients, caregivers, and clinicians. Last month, patients and activists marched outside Lilly's headquarters demanding "insulin for all."

When Smith-Holt's son had health insurance, he paid between \$200 and \$300 a month for the insulin and supplies he needed for his type 1 diabetes. He died on June 27, 2017 — less than a month after his 26th birthday, when he could no longer stay on his mother's health insurance plan. Without insurance, the restaurant manager was facing about \$1,300 a month in out-of-pocket costs, according to Smith-Holt.

"Unfortunately, he didn't reach out to anyone for help. He was trying to make what he had last," Smith-Holt said. After he called out sick from work, Smith's girlfriend went to check on him in his apartment. She heard his phone ringing, but he never picked up. She found him on the bedroom floor.

"This is a crisis," said Smith-Holt. She will lead the protest with Antoinette Worsham, an Ohio mother whose 22-year-old daughter, Antavia, died in April 2017. Worsham went on to found a nonprofit that aims to raise awareness and provide financial help to patients with diabetes who can't afford treatment.

A 2016 study published in the Journal of the American Medical Association found that the price of a milliliter of insulin climbed 197 percent between 2002 and 2013. And an analysis published in September found that insulin prices could be much lower and drug companies would still turn a healthy profit.

In a statement, Sanofi acknowledged that many people with diabetes have significant difficulty accessing the medicines they need.

"We take this issue seriously, and continue to explore innovative ways to find long-term solutions to help eliminate or significantly reduce the out-of-pocket expenses for patients," said Ashleigh Koss, a spokesperson for Sanofi.

Koss also noted that the company has a savings program and a copay program, and provides free medications for some low-income, uninsured patients through its assistance program.

Smith-Holt isn't satisfied with the answers she's received from drug makers so far. She wants to see more price transparency.

"We want to know how much it costs to manufacture insulin, what their profits are on a vial of insulin, how much they spend on advertising and marketing," she said.

Smith-Holt and other advocates joining the protest hope to raise awareness on the issue of insulin access. But they're also hoping to get the attention of leaders at Sanofi and have an opportunity to share their stories with the company.

"We really want to drive home the point that this lifesaving medication is far too expensive," she said. "Something has to be done."

Exhibit 4

Extraordinary tactics, perverse incentives: Makers of top-selling drugs hike prices in lockstep, and patients bear the cost

By Casey Ross [@caseymross](#)

November 14, 2018



Anna

Legassie, who was diagnosed with systemic arthritis as a child, at her home in Boston. She has struggled to get access to expensive biologic drugs, and as a result has undergone a series of surgeries, including six hip replacements. *Kayana Szymczak for STAT*

The drug giants moved in near-perfect synchronicity, raising prices for their top-selling arthritis treatments as though they were opposite-corner gas stations bumping up the price of unleaded.

On Jan. 3, 2013, AbbVie (ABBV) hiked the price of Humira, its blockbuster biologic drug for arthritis and related conditions, by 6.9 percent. A day later, Amgen (AMGN) followed with an identical increase for Enbrel, another biologic used to treat similar patients. The pattern repeated 10 more times between 2014 and early 2018. In every instance, prices of both drugs jumped by nearly the same percentage, usually within days of each other, topping out at the exact same amount, \$63,363 per year, according to a STAT analysis of pricing data.

The rapid run-up, almost a 140 percent increase overall, reflects the companies' clout in a market where patients suffer from autoimmune diseases that shackle them with blinding pain and can make everyday activities — eating, sleeping, raising kids — an ordeal. Humira is the world's best-selling drug, while Enbrel holds the No. 5 slot, and neither therapy has competition from generic versions known as biosimilars.

STAT found that the extraordinary tactics employed to preserve the exclusivity of these drugs in the United States have undermined the care of patients and created perverse incentives that increased costs, led to seemingly nonsensical insurance coverage decisions, and left patients and doctors in the dark as to the reasons why.

Those consequences have triggered antitrust concerns in Congress. Senators have urged the Federal Trade Commission to look for evidence of anticompetitive conduct in confidential legal settlements that have delayed biosimilar competition. The price hikes for Humira and Enbrel, well above the rate of inflation, were not linked to a sharp rise in the cost of raw materials or changes in the composition of the products. The companies raised the prices for a much simpler reason — because they could.

That is about to change in Europe, where rival companies now have approval to sell biosimilars of Humira, forcing AbbVie to offer steep discounts to remain competitive. No such relief is in store for U.S. patients anytime soon.

President Trump has argued that European countries — which place stricter limits on market exclusivity and outright refuse to pay for some high-priced medicines — are effectively offloading the cost of drugs, and biomedical innovation, on American patients and payers. But experts said U.S. patent laws, and the inventiveness of drug companies in exploiting them, leave the administration without many of the levers it would need to ratchet down the prices of biologic drugs.

Last year, AbbVie and Amgen reached a confidential legal settlement that extends the exclusivity of their products in America. Amgen agreed to hold off selling a Humira biosimilar in the U.S. until 2023. AbbVie has forged similar agreements with other biosimilar makers. But the deal with Amgen offers an added boost to both parties, as it allows them to continue charging high prices for Humira and Enbrel without the threat of competition.

The annual cost of Humira and Enbrel increased in lockstep from 2013 to 2018

Date	Enbrel	Humira
13-Jan	28,741	28,469
13-Jun	30,725	30,434

Date Enbrel Humira

13-Jan 28,741 28,469

13-Jun 30,725 30,434

Date Enbrel Humira		
14-Jan	32,884	32,534
14-Jun	35,110	35,104
14-Nov	37,884	37,877
15-May	41,634	41,627
15-Sep	44,924	44,916
15-Dec	48,472	49,362
16-Jul	53,271	53,262
17-Jan	57,746	57,736
18-Jan	63,336	63,336

Megan Thielking/STAT Prices are based on wholesaler acquisition cost. Source: First Databank

The value of that exclusivity is just now becoming clear, as AbbVie is proposing to slash Humira's price by up to 80 percent in some Nordic countries. Meanwhile, Amgen, already losing sales to Enbrel biosimilars in Europe, is locked in a separate legal fight to block the introduction of generic versions of its drug in the U.S.

"That's the opposite of a free market," said Dr. William Harvey, clinical director of the division of rheumatology at Tufts Medical Center in Boston. "There's no question this whole series of events has conspired to limit competition."

In 2017, AbbVie recorded \$18.4 billion in global sales of Humira, while Amgen collected \$8 billion from sales of Enbrel. For both drugs, about two-thirds of this revenue came from the United States. The pricing information reviewed by STAT refers to the wholesaler acquisition cost of the drugs, or the price charged by drug manufacturers to wholesalers and other direct purchasers before any discounts are factored in. It was supplied by First Databank, which tracks changes in drug prices and other health care information.

In separate statements, AbbVie and Amgen declined to disclose the terms of their Humira settlement. But both parties said AbbVie will not make any payments to Amgen in exchange for the delayed introduction of its biosimilar. Instead, Amgen will pay royalties to AbbVie once it begins selling the product.

AbbVie struck similar settlements with six other companies that have developed Humira biosimilars. A company spokeswoman said the geographic variation in the dates of biosimilar introduction reflect the "scope, strength, regulatory and legal considerations which are individual to each country."

"Through these settlements, AbbVie has achieved the balance between protecting investment in innovation and providing access to biosimilars, which will play an important role in the health care system," said the spokeswoman, Adelle Infante.

Kelley Davenport, a spokeswoman for Amgen, said the settlement "provides certainty and clarity on timing, eliminates costly litigation, and brings Amgen closer to the launch of one of our first approved biosimilars."

Davenport suggested that the price increases for Enbrel are driven by the large discounts Amgen and other manufacturers pay to insurers and pharmacy benefit managers to secure preferred placement on their formularies, or lists of drugs approved for use by patients.

“To maintain formulary position, the rebates that Amgen pays to insurers and PBMs must be competitive,” Davenport said. “The rebates are paid off the list price. Therefore, in response to recent list price increases by others in the class, we took a commensurate list price increase on Enbrel. As we mentioned in previous earnings calls, Amgen expects relatively little benefit from net selling price changes for Enbrel.”



The medications that Legassie takes to control her arthritis symptoms. *Kayana Szymczak for STAT*

As prices rise, patients lose control

Despite the drug makers’ efforts to downplay the impact, patients say the price hikes, and associated insurance denials, have had serious consequences for their health.

Anna Legassie, 35, of Boston said she was first denied access to Enbrel when she was a teenager in the late 1990s, a time when the drug was still new and backed by limited data on its use by children and teens. She was diagnosed at age 11 with systemic juvenile idiopathic arthritis, a condition that causes painful swelling of the joints and can lead to heart inflammation and malfunctioning of the lymphatic system and vital organs.

Her insurer declined to cover Enbrel despite her doctor’s belief that the drug could help control

symptoms that had left Legassie unable to participate in sports and attend school without prolonged absences.

“The worst part of this is feeling that so much of my life has been out of my control,” said Legassie, now a health care communications specialist.

She finally got access to Enbrel when she turned 18, a threshold that made her eligible in the eyes of her insurer. From the earliest doses, it was like someone had flicked a switch on her disease after years of suffering and social isolation.

“It was so life-changing that it was infuriating to know I had to wait all those additional years to get on it,” said Legassie, who kept the self-administered injectable stored in her dorm room refrigerator.

Her body eventually built up antibodies that rendered Enbrel ineffective. She switched to Humira after college but struggled to afford the \$180 copayment and found the drug to be less effective than Enbrel for her condition. Legassie said she dropped it and tried managing her symptoms with cheaper substitutes, such as steroids and Tylenol.

Then came the pain in her hips, both of which had been replaced in high school. An orthopedic surgeon told her the replacements had failed “catastrophically” and that she would need surgery to replace them again.

“In the time I wasn’t on a biologic, my body basically ate the bone around my hip replacement,” said Legassie, whose intermittent access to effective biologics has coincided with six hip surgeries, three knee operations, and a wrist procedure that together have cost her, and the broader health care system, hundreds of thousands of dollars.

Her story is far from uncommon among patients with autoimmune disorders such as rheumatoid arthritis, psoriasis, and Crohn’s disease. Every day, their rage over rising prices and insurance denials spills onto Twitter and other social media platforms, where they collectively strategize ways to short-circuit the system and get access to biosimilars.

Patients and doctors told STAT that, in some cases, insurers required patients to take drugs they’d already tried — and didn’t work — before approving costlier, and likely more effective, medicines. In others, patients simply couldn’t afford ever-increasing copays and deductibles, forcing them to skip doses or altogether stop taking biologics that had driven their diseases into remission.

Their stories highlight deep-rooted problems in America’s system of pricing, and paying for, breakthrough therapies. Experts said responsibility for high prices, and their consequences, cannot be pinned on any one party. Drug companies cannot be blamed for pursuing profits on behalf of their shareholders any more than insurance companies can be blamed for seeking to control their costs by using formulary placement to extract discounts.

But the tactics employed in pursuit of these goals are largely left unchecked in the U.S., leading to a steady run-up in prices that inevitably lands on the people least equipped to handle them: desperately ill patients.

Biologics, which are complex proteins made in living cells, often cost tens of thousands of dollars a

year. Between 2010 and 2015, they accounted for almost 40 percent of U.S. prescription drug spending and 70 percent of drug spending growth, according to one recent study.

Last year alone, biologics racked up sales of \$120 billion in the U.S., even as regulators and lawmakers, facing intense pressure to control costs, sought to spur approval of biosimilars that have reduced prices in other countries.

IQVIA's research arm forecasts that biosimilars could save the U.S. between \$27 billion and \$58 billion by 2021. But so far only four have landed on the market here, compared to more than 40 in Europe, due to aggressive patent litigation by makers of brand-name biologics, among other factors.



patient holds a Humira Pen box after receiving a weekly injection. *Aram Boghosian for STAT*

A pioneering patent strategy

AbbVie's main patent for the composition of Humira expired at the end of 2016. In anticipation of that date, the company for years accumulated an array of additional patents related to its manufacturing processes, changes in drug formulation, and different administration methods.

The company filed lawsuits alleging that several makers of FDA-approved Humira biosimilars violated dozens of those later patents. One AbbVie strategy presentation from 2015 shows that the company's top executives were telling investors that its "broad patent estate" was part of a comprehensive plan to protect Humira against biosimilar introduction.

The document outlines 75 patents on Humira, some with expiration dates as late as 2034. It asserts that

“AbbVie has patent protection covering all of the approved indications” and that litigation tied to a patent case would take “4 to 5 years.”

In 2017, AbbVie settled lawsuits with several biosimilar manufacturers, including Amgen, that effectively extended the exclusivity of its flagship drug for that full five years — until 2023.

Infante, AbbVie’s spokeswoman, said the extension of Humira’s exclusivity in the U.S. is proportionate to the strength of its patent protection. She noted that AbbVie has successfully guarded its patents in proceedings before the U.S. Patent and Trademark Office, where the company has prevailed over rivals in 15 challenges to its patents.

“Our patents expire after the 12-year exclusivity,” Infante said, referring to a provision of the Affordable Care Act that established the duration of patent protection for biologics. “This is a function of the innovation that went into making and developing HUMIRA. Our settlements and licensing will provide access to patients about a decade before our last patents expire.”

But one biosimilar maker, Boehringer Ingelheim, has refused to settle its litigation with AbbVie, resulting in the release of new details, reported by STAT last week, about the company’s use of patents to guard Humira’s position in the market.

The documents include a slide that summarizes a brainstorming meeting from 2010 that was convened to “generate ideas to broaden our Humira patent estate in response to biosimilars.”

AbbVie executives have not been shy about discussing the strategy.

During a May 2017 Deutsche Bank conference, AbbVie executive vice president of finance William Chase explained how the litigation could keep Amgen’s biosimilar off the market for several years.

“We are in litigation with Amgen, and we have filed our complaint against Amgen, and we’ve made that publicly known that ... we feel that their product infringes 61 patents that we have and that we intend to assert all 61 patents, when we have an opportunity to do so,” Chase said. “... We still stand by the fact that we believe, when we look at that intellectual property, there are certain patents that will protect Humira in the U.S. out to 2022.”

A federal judge has ruled that AbbVie must produce additional documents requested by Boehringer Ingelheim, which is arguing that AbbVie used “unclean hands,” or untoward behavior, to create and establish its Humira patent thicket.

Meanwhile, Amgen is fighting its own patent litigation with Sandoz, which wants to begin selling a biosimilar to Enbrel in the United States. In that case, Amgen is pursuing a similar strategy to the one it was fighting in its case against AbbVie.

It is arguing that Sandoz is infringing on several patents relating to methods of manufacturing Enbrel, materials used in manufacturing, and certain uses of the drug. It filed the cases shortly after Sandoz gained FDA approval to begin selling the drug in the United States in 2015. Enbrel already faces biosimilar competition in Europe, which has contributed to a 6 percent decline in sales per quarter.

Davenport, Amgen’s spokeswoman, did not respond directly to questions about the company’s patent

strategy. But she said it is heavily invested in biosimilars and believes they will eventually help to increase competition and lower costs. “Our experience demonstrates that the current regulatory and reimbursement incentives [are] sufficient for biosimilars to succeed,” she said. “Amgen believes that a level playing field will drive rapid uptake of well-priced and supported biosimilars in the US market.”

Patients concerned about the high costs of Humira and Enbrel contend that the playing field remains heavily slanted against their interests.

“Here we are looking at a perfect example of the system being rigged against patients being able to make the best financial decision. Basically a scam is happening, and patients are left footing the bill, and the blame.”

Jess Caron, takes Humira for Crohn's disease

Jess Caron, a 32-year-old New Hampshire mother of two with Crohn’s disease, said she has watched with alarm as her annual deductible and copays have risen along with Humira’s list price. She said Humira has saved her from gastrointestinal problems that had previously made it difficult to leave the house, but paying for it is becoming a challenge. She said her drug costs eat up her annual \$3,500 deductible in a single month, forcing her to pay it all at once.

News of AbbVie’s proposed 80 percent price drop in Europe is hard for her to accept.

“It’s frustrating as hell,” Caron said, noting that chronically ill patients are often faulted for failing to make cost-efficient treatment choices. “And here we are looking at a perfect example of the system being rigged against patients being able to make the best financial decision. Basically a scam is happening, and patients are left footing the bill, and the blame.”



Legassie fills her dog’s water bowl as she prepares to go to work. *Kayana Szymczak for STAT*

The influence of hidden payments

As the prices for Humira and Enbrel have increased in recent years, a paradoxical effect has unfolded in the market: They have become the drugs of choice for many insurers who have given them preferred placement on their formularies.

An analysis for STAT by Dr. James Chambers of Tufts Medical Center in Boston found that 12 of 17 major insurers in the hospital's Specialty Drug Evidence and Coverage database issued policies for Enbrel and Humira. Of the 12, 11 classified them as first-line biologic therapies for patients with rheumatoid arthritis.

Nearly all of those insurers required patients to first try cheaper, non-biologic drugs such as methotrexate. But the positioning of Enbrel and Humira as first-line biologics means patients must try them before other brand-name biologics that might prove more effective.

Chambers, who studies how coverage policies affect access to care, next wants to figure out why Humira and Enbrel are given preferred placement by some insurers, while others favor different products. Another question is why the biologics on the market — about 10 are available to treat rheumatoid arthritis, for example — are subject to varying levels of restrictions by insurers.

If their restrictions were based solely on clinical evidence, Chambers said, it stands to reason that insurers would implement similar coverage policies for these drugs, since they all have access to the same studies. But he said the wide variability suggests other factors, such as payments from drug makers, are coming into play.

Insurers and PBMs often extract large volume discounts from drug companies whose products benefit from preferred placement on their formularies. The larger the discount, the larger the spread between the manufacturer's list price and the net price paid by insurers and PBMs, and the greater the opportunity for those latter parties to profit.

"It would be my hypothesis that volume-based discounts are driving a lot of this," Chambers said. He added that plenty of other factors may explain why Humira and Enbrel are favored. He noted that they have been on the market longer than their competitors, and therefore have more safety and efficacy data behind them. Insurers may also like that they are approved for use on multiple conditions — both drugs treat multiple forms of psoriasis and arthritis, while Humira is also used by patients with gastrointestinal conditions such as Crohn's disease and colitis, among other illnesses.

"I don't believe these decisions are wholly driven by the negotiated discounts," Chambers said. "But I do believe that they are having an influence, and the findings of our empirical work would certainly suggest that."

Chambers said he must hedge on his conclusions because insurers and PBMs do not fully explain their rationale or disclose the extent of the discounts they're getting from manufacturers.

"A big deficiency in the U.S. health care system is that we simply don't know what these insurance companies are paying for the products," he said. "... The lack of transparency in pricing makes all of this very difficult to understand."

Legassie, the patient diagnosed with idiopathic arthritis as a child, has watched insurers' initially guarded approach to Humira and Enbrel turn into an overflowing embrace in recent years.

In 2015, she and her doctor began searching for a new biologic to treat her disease. They eventually settled on a drug called Orencia, manufactured by Bristol-Myers Squibb (BMJ). But her insurer, Blue Cross Blue Shield of Massachusetts, declined to cover it, citing policies requiring that Legassie first try

Enbrel and Humira, whose prices were spiking at the time. AbbVie and Amgen instituted five price increases in 2014 and 2015, boosting their prices by more than 38.5 percent, to more than \$48,000.

Legassie said she and her doctor were perplexed by the denial. Not only were the prices rising for Humira and Enbrel, but her medical record also showed her previous use of both drugs had failed to halt her disease.

Legassie quickly appealed, but Blue Cross persisted with its denial. "It wasn't enough that I'd already been on the [drugs]," Legassie said of the insurer's reasoning. "I hadn't been on them in the past 130 days."

The decision appeared to have little grounding in medical evidence. Given that her body had built up antibodies to the drugs, Blue Cross was essentially insisting on paying for expensive drugs that were not going to work. For Legassie, the drugs also carried a higher copayment than Orencia, which was fully covered under her medical benefits because it is an infusion drug administered in a clinical setting.

Fed up, Legassie took her case to Twitter, where she has thousands of followers. In late May 2015, she tweeted at Blue Cross: "Your use of step therapy for EVERY SINGLE Immune Modulating Drug used to treat Rheumatoid Arthritis is nothing short of predatory."

The retweets and comments that followed led Blue Cross to send a direct message to Legassie on Twitter within 24 hours. The insurer reversed its decision, giving her access to Orencia. In a statement, Blue Cross did not directly address the specifics of Legassie's case. The company said it provides members with an opportunity to appeal its coverage decisions and that Humira and Enbrel have been first step drugs on its formulary for more than a decade "due to favorable safety and efficacy profiles."

Legassie said her use of Orencia almost instantly improved her life and made her symptoms more manageable. She began to run again, eventually ramping up to Spartan races and Tough Mudders. This year, she said, she has run a race every month to raise money for the Arthritis National Research Foundation.

"It's emotionally overwhelming to talk about my life as it exists today," she said. "There were so many years that this quality of life I have now felt so far out of reach. I never even daydreamed I would get this gift."

Exhibit 5

Pfizer to raise prices on 41 prescription drugs next year despite pressure from Trump

- Pfizer will raise list prices on 41 prescription drugs in January.
- Pfizer this summer deferred planned price increases after President Donald Trump criticized the drug giant.
- Trump said Pfizer and other drugmakers "should be ashamed" of themselves.

Angelica LaVito | @angelicalavito

Published 3:24 PM ET Fri, 16 Nov 2018 Updated 7:26 PM ET Fri, 16 Nov 2018 CNBC.com



Andrew Harrer | Bloomberg | Getty Images

Ian Read, chairman and chief executive officer of Pfizer, speaks as President Donald Trump, left, listens during an announcement on a new pharmaceutical glass packaging initiative in the Roosevelt Room of the White House in Washington, D.C., July 20, 2017.

Pfizer will raise prices on 41 of its prescription drugs in January after initially putting off those plans this summer amid pressure from President Trump.

The drug giant will increase the list price of about 10 percent of its drugs Jan. 15, the company announced Friday. Most of the increases will be 5 percent, though Pfizer will raise three drugs' list prices by 3 percent and one drug's by 9 percent.

List prices are the advertised price of a drug, not necessarily the price insurers pay after discounts, known as rebates.

"We believe the best means to address affordability of medicines is to reduce the growing out-of-pocket costs that consumers are facing due to high deductibles and co-insurance, and ensure that patients receive the benefit of rebates at the pharmacy counter," Pfizer's outgoing CEO Ian Read said in a statement.

Trump criticized Pfizer this summer when the company said it would raise prices on about 40 drugs. He tweeted that Pfizer and other drugmakers "should be ashamed" for increasing drug prices.

Pfizer reversed course and said it would hold off on making these increases until the end of the year or until Trump's blueprint to lower drug prices went into effect. On an earnings call with Wall Street analysts last month, Read said by the end of the year, the company's strategy on price increases would be back to "business as normal."

Exhibit 6

STAT+

Never mind the rebates. Maybe behind-the-scenes fees are boosting drug prices

By [Ed Silverman @Pharmalot](#)

August 16, 2018



Adobe

File this under, “It’s the fees, stupid!”

At a time when rebates are increasingly blamed for rising medicine costs, another type of behind-the-scenes payment in the pharmaceutical supply chain is being cited as an explanation for high drug prices

— the various fees that pharmacy benefit managers charge drug makers.

Unlike rebates, there are certain circumstances when fees are not required by federal law to be individually reported for medicines purchased for the Medicare Part D program. As a result, their effect on pricing is not fully known, since contracts between drug makers and PBMs are kept confidential.

For this reason, some experts say the fees deserve increased scrutiny.

“This is part of the whack-a-mole in drug pricing, because we regulate rebate disclosures, but the system

has found an alternative way to make money in the form of fees,” said Rena Conti, an assistant professor of public health at the University of Chicago.

The issue is gaining attention as controversy intensifies over the effects rebates have on drug pricing.

The Trump administration, for instance, is considering ways to reduce or restrict rebates, which are essentially a type of discount that drug makers provide PBMs, off the wholesale, or list, price for their medicines in order to receive favorable placement on formularies, which are lists of insured drugs.

Drug makers claim PBMs, which keep a percentage of rebates, demand higher amounts to bolster profits and in turn, they must respond by raising list prices. PBMs counter that rebates blunt price hikes that drug makers regularly take in order to boost their own profits.

Over the past year, the pharmaceutical industry has been winning the debate and, in response, such big PBMs as Express Scripts (ESRX¹) and CVS Caremark (CVS²) have defensively argued that they keep only a small portion of rebates which, in turn, account for a small portion of profits.

To emphasize the point, CVS argued “rebate retention also has no correlation to higher drug prices.” The PBM released data showing average member spending on brand-name drugs rose to \$831 last year, up from \$608 in 2011, but the average rebate retained was less than \$20 per member over that time.

So if rebates are not the primary culprit that is inflating drug prices, what about fees?

The fees, some of which may be calculated as a percentage of list prices, constitute a complicated but little-understood piece of the opaque pricing system. One aspect of the discussion, in particular, involves so-called bona fide service fees, which is a term used by the federal government to describe legitimate fees for various products or services provided by a PBM to a drug maker.

Sorting out which fees are bona fide requires a government smell test, notably whether a fee exceeds fair market value. If a fee passes the test, it does not have to be reported for each specific drug to Medicare

Part D sponsors (read more on pages 21 and 29⁵). Although the idea is to ensure Medicare pays the true value of a medicine, only aggregated bona fide fee amounts must be disclosed, obscuring costs to an unknown degree.

“In order to have a full understanding of why drug prices continue to rise, we also need to have a full understanding of everything that’s involved in pricing drugs and the transactions that occur between PBMs and manufacturers,” said Nicodemo Fiorentino, an attorney and consultant who specializes in pharmaceutical industry regulatory matters. “In fairness, consumers deserve to know more about this.”

Moreover, there are concerns some fees are not actually bona fide, and that this characterization is improperly used to describe fees for any number of products and services that should be reported, such as health management, education services, or data processing. And if such fees are inappropriately tacked on to purchases, then experts say drug costs may be inflated.

“PBMs are in a position to play an immense labeling game,” said Linda Cahn, a consultant who advises health plans and employers on PBM contracts. “If money is called rebates in contracts with manufacturers, they have to pass money through to clients. If they call money something else, they can keep the money. But no one knows what those labels are because contracts are kept secret.”

The issue has been highlighted in a pair of whistleblower lawsuits filed five years ago by a former portfolio manager at a Boston investment firm named John Borzilleri (see here⁶ and here⁷). Both suits, which were recently unsealed and noted in a securities filing by Biogen (BIIB⁸) (see page 40⁹), argue that drug makers and PBMs have schemed to raise list prices and obscure bona fide fees in order to fatten their bottom lines.

An Express Scripts spokeswoman wrote us to say that “we deny the allegations in the suit, including that admin fees do not meet fair market value.” Similarly, a CVS spokesman wrote us that the company believes “these complaints are without merit and we intend to vigorously defend ourselves against these allegations.”

To what extent he can prove his case is unclear. The U.S. Department of Justice declined to join the litigation and Borzilleri based his argument, in large part, on information learned at a private investor meeting as well as research. Fiorentino explained that he may need greater detail to convince a judge that the companies violated federal laws governing false claims and kickbacks.

“Both cases raise important issues that deserve discussion, because there’s a lack of transparency,” said Fiorentino. “But it’s a big mountain to climb. He needs compelling evidence to support his claims which, at the end of day, would have to explain the extent to which the bona fide service fees may be used as a loophole.”

Like rebates, though, administrative fees are starting to get debated by the warring sides. In a report¹² issued last November, the Pharmaceutical Research and Manufacturers of America, the industry trade group, maintained that “the variety and level of administrative and service fees charged by supply chain entities have also increased.” And PhRMA contends the fees have increased “rapidly.”

Conversely, the Pharmaceutical Care Management Association, a trade group for PBMs, released a paper¹³ on Wednesday that contended rebates are not contributing to rising drug prices and that administrative expenses have been declining over the past six years. And a spokesman wrote us to say that fees “don’t contribute to rising prices.”

Exhibit 7

Fwd: A few thoughts ahead of our cc today...

Jun 19, 2013,
1:20 PM

To: Daniel Gilman FTC; dgilman@ftc.gov

John Borzilleri [REDACTED] >
to Daniel, bcc: me

Mr Gilman: I thought I would forward some recent thoughts/information to you that might be of some value ahead of our call tomorrow. Look forward to speaking with you.

To all:

Yesterday I was reviewing public information regarding the Medicare Part D program and wanted to share some thoughts ahead of our conference call. Very interested in your thoughts/comments. I apologize if this is redundant to any of you (or too late to look at before call), but I am trying to want to make sure I understand what is really going on between PBMs and manufacturers within Part D.

First, the public report that stands out to me is the OIG report from March 2011 which I have forwarded before (but do so again below) entitled "Concerns with Rebates in the Medicare Part D program. In the text it states: "Prior to this review, little information was publicly available about the extent to which sponsors receive rebates for Part D drugs and pass them on to the Government and beneficiaries." While the report highlights many concerns regarding Part D rebates, the data that stood out to me was the modest level of overall rebates reported to CMS for 2008 (\$6.5 billion, or about 10% of \$63 in Part D spending that year), and more importantly, the ridiculously low amount of rebates (\$24 million, less than 1% of all rebates) that the PBMs claim to have retained.

Second, on page 5 of the attached document from April 13, 2010, CMS discusses the items to be included in "PBM Retained Rebates" that must be reported to the government. As indicated, this item includes numerous "direct and indirect remuneration (DIR), such as "rebates, discounts and other price concessions from the pharmaceutical manufacturers". A Part D sponsor must report "100% of manufacturer rebates, discounts and other price concessions (WITH THE EXCEPTION OF BONA FIDE SERVICE FEES FROM MANUFACTURERS) retained by its PBM.

Third, Section 42 1395w-102 of the Part D regulation requires Part D sponsors to "provide enrollees access to negotiated prices" and these "negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs". Furthermore, according to an interesting legal brief I found from a Texas assistant Attorney General, Jose Vela (attached), the same statute requires "sponsors to disclose all negotiated discounts (i.e., rebates, subsidies, remunerations) to the federal government and to PASS ALONG THE SAVINGS TO THE GOVERNMENT AND BENEFICIARIES".

With these CMS requirements, PBMs have a huge incentive to report as low an amount as possible of rebates for both their Sponsors and retained by themselves, consistent with the data in the 2008 OIG report. If they report high sponsor or retained rebates, the savings will be passed along to CMS and beneficiaries via lower premiums the following year. From the OIG report and other documents, due to the astounding ambiguity of the Part D legislation, it appears that the PBMs have many ways to hide escalating profits from the recent massive specialty drug price inflation. First, they appear to have nearly free reign to assign rebates across plans both within and outside of Medicare Part D to maximize profits. For instance, assigning most of rebates to commercial plans they manage rather than report to CMS for Part D plans. Second, it would appear that these so-called "Bona Fide Service Fees" are likely a major source of PBM profits within Part D. Interestingly, it appears that CMS is aware of potential abuse in this area and updated some related rules in January 2012 within the Affordable Care Act. Unfortunately, it does not appear that the changes have any real muscle, with many basic and abusable PBM services still excluded from the CMS drug price calculations. And of course, as per the OIG report, most Part D Sponsors appear to have little transparency regarding any of these practices at PBMs.

According to section 2503 of the Affordable Care: "Bon fide services by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs). " Supposedly, the PBMs are only allowed to exclude payments for these services from rebate/price calculations to the extent they represent "fair market value", but unfortunately CMS continues to provide no definition for the latter. In CMS own words from the Affordable Care update: "We continue to be concerned that these (Bona fide) fees could be used as a vehicle to provide discounts, as opposed to fees at "fair market value" for bona fide services. Thus to avoid potential fraud concerns, we are retaining our definition, BUT WE HAVE CHOSEN NOT TO DEFINE "FAIR MARKET VALUE" AT THIS TIME".

Sorry to be so long-winded with this all. So in summary, both the manufacturers and the PBMs have a strong incentive to both maximize drug prices and report low rebates within Part D. In this strategy, the PBMs make increased profits by either shifting reported rebates away from Part D plans and/or getting escalating payments for these "bona fide services".

I am not sure how this affects our efforts, but confusion and complexity is central to practices that have been very successful for the PBM industry for decades now. BTW the above seems quite consistent with XXX's insight that the PBMs are hiding their profits within their specialty pharmacies. I seem to end up back at the central premise of my report; namely that "anticompetitive practices" can be the only explanation for old drugs in crowded therapeutic areas increasing by 400-500% in 5-6 years, which is clearly harming consumers and appears to greatly surpass "unreasonable" threshold from my read of FTC antitrust statutes.

John

Exhibit 8

Qui Tam complaint for pharmaceutical fraudulent pricing to Medicare Part D

Inbox

Paul Barone - Comcast<paul.barone@comcast.net>

Tue, Oct 22, 2013,
11:39 AM

to Andy, edwin.winstead, sara.bloom, George

HIGHLY CONFIDENTIAL

Dear Ms. Bloom and Messrs. Mao, Winstead and Henderson,

My client, a physician and investment fund manager, has, after a nearly year-long extensive investigation, uncovered incontrovertible and extensive evidence of the largest US pharmaceutical industry fraud in history, by a wide margin, centered on pharmaceutical companies' egregious overcharging for pharmaceutical products reimbursed by the Federal Government under the Medicare Part D drug program. My client has discovered that the drug manufacturers' pricing practices have violated the Stark Anti-kickback laws and the False Claims Act by over-compensating service providers which charges have, in turn, been billed to and paid by the federal government pursuant to the Medicare Part D program.

In addition to uncovering the specific methods by which pharmaceutical companies have overcharged Medicare Part D and estimating the damages to the federal government, my client has witnessed and heard admissions of such practices by pharmaceutical company employees at industry conferences, i.e., smoking guns, and documented such admissions. His report is very clear, comprehensive, and objective and will serve as an excellent roadmap for what should be a relatively simple discovery process to prove the case. It truly requires a simple auditing exercise to follow the money that will not be time nor resource consuming for your office and the level of money damages is astounding.

We are trying to determine the best way to proceed with my client's Qui Tam claim and have learned from our research that your office has handled some of the largest of these cases (GSK's 2012 \$3 billion settlement, Pfizer's 2009 \$1.3 billion settlement) in history. Because this case is so far reaching and consequential for your office and the pharmaceutical industry, I think a meeting among you, me and my client would be the best next step in the process at which you will quickly understand the importance of this case and my client's unimpeachable credibility. Alternatively, we are happy to discuss this with you by phone but in either case we would like to have a confidentiality agreement in place or some other assurances of confidentiality that you can provide.

Thank you for your consideration and we look forward to working with you on what will most assuredly be the biggest Whistleblower case in history and, though you don't know me, I am not prone to overstatement or bluster.

All the best.

Paul H. Barone

Attorney at Law

Paul.barone@comcast.net 233

Mt. Airy Road, Suite 100

Basking Ridge, NJ 07920 Cell:

[REDACTED]

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From: Bloom, Sara (USAMA) [mailto:Sara.Bloom@usdoj.gov]
Sent: Tuesday, October 22, 2013 2:58 PM
To: Paul Barone - Comcast; Mao, Andy (CIV); Winstead, Edwin (USACO)
Subject: RE: Qui Tam complaint for pharmaceutical fraudulent pricing to Medicare Part D

We would be happy to talk to you. Is there a time, maybe tomorrow around 1:00 Eastern time? I am sure Andy will give us a call in number when we find a time. Sara

Paul Barone - Comcast<paul.barone@comcast.net>

Tue, Oct 22, 2013,
3:31 PM

to Sara, Andy, Edwin, me

Dear Sara,

Thank you so much for your email and offer to speak with me and Dr. John Borzilleri, copied on this email, who has expended an incredible amount of effort analyzing and documenting the offending pricing practices and estimating the damages, which are truly extraordinary.

We are both available tomorrow at 1pm and look forward to speaking with you and Andy.

All the best,

Paul

Paul Barone - Comcast<paul.barone@comcast.net>

Tue, Oct 22, 2013,
6:04 PM

to Sara, Andy, Edwin, me

Thanks for your email Sara and thank you Andy for arranging the 1pm call tomorrow. I've attached a summary of the case, which John has drafted, and I've also provided his resume.

We look forward to speaking with you both tomorrow and hope you have a great evening.

Paul

Paul H. Barone

Attorney at Law
Paul.barone@comcast.net 233
Mt. Airy Road, Suite 100
Basking Ridge, NJ 07920 Cell:
[REDACTED]

Clear Example of the Insidious Nature of Collusive Pricing Activity in the US...

Inbox

John Borzilleri [REDACTED]

Fri, Oct 25, 2013,
11:01 AM

to sara.bloom, andy.mao, edwin.winstead, Paul, George.Henderson2, bcc: me

To all:

In the investment world, we are in the middle of quarterly reporting season. As such, I thought I would send you one of the numerous examples of insidious, but extreme, specialty drug price inflation that has been occurring routinely in recent years. I have attached the 3Q press release from Abbvie, whose lead product Humira, a biologic for rheumatoid arthritis, accounts for 53% of its US sales and 59% of worldwide sales for this quarter.

As you will see in the press release, Abbvie highlights the strong 19% global growth of Humira, which accounts for more than 100% of the company's overall revenue growth (only 3.3%) in the quarter. US Humira sales growth was even stronger at 22.3% year over year. The initial bullets of the press release also indicates strong growth for several other key portfolio products.

Most importantly, there is no mention in the press release of the role of price, volume and other factors in revenue growth for the quarter.

I have also enclosed the just released analyst report from Morgan Stanley, I believe the only firm to provide information regarding price inflation contribution for Abbvie's

product, despite this data being publicly available in numerous databases (including IMS which is referenced). In Exhibit 5 on page 5, "PI" stands for "Price Inflation". For the 3Q, a year/year US price increase of about 14% accounted for nearly two-thirds of Humira's 22% US revenue growth. As you can see, the contribution of price inflation was far greater for other Abbvie products. While I have not done a specific estimate, clearly US Abbvie sales would be in significant decline without the large pricing benefit, which is not discussed. The growth profile for ABBVIE has been the same ever since the company was spun out a couple years ago. Furthermore, I can almost assure that, as with prior quarters, the discussion of the role of pricing in Today's management quarterly conference call with analysts will either be non-existent or minimal. I will send you the transcript when it becomes available in a few hours.

These same revenue, reporting and disclosure dynamics can be seen in virtually all companies driven by specialty drugs in recent years. All (companies, investors) are aware of the broad reliance on extreme price inflation, but it is not disclosed or discussed. I focus primarily on the MS market in my report because the abuse has been most severe (most extreme price inflation, severe competition, severely declining volume) and I believe the link to BFSF/FMV fraud would

be most straightforward to prove. However, the collusive practices between manufacturers and PBMs are unfortunately a very broad, far-reaching phenomena.

I hope this information is helpful. I have a lot more stuff I could send you. Believe it or not, there is only so much one can put in a 100-page report. I hope we can convince you to thoroughly investigate this issue that I believe is causing considerable harm, financial and otherwise.

Sincerely,

John

Fwd:link

Inbox

John Borzilleri [REDACTED]

Fri, Oct 25, 2013,
12:43 PM

to sara.bloom, edwin.winstead, andy.mao, Paul, george.henderson2, bcc: me

To all:

I apologize for overloading your email, but I thought it very important to make you aware of a recent watershed development in the PBM industry that is sending ripples throughout the drug and investment worlds. If you follow the link below, you will see that in recent weeks for the very FIRST TIME Express Scripts, the largest PBM, is removing some specialty drugs from its formulary. A few weeks ago they restricted Novo

Nordisk's biologic products in the diabetes space. Just the other day, ESRX also announced a larger list of drugs that will be excluded from their formulary starting in 2014, including Bayer's Betaseron for MS. In the box listing excluded products, you will also see a few specialty drugs in the crowded immunologic area (rheumatoid arthritis, etc) that are being excluded for the first time, namely Xeljanz, Simponi and Stelara. - another watershed event.

<http://www.drugchannels.net/2013/10/express-scripts-and-inevitability-of.html#more>

These restrictions are finally starting to occur due to increased payer pressure now that the focus on specialty drugs has increased, since they now account for a far larger part of drug spending (and virtually all of the growth in spending), largely driven by massive price increases as I have detailed to you already.

Of particular note, you will see in the link that the very FIRST reason for the exclusions is:

- **Therapeutic interchangeability** ("...clinical data shows there are other products effective in the marketplace.")

If go to the secondary link regarding the interview with the ESRX Chief Medical Officer, Steven Miller, you find the below quote, providing a broad admission of the "interchangeability" of drugs in the marketplace.

"And 85 percent of drugs are clinical optional – where clinical outcomes data demonstrates other drugs are equally well suited. Maybe there are 10 penicillins and the (committee) will let the company decide. That's when you can apply economics to the equation and pit the different providers against each other... So for the 48 (excluded) drugs, clinical data shows there are other products effective in the marketplace."

Of course, he slyly only mentions penicillin specifically as an example (a category that has been generic for decades and accounts for minimal drug spending), but the implications are obvious. This admissions provides clear validation of what I have known all along, as both a physician and healthcare analyst - namely that there has been enormous potential for huge savings in crowded specialty drug categories for years, but massive inflation has occurred instead due to collusion/fraud.

The PBMs are now being forced to begin to seek specialty savings due to rising market pressures, although ESRX clearly states these recent changes only affect a minimal part of their business/patients thus far. No doubt the smaller PBMs will be following suit in the near future and we are only in the early stages of increased price competition.

Finally, I believe these recent ESRX changes, however modest, provide clear validation of all the market dynamics discussed in my report. Unfortunately for manufacturers and

PBMs, the massive pricing abuse and potential fraud has already occurred. One can not rewrite the past.

Thanks,

John

Possible qui tam complaint re pharmaceutical pricing

Inbox

Henderson, George (USAMA) <George.Henderson2@usdoj.gov> Wed, Nov 13, 2013, 4:27 PM
to me, Paul.barone@comcast.net, Andy, Sara

Dear Mr. Borzilleri and Mr. Barone,

We have reviewed the information you sent us, and I can give you my impressions. If you wish, give me some dates and times for a phone call. I am available in the middle of the day tomorrow, and most of the day Friday. I also have times available next week.

Regards,

Bunker Henderson

George B. Henderson, II Assistant
U.S. Attorney
John J. Moakley U.S. Courthouse, Suite 9200 1
Courthouse Way
Boston, MA 02210
Phone: (617) 748-3272
Fax: (617) 748-3971
george.henderson2@usdoj.gov

RE: Possible qui tam complaint re pharmaceutical pricing

Inbox

Henderson, George (USAMA) <George.Henderson2@usdoj.gov> Wed, Nov 13, 2013, 5:26 PM
to Paul, me, Andy, Sara

2:00 pm EST tomorrow is good for me. We can use the following conference number:

Dial-in: [REDACTED]
Participant passcode: [REDACTED]

RE: Possible qui tam complaint re pharmaceutical pricing

Inbox

Paul Barone - Comcast <paul.barone@comcast.net>

Thu, Nov 14, 2013,
4:51 PM

to George, sara.bloom, me

Dear George and Sara,

Thank you very much for the call today, your time and helpful feedback. I've already contacted one former colleague at Medco to try and get a contract and will try to find other avenues to obtain one. However, I would say that if the percentage of revenues method for calculating BFSFs, which has no correlation with FMV, wasn't common and current that conference would never have been held *this* year and the attendees wouldn't have spent so much time talking about the risks of paying for the services on a percentage-of-revenue because it might not represent FMV. In fact one of the consultants said she was NOT worried about it because she could back into and justify any number and hoped the conference wasn't being recorded.

In addition to trying to obtain more evidence, we will provide the complaint which may be better organized and more compelling in regard to reaching the conclusion that but for the overpayment of BFSFs based on percentage-of-revenue to the PBMs the four commodity-like MS products wouldn't have seen prices quintuple in lockstep AND rebates remain miniscule. I can tell you from my experience at Medco that twenty years ago Medco would've played all four of those manufacturers off against each other and realized huge rebates and discounts – often far into double digits, e.g., 50-60% - and would've kept the lion's share. In those days the rebates represented virtually ALL their profit but now those rebates and discounts are immaterial to the business.

One question I have is if we file the complaint and you do decide to take it on, can you obtain the contracts through discovery or other process, e.g., subpoena, *before* the court allows the inevitable motion to dismiss on which it must rule? My second question is can you provide your colleague Zach's contact information and do you want to be on a call that we'd like to have with him? Lastly, can we go ahead now and send him the materials and schedule that call?

Thank you again for your help, advice and consideration. As you can tell from our calls, John and I are totally committed to exposing the fraudulent and illegal BFSFs percent-of-revenue pricing practice and, despite the typical evidentiary challenges, are very confident we will prevail provided we can get into discovery.

Best Regards.

Paul

Paul H. Barone
Attorney at Law
Paul.barone@comcast.net 233
Mt. Airy Road, Suite 100
Basking Ridge, NJ 07920 Cell:
[REDACTED]

RE: Qui tam complaint re pharmaceutical pricing

Inbox

Paul Barone - Comcast<paul.barone@comcast.net>

Sun, Nov 17, 2013,
1:26 PM

to zach.cunha, me, George, Sara

Dear Mr. Cunha,

As suggested by Sara and Bunker, I am writing you in regard to Dr. John Borzilleri's Qui tam complaint, a rough draft of which is attached for your information along with John's very comprehensive report. John is a physician and investment fund manager and has, after a nearly year-long extensive investigation, uncovered evidence of what could be the largest US pharmaceutical industry fraud in history, centered on pharmaceutical companies' egregious overcharging for pharmaceutical products reimbursed by the Federal Government under the Medicare Part D drug program. He has discovered that the drug manufacturers' pricing practices have violated the Stark Anti-kickback law and the False Claims Act by over-compensating service providers which charges have, in turn, been billed to and paid by the federal government pursuant to the Medicare Part D program.

In addition to uncovering the specific methods by which pharmaceutical companies have overcharged Medicare Part D and estimating the damages to the federal government, my client has witnessed and heard admissions of such practices by pharmaceutical company employees at industry conferences, i.e., smoking guns, and documented such admissions. His report is very clear, comprehensive, and objective and will serve as an excellent roadmap for what should be a relatively simple discovery process to prove the case. An examination of the pharmaceutical manufacturers' contracts with pharmacy benefit managers should provide the details necessary to prove liability and damages so it should not be as time nor resource consuming for the DOJ as was the GSK and Pfizer off-label promotion cases.

We are happy to discuss this with you by phone at your convenience so please let me know if that is of interest and, if so, your availability for such a call.

Thank you for your consideration and I hope we have the opportunity to discuss this case with you.

All
the
best.
Paul

Paul H.
Barone
Attorney
at Law
Paul.barone@comcast.net
t 233 Mt. Airy Road,
Suite 100 Basking
Ridge, NJ 07920 Cell:
[REDACTED]

RE: Venue for Qui tam complaint re pharmaceutical pricing

Inbox

Paul Barone - Comcast<paul.barone@comcast.net>

Mon, Dec 9, 2013,
3:18 PM

to Sara, Zachary, George, me

Dear Sara, Zach and Bunker,

We are still fine-tuning the complaint but getting close to filing and just need to decide whether it will be Boston or Rhode Island. Would it be possible for one more call in the near future?

Thank you again for all of your help and
guidance. All the best,

Paul

Paul H.
Barone
Attorney

Exhibit 9**Defendant Drugs****Total Part D Claims for Payment: 2012-2016**

in thousands

	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>	
Enbrel	308	354	375	366	344	
Humira	267	325	362	401	447	
Humulin	1,576	1,814	1,897	1,925	1,955	
Celebrex	3,186	3,628	3,359	247	68	
Chantix	253	358	373	360	446	
Gleevec	95	111	118	125	77	
Tasigna	15	21	26	30	33	
Sprycel	14	20	26	31	34	
Lantus	7,764	8,466	8,727	8,855	8,627	
Lyrica	3,440	4,111	4,487	4,733	4,941	
Premarin	2,149	2,432	2,115	1,797	1,344	
Pristiq	547	595	576	557	543	Change
Relpax	39	54	58	61	63	2012-
Viagra	273	327	160	162	185	<u>2016</u>
Total Defendant Drugs	19,927	22,617	22,661	19,650	19,107	-4%
	-	13%	0%	-13%	-3%	
Total Part D Claims (000)	1,125,355	1,308,746	1,400,322	1,446,458	1,444,588	28%
	-	16%	7%	3%	0%	
Defendant Share of Part D (%)	1.8%	1.7%	1.6%	1.4%	1.3%	

Source: CMS

Exhibit 10**Defendant Drugs****Total Part D Spending: 2012-2016**

in \$thousands

	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>	<u>Change</u> <u>2012-</u> <u>2016</u>
Enbrel	\$721,976	\$976,955	\$1,198,328	\$1,385,069	\$1,572,038	118%
Humira	674,609	955,332	1,239,854	1,662,182	2,197,989	226%
Humulin	282,452	383,941	519,950	654,697	733,282	160%
Celebrex	693,254	947,002	1,065,606	87,091	36,795	-95%
Chantix	44,629	72,708	86,815	98,231	142,360	219%
Gleevec	601,650	779,576	995,836	1,232,940	762,555	27%
Tasigna	109,347	154,917	204,570	260,372	307,612	181%
Sprycel	105,310	158,278	214,598	279,636	321,854	206%
Lantus	1,943,100	2,683,060	3,742,568	4,359,504	4,214,423	117%
Lyrica	767,435	1,073,705	1,404,488	1,766,474	2,099,262	174%
Premarin	246,074	355,582	372,984	383,046	342,283	39%
Pristiq	95,290	124,493	146,344	171,123	196,707	106%
Relpax	11,867	18,712	22,099	27,236	35,513	199%
Viagra	33,502	54,794	22,681	25,575	36,713	10%
Defendant Total	\$6,330,495	\$8,739,056	\$11,236,723	\$12,393,175	\$12,999,387	105%
	-	38%	29%	10%	5%	
Total Part D	\$82,844,605	\$100,023,664	\$119,454,929	\$129,995,220	\$137,003,060	65%
	-	21%	19%	9%	5%	
Defendant Share (%)	7.6%	8.7%	9.4%	9.5%	9.5%	

Source: CMS.

Exhibit 11**Part D Spending, Claims and Pricing Trends: 2012-2016****Massive Defendant Drug Spending Increases****Driven by Price Increases**

	<u>Enbrel (AMGN)</u>	<u>Humira (ABBV)</u>
2016 Part D Spending (\$000)	\$1,572,038	\$2,197,989
2012-16 Change Part D Spending	118%	226%
2012-16 Change Part D Claims/Enrollee	-14%	28%
2012 Part D Cost/Patient/Year (\$)	\$28,163	\$30,304
2016 Part D Cost/Patient/Year (\$)	\$54,766	\$58,963
2012-2016 Part D Change Cost	1.9	1.9
	<u>Lantus (SNY)</u>	<u>Humulin (LLY)</u>
2016 Part D Spending (\$000)	\$4,214,423	\$733,282
2012-16 Change Part D Spending	117%	160%
2012-16 Change Part D Claims/Enrollee	-15%	-5%
2012 Part D Cost/Patient (\$)	\$3,003	\$2,150
2016 Part D Cost/Patient (\$)	\$5,862	\$4,501
2012-2016 Part D Change Cost	2.0	2.1
	<u>Lyrica (PFE)</u>	<u>Premarin (PFE)</u>
2016 Part D Spending (\$000)	\$2,099,262	\$342,283
2012-16 Change Part D Spending	174%	39%
2012-16 Change Part D Claims/Enrollee	10%	-52%
2012 Part D Cost/Patient (\$)	\$2,677	\$1,374
2016 Part D Cost/Patient (\$)	\$5,099	\$3,056
2012-2016 Part D Change Cost	1.9	2.2
	<u>Gleevec (NVS)²</u>	<u>Tasigna (NVS)</u>
2016 Part D Spending (\$000)	\$1,232,940	\$307,612
2012-16 Change Part D Spending	105%	181%
2012-16 Change Part D Claims/Enrollee	6%	65%
2012 Part D Cost/Patient (\$)	\$76,115	\$85,095
2016 Part D Cost/Patient (\$)	\$119,587	\$111,168
2012-2016 Part D Change Cost	1.6	1.3

¹ Celebrex Part D Sales for 2014, prior to US patent expiry.² Gleevec Part D Sales for 2015, prior to US patent expiry.

Source: CMS

Exhibit 12**Part D Share of Defendant US Sales****Part D a Greater Share vs SAC Estimates**

<u>Defendant Product</u>	<u>Relator Estimate</u>	<u>Part D Actual</u>
Enbrel	30%	27%
Humira	30%	21%
Humulin	30%	85%
Celebrex	35%	61%
Chantix	15%	24%
Gleevec	60%	31%
Tasigna	60%	43%
Sprycel	60%	33%
Lantus	30%	65%
Lyrica	30%	67%
Premarin	30%	36%
Pristiq	25%	62%
Relpax	15%	12%
Viagra	20%	2%
Total Defendants	30%	39%

Source: Relator Estimates and CMS.

Exhibit 13**SDNY Defendant Drugs****Est. ANNUAL Part D Fraudulent Sales (\$000)**

	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>
Enbrel	\$145,565	\$317,630	\$526,978	\$763,636
Humira	133,995	324,931	649,497	1,068,349
Humulin	58,866	179,974	309,710	382,996
Celebrex	157,636	334,702	33,428	22,014
Chantix	9,517	20,963	34,756	63,615
Gleevec	2,435	2,790	3,276	3,826
Tasigna	7,802	22,247	45,968	72,147
Sprycel	8,016	24,926	51,531	72,559
Lantus	564,364	1,558,445	2,143,264	2,055,432
Lyrica	156,680	403,594	710,788	997,150
Premarin	77,147	130,851	177,244	188,390
Pristiq	20,778	45,895	73,983	102,047
Relpax	2,298	4,500	8,633	16,185
Viagra	14,578	3,007	5,730	14,056
Total Defendant Drugs	\$1,359,678	\$3,374,454	\$4,774,786	\$5,822,402
	-	148%	41%	22%

Source: CMS

Exhibit 14**SDNY Defendant Drugs****Est. CUMULATIVE Part D Fraudulent Sales (\$000)**

	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>
Enbrel	\$145,565	\$463,195	\$990,173	\$1,753,809
Humira	133,995	458,926	1,108,423	2,176,772
Humulin	58,866	238,840	548,551	931,547
Celebrex	157,636	492,338	525,765	547,780
Chantix	9,517	30,480	65,236	128,851
Gleevec	77,682	323,032	762,626	1,039,828
Tasigna	7,802	30,049	76,017	148,164
Sprycel	8,016	32,942	84,473	157,032
Lantus	564,364	2,122,809	4,266,072	6,321,504
Lyrica	156,680	560,275	1,271,063	2,268,213
Premarin	77,147	207,998	385,242	573,632
Pristiq	20,778	66,673	140,656	242,703
Relpax	2,298	6,798	15,431	31,616
Viagra	14,578	17,584	23,315	37,371
Total Defendant Drugs	\$1,434,925	\$5,051,938	\$10,263,043	\$16,358,820
	-	252%	103%	59%

Source: CMS.

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,
ex rel. JOHN R BORZILLERI, M.D. et al.,

Plaintiffs,

vs.

ABBVIE, INC., et al.,

Defendants.

Case No. 15-cv-7881(JMF)

**MEMORANDUM OF LAW IN SUPPORT OF
MANUFACTURER DEFENDANTS' JOINT MOTION
TO DISMISS RELATOR BORZILLERI'S
SECOND AMENDED COMPLAINT**

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42 U.S.C. § 1395, <i>et seq.</i>	7
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Colo. Rev. Stat. § 25.5-4-306(2)(e)	17
Colo. Rev. Stat. § 25.5-4-306(5)(c)	40
Conn. Gen. Stat. § 4-277(d)	17
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D.C. Code § 2-381.03(b)(6)	17
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Fla. Stat. § 68.083(7)	17
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INTRODUCTION

The *qui tam* provision of the federal False Claims Act (FCA) is intended to incentivize whistleblowing insiders to bring genuinely valuable information to the attention of the United States. It is not intended to encourage generalized speculation of alleged wrongdoing to advance the short-selling goals of opportunist individuals looking for personal gain. Relator John Borzilleri falls squarely in the latter camp. He is a (now former) health care investment fund manager who admits that he is accusing the thirteen defendant companies of fraud on the Medicare Part D program based on absolutely no personal knowledge of anything that any of them have done in connection with this federal drug prescription program. Instead, his 922-paragraph Second Amended Complaint (SAC or N.Y. SAC) spins a meandering and speculative conspiracy theory based on his purported analysis of public sources and conversations with individuals unconnected to any of the companies he has named as defendants.

This suit is subject to dismissal for many reasons. First, before Borzilleri filed this suit, he filed another *qui tam* complaint in the District of Rhode Island offering a substantively identical Medicare Part D fraud theory, which was pending at the time he filed this suit (and remains pending). As a result, this suit is precluded by the FCA's first-to-file bar. *U.S. ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 167 (2d Cir. 2018) ("The command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed." (citation omitted)). Second, the SAC is deficiently pled in its entirety. Among other things, the SAC does not come remotely close to pleading fraud with particularity as required by Rule 9(b). It hypothesizes that the "Manufacturer Defendants" paid service fees to the "Pharmacy Benefit Manager (PBM)

Defendants”¹ that were criminal kickbacks, were not properly reported by Medicare Part D plan sponsors to Medicare, and caused false claims. But Borzilleri admits he lacks any knowledge of the existence or terms of any contract he says included a service-fee provision, has no knowledge of how any service fees were reported by PBMs to the plan sponsors or by the plan sponsors to Medicare, and has no knowledge of any false claims. Such generalized speculation is the antithesis of pleading fraud with particularity. Third, because Borzilleri is not an insider, he derives all of his allegations from the public domain. His allegations amount to nothing more than the notion that undisclosed, excessive service fees between manufacturers and PBMs can lead to an inference of fraud—a notion that the SAC confirms had been publicly disclosed in various qualifying sources before he filed suit, including (among other places) in a report that the Office of the Inspector General (OIG) for the Department of Health and Human Services published entitled “Concerns with Rebates in Medicare Part D.” The FCA’s public-disclosure bar precludes precisely this type of *qui tam* claim, unless a relator qualifies as an original source. Borzilleri plainly does not.

The SAC should be dismissed in its entirety and without leave to amend. Borzilleri has already repeatedly amended his complaint and has no way to cure basic pleading deficiencies that result from either (1) his admitted lack of actual knowledge of any conduct by any Defendant or (2) the public-disclosure bar. The Manufacturer Defendants incorporate by reference the arguments made in the PBM Defendants’ motion to dismiss.

¹ Relator Borzilleri refers to AbbVie Inc., Amgen Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Novartis Pharmaceuticals Corporation, Pfizer, Inc., and sanofi-aventis U.S. LLC collectively as the “Manufacturer Defendants,” and he refers to Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc., and UnitedHealth Group, Inc. collectively as the “Pharmacy Benefit Manager (PBM) Defendants.” SAC ¶ 1.

BACKGROUND

Borzilleri filed this *qui tam* action under seal on October 6, 2015. Dkt. 1. After investigating the allegations, the federal government, all state governments, and the District of Columbia declined to intervene, and the complaint was unsealed on April 13, 2018. Dkt. 20, 141. Borzilleri filed a First Amended Complaint on July 4, 2018, Dkt. 58, and he filed the SAC on August 3, 2018. Dkt. 148.

Borzilleri describes himself as a “professional healthcare investment fund manager.” SAC ¶ 1. Defendants are pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and private health insurers. While employed at the investment firm Shepherd Kaplan Krochuk, LLC, Borzilleri came to believe that rising drug prices were the result of “a straightforward price collusion scheme between certain pharmaceutical companies” and PBMs. SAC ¶ 11. In an effort to capitalize on his hypothesis, Borzilleri filed two separate FCA lawsuits against pharmaceutical manufacturers and PBMs and then began short-selling the stock of the companies that he had sued. Complaint, *John R. Borzilleri, MD, v. Shepherd Kaplan Krochuk, LLC*, No. 18-cv-04654-RJS (S.D.N.Y. May 25, 2018), Dkt. 1, ¶¶ 24, 29.²

A. Borzilleri’s Allegations³

1. Borzilleri’s First *Qui Tam* Lawsuit

In January 2014, Borzilleri filed a *qui tam* complaint in the District of Rhode Island against pharmaceutical manufacturers, PBMs, and health insurers. On May 1, 2014, Borzilleri

² In considering a motion to dismiss, the Court may consider materials referenced in the complaint and matters of public record. *See, e.g., Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 75 (2d Cir. 1998). “[M]atters of public record” that may be considered include “pleadings in another action.” *Rahman v. Schriro*, 22 F. Supp. 3d 305, 311 (S.D.N.Y. 2014) (citation omitted); *see also In re RadPro SecurPass Scanner Cases*, No. 13-cv-6095-CS, 2014 WL 4054310, at *4 (S.D.N.Y. Aug. 13, 2014).

³ Borzilleri’s well-pleaded factual allegations are assumed to be true solely for purposes of this motion.

filed a first amended complaint in that action, which was the operative complaint pending when Borzilleri filed this lawsuit. *See* Exhibit A, First Amended Complaint, *U.S. ex rel. John R. Borzilleri, M.D. v. Bayer AG, et al.*, No. 14-cv-00031-WES-LDA (D.R.I. May 1, 2014), Dkt. 6 (R.I. FAC). The R.I. FAC was unsealed on April 5, 2018, after the United States declined to intervene. *See* Order, *id.*, Dkt. 36, 37. On August 17, 2018, Borzilleri filed a second amended complaint in the Rhode Island action. *See* Exhibit B, Second Amended Complaint, *id.*, Dkt. 95 (R.I. SAC). The crux of Borzilleri's Rhode Island complaint—just like his complaint in this case—is the contention that pharmaceutical manufacturers paid excessive service fees to PBMs that amounted to criminal kickbacks and were not properly reported by Part D plan sponsors to the Centers for Medicare & Medicaid Services (CMS). *Id.* ¶¶ 14-15, 29, 31, 152-153. The Rhode Island case remains pending.

2. Borzilleri's Second *Qui Tam* Lawsuit

On October 6, 2015, while the United States was still investigating his Rhode Island complaint, Borzilleri filed this action. Dkt. 1. Defendants include eight companies that are also defendants in his Rhode Island suit (Pfizer, Novartis, Express Scripts, CVS, Aetna, UnitedHealth Group, Humana, and Cigna) and five additional companies (AbbVie, Amgen, Bristol-Myers Squibb, Eli Lilly, and sanofi-aventis U.S. LLC). SAC ¶ 1.

The allegations in the N.Y. SAC are nearly identical to those in the Rhode Island action. In fact, hundreds of paragraphs in the two operative complaints are materially identical to one another, the product of copying-and-pasting and only minor editing to reflect different parties or products.⁴ In both suits, Borzilleri alleges:

- The *same* purported “kickbacks” and price collusion scheme (manufacturers’ payment to PBMs of service fees in excess of fair market value to enable drug price increases);

⁴ Compare generally R.I. SAC with N.Y. SAC.

- through the *same* means (“secretive” Medicare Part D service fee contracts);
- over the *same* period (2006 to present);
- resulting in the *same* false claims (false reports to CMS and false certifications); and
- in violation of the *same* laws (the FCA, the Anti-Kickback Statute, and state false-claims laws).

Compare id. at ¶¶ 28, 169, 170, 806-921 *with* R.I. SAC at ¶¶ 29, 152, 153, 691-806.

The SAC’s factual allegations are based overwhelmingly upon publicly available documents and data. Borzilleri relies, for instance, on press releases (¶ 219); SEC filings (¶¶ 220-22, 283, 605, 668-671, 780-804); publicly disclosed PBM contracts (¶¶ 193, 691-700, 704-713); reports and other publications from the OIG (¶¶ 36, 156, 227-228, 340, 344-345, 645, 676-680, 761, 763-765); court filings (¶¶ 90, 301-304, 329-331); congressional documents (¶¶ 407, 755); and widely accessible reports and articles (¶¶ 67, 99-101, 177-213, 498, 616, 658). Borzilleri also describes communications allegedly made at an October 2013 compliance conference. *See id.* at ¶¶ 445-489.

Indeed, as Borzilleri acknowledged in response to a recent suit filed by his now-former employer, “the DOJ indicated that Dr. Borzilleri’s investigation and [the] Qui Tam actions were not based upon any ‘insider information,’ ” but rather on “Dr. Borzilleri’s extensive proprietary research, based upon public information.” Exhibit C, Answer and Counterclaim, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418, ¶ 32 (Mass. Super. Ct. May 31, 2018).

Borzilleri’s reliance on public information has resulted in a *qui tam* lawsuit that lacks *any* specifics regarding any Defendant’s supposed misconduct. For example, Borzilleri argues that the Manufacturer Defendants paid “straightforward ‘kickbacks’ ” to the PBM Defendants. SAC ¶ 169(1)-(2) (emphasis omitted). But he concedes that he does not know the timing or amount of any payment(s) by a Manufacturer Defendant to any PBM Defendant, on what terms any such

payments were made, or even whether any Manufacturer Defendant had a contract that included a service-fee term with any PBM Defendant: “Of note, the individual ‘service fee’ contracts between the Manufacturer and PBM Defendants remain a closely guarded secret, obtainable by the non-insider Relator only via discovery.” *Id.* at ¶ 180 (emphasis omitted); *see also id.* at ¶ 218 (admitting that he lacks information regarding “financial terms and transactions” between pharmaceutical manufacturers and PBMs). Nor does the SAC contain any details regarding any allegedly false report submitted by any Part D plan sponsor to Medicare regarding service-fee payments to PBMs by any Manufacturer Defendant. *See generally* SAC.

B. The Government’s Declination and Borzilleri’s Short-Selling

On March 8, 2018, the federal government, the named states, and the District of Columbia all declined to intervene in the Rhode Island action. D.R.I. Dkt. 36, 37. Five days later, this Court issued an order stating that the federal government, the named states, and the District of Columbia declined to intervene in this action. Dkt. 19. Borzilleri’s complaint in Rhode Island was unsealed on April 5, 2018, and his complaint before this Court was unsealed on April 13, 2018. D.R.I. Dkt. 37; S.D.N.Y. Dkt. 19.

Knowing the unsealing was coming, Borzilleri “significantly increased” his “short positions in the securities of the defendants.” Exhibit D, Complaint, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418, ¶¶ 35, 52 (Mass. Super. Ct. May 8, 2018); *see also* Answer and Counterclaim, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418, ¶ 35. Borzilleri’s employer noticed those “unusually large short positions” and “restricted [his] Fund from trading the two largest positions, both of which were securities of defendants” in one or both of the complaints Borzilleri had filed. Complaint, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, at ¶ 36. In fact, “by April 17, 2018, the seven largest short positions in the Fund were against the securities of the defendants” named in one or both of Borzilleri’s

complaints. *Id.* at ¶ 37. On that same day, Borzilleri issued a press release to numerous media outlets and financial institutions, describing his allegations and attaching the two complaints. *Id.* at ¶ 38. After an internal investigation by his employer, Borzilleri was terminated for “aggressive trading during the period in which he knew that information about the [lawsuits] would soon be made available to the public.” *Id.* at ¶ 52.

REGULATORY FRAMEWORK

A. The Medicare Part D Program

Medicare is a federal government health insurance program operated by CMS for the elderly and those with certain disabilities. There are four parts to the Medicare program: Parts A through D. 42 U.S.C. § 1395 *et seq.* The SAC concerns only the Medicare Part D program.

Medicare Part D is a prescription drug benefit program that was fully implemented in 2006. Over 40 million Medicare beneficiaries today receive coverage for prescription drugs through a Part D plan. *See* Kaiser Family Foundation, Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing (May 17, 2018).⁵ Part D plans are operated by Part D “sponsors,” private health insurers that contract with CMS to offer outpatient drug benefits to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-111(b). Part D plan sponsors negotiate drug prices with pharmaceutical manufacturers, establish formularies, and otherwise manage Part D plans, sometimes using the services of PBMs. *See* 42 C.F.R. Part 423.

PBMs may also perform services for drug manufacturers and receive payment for doing so. For instance, as Borzilleri acknowledges, PBMs can be “directly compensated by drug manufacturers via designated ‘bona fide service fees[.]’ ” SAC ¶¶ 13, 155. The Part D regulations define bona fide service fees (BFSFs) as “fees paid by a manufacturer to the entity

⁵ Available at <http://files.kff.org/attachment/Issue-Brief-Medicare-Part-D-in-2018-The-Latest-on%20Enrollment-Premiums-and-Cost-Sharing>.

that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer.” 42 C.F.R. § 423.501. The service should be one that the manufacturer would otherwise perform or contract for and that fee must not be “passed on” to the PBM’s clients. *Id.*

Under the Part D program, plan sponsors report direct and indirect remuneration (DIR) to CMS, which reduces CMS’s payments to plan sponsors. *See* 42 C.F.R. § 423.308. CMS defines DIR as “including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.” *Id.* BFSFs, however, are excluded from DIR. 42 C.F.R. § 423.514(d)(4) (stating that DIR is to “exclud[e] bona fide services fees”).

Part D plan sponsors and PBMs have reporting obligations under Part D. For example, Part D plan sponsors report DIR directly to CMS. *See, e.g.,* Exhibit E, CMS Memo from Cheri Rice to All Part D Plan Sponsors, *Final Medicare Part D DIR Reporting Requirements for 2016* at 1 (June 23, 2017). Similarly, PBMs must provide information to plan sponsors so that plan sponsors can report DIR. 42 C.F.R. § 423.514(d) (“[e]ach entity that provides pharmacy benefits management services” must provide certain information to Part D sponsors); *see also* SAC ¶ 285. After the Part D program was launched, BFSFs were also required to be reported by Part D plan sponsors to CMS. *See, e.g.,* CMS Memo from Cheri Rice, *supra*, at 28-29 (directing plan sponsors to “[i]nclude in this column” of the Summary DIR Report the portions of all fees that meet the definition for “bona fide service fees”). Manufacturers have no reporting obligations for DIR or BFSFs under Part D. *See id.*; *see also* 42 C.F.R. § 423.514.⁶

⁶ Borzilleri is legally incorrect in asserting that “service fees” exceeding fair market value must be reported “by the Drug Manufacturer to the plan sponsor in Medicare Part D.” SAC ¶ 30; *see also* ¶ 169(5).

The Part D program does not prohibit service fees that exceed fair market value; it only requires that plan sponsors report any amount that exceeds fair market value as DIR. *See, e.g.*, CMS Memo from Cheri Rice, *supra*, at 11, 16, 21. Borzilleri acknowledges that CMS permits payments for service fees under Part D that exceed fair market value. SAC ¶¶ 291, 640.

B. The Federal Anti-Kickback Statute (AKS)

The AKS prohibits the knowing and willful payment, receipt, solicitation, or offer of “remuneration” to induce the purchase or recommendation of “any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). Congress, however, specifically protected a variety of arrangements under the AKS. For instance, “discounts or other reductions in price,” including rebates, are protected under a statutory exception. *Id.* § 1320a-7b(b)(3)(A).

Separately, Congress delegated authority to OIG to create additional safe harbors for various arrangements that might otherwise constitute “remuneration” under the AKS. *Id.* § 1320a-7b(b)(3)(E). One safe harbor created by the OIG protects payments made to Group Purchasing Organizations (GPOs). The OIG has stated, in longstanding guidance, that payments from manufacturers to PBMs can be protected under the GPO safe harbor. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003) (GPO “rebates and other payments” are afforded “[p]rotection” under the AKS by “structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j).”). When this safe harbor applies, percentage-based fees paid by a vendor, such as a pharmaceutical manufacturer, to a GPO are protected. 42 C.F.R. § 1001.952(j)(1). Other safe harbors exist in addition to the GPO safe harbor, and they may be applicable to various PBM-manufacturer relationships. Further, an arrangement need not comply with a safe harbor to be permitted under

the AKS. OIG, *Federal Anti-Kickback Law and Regulatory Safe Harbors, Fact Sheet* (Nov. 1999).⁷

ARGUMENT

I. THE FIRST-TO-FILE BAR MANDATES DISMISSAL OF THIS ACTION.

This case should be dismissed because it mirrors an FCA suit that was pending in the District of Rhode Island when Borzilleri filed the present action. Under the FCA's first-to-file bar, "[w]hen a person brings an action under [the FCA], *no person* other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5) (emphasis added). As the Second Circuit held recently, this bar means that "as long as a first-filed complaint remains pending, no related complaint may be filed." *Wood*, 899 F.3d at 167 (quoting *U.S. ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011)). The command is "exception-free," applying even if the same relator brought both actions. See *U.S. ex rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 11-12 (1st Cir. 2016) (collecting cases).

The first-to-file rule "furthers the FCA's goal of avoiding piecemeal and duplicative litigation that does not advance the [G]overnment's investigation of alleged fraud." *Id.* at 11; see also *U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 233-34 (3d Cir. 1998) ("[D]uplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds."). Thus, as the Second Circuit has stated, "[i]f the first-filed complaint ensures that the Government would be equipped to investigate the fraud alleged in the later-filed complaint," then the first-to-file bar applies and the second suit must be dismissed. *Wood*, 899 F.3d at 169 (citation omitted). This Court put it even more succinctly:

⁷ Available at <https://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm>.

“notice to the Government is key.” *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 792 (S.D.N.Y. 2017), *aff’d in part, rev’d in part on other grounds*, 889 F.3d 163 (2d Cir. 2018).

Here, Borzilleri’s original complaint, filed on October 6, 2015, duplicated the *qui tam* lawsuit that Borzilleri had filed in Rhode Island nearly two years earlier. *See U.S. ex rel. Borzilleri v. Bayer Healthcare Pharm., Inc.*, No. 14-00031 (D.R.I., filed under seal Jan. 16, 2014). The Rhode Island case—in which the Government also declined to intervene—was “pending” on the day Borzilleri filed this action (and remains pending today). Therefore, his New York suit is barred so long as the two suits are “related.” *See* 31 U.S.C. § 3730(b)(5); *Wood*, 899 F.3d at 172 (“[A] claim is barred by the first-to-file bar if at the time the lawsuit was brought a related action was pending.” (emphasis in original)).

Borzilleri’s Rhode Island and New York complaints are clearly “related.” To be related for purposes of the first-to-file bar, two suits need not be precisely the same. Rather, two actions are related when “the claims incorporate ‘the same material elements of fraud,’ ” even if the later-filed “allegations [also] incorporate additional or somewhat different facts or information.” *Wood*, 899 F.3d at 169 (citation omitted). Applying this test requires nothing more than “a side-by-side comparison” of the two complaints. *Wood*, 246 F. Supp. 3d at 790 (citing *In re Natural Gas Royalties*, 566 F.3d 956, 964 (10th Cir. 2009)); *see also U.S. ex rel. Hanks v. U.S. Oncology Specialty, LLP*, No. 08-3096, 2018 WL 4409832, at *19 (E.D.N.Y. Sept. 17, 2018) (“To determine relatedness, the Court compares Relator’s original pleading to the pleadings in actions that were pending at the time this action was commenced.”).

The overlap between Borzilleri’s original New York complaint and the Rhode Island FAC, which was pending when he filed his New York suit, is striking. Both complaints alleged the *same fraud*: “fraudulent overpayments of ‘Bona Fide Service Fees’ (BFSFs) far in excess of

the legally-required ‘Fair Market Value’ (FMV) to the PBM Defendants, as part of a nationwide [systemic] collusive [price-inflation] scheme in the Medicare Part D program.” R.I. FAC ¶ 10; N.Y. Compl. ¶ 2 (alterations appear in N.Y. Compl.). Both complaints alleged the Manufacturer Defendants compensated the PBM Defendants with fraudulent BSFSs based upon “percent of revenue” service contracts. R.I. FAC ¶ 26; N.Y. Compl. ¶ 7. Both complaints alleged the PBM Defendants accepted these BSFSs as “kickbacks” in exchange for favorable formulary placement. R.I. FAC ¶ 167(1); N.Y. Compl. ¶ 10. And both complaints alleged the purported scheme facilitated massive price inflation benefitting the Manufacturer Defendants and PBM Defendants alike. R.I. FAC ¶ 26; N.Y. Compl. ¶¶ 25, 60. Finally, both complaints alleged this “scheme” resulted in the PBM Defendants submitting a “myriad of false claims” to the Government in violation of the FCA and Anti-Kickback Statute. R.I. FAC ¶ 95; NY Compl. ¶¶ 450-51. In short, the two actions “incorporate the same material elements of fraud,” and are thus “related” under the FCA. *Wood*, 869 F.3d at 169.

The operative complaints in both actions further confirm Borzilleri has alleged the same material elements of fraud in the two *qui tam* cases. Indeed, the operative Rhode Island and New York complaints frequently use verbatim language, with more than 600 paragraphs essentially copied from the former and pasted into the latter. *Compare* R.I. SAC ¶¶ 15, 29, 81 (alleging payment by pharmaceutical manufacturers of “kickbacks” to the same PBMs in the form of “service fees” that are “often linked to massive drug prices” with “no legitimate ‘services’ provided by the PBM Defendants and their specialty pharmacy subsidiaries” and that this fraud involved “the Manufacturer and PBM Defendants enter[ing] into an intentional, secretive and fraudulent price inflation scheme, based upon ‘service fee’ contracts, in gross violation of the [FCA] and the Anti-Kickback Statute (AKS)”) with N.Y. SAC ¶¶ 14, 28, 79 (same); *compare*

also R.I. SAC ¶¶ 7, 20, 27, 88, 198-99, 205, 302, 443 with N.Y. SAC ¶¶ 7, 19, 26, 86, 220-21, 227, 284, 445 (asserting virtually verbatim allegations in both complaints).

Aside from their venues and filing dates, the two cases differ in only two basic respects: they focus on different drugs, and each includes some additional defendants. But neither of these differences can save this case from dismissal under the first-to-file bar.

First, it does not matter that the Rhode Island suit “focuses” on multiple sclerosis (“MS”) medications, *see* R.I. FAC ¶ 10, whereas this New York suit mainly focuses on “the next three largest Part D spending categories”—“anti-tumor necrosis factor (TNF) drugs (for rheumatoid arthritis, etc.), chronic myeloid leukemia (CML) oral cancer drugs and diabetes therapies,” *see* N.Y. Compl. ¶ 39. Because the two suits allege the same fraudulent scheme, the Government would be “equipped to investigate the fraud alleged in” this action based on the Rhode Island action. *Wood*, 899 F.3d at 169.

This Court’s and the Second Circuit’s opinions in *Wood* are controlling on this score. In *Wood*, the relator alleged Allergan paid “kickbacks” in the form of “surgical care kits” to induce physicians to prescribe three Allergan drugs to treat cataract patients. *Wood*, 246 F. Supp. 3d at 792. When the *Wood* relator filed his complaint, there was an already-pending *qui tam* action that alleged a similar scheme by Allergan—but that scheme involved only a single Allergan drug used to treat conjunctivitis. *Id.* at 788, 792. The *Wood* relator claimed his complaint’s “additional drugs” precluded a first-to-file dismissal because the prior action was not “related.” *Id.* at 792. This Court rightly disagreed—finding the second action’s different drugs to be “of no moment”—because the two complaints otherwise “were based on the same essential facts and involved the same elements of fraud.” *Id.* at 790, 792. The Second Circuit affirmed this Court’s ruling, finding both complaints alleged “very similar kickback schemes” even though different

drugs were involved. *See Wood*, 899 F.3d at 169 (holding the first-to-file bar applied because both cases “allege a scheme where Allergan provided free cataract surgery recovery kits to induce increased use of Allergan products”).

This action fails for the same reason. Borzilleri’s Rhode Island and New York complaints may focus on different drugs, but both actions allege the same scheme with the same elements: (1) “kickbacks” in the form of “service fees” exceeding FMV; (2) paid to an identical list of PBMs and payors, and paid by two of the same manufacturers; (3) to advance a “fraudulent price inflation scheme”; (4) causing the submission of false claims under Medicare Part D. And though the Rhode Island action focuses on MS medications, there Borzilleri *explicitly alleged* that the same “fraudulent practice is occurring in *other drug therapeutic categories* in Medicare Part D as well, including treatments for *cancer, diabetes and inflammatory conditions (rheumatoid arthritis, psoriasis, etc.)*.” R.I. FAC ¶ 10 (emphasis added); *see also id.* at ¶ 285 (alleging “anticompetitive behavior in other specialty drug therapeutic categories, including . . . rheumatoid arthritis, diabetes and cancer”).

These “other drug therapeutic categories” identified in Rhode Island are the focus of the New York action. N.Y. Compl. ¶ 39. In other words, Borzilleri’s Rhode Island complaint notified the Government that it should investigate the very “scheme” Borzilleri subsequently made the focus of his New York *qui tam* lawsuit. Indeed, the Rhode Island FAC references repeatedly the drugs at issue in the New York case. *See, e.g., id.* Exhibit 26 (listing drugs and therapeutic categories targeted in second-filed action), Exhibit 28 (identifying Enbrel and Gleevec); Exhibit 34 (identifying Enbrel, Humira, and Gleevec), Exhibit 49 (discussing products manufactured by Novartis, BMS, and Pfizer), Exhibit 50 (listing drugs in therapeutic categories targeted in second-filed action), Exhibit 56 (discussing Enbrel, Humira, Gleevec, Sprycel,

Simponi, Tassigna, Cimzia, among others). There can thus be no question the first-filed Rhode Island action equipped the Government to investigate the fraud later alleged in Borzilleri's New York *qui tam* action. *Wood*, 899 F.3d at 169.

Second, for similar reasons, the addition of new defendants to this case cannot save the action from dismissal under the first-to-file bar. Eight of this suit's thirteen Defendants—all six PBM Defendants and two of the Manufacturer Defendants (Novartis and Pfizer)—are named as defendants in the Rhode Island action. The remaining five Manufacturer Defendants are named as defendants in this action only. Under the first-to-file bar, however, "the fact that the later action names different or additional defendants is not dispositive as long as the two complaints identify the same general fraudulent scheme." *U.S. ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 517 (6th Cir. 2009). Thus, courts applying the first-to-file bar—including the first court to apply the Second Circuit's decision in *Wood*—find regularly that two actions are related, despite different defendants, so long as the two complaints allege "the same material elements of fraud." *See Hanks*, 2018 WL 4409832, at *19 (applying *Wood* and holding it is "irrelevant to the first-to-file analysis" that an earlier-filed action named "only one" of the defendants named in a later-filed action); *U.S. ex rel. Denis v. Medco Health Sols., Inc.*, No. 11-684-RGA, 2017 WL 63006, at *10 (D. Del. Jan. 5, 2017) ("[c]ourts will find that two actions are related, despite different defendants," when the first-filed complaint equipped the government to discover the "fraud alleged in the second-filed complaint, including the identity of the new defendants"); *U.S. ex rel. Szymoniak v. ACE Secs. Corp.*, No. 13-cv-464, 2014 WL 1910876, at *5 (D.S.C. May 12, 2014) (dismissing second-filed suit naming sixteen defendants not named in earlier action because of first-filed suit's "significant overlap and allegations of industry-wide fraud," which made the government "aware of the essential or material facts of the scheme" and "put the government on

notice to investigate the fraudulent scheme alleged” in the second suit); *U.S. ex rel. Bane v. Life Care Diagnostics*, No. 06-cv-467, 2008 WL 4853599, at *7 (M.D. Fla. Nov. 10, 2008) (dismissing second-filed suit against defendant identified in first-filed suit’s complaint as having “engaged in false or fraudulent Medicare billing” though not named as a defendant in the first suit); *U.S. ex rel. Wilson v. Emergency Med. Assocs. of Ill., Inc.*, No. 01 C 4558, 2000 WL 34026709, at *2 (N.D. Ill. Sept. 24, 2000) (dismissing second-filed suit that “name[d] additional parties involved in the alleged billing scheme” where “claims arise out of the same underlying facts” alleged in first-filed suit).

This standard is easily met here. The Rhode Island action explicitly alleged an industry-wide scheme in which fraud was ongoing with MS treatments and in “drug therapeutic categories” raised in this action. R.I. FAC ¶ 10. And the Rhode Island action even described the drugs and expressly identified the manufacturers named in this action. *Id.* at ¶¶ 10, 209, 232-36 (describing conference allegedly offering “definitive confirmation of the scheme” attended by, among others, Amgen, AbbVie, BMS, Pfizer, and Sanofi), 272-73 (describing founding of the scheme and identifying, among others, defendants BMS and Eli Lilly), 285 (alleging “uncompetitive behavior” in “treatments for . . . rheumatoid arthritis, diabetes and cancer” and specifically implicating BMS, Novartis, and Pfizer), and Exhibits 26 (identifying Amgen, AbbVie, Novartis, and BMS), 28 (identifying Amgen and Novartis), 34 (identifying Amgen, AbbVie, and Novartis), 49 (identifying Novartis, BMS, and Pfizer). The products at issue here are, according to Borzilleri, the top spending drugs in Medicare Part D in the “other drug therapeutic categories” that he identified in Rhode Island. NY Compl. ¶ 39; N.Y. SAC ¶ 375.

For all of these reasons, the present action is “related” to the earlier-filed and still-pending Rhode Island action and, under the FCA’s first-to-file bar, Borzilleri’s New York

lawsuit was “incurably flawed from the moment he filed it.” *Wood*, 899 F.3d at 171 (quoting *U.S. ex rel. Shea v. Cellco P’ship*, 863 F.3d 923, 930 (D.C. Cir. 2017)). Accordingly, the FCA “require[s], in express terms, the dismissal of [Borzilleri’s] action.” *Id.* (quoting *State Farm Fire & Cas. Co. v. U.S. ex rel. Rigsby*, 137 S. Ct. 436, 442-43 (2016)).

Finally, Borzilleri seeks recovery in the New York action under the FCA analogues of numerous States and the District of Columbia, just as he did in the Rhode Island action. *Compare* N.Y. Compl. Counts 5-34 *with* R.I. FAC Counts 5-34. These Counts fail here for the same reasons as his federal causes of action, because each State has its own first-to-file provision materially identical to the federal first-to-file bar.⁸

II. THE SAC IS DEFICIENTLY PLED UNDER RULES 9(b) AND 12(b)(6).

The SAC also is subject to dismissal for an assortment of pleading deficiencies. An FCA complaint must satisfy both Rule 9(b)’s heightened pleading standard and Rule 12(b)(6)’s plausibility pleading standard. To meet the plausibility standard, a complaint’s well-pled factual content must “allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Claims that do not cross the line “from conceivable to plausible” must be dismissed. *Id.* To satisfy Rule 9(b)’s heightened pleading standard, a complaint must “(1) specify the statements that the plaintiff

⁸ Cal. Gov’t Code § 12652(c)(10); Colo. Rev. Stat. § 25.5-4-306(2)(e); Conn. Gen. Stat. § 4-277(d); D.C. Code § 2-381.03(b)(6); Del. Code Ann. tit. 6, § 1203(b)(5); Fla. Stat. § 68.083(7); Ga. Code § 49-4-168.2(c)(6); Haw. Rev. Stat. § 661-25(e); 740 Ill. Comp. Stat. § 175/4(b)(5); Ind. Code § 5-11-5.5-4(g); Iowa Code § 685.3(2)(e); La. Stat. Ann. § 46:439.2(A)(3); Md. Code Ann., Gen. Provis. § 8-104(a)(8); Mass. Gen. Laws ch. 12, § 5C(6); Mich. Comp. Laws § 400.610a(4); Minn. Stat. § 15C.05(b); Mont. Code Ann. § 17-8-406(7); N.H. Rev. Stat. Ann. § 167:61-c(II)(b); Nev. Rev. Stat. § 357.080(2); N.J. Stat. Ann. § 2A:32C-5(i); N.M. Stat. Ann. § 44-9-5(E); N.Y. State Fin. Law § 190(4); N.C. Gen. Stat. § 1-608(4); Okla. Stat. tit. 63, § 5053.2(5); 9 R.I. Gen. Laws § 9-1.1-4(b)(5); Tenn. Code Ann. § 71-5-183(b)(5); Tex. Hum. Res. Code Ann. § 36.106; Va. Code Ann. § 8.01-216.5(E); Wash. Rev. Code § 74.66.050(5); Wis. Stat. § 20.931(5)(e) (repealed July 13, 2015).

contents were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *U.S. ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016) (internal quotation marks omitted). “In other words, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.” *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (internal quotation marks omitted).

Rule 9(b)’s heightened pleading standard applies both to allegations about the underlying fraud scheme and to allegations that false claims were submitted to CMS. *U.S. ex rel. Chorchos for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 83 (2d Cir. 2017). A relator can satisfy this standard by alleging personal knowledge of specific false claims or by making “plausible allegations creating a strong inference that specific false claims were submitted to the government” and “pleading that the particulars of those claims were peculiarly within the opposing party’s knowledge.” *Id.* at 86. But a relator cannot satisfy Rule 9(b) by “bas[ing] claims of fraud on speculation and conclusory allegations.” *Id.* (internal quotation marks omitted); *see also Ladas*, 824 F.3d at 26-27 (“hypotheses,” “conclusory statements,” and assertions “not supported by particularized allegations of fact” did not satisfy Rule 9(b)); *U.S. ex rel. Tessler v. City of New York*, 712 F. App’x 27, 30 (2d Cir. 2017) (affirming dismissal where relator’s complaint “alleges only ‘hypotheses’ and conclusory allegations”).

A. Borzilleri’s Allegations Regarding A “Service Fee” Scheme Fail To Plead Fraud With Particularity.

Borzilleri alleges a scheme in which the Manufacturer Defendants contractually agreed to pay a percentage of their drugs’ list price as “service fees” to the PBM Defendants. SAC ¶ 26. He claims that at least a portion of the service fees are not BFSFs within the meaning of Part D because as the drugs’ prices increased over time, the percentage-based service fees exceeded the

fair market value of any services being provided by the PBM. *See generally* SAC ¶¶ 34-46.

Plan sponsors must report to CMS any portion of service fees paid by manufacturers to PBMs that exceed fair market value, *see supra* 8-9, which, according to Borzilleri, did not occur. SAC ¶ 30. His theory is that Medicare Part D plan sponsors' misreporting of service fees affected the amount that CMS paid plan sponsors, making plan sponsors' requests to CMS for payment "false claims" within the meaning of the FCA.

Borzilleri's service-fee FCA theory does not satisfy the standard articulated in *Chorches*. Because Borzilleri has no "personal knowledge" of anything in the SAC, let alone any "specific claims," he must rely on the second prong of *Chorches*. That requires pleading both "plausible allegations creating a strong inference that specific false claims were submitted to the government" and "plead[ing] that the particulars of those claims were peculiarly within the opposing party's knowledge." 865 F.3d at 86. But he cannot satisfy that prong either. His generalized allegations—which are conjecture based on information in the public domain—do not plausibly implicate any Manufacturer Defendant in fraudulent conduct, are often contradicted or unsupported by the sources he cites, and do not create a strong inference that specific false claims were submitted to CMS. Moreover, he has not pled that the particulars of any claims he says are false are "peculiarly within" any Manufacturer Defendant's knowledge, which is unsurprising given that manufacturers submit neither claims nor DIR reports.

1. Borzilleri pleads no details of any fraudulent service fee paid by any Manufacturer Defendant or any fraudulent claim.

Borzilleri does not identify the amount of any service fee paid by any Manufacturer Defendant to any PBM, or the terms of any contract by which any such payment was made. The SAC does not specify whether any PBM reported the unidentified payment (or any portion of the payment) to the plan sponsor, or whether the plan sponsor then reported the amount to CMS in a

DIR report. And it does not allege any details about any claims for payment from CMS that were affected by any misstated DIR reporting. Without these missing details, there is no plausible basis to conclude—let alone find a strong inference—that any Manufacturer Defendant paid fraudulent service fees that caused the submission of any false claims.

The SAC pleads a daisy chain of hypotheses, and nothing more. Because the prices of certain drugs have increased over time, Borzilleri believes that the Manufacturer Defendants *must have* entered into secret contracts with PBMs to pay service fees that exceed fair market value for any services, which *must have* led to above-fair-market-value service fees, which a PBM *must not have* reported as a price concession to the plan sponsor, which the plan sponsor *must not have* reported as a price concession in its DIR reports. But that is all speculation. He does not claim to know (1) how any such contract was negotiated, (2) the scope, methodology, or amount of any service-fee term, (3) whether the contract required that service fees be treated as price concessions, (4) when any contract took effect, or (5) how any service fees changed over time. He admits that he is guessing at every turn. *See* SAC ¶ 180 (“the individual ‘service fee’ contracts between the Manufacturer and the PBM Defendants remain a closely guarded secret”) (emphasis omitted); *see also id.* at ¶¶ 241, 306.⁹

Because the SAC lacks any of these details, it does not plead with particularity that any Manufacturer Defendant paid any PBM a service fee that should have been, but was not,

⁹ Borzilleri also makes passing reference to the service fees being criminal kickbacks paid to the PBMs in exchange for “formulary access” and the PBMs’ agreement to forego “standard cost-savings practices that would lead to far lower Defendant drug prices.” SAC ¶¶ 79, 169(2). He offers nothing beyond a couple speculative suggestions, and he never identifies any supposed payment for formulary access by any Manufacturer Defendant to any PBM or any circumstances that indicate that the payment was intended as an inducement for formulary access or to avoid cost-saving measures. A generalized assertion that the Manufacturer Defendants paid unlawful kickbacks for formulary access falls woefully short of Rule 9(b). *Polansky*, 2009 WL 1456582, at *4 (“Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.”) (citation omitted).

reported in part or whole as a price concession by plan sponsors. *See U.S. ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806 FB VVP, 2013 WL 1346022, at *4 (E.D.N.Y. Apr. 3, 2013) (FCA claim failed where it did not identify “specific payers or recipients” of alleged kickbacks and vaguely referred to participants in alleged scheme without “identify[ing] what specific roles they played or what false claims they submitted”). Borzilleri admits that whether a manufacturer pays a service fee to a PBM for a given drug—and if so, whether the fee is a percentage of the list price or something else—“depend[s] upon specific contractual terms” of contracts that he has never seen and is speculating exist. SAC ¶¶ 242-43; *see also id.* at ¶ 296 (“a detailed review of all financial transactions between the Manufacturer Defendants and a given PBM Defendant for a particular drug product, at the corporate level, will be required in a thorough investigation”). Borzilleri knows nothing about the Manufacturer Defendants’ actual contracts with PBMs.

Nor does he know anything about any plan sponsor’s DIR reporting. The SAC never alleges with particularity (or even plausibility) that any plan sponsor improperly characterized a service fee in its DIR reports. Borzilleri does not claim to know who prepared or submitted any DIR report, what service-fee price concessions were or should have been included in any report, how any reported amount was calculated, why any calculation was improper, or whether any Manufacturer Defendant had any knowledge of what DIR was reported. These are gaping holes in his theory. *See id.* at ¶ 30. As the SAC acknowledges, manufacturers can lawfully pay PBMs service fees that exceed fair market value; the amount that exceeds fair market value is simply reported to CMS as DIR by the plan sponsor and used by CMS in determining a Part D plan’s drug costs. *See, e.g., id.* at ¶ 290; *see also* CMS Memo from Cheri Rice, *supra*, at 6 (“Administrative fees charged to manufacturers must be reported as DIR only to the extent that they exceed fair market value or if they do not qualify as bona fide service fees.”). The OIG

report that Borzilleri cites (SAC ¶ 227) makes this same basic point: only service fees that qualify as BFSFs need not be reported. *See* OIG, *Concerns with Rebates in the Medicare Part D Program*, OEI-02-08-0050 at 4 & n.16 (Mar. 2011) (2011 OIG Report).¹⁰ And the OIG report specifically notes that some plan sponsors report service fees as DIR. *Id.* at 19, 21.

Knowing nothing about any DIR reporting, Borzilleri unsurprisingly offers no details of any false claims for payment by a plan sponsor. Instead, he just asserts that there has been “staggering” harm to the public fisc and offers his guess, without any factual support, that “30%” of the sales of the Manufacturer Defendant’s products is “attributable to the Part D program.” SAC ¶¶ 32, 92.

Borzilleri believes that he can use discovery to fill in all these holes: to obtain contracts from the Defendants, to analyze financial transactions between the parties, to determine the propriety of DIR reporting by plan sponsors, and to find false claims. *E.g., id.* at ¶¶ 122, 218, 433, 720. He is wrong. As the Second Circuit has long emphasized, Rule 9(b) requires a plaintiff to have a particularized basis to allege fraud *before* filing suit. *See Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989) (“One of the purposes of Rule 9(b) is to discourage the filing of complaints as a pretext for discovery of unknown wrongs.” (internal quotation marks omitted)). Borzilleri, however, can offer nothing but his conjecture that a contract *might* exist between some Manufacturer Defendant and some PBM Defendant, that under this hypothetical contract some service fee *may* have been paid, that the hypothetical service fee *may* have exceeded the fair market value for the services provided, that the hypothetical amount over fair market value *may* not have been reported to CMS as DIR, and that false claims *may* exist. That is a far cry from the particularity necessary to satisfy Rule 9(b). *Ladas*, 824 F.3d at 26-27;

¹⁰ Available at <https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf>.

Tessler, 712 F. App'x at 30.

2. Nothing alleged in the SAC overcomes Borzilleri's lack of knowledge of any fraudulent service fee paid by any Manufacturer Defendant.

Given his admitted lack of knowledge of any actual service-fee payment made by any Manufacturer Defendant and any DIR report submitted by any plan sponsor, Borzilleri spends the bulk of the SAC on two subjects: (1) allegations about the price and usage of drugs, total sales figures, and whether competitor products are available; and (2) Borzilleri's basis for his speculation that service-fee fraud is occurring. He then offers a group indictment of the Manufacturer Defendants and the PBM Defendants. None of this pleads fraud with particularity.

a. The SAC's few allegations about individual Manufacturer Defendants relay pricing, sales, and usage data, but do not allege fraud.

The SAC's allegations that relate to the individual Manufacturer Defendants are small in number and narrow in scope. For each of the fourteen drugs at issue, Borzilleri alleges (at length) that the drug's list price, revenues, and profits have increased over time. For some of the drugs, he alleges that usage has gone down over time and constructs charts depicting how (according to him) the total dollar value of sales for those drugs would have been lower without price increases. For others, he alleges that usage has gone up over time. Finally, for some of the drugs, he makes allegations about other available drugs in the same drug class and market share.

These allegations have one thing in common: they say nothing about any supposedly fraudulent service fee paid by any Manufacturer Defendant or any allegedly false claims submitted to Part D. They thus do not help Borzilleri satisfy Rule 9(b).

b. The SAC's "sources" contradict its allegations, do not ascribe conduct to any Manufacturer Defendant, or both.

Nor can Borzilleri meet Rule 9(b)'s requirements by virtue of the "sources" underlying his allegations. None of these sources comes close to pleading with particularity any fraudulent

service fee paid by any Manufacturer Defendant or any resulting false claim for any drug.

For starters, the SAC repeatedly claims that an “incriminating” (§§ 67, 178) report published by PhRMA “discloses” that drug manufacturers pay PBMs a “standard,” “typical,” or “average” service fee of 8% of a “specialty” drug’s list price and 4% of a “traditional” drug’s list price. SAC §§ 67, 70, 95, 109, 179, 182-83, 190, 271, 389. Far from being “incriminating,” this report (attached as Exhibit F) directly contradicts Borzilleri’s position that it “disclosed average contract terms for ‘service fees.’ ” *Id.* at § 179 (emphasis omitted). The report describes complexities in the drug distribution and payment system and emphasizes that “[b]ecause payment terms are determined through confidential, private negotiations, the terms of individual contracts are highly variable[.]” PhRMA Report at 2 (emphasis added); *see also id.* at 1, 9. While the report offers “illustrative examples” depicting what three patients might pay for a drug under different cost-sharing mechanisms (copayment, deductible, and coinsurance), the report says nothing about standard, typical, or average levels of service fees in Part D contracts. *Id.* at 10-15. And the report certainly does not mention any conduct by any Manufacturer Defendant. The report thus contradicts Borzilleri’s claim that it provides a basis to infer a standard service fee across manufacturers and contracts. “If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control, and the court need not accept the allegations in the complaint as true.” *TufAmerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013); *see also Roth v. Jennings*, 489 F.3d 499, 511 (2d Cir. 2007) (“the contents of the document are controlling where a plaintiff has alleged that the document contains, or does not contain, certain statements”); *Equinox Gallery Ltd. v. Dorfman*, 306 F. Supp. 3d 560, 576 (S.D.N.Y. 2018) (similar); *Poindexter v. EMI Record Grp. Inc.*, No. 11 CIV. 559 LTS JLC, 2012 WL 1027639, at *2 (S.D.N.Y. Mar. 27, 2012) (similar). Because the

PhRMA report contradicts the SAC's characterization of it, those allegations cannot help Borzilleri survive dismissal.¹¹

Borzilleri relies on a second document that he describes as “definitively incriminat[ing] both Defendant parties in the ‘service fee’ scheme.” SAC ¶ 199. This document, a report prepared for the Pharmaceutical Care Management Association (PCMA) and attached as Exhibit G, also does not help him establish an inference of fraudulent service fees paid by any Manufacturer Defendant. The document is limited to discussing rebates and price increases; it contains no discussion—none—of service fees, much less any fraudulent service fees. It therefore provides no support for an allegation that any Manufacturer Defendant violated the FCA through service-fee payments.

The remaining sources of “information” on which Borzilleri’s speculative theory is based are just as unhelpful to him. He claims to rely on consultants who he alleges told him “that they had never seen or reviewed a single ‘service fee’ contract between a PBM and a drug manufacturer.” SAC ¶ 192. As a result, those consultants plainly have not seen or reviewed any service-fee contract that Borzilleri theorizes might exist for the drugs at issue. Similarly, Borzilleri’s alleged discussion with the CEO of a company *not named as a defendant* (*id.* at ¶¶ 448-49) does nothing to make plausible Borzilleri’s speculative theory that each Manufacturer Defendant paid kickbacks in the form of service fees or caused false claims. Nor does his description of a conference in which there was general discussion about service fees and various fair market valuation methodologies (*id.* at ¶¶ 452-89) provide an indication that any manufacturer generally, or any Manufacturer Defendant specifically, was paying Part D service

¹¹ All of the SAC’s allegations that purport to identify a specific service-fee amount for a drug are calculated by Borzilleri multiplying the drug’s publicly available list price by his made-up “standard” 4 and 8 percent service fee. *E.g.*, SAC ¶¶ 250, 259. Thus none of those allegations help Borzilleri either.

fees that were improperly reported in a plan sponsor's DIR reports. Certainly nothing about this conference indicates any Manufacturer Defendant participated in a price collusion scheme designed to cheat Medicare. And finally, the handful of contracts between PBMs and employers providing employees insurance that the SAC references (*id.* at ¶¶ 689-713) also provide no information from which the Court could infer that any Manufacturer Defendant paid fraudulent service fees. That leaves Borzilleri with just his own self-serving speculation and conclusions.

c. Group pleading does not satisfy Rule 9(b).

Lacking specific facts and relying on “sources” that contradict or are silent on any Manufacturer Defendant’s conduct, the SAC attempts to rely on group pleading. Many of the SAC’s allegations refer only to the “Manufacturer Defendants”—seven separate companies—and “PBM Defendants”—six separate companies. Using those terms, the SAC then makes the sweeping allegation that drug manufacturers and PBMs have defrauded the government through percent-of-list-price service fees that are not reported as price concessions on DIR reports. *E.g.*, SAC ¶ 35 (“The fraudulent Manufacturer Defendant ‘service fee’ payments to the PBM Defendants are standardly calculated via secretive ‘percent of revenue’ contracts[.]”). Such group pleading fails to satisfy Rule 9(b)’s heightened pleading standard. As this Court recently held, a complaint that “lumps all Defendants together” and identifies “no specific statements” and “no specific speakers” is “plainly insufficient to satisfy Rule 9(b)’s heightened pleading requirements.” *City of Perry, Iowa v. Procter & Gamble Co.*, 188 F. Supp. 3d 276, 290 (S.D.N.Y. 2016); *see also, e.g., U.S. ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 696 (S.D.N.Y. 2018) (complaint insufficient under Rule 9(b) “where it alleges ‘nothing at all’ with respect to how each individual defendant ‘did or did not perform’ its obligations ” (citation omitted)); *Lankau v. Luxoft Holding, Inc.*, 266 F. Supp. 3d 666, 674

(S.D.N.Y. 2017) (“Rule 9(b) prohibits ‘lump[ing]’ separate defendants together in vague and collective fraud allegations” and requires “inform[ing] each defendant of the nature of his alleged participation in the fraud’ ” (citation omitted)).

Each Manufacturer Defendant is entitled to know—specifically—the PBM(s) with which it is being accused of committing service-fee fraud, during what time period, and with what supposedly improper service-fee terms. Courts have repeatedly made clear that fraud claims against multiple defendants must separately set forth each defendant’s allegedly fraudulent acts. *See, e.g., Aronov v. Mersini*, No. 14-CV-7998 PKC, 2015 WL 1780164, at *4 (S.D.N.Y. Apr. 20, 2015); *United States v. N.Y. Soc. for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 CIV. 292 PKC, 2014 WL 3905742, at *19 (S.D.N.Y. Aug. 7, 2014); *Bruno v. Zimmer, Inc.*, No. CV156129LDWAKT, 2017 WL 8793242, at *7 (E.D.N.Y. Aug. 11, 2017). That requirement aligns with Rule 9(b)’s purposes, which are “to provide a defendant with fair notice of a plaintiff’s claim, to safeguard a defendant’s reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit.” *Ladas*, 824 F.3d at 25 (internal quotation marks omitted).

The SAC’s group pleading contravenes each of these purposes. The SAC generically hypothesizes that Part D plan sponsors *could* have failed to report service fees as price concessions on DIR reports when those amounts should have been reported. It makes no specific allegation that such misreporting occurred or that any of the Manufacturer Defendants knew about and played a role in it. Just the opposite: the SAC repeatedly acknowledges that Borzilleri cannot offer individualized allegations absent discovery. *E.g.*, SAC ¶ 180 (Borzilleri has no knowledge of individual contracts absent discovery), ¶ 296 (Borzilleri needs to obtain and review “all financial transactions between the Manufacturer Defendants and a given PBM Defendant for

a particular drug product, at the corporate level” to make individualized allegations); ¶ 720 (Borzilleri needs discovery to learn what support services, if any, are being provided for any specific drug under any contract). Borzilleri’s reliance on group pleading renders the SAC deficient—and subject to dismissal—under Rule 9(b).

3. Borzilleri fails to plead scienter.

The SAC also fails to state an FCA claim because it does not sufficiently plead any Manufacturer Defendant’s conduct satisfied the FCA’s “knowing” scienter requirement. That requirement is “rigorous,” *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, --- U.S. ---, 136 S. Ct. 1989, 2002 (2016), and it is not met here. Even indulging Borzilleri’s speculation that a Part D plan sponsor submitted a DIR report that failed to correctly characterize service fees, Borzilleri does not allege any facts demonstrating that any Manufacturer Defendant knew or should have known of such misreporting. Although “Rule 9(b) allows a plaintiff to allege intent ‘generally’ rather than ‘with particularity,’ ” it is not “a license to base claims of fraud on speculation and conclusory allegations.” *Sanchez v. ASA Coll., Inc.*, No. 14-CV-5006 JMF, 2015 WL 3540836, at *7 (S.D.N.Y. June 5, 2015) (citations omitted). A relator still must plead facts plausibly demonstrating the scienter element of an FCA violation. Because the SAC fails to do so, dismissal is warranted. *See Grubea*, 318 F. Supp. 3d at 694-95 (dismissing FCA claims against certain defendants for failure to plead scienter where relator had no information about whether other parties actually passed charges on to the government, and if they did, whether they did so recklessly).

B. Borzilleri’s Remaining Theories Are Deficiently Pled.

1. No FCA conspiracy is plausibly pled.

Borzilleri also attempts to plead an FCA conspiracy. Like other FCA liability theories, “[c]onspiracy claims under the FCA must be pleaded with particularity under Rule 9(b).” *N.Y.*

Soc. for the Relief of the Ruptured & Crippled, 2014 WL 3905742, at *25. The SAC flunks this requirement because it offers no particularized allegations of a conspiracy to defraud the government. *Id.* Even under Rule 12(b)(6), the conspiracy claim fails because Borzilleri has not plausibly alleged facts showing an unlawful agreement between any Manufacturer Defendant and any PBM Defendant or any overt act taken pursuant to that agreement. *See U.S. ex rel. Scharff v. Camelot Counseling*, No. 13-cv-3791 (PKC), 2016 WL 5416494, at *9 (S.D.N.Y. Sept. 28, 2016); *U.S. ex rel. Sterling v. Health Ins. Plan of Greater N.Y., Inc.*, No. 06-cv-1141 (PAC), 2008 WL 4449448, at *4 (S.D.N.Y. Sept. 30, 2008).

Borzilleri instead vaguely claims “collusion” exists and offers the entirely conclusory statement that Defendants conspired “to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims” and “took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.” SAC ¶ 815. The SAC never details any Defendant’s entry into an agreement to violate the FCA—*when* the agreement occurred, *who* was involved, *how* it originated, and *what* the details of it were—or what overt acts in furtherance of the agreement followed. *See U.S. ex rel. Capella v. Norden Systems, Inc.*, No. 94 Civ. 2063, 2000 WL 1336487, at *11 (D. Conn. Aug. 24, 2000) (dismissing complaint that “merely alludes to an agreement between Defendants and does not specify . . . what act was committed in furtherance of the conspiracy”). As a result, his FCA conspiracy claim should be dismissed. *See Sterling*, 2008 WL 4449448, at *4 (general allegation of FCA conspiracy is “the type of conclusory allegation that Rule 9(b) was intended to prevent”); *N.Y. Soc. for the Relief of the Ruptured & Crippled*, 2014 WL 3905742, at *25 (FCA conspiracy claim fails where complaint “does not identify the purported roles of the three defendants” and

offers only a “generalized allegation that they entered ‘into one or more conspiracies’ ”); *Morgan ex rel. U.S. v. Sci. Applications Int’l Corp.*, No. 07 CV 4612, 2008 WL 2566747, at *6 (S.D.N.Y. June 26, 2008) (dismissing FCA conspiracy claim).

2. The SAC lacks facts showing that any Manufacturer Defendant waived catastrophic cost-sharing.

Borzilleri accuses drug manufacturers of “routinely ‘forgiving’ ” a cost-sharing obligation that is triggered for Part D plan sponsors when a participant’s drug costs exceed a threshold amount. SAC ¶ 33, *see also, e.g., id.* at ¶¶ 347, 399. Borzilleri concludes that because drug prices have gone up over the past decade, the Manufacturer Defendants must be forgiving this cost-sharing obligation “to further the ‘service fee’ pricing scheme.” *Id.* at ¶ 352.

Borzilleri pleads no details of any Manufacturer Defendant waiving any cost-sharing obligation of any Part D plan sponsor. He appears to theorize that there is the “potential” for abuse because sometimes a PBM Defendant is also a plan sponsor (*id.* at ¶¶ 353, 401), but this theory relies entirely on improper group pleading. *See supra* at 26-28. And his unsubstantiated conjecture that there can be no other explanation for PBMs having avoided “havoc” from increased catastrophic cost-sharing obligations, SAC ¶ 416, is insufficient by leaps and bounds to plausibly plead a strong inference of specific false claims. *See De Jesus v. Sears, Roebuck & Co., Inc.*, 87 F.3d 65, 70 (2d Cir. 1996) (allegations “devoid of any specific facts or circumstances” and that consist “of conclusory allegations unsupported by factual assertions” cannot survive a motion to dismiss) (citation and emphasis omitted). Finally, even if Borzilleri’s allegations did not fall woefully short of satisfying Rule 9(b), his cost-sharing-waiver theory would still fail because he does not come close to alleging how a waiver of a plan’s cost-sharing obligations ties into a Part D claim for payment and could render it false.

3. To the extent Borzilleri is asserting a false-certification theory against the Manufacturer Defendants, it is deficiently pled.

Borzilleri vaguely alludes to the Manufacturer Defendants being liable because of an “express certification requirement[].” SAC ¶ 169(8) (emphasis omitted). Borzilleri provides no additional details, and any such theory should be dismissed. “ ‘Express’ legal falsity generally arises where ‘a government program requires participants to submit forms explicitly stating that they have complied with certain statutes,’ ” *Wood*, 246 F. Supp. 3d at 810 (internal citations omitted), and “the defendant explicitly misstates compliance” with those statutes. *N.Y. Soc. for the Relief of the Ruptured & Crippled*, 2014 WL 3905742, at *17. Borzilleri has not pointed to any express certification that the Manufacturer Defendants made to the government relating to service fees or data submission and has not specified any document or submission supposedly containing a misstatement. *See United States v. TEVA Pharm. USA, Inc.*, No. 13 CIV. 3702 (CM), 2016 WL 750720, at *27 (S.D.N.Y. Feb. 22, 2016) (“conclusory allegations” do not state a claim premised on express certification; a relator “must identify the express certification”).

4. The SAC’s “reverse false claims” theory lacks a factual predicate.

Count 3 asserts a claim under the FCA’s “reverse false claims” provision, 31 U.S.C. § 3729(a)(7) (now 31 U.S.C. § 3729(a)(1)(G)). Liability under this provision “must be premised on a ‘false statement[] designed to conceal, reduce, or avoid an obligation to pay money or property to the Government.’ ” *Wood*, 246 F. Supp. 3d at 826 (citing *Wood ex rel. U.S. v. Applied Research Assocs., Inc.*, 328 F. App’x 744, 748 (2d Cir. 2009)). Borzilleri fails to plead at all—let alone with particularity—“any financial obligation that the [Manufacturer Defendants] owed to the government” and “any false records or statements used to decrease such an obligation.” *Wood*, 328 F. App’x at 748. Count 3 is therefore not pled plausibly or with particularity. *Id.*; *see also Haas v. Gutierrez*, No. 07-CV-3623 (GBD), 2008 WL 2566634, at *5

(S.D.N.Y. June 26, 2008).

C. Borzilleri Lacks Standing To Pursue Claims For Unjust Enrichment And Common Law Fraud.

Borzilleri asserts claims for unjust enrichment and common law fraud in Counts 33 and 34. SAC ¶¶ 916, 921. He lacks standing to bring those claims. “While the FCA gives a relator the right to bring an action for violation of the FCA, it ‘does not give relators the right to assert common law claims on behalf of the United States.’ ” *U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 452 (S.D.N.Y. 2001) (internal citations omitted) (dismissing relator’s unjust-enrichment and common-law-fraud claims); *see also Conn. Action Now, Inc. v. Roberts Plating Co.*, 457 F.2d 81, 84 (2d Cir. 1972) (“[T]here is no common law right to maintain a *qui tam* action; authority must always be found in legislation.”); *Morgan*, 2008 WL 2566747, at *3 (“the Congressional grant of private standing to sue in FCA cases does not extend to common law causes of action”). As a result, those claims should be dismissed.

D. Borzilleri’s State-Law “Reverse False Claim” Counts Fail To State A Claim.

Borzilleri also asserts claims (Counts 5-32) under the “reverse false claims” provision of 28 state FCA analogues. Those provisions, like the federal provision discussed above, prohibit knowingly concealing, avoiding, or decreasing an obligation to pay money to the state. *E.g.*, SAC ¶ 832 (California), ¶ 836 (Colorado), ¶ 839 (Connecticut). But the SAC does not plead that any Manufacturer Defendant *had* any obligation to pay any money to any State in the first place—let alone that the Manufacturer Defendant concealed, avoided, or decreased that obligation. These claims fail on that basis alone.

Borzilleri’s theory seems to be that each State overpaid the federal government to fund some portion of the federal government’s Part D spending on individuals from the State who are “dual eligible[s].” *Id.* at ¶ 166. These so-called “clawback payments” by States, Borzilleri

speculates, were higher than they would have been if Defendants had not engaged in service-fee fraud. *E.g., id.* at ¶ 832. Even if Borzilleri had pled some other provision of state law besides the “reverse” false claims provisions in Counts 5-32, his clawback-payment theory would fail because the SAC does not plead that any Manufacturer Defendant actually engaged in any service-fee fraud. That too requires dismissal of Counts 5-32.¹²

III. THE PUBLIC-DISCLOSURE BAR MANDATES DISMISSAL OF THE FCA CLAIMS.

The SAC is subject to dismissal for yet another reason: it is barred by the FCA’s public-disclosure bar. 31 U.S.C. § 3730(e)(4). That bar precludes “parasitic lawsuits” by those who allege fraud based on publicly available information. *U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992).¹³ It applies when (1) a relator’s allegations are “substantially similar” to prior public disclosures, and (2) the relator is not an “original source.” *U.S. ex rel. JDJ & Assocs. LLP v. Natixis*, No. 15-cv-5427 (PKC), 2017 WL 4357797, at *5 (S.D.N.Y. Sept. 29, 2017). The bar is “broad” and “applies to claims based *in any part* upon” public disclosures. *Patriarca*, 295 F. Supp. 3d at 196 (internal quotation marks omitted).

Remarkably, Borzilleri *admits* that his allegations are based entirely on a mosaic of

¹² Alternatively, the Court can dismiss the federal FCA claims and decline to retain supplemental jurisdiction over Borzilleri’s state-law claims. *See, e.g., Ruotolo v. Fannie Mae*, 933 F. Supp. 2d 512, 527 (S.D.N.Y. 2013).

¹³ The public-disclosure bar was jurisdictional, *see Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 285 (2010), until Congress amended it as part of the Affordable Care Act of 2010 (“ACA”). *See* Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02 (Mar. 23, 2010). Because the ACA amendment was not retroactive, it does not apply to pre-ACA conduct. *See, e.g., U.S. ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.*, 295 F. Supp. 3d 186, 195 (E.D.N.Y. 2018). As a result, this Court should apply the jurisdictional version for conduct that allegedly occurred before March 23, 2010, and the non-jurisdictional version for conduct after that date. *See id.* In addition, Borzilleri has the burden of establishing jurisdiction as to the pre-ACA claims. *See Morrison v. Nat’l Australia Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008), *aff’d*, 561 U.S. 247 (2010). Under both versions of the bar, however, the result is the same—dismissal under Rule 12(b)(1) for pre-ACA claims and dismissal under Rule 12(b)(6) for post-ACA claims.

public disclosures, and the disclosures themselves include the elements from which he infers fraud.¹⁴ Far from being an insider or “original source,” Borzilleri is a quintessential “opportunistic plaintiff[] who ha[s] no significant information to contribute.” *Graham Cty.*, 559 U.S. at 294 (citation omitted, internal quotation marks omitted). He is a former investment fund manager who, with no affiliation to any Defendant, filed this action in an attempt to drive Defendants’ stock prices down and improve his short positions. *See supra* at 6-7. As such, the FCA’s public-disclosure bar requires dismissal of the SAC.

A. Borzilleri’s Allegations Are Substantially Similar To Prior Public Disclosures.

A relator’s allegations are substantially similar to prior public disclosures where, as here, the “essential elements” of the purported fraudulent transaction were publicly disclosed. *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 437 F. App’x 13, 17 (2d Cir. 2011). This includes instances where a relator like Borzilleri alleges that he “infer[s]” a fraudulent transaction from facts revealed in public disclosures. *U.S. ex rel. Lissack v. Sakura Glob. Capital Markets, Inc.*, No. 95 Civ. 1363 (BSJ), 2003 WL 21998968, *10 (S.D.N.Y. Aug. 21, 2003), *aff’d* 377 F.3d 145 (2d Cir. 2004). In other words:

[I]f $X + Y = Z$, Z represents the *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z , *i.e.*, the conclusion that fraud has been committed.

Id. (alteration in original, internal quotation marks omitted). In these circumstances, the public-

¹⁴ Because Borzilleri admits that he based his allegations entirely on qualifying public disclosures, the Court need not look beyond the SAC to dismiss. *See, e.g., Iqbal*, 556 U.S. at 678 (“[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” (internal quotation marks omitted)); *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 56-57 (2d Cir. 2016) (noting that a defendant can make a “facial” or a “fact-based” challenge to the Court’s jurisdiction under Rule 12(b)(1), and that a facial challenge is “based solely on the” pleading). Even if Borzilleri had not admitted this, however, the disclosures themselves, of which the Court should take judicial notice, reveal that the complaint is based on qualifying public disclosures, also requiring dismissal.

disclosure bar applies even if the relator “decod[ed] . . . publicly available complex or technical information,” *Patriarca*, 295 F. Supp. 3d at 197, or “spen[t] hundreds of hours compiling facts into a ‘mosaic,’ ” *JDJ & Assocs.*, 2017 WL 4357797, at *6 (citation omitted).

The SAC itself confirms that Borzilleri did not uncover the alleged fraudulent scheme through insider information, but instead is inferring it from his review of federal regulations and administrative reports, SEC filings, and published drug-pricing and sales data that existed before he filed suit.

First, Borzilleri alleges that the Manufacturer Defendants must have paid inflated service fees to the PBM Defendants because various federal administrative reports¹⁵ reveal that PBMs earned high profits, despite retaining minimal rebates and allegedly facing high catastrophic cost-sharing exposure. Specifically, based on public sources, Borzilleri alleges:

- PBMs retained minimal rebates for drugs reimbursed by Part D, which were less than rebates for drugs reimbursed by Medicaid, *see* SAC ¶¶ 227-31, 761-68 (citing 2011 OIG Report, *supra*); HHS-OIG, OEI-03-13-00650, *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin* (2015)); *id.* at ¶¶ 234, 258, 759, 771-78 (citing U.S. Gov’t Accountability Office, GAO-10-242, *Spending, Beneficiary Cost Sharing, and Cost-Containing Efforts for High-Cost Drug Eligible for a Specialty Tier* (2010));
- PBMs had high catastrophic cost-sharing exposure that should have negated profits, absent a fee scheme, *id.* at ¶¶ 395-444 (citing *Medicare Payment Advisory Comm’n, Report to the Congress: Medicare and the Health Care Delivery System* (June 2015));
- PBM Medco generated significant profits from service fees and relied less on rebates for profits, *id.* at ¶¶ 779-805 (citing Medco Health, Annual Reports (SEC Forms 10-K) (2003-2011)); and
- Profits of Defendant Express Scripts nearly tripled between 2013 and 2017, *id.* at ¶¶ 115-

¹⁵ An OIG report is a “paradigmatic example” of a qualifying public source. *U.S. ex rel. Davis v. Prince*, 753 F. Supp. 2d 569, 591 (E.D. Va. 2011). SEC filings also qualify as public disclosures under 31 U.S.C. § 3730(e)(4)(A). *See, e.g., U.S. ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App’x 244, 257 (4th Cir. 2012); *U.S. ex rel. Ryan v. Endo Pharm., Inc.*, 27 F. Supp. 3d 615, 628 n.16 (E.D. Pa. 2014), *aff’d sub nom. U.S. ex rel. Dhillon v. Endo Pharm.*, 617 F. App’x 208 (3d Cir. 2015).

20 (citing unidentified “SEC-reported financial statements of Express Scripts”).¹⁶

Second, Borzilleri alleges that these service fees could not have been fair market value or BFSFs because SEC filings reveal that a non-defendant pharmacy received more modest service fees, and one PBM Defendant spent little on performing actual services. For example, Borzilleri alleges that:

- “SEC filings . . . of Diplomat Pharmacy, Inc., verify that the appropriate ‘arm’s length’ compensation to the PBM Defendants for providing manufacturer services should be very modest, even for ‘complex’ specialty drugs,” *id.* at ¶¶ 668-73 (citing Diplomat Pharmacy, Inc., Registration Statement (SEC Form S-1) (July 3, 2014)); and
- Expenditures of Defendant Express Scripts allocated to “Selling, General and Administrative” in 2013-2017 “sharply declin[ed],” *id.* at ¶¶ 115-20 (citing unidentified “SEC-reported financial statements of Express Scripts”).¹⁷

Third, Borzilleri alleges that the fees must have been kickbacks in exchange for favorable formulary placement, in violation of the AKS, because various federal administrative reports and published drug pricing and sales data¹⁸ reveal that the Manufacturer Defendants’ drug prices and sales have risen despite the availability of cheaper alternative drugs. *See, e.g., id.* at ¶¶ 7-12, 21, 82-83, 123, 759, 770, 799, Exs. 1-11, 15-20 (citing “public” CMS data; and drug pricing and sales data published by Truven Health Analytics Inc., *Red Book*, IMS Health, PhRMA, and

¹⁶ Borzilleri also alleges that two industry news publications released after he filed this action, but before he filed the SAC, “publicly corroborated” his suspicions of inflated service fees. *See* SAC ¶¶ 67, 95-96, 99-101, 109, 182-85, 198-213 (citing PhRMA and PCMA reports). To the extent the SAC makes new allegations based on inferences he is drawing from those publications, those new allegations are equally barred by the public-disclosure bar.

¹⁷ Borzilleri also alleges that participants in a public conference, presented by an independent organization, opined that percent-of-revenue-based fees could raise fraud risks. SAC ¶¶ 128, 445-47, 452-89.

¹⁸ Data published by CMS qualifies as a public disclosure under 31 U.S.C. § 3730(e)(4)(A). *See, e.g., U.S. ex rel. Conrad v. Abbott Labs., Inc.*, No. CIV. A. 02-11738-RWZ, 2013 WL 682740, *5 (D. Mass. Feb. 25, 2013). The same holds for drug-pricing data published in nongovernmental sources. *See U.S. ex rel. Lager v. CSL Behring, L.L.C.*, 855 F.3d 935, 945-46 (8th Cir. 2017) (*Red Book* data is a public disclosure), *aff’d*, 855 F.3d 935 (8th Cir. 2017); *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (holding that “publicly available websites . . . intended to disseminate information . . . qualify as news media”).

company reports). The alleged fraudulent scheme, Borzilleri concludes, is “the only viable explanation.” *Id.* at ¶ 123.

Fourth, Borzilleri alleges that the Manufacturer Defendants must have caused the submission of false claims because federal regulations condition Part D participation on certain submissions, which must have been false due to unreported inflated service fees and AKS violations. *See id.* at ¶¶ 30, 88, 151-53, 168, 297-300 (citing 42 C.F.R. § 423.505).

In addition, even if the SAC did not confirm that Borzilleri’s allegations rely entirely on public disclosures, the disclosures themselves confirm this as detailed in the PBM/Payor brief. For instance, the SAC lifts concerns directly from the 2011 OIG Report that found, among other things, that “[s]elected sponsors reported that their PBMs collected fees from drug manufacturers that were not always passed on to the Part D program,” that the “fees were structured like rebates in that they were generally based on a fixed percentage of WAC [the drug’s list price],” that in some cases “the sponsors did not report the fees to CMS and therefore they were not passed on to the program” because “the PBMs considered these fees to be bona fide services fees, which CMS does not consider price concessions if they are at fair market value,” and that “[b]ecause sponsors may not always be able to verify whether these fees should be considered rebates or bona fide service fees, they may be inaccurately reporting this information to CMS.” 2011 OIG Report, *supra*, at 18-19. The SAC simply recasts these concerns as unsubstantiated fraud allegations. The Court should take judicial notice of this report, and the other disclosures cited in the PBM/Payor brief, and dismiss on this ground too.

These disclosures are more than sufficient to trigger the public-disclosure bar. Numerous courts have recognized that a prior disclosure does not need to identify a specific defendant to be a sufficient disclosure. *See, e.g., In re Natural Gas Royalties*, 562 F.3d 1032, 1043 (10th Cir.

2009); *United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 569-72 (10th Cir. 1995). The import of those decisions seems particularly applicable when, as here, the relator offers no allegations specific to any Defendants either. Moreover, the government could easily identify from DIR reports all Part D plan sponsors that use the services of a PBM which has entered into a service-fee contract with a manufacturer.

In sum, because Borzilleri “infer[red]” the alleged fraudulent scheme (“Z”) entirely from qualifying public disclosures (“X + Y”), and the disclosures themselves confirm this, the public-disclosure bar precludes his FCA claims unless he is an “original source”—which he is not. *Lissack*, 2003 WL 21998968, at *10.

B. Borzilleri Is Not An “Original Source.”

Borzilleri is not an “original source” under either the pre-ACA or post-ACA versions of the bar because he admits that he derived all of his alleged information from public disclosures. *See U.S. ex. rel. Keshner v. Immediate Home Care, Inc.*, No. 06-CV-01067 (FB) (VPP), 2016 WL 3545699, at *3 (E.D.N.Y. June 24, 2016) (relator’s “self-serving, conclusory assertion that he is an ‘original source’ will not save his complaint”) (citation omitted).

Under the pre-ACA version of the bar, the FCA defined an “original source” as an “individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action.” 31 U.S.C. § 3730(e)(4)(B) (2006). Under the post-ACA version, an “original source” is an individual who either (1) “prior to a public disclosure . . . voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based,” or (2) “has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before

filing an action.” 31 U.S.C. § 3730(e)(4)(B) (2012).

Borzilleri fails to qualify as an “original source” under the pre-ACA public-disclosure bar because the core information he alleges derives exclusively from third-party disclosures, and he does not allege having “knowledge obtained from actually viewing source documents, or firsthand observation of the fraudulent activity.” *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 300 (S.D.N.Y. 2013) (internal quotation marks omitted); *see also U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993) (“Nor does the fact that [relator’s] background knowledge enabled it to understand the significance of the information acquired . . . make its knowledge independent of the publicly disclosed information.”); *U.S. ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002) (relator not an “original source” despite spending hours compiling a “ ‘mosaic’ of information that shows a fraud . . . that an average member of the public could neither understand . . . nor perceive”), *aff’d*, 53 F. App’x 153, 154 (2d Cir. 2002).

Borzilleri also fails to qualify as an “original source” under the post-ACA public-disclosure bar. He neither disclosed his alleged information to the government prior to its public disclosure, nor has “knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions.” 31 U.S.C. § 3730(e)(4)(B) (2012); *see U.S. ex rel. Coyne v. Amgen Inc.*, 229 F. Supp. 3d 159, 172-73 (E.D.N.Y. 2017) (information must “add some new value” and be “qualitatively different,” rather than a mere “outgrowth of publicly disclosed information” (internal quotation marks omitted)), *report and recommendation adopted*, 243 F. Supp. 3d 295 (E.D.N.Y. 2017), *aff’d* 717 F. App’x 26 (2d Cir. 2017). His suit is based entirely on preexisting, publicly disclosed information, and he contributes no inside or valuable

information.¹⁹

CONCLUSION

For the foregoing reasons, and those in the Motion to Dismiss filed by the PBM Defendants, Borzilleri's SAC should be dismissed. The dismissal should be without prejudice if it is based on the first-to-file bar or for lack of jurisdiction, and with prejudice on all other grounds.²⁰

October 1, 2018

Respectfully submitted,

[counsel listed on next page]

¹⁹ Because the Court lacks jurisdiction over the pre-ACA FCA claims, the Court also lacks jurisdiction over all of the pre-ACA state-law claims. 31 U.S.C. § 3732(b). In addition, for substantially the same reasons that the FCA's public-disclosure bar precludes the FCA claims in this case, various state public-disclosure bars preclude the state-law claims. *See* Cal. Gov't Code § 12652(d)(3)(A); Colo. Rev. Stat. § 25.5-4-306(5)(c); Conn. Gen. Stat. § 4-282(b); 6 Del. Code Ann. tit. 6, § 1206(b); D.C. Code § 2-381.03(c-1)(1); Fla. Stat. § 68.087(3); Ga. Code Ann. § 23-3-122(j)(3); Haw. Rev. Stat. Ann. § 661-31(b); 740 Ill. Comp. Stat. 175/4(e)(4)(A); Ind. Code § 5-11-5.5-7(f); Iowa Code § 685.3(5)(c); La. Stat. Ann. § 439.1(D); Mass. Gen. Laws. ch. 12 § 5G(c); Mich. Comp. Laws. § 400.610a(13); Minn. Stat. § 15C.05(f); Mont. Code Ann. § 17-8-403(6)(a); Nev. Rev. Stat. Ann. § 357.100; N.J. Stat. Ann. § 2A:32C-9(c); N.M. Stat. Ann. § 27-14-10(C); N.Y. State Fin. Law § 9(b); N.C. Gen. Stat. § 1-611(e); Okla. Stat. § 5053.5(B); R.I. Gen. Laws § 9-1.1-4(e)(4)(A); Tenn. Code Ann. § 4-18-104(d)(3); Tex. Code Ann. § 36.113(b); Va. Code Ann. § 8.02-218.8; Wash. Rev. Code § 74.66.080(2).

²⁰ As discussed, *supra* at 6-7, Borzilleri is a former investment fund manager who has never been employed by any of the Defendants and, as such, has no "insider" information from which to amend his complaint; he has presumably exhausted the information he could mine from public sources since he filed suit three years ago and amended his complaint for a second time in August 2018. For that reason, amendment would be futile and any dismissal other than under the first-to-file bar or for lack of jurisdiction should be with prejudice. *See Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000); *U.S. ex rel. Tessler v. City of New York*, No. 14-CV-6455, 2016 WL 7335654, at *5 (S.D.N.Y. Dec. 16, 2016), *aff'd*, 712 F. App'x 27 (2d Cir. 2017).

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,
ex rel. JOHN R BORZILLERI, M.D. et al.,

Plaintiffs,

vs.

ABBVIE, INC., et al.,

Defendants.

Case No. 15-cv-7881(JMF)

**MEMORANDUM OF LAW IN SUPPORT OF
THE PHARMACY BENEFIT MANAGER DEFENDANTS' JOINT MOTION
TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT**

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In this *qui tam* action, in which all governmental entities have declined to intervene, Relator John Borzilleri, M.D., alleges that “secretive” “service fees” paid by drug manufacturers to pharmacy benefit managers (“PBMs”) and plan sponsors are to blame for the high cost of prescription drugs. Relator’s theory is that, for years, drug manufacturers have agreed to pay excessive service fees to PBMs and plan sponsors in exchange for favorable placement on the PBMs’ covered drug lists (formularies) and to ensure the acquiescence of the PBMs in the manufacturers’ price increases. Relator contends, in turn, that these excessive fees have not been reported to the government as discounts, thus causing the government to overpay Medicare Part D (“Part D”) plans for the drugs those plans provide to enrollees.

Despite its length, the Second Amended Complaint (“SAC”) fails to satisfy the most elemental pleading standards for bringing a fraud case. It does not contain a *single* specific allegation about any of the defendants or any of the particular fees in their contracts with the manufacturers for the Part D drugs. Instead, the SAC is based on speculation about what Relator might “ascertain” by pursuing this lawsuit and how he “anticipates” that discovery might confirm his hypotheses about the relationship between service fees and drug prices. That kind of “fishing expedition” approach to litigation is insufficient under governing federal pleading standards.

The reason for the SAC’s shortcomings is obvious. Relator is not a well-meaning *qui tam* plaintiff who used inside information to build his case. Relator is instead a former hedge fund manager, with access only to public information, whose only connection to the Defendants was that he specialized in “short selling” their stocks, thereby profiting from bad news about them. As a related lawsuit recently brought against Relator by his former employer shows, this case is about entrepreneurial opportunism, not sincere whistleblowing activity aimed at remedying fraud against the government.

These pleading deficiencies warrant dismissal with prejudice. Relator filed his initial complaint on October 6, 2015, and amended his complaint two times after the government had investigated his case over a period of years (and at considerable cost to the Defendants). But the United States, every State named in the SAC, and the District of Columbia declined to intervene after their investigations. If Relator had viable theories to pursue or relevant facts to offer, he would have included them in the SAC.

Beyond its overarching pleading deficiencies, the SAC also fails for two additional and independent reasons under the False Claims Act (“FCA”) that bar this action. First, it violates the FCA’s “public disclosure” bar because service fees are a well-known form of compensation that is routinely reported to the Centers for Medicare & Medicaid Services (“CMS”) by manufacturers and plan sponsors, and allegations that such fees are allegedly excessive or misreported have been the subject of multiple public reports. Indeed, some of the very sources upon which Relator bases his allegations in the SAC constitute public disclosures. Second, the SAC violates the FCA’s “first-to-file” bar, since Relator indisputably filed a previous lawsuit making the very same allegations.¹ For these reasons, too, as well as those set forth in the Manufacturer Defendants’ Motion to Dismiss, the SAC should be dismissed.

BACKGROUND

I. FACTUAL BACKGROUND

Relator filed this *qui tam* action on October 6, 2015, more than a year and a half after filing a nearly identical case in Rhode Island federal court.² After the government (federal and state)

¹ A dismissal under the “first to file” bar would be without prejudice. See e.g., *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 175 (2d Cir. 2018).

² Though that case has been unsealed, Relator’s initial complaint in the District of Rhode Island has not been unsealed and is unavailable on the public docket. The case docket lists the “Date Filed” as January 16, 2014 (No. 1:14-cv-00031). Relator’s first (May 2014) and second amended complaints (July 2018) in that action are unsealed, and he is proceeding to litigate that action despite the government’s decision not to intervene.

investigated both matters and declined to intervene, the cases were unsealed.

During this time, Relator managed a health care hedge fund with a short-side focus at Shepherd Kaplan Krochuk, LLC (“SKK”). Relator was also the fund’s largest investor. After SKK learned about the unsealing of these *qui tam* actions, it summarily terminated Relator, liquidated his fund, and sued him in Massachusetts state court.³ According to its lawsuit, SKK found that “throughout 2016 and 2017, and escalating in early 2018, Borzilleri established highly significant short positions” against the “stock value” of certain of the Defendants in this FCA lawsuit and those in the nearly identical suit he filed in Rhode Island. *See* Ex. A, SKK Compl. at 1, 33, 35. SKK also found that Relator increased his short positions through early April 2018 while he had “non-public information both that the lawsuits had been filed, and that they would soon be unsealed.” Ex. B, SKK Mot. to Dismiss Counterclaims at 4. By April 17, 2018, the seven largest short positions in the fund were against the securities of the defendants in this case, including a number of the PBM Defendants. Ex. A ¶ 37.

This case was unsealed on April 13, 2018. ECF No. 19. Just four days later, Relator authored and distributed a press release to major media outlets and financial institutions to which he attached both of his now-public *qui tam* complaints. Relator admits that his complaints “make substantially negative allegations about the defendants . . . against which [he] had established large short positions in the Fund,” Ex. A ¶ 40; Ex. C, Borzilleri Ans. & Counterclaim at 9 ¶ 40, and he has described these cases as “the greatest financial opportunity of his career.” Ex. C at 24 ¶ 70.

³ Relator and SKK currently are engaged in two lawsuits, one in Massachusetts Superior Court and one in the Southern District of New York (Sullivan, J.). This Court may rely on items in the public record in evaluating a motion to dismiss, including pleadings in other actions. *See, e.g., Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 75 (2d Cir. 1998) (“It is well established that a district court may rely on matters of public record in deciding a motion to dismiss under Rule 12(b)(6), including case law and statutes.”); *see also Rahman v. Schriro*, 22 F. Supp. 3d 305, 311 (S.D.N.Y. 2014) (“Courts that consider matters of public record in a Rule 12(b)(6) motion are limited to things such as statutes, case law . . . or pleadings in another action.”) (brackets omitted) (quoting *Moore U.S.A., Inc. v. Standard Register Co.*, 139 F. Supp. 2d 348, 363 (W.D.N.Y. 2001)).

Unsurprisingly, given his intent, Relator named as Defendants in this case the holding companies that issue shares to the public, such as UnitedHealth Group, Inc., Humana, Inc., CVS Health Corporation, and Express Scripts Holding Co., rather than their respective operating subsidiaries that actually perform the activities challenged in the SAC.⁴

II. REGULATORY BACKGROUND

This case concerns Part D of the Medicare program, under which the federal government makes prescription drug benefits available to the elderly and disabled.⁵ To deliver these benefits, CMS contracts with private insurance companies, often referred to as plan sponsors, who then agree to administer drug benefits to Part D beneficiaries in accordance with CMS rules. *See* 42 U.S.C. § 1395w-102(e).

PBMs play an important role in the administration of Part D. PBMs may provide a variety of services to plan sponsors, including negotiating and administering drug rebate programs, establishing and administering claims processing systems, offering formulary design and management tools, and negotiating reimbursement rates with pharmacies. SAC ¶ 154.⁶ PBMs are compensated for these services. *E.g., id.*

CMS pays plan sponsors in part based on their cost to acquire drugs for their Part D

⁴ The PBM and Part D Plan Sponsor Defendants (“PBM Defendants”) are: Aetna Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc., and UnitedHealth Group, Inc. Notably, these entities are not correctly named. In each case, the proper party would be the applicable subsidiary of each that operates as a PBM or Part D plan sponsor. Several of these Defendants have raised this issue with Relator, identified the correct subsidiary, and requested that the correct party be named; however, Relator’s counsel has refused.

⁵ Part D Plans (“PDPs”) offer coverage for “covered part D drugs.” *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066. “[C]overed part D drugs” excludes various categories of drugs, such as drugs prescribed for the treatment of erectile dysfunction and drugs that are payable under Part A (hospital insurance) or Part B (medical insurance). *See* 42 U.S.C. § 1395w-102(e). Relator’s multiple references to the prices of Viagra fail to recognize that Viagra, when prescribed for the treatment of erectile dysfunction, is statutorily excluded from Part D coverage.

⁶ *See* Ex. D, CMS Pub 100-18, Ch. 9, § 20, Definitions at 3 (2018), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf>.

enrollees as reported in annual cost estimates called “bids” and cost data submitted periodically by plans to CMS during the year. *See* 42 C.F.R. § 423.265. Because CMS pays plan sponsors based on their costs, CMS also needs to know about discounts that plan sponsors receive from manufacturers that offset the cost paid by the plan sponsors.⁷ *E.g.*, SAC ¶ 30. While discounts often take the form of rebates from the manufacturers to the plan sponsors, CMS also considers as discounts other payments that plan sponsors, or in this case PBMs, receive from drug manufacturers. *See* 42 C.F.R. § 423.308.⁸

One common form of payment by drug manufacturers to PBMs is known as a “service fee.”⁹ A PBM might, for example, provide data services to a manufacturer or assist with rebate program management, and be paid a service fee as a result. SAC ¶ 155. There is nothing new or unusual about this form of payment. CMS has recognized the existence and legitimacy of fees manufacturers pay for PBMs’ services, including bona fide service fees (“BFSFs”),¹⁰ and has considered how those fees should be reported for various drug pricing purposes, for more than

⁷ *See, e.g.*, Ex. E, Final Medicare Part D DIR Reporting Requirements for Plan Year 2017.

⁸ Plan sponsors, typically via their contracted PBMs, negotiate with manufacturers to reduce the price paid by the plan sponsor for the manufacturers’ drugs, often in the form of rebates. These rebates may be retained by the PBMs or passed through to the plan sponsor. Over time, plan sponsors have obtained a higher percentage of manufacturer rebates (and PBMs have retained a lower share). Regardless of whether the plan sponsor actually obtains the rebate, all manufacturer rebates are reported by the plan sponsor to CMS as discounts. SAC ¶ 162.

⁹ There are various types of service fees that manufacturers may pay to PBMs (and other entities) that are recognized and regulated by CMS. *See* for example the discussion in CMS, Medicare Part D Reporting Requirements for Payment Reconciliation (2018), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2018_Part-D-Reporting-Requirements-12072017.pdf.

¹⁰ *See* 77 Fed. Reg. 22170 (Apr. 12, 2012) (regulatory definition of BFSF for purposes of Part D, incorporated into 42 C.F.R. § 423.501).

twenty years—first in Medicaid,¹¹ then in Medicare Part B,¹² and most recently in Medicare Part D.¹³ BFSFs are wholly permissible under Part D and are not treated as discounts by CMS when they are consistent with fair market value (“FMV”). *See* 42 C.F.R. § 423.501. Indeed, even if service fees exceed FMV, they still are permissible so long as they are disclosed to CMS through a process known as Direct and Indirect Remuneration (“DIR”) Reporting.¹⁴ CMS, in fact, reduces payments to plan sponsors—and therefore benefits from—the portion of such fees that may exceed FMV, so long as they are properly reported.¹⁵

III. RELATOR’S ALLEGATIONS

The core premise of the SAC is that drug manufacturers have agreed for years to pay PBMs excessive service fees, thereby increasing the price of drugs paid by CMS. *See, e.g.*, SAC ¶ 26. The SAC alleges that these excessive service fees are paid by pharmaceutical companies in exchange for favorable placement on the PBMs’ formularies and for acquiescence by the PBMs in manufacturer price increases. *See, e.g., id.* ¶ 79. And the SAC contends that these excessive service fees were not disclosed to CMS through the DIR reporting process. *See, e.g., id.* ¶ 86.

¹¹ *See* Drug Rebate Program, Medicaid Release No. 14, at 1 (Dec. 21, 1994), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-014.pdf> (discussing services and fees paid by manufacturers for them).

¹² *See* 71 Fed. Reg. 69624, 69667 (Dec. 1, 2006) (regulation defining BFSF for purposes of determining the “Average Sales Price” used in the Medicare Part B program).

¹³ *See supra* note 7 and *infra* note 15.

¹⁴ DIR includes, for example, discounts, chargebacks or rebates, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities, obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted (such as a PBM), regardless of whether the intermediary has retained or passed on to the plan sponsor all or a portion of those discounts or other benefits. 42 C.F.R. § 423.308.

¹⁵ *See* Ex. F, CMS, Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation, at 9 (June 10, 2010). Prior to this time, CMS was well aware of BFSFs, as reflected in sub-regulatory program guidance. For example, CMS discussed these fees in its 2007 guidance and has required reporting of BFSFs since the 2009 Plan Year. *See* Ex. G, CMS, Final Medicare Part D DIR Reporting Requirements for 2007 Payment Reconciliation, at 2 (June 13, 2008); Ex. F at 9.

Based on the existence of this alleged scheme, the SAC alleges that all Defendants must be submitting a “myriad of false claims . . . for reimbursement in the Medicare Part D program, including Prescription Drug Event (PDE) reports, [DIR] reports, Part D annual plan bids, . . . [and] financial data required for Part D subsidy reconciliation.” *Id.* ¶¶ 86, 87; *accord, e.g., id.* ¶¶ 28–29. Relator also appears to present the alternative theory that Manufacturer Defendants forgave unidentified debts allegedly owed by the PBM Defendants’ affiliated Part D plan sponsors in connection with expensive drugs that trigger “catastrophic coverage” requirements, and then failed to report those forgiven amounts to the government as discounts or rebates. *See, e.g., id.* ¶¶ 395–444.

ARGUMENT

I. THE SAC FAILS BASIC PLEADING REQUIREMENTS AND SHOULD BE DISMISSED WITH PREJUDICE.

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Wood ex rel. United States v. Applied Research Assocs. (“ARA”)*, 328 F. App’x 744, 746 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). “‘The plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully.’” *Id.* at 746–47 (quoting *Iqbal*, 556 U.S. at 678). A statement of facts that “merely creates a suspicion [of] a legally cognizable right of action,” is insufficient, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and “stops short of the line between possibility and plausibility of entitlement to relief,” *ARA*, 328 F. App’x at 747 (quoting *Iqbal*, 556 U.S. at 678).

In addition, Rule 9(b) requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). The requirement applies to complaints, like this one, that assert violations of the FCA and its state-law

analogues. *See, e.g., United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016); *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995). And because one essential element of any such violation is the submission of a false claim or statement to the government, Rule 9(b) demands that Relator “(1) specify the statements that the [he] contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Ladas*, 824 F.3d at 25 (internal quotation marks omitted). While Relator need not have direct personal knowledge of the actual submission of the claims to the government, he must offer “plausible allegations creating a strong inference that *specific* false claims were submitted to the government.” *United States ex rel. Chorchos v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017) (emphasis added).

A. The SAC’s Speculative Allegations Lack Plausibility and Particularity as to Even the Most Basic Elements of the Schemes It Purports to Plead.

The SAC is a textbook example of the sort of speculative allegations Rules 12(b)(6) and 9(b) exist to foreclose. Far from identifying facts that could plausibly support his allegations or specific instances of fraud by specific defendants in connection with specific drugs, the SAC pleads literally no facts specific to any of the PBM Defendants or their Part D contracts. Instead, the SAC espouses pure hypothesis in repeatedly seeking to conduct “discovery of unknown wrongs.” *Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989) (internal quotation marks omitted); *see, e.g., SAC* ¶ 122 (“For all the PBM Defendants, we expect discovery to determine that the manufacturer ‘service fee’ scheme has been a primary driver of both their PBM and overall corporate profit growth over the past decade.”).¹⁶

¹⁶ *See also* SAC ¶ 218 (“Close scrutiny of the financial terms and transactions related to these secretive arrangements will be a key part of case discovery.”); *id.* ¶ 296 (“[A] detailed review of all financial transactions between the Manufacturer Defendants and a given PBM Defendant for a particular drug product, at the corporate level, will be required in a thorough investigation.”); *id.* ¶ 433 (“[W]e expect discovery to uncover wide-ranging ‘cost-sharing’ reporting and financial fraud for Gleevec and other extreme-priced ‘specialty’ oral cancer drugs.”); *id.* ¶ 720 (“We expect discovery to uncover even less legitimate ‘support services’ for the Defendant ‘traditional’ drugs.”).

This approach puts the cart before the horse. A plaintiff may not, under Rule 9(b), plead speculative generalizations on the off chance that discovery will theoretically prove those allegations correct. *Madonna*, 878 F.2d at 66. Yet that is *precisely* what Relator has done here. Over the course of almost 200 pages, Relator offers little more than generalized, industry-wide assertions that lack connection to any of the drugs at issue here, any of the contractual relationships between the Defendants, any of the disclosures made by any of the Defendants to CMS, or, for that matter, any specific conduct of any PBM Defendant.

The lack of actual facts is staggering. Relator never *once* identifies a particular Part D contract or sub-contract, an allegedly false statement made by any Defendant, or a specific false claim submitted, or caused to be submitted, by any of the PBM Defendants (or anyone else); never once identifies the services performed or service fees actually paid in connection with any of the drugs at issue for Part D beneficiaries; never once identifies what he believes the FMV for those services truly was; and never once explains how or why any alleged excessive service fee was not disclosed to CMS. On Relator's ancillary theory regarding "catastrophic coverage" debt forgiveness, he does not identify a single forgiven debt that he claims was not properly reported to the government. Particularly given the government's own investigation and declination of this case, this Court should decline Relator's request to submit the Defendants to further discovery so he can further explore whether his hypotheses are anything more than a flight of fancy.

1. The SAC Recites Alleged Elements of the FCA Yet Offers No Plausible Allegations.

Relator asserts that the "PBM Defendants have caused or directly submitted a myriad of false claims via the array of submissions required for reimbursement in the Medicare Part D program." SAC ¶¶ 86, 170. Without connecting the alleged fraudulent scheme to any actual claims or other submissions, Relator merely recites *alleged* legal requirements and labels the

submissions as “false.”¹⁷ *Id.*; *see also id.* ¶¶ 808–09. Pleading such “labels and conclusions” or “a formulaic recitation of the elements of a cause of action” is insufficient to survive a motion to dismiss. *Twombly*, 550 U.S. at 555. Because Relator has only advanced bald assertions and conclusions of law, the SAC should be dismissed. *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996).

2. The SAC Also Lacks Particularized Allegations as Required by Rule 9(b) about the Allegedly Unlawful Service Fees.

Relator’s theory relies on at least three key factual premises that must be pled with particularity under Rule 9(b). *First*, Relator must identify the service fees a particular PBM Defendant received for services provided to a Manufacturer Defendant in connection with a particular drug provided under a particular Part D plan. *Second*, Relator must identify the actual (and lower) FMV of those services. *Third*, Relator must allege that the PBM Defendant did not report (or, more precisely, caused the contracted plan sponsor not to report) the difference between those figures to CMS. The SAC does not contain particularized allegations about *any* of those essential facts and thus fails to satisfy the rigorous pleading standard set by Rule 9(b). *See, e.g., United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (“Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.” (internal quotation marks omitted)).

a. Relator Admits He Does Not Know the Amounts of Any Service Fees.

Relator acknowledges that the compensation structure for service fees can vary from one contract to the next, with many industry participants using “[a] ‘percent of revenue’ arrangement”

¹⁷ Relator references pre-2009 violations of the FCA but does not explain why the pre-2009 statute applies. *See, e.g., SAC* ¶¶ 87, 92. In the Second Circuit, § 3729(a)(1)(B) of the FCA “applies retroactively to any claim pending before a court on or after June 27, 2008.” *United States v. N.Y. Soc’y for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07-cv-292 (PKC), 2014 WL 3905742, at *9 (S.D.N.Y. Aug. 7, 2014) (internal citation omitted).

while others employ “flat fees and lump sum payments” instead. SAC ¶ 660. He thus recognizes (as he must) that “the PBM Defendant compensation for any particular . . . drug will depend upon specific contractual terms.” *Id.* ¶¶ 242, 243. Yet Relator concedes that he does not know what the terms of *any* of those contracts are. *Id.* ¶ 180.

Relator tries to paper over his patent pleading deficiency by relying on what he claims are the “*average* contract terms for ‘service fees’” in the *private* insurance market as reported in an advocacy piece published by PhRMA, a nonprofit organization that asserts the interests of pharmaceutical manufacturers. *Id.* ¶ 179. But *average* fees in the *private* insurance market, even if they were accurate, have no bearing on *specific* fees related to particular *Part D* contracts.¹⁸

Relator next inserts that “average” service fee rate into a series of three examples that purport to “illustrate” how his theory works in connection with specific drugs—Enbrel, Gleevec, and Premarin. *See id.* ¶¶ 246–75. But in each case, the SAC makes clear that it is just *assuming* that the supposed industry-wide “average” rate for the private insurance market is: (a) applicable to contracts with the manufacturer of each of the three drugs; and (b) specifically relates to contracts regarding Part D. *See, e.g., id.* ¶ 250 (“Using the ‘8% of sales’ PhRMA average ‘specialty’ contract rate, the annual PBM/specialty pharmacy ‘service fee’ payment from Defendant Amgen *would be* \$1,479 for each Enbrel-treated patient in 2006”); *id.* ¶ 259 (substantively identical allegation regarding Gleevec); *id.* ¶ 271 (similar allegation regarding Premarin, “[u]sing the ‘4% of sales’ PhRMA average ‘traditional’ contract rate”). Relator does

¹⁸ Prescription drug coverage may be provided by private insurance companies that offer policies in the commercial market, employer-based market, or under government programs, or by employers or unions—all of which are subject to very different laws, regulations, and financial arrangements. A fundamental flaw throughout the SAC is that Relator assumes that national revenue and rebate data reflects the financial aspects of the Part D program. *See, e.g., SAC* ¶¶ 242–44. For example, the “incriminating” PhRMA report, *id.* ¶¶ 177–91, and the “incriminating” PCMA report, *id.* ¶¶ 198–213, do not report on Part D drug costs, rebates, or fees. The three examples of financial relationships given in the PhRMA report pertain specifically to commercial insurance and employer-sponsored insurance, which is why Relator admits that the data relates to “private insurance.” *Id.* ¶ 190.

not allege with any specificity the relevant contract terms or fee rates—let alone actual fees paid for the services provided. And Relator does not explain on what factual basis he extrapolates these averages to Part D contracts.

Industry-wide averages are the antithesis of the “particularity” that Rule 9(b) demands. For this reason, courts have repeatedly rejected the use of industry-wide assertions that any given participant in the industry is more likely than not to have engaged in the alleged conduct. This sort of “probabilistic reasoning,” they have concluded, “fails under Rule 9(b)’s heightened pleading standard.” *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 257 (6th Cir. 2012) (reasoning that plaintiff’s reliance on “the industry-wide existence of questionable appraisal practices” is insufficient because “this argument involves only probabilities”); *see also, e.g., Plumbers’ Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 774 (1st Cir. 2011) (allegation that “other banks engaged in such practices, some of which probably distorted loans, and therefore this may have happened in this case” was insufficient because “there is no allegation that any specific bank that supplied mortgages to the trusts did exert undue pressure”). Relator has not alleged—and has no basis to say—whether any given Defendant’s contractual fee rate for Part D services resembles the industry-wide “average” figure that he asserts—and without that, his claims fail.

Unaware of any specific terms or fees in the PBM-Manufacturer Part D contracts supposedly at issue, Relator resorts to a pair of contracts to which CVS and Express Scripts allegedly were parties—specifically contracts with *private employers* providing their employees insurance coverage. *See* SAC ¶¶ 689–713. But Relator’s references to the CVS contract make no allegation or any reference *at all* to the amount of service fees that CVS was receiving from manufacturers. *See id.* ¶¶ 704–05. According to Relator’s allegations, the Express Scripts contract

provides a ceiling for service fees it receives from manufacturers, but does not identify the fees paid in connection with any particular drug (which, of course, could be significantly lower than the ceiling described). *Id.* ¶ 692. These contracts are thus irrelevant and add nothing to Relator's theory in this case, against CVS and Express Scripts or otherwise.

Relator cannot satisfy even the most basic pleading requirements. The SAC does not allege with any specificity the amount of any service fees paid by a Manufacturer Defendant to any PBM Defendant related to Part D, or the terms of any Part D contractual relationships between these parties. Relator has a hypothesis, but a hypothesis does not state a cause of action for false claims or kickbacks—both sounding in fraud—under Rules 12(b)(6) and 9(b). *Ladas*, 824 F.3d at 26–27 (“hypotheses,” “conclusory statements,” and assertions “not supported by particularized allegations of fact” do not satisfy Rule 9(b)).

b. Relator Does Not Allege the FMV of the Services PBMs Provided and Does Not Even Know What Those Services Were.

The second essential component of Relator's theory is that the PBM Defendants were paid more than they should have been paid or, put another way, that the PBM Defendants were paid in amounts that exceeded FMV. Relator does not back up this claim with any of the requisite particularity. In fact, it appears that Relator—a former hedge fund manager—does not even know the services PBMs generally (let alone these PBM Defendants specifically) provide in exchange for services fees. *See, e.g.*, SAC ¶ 720 (describing what he “expect[s] discovery to uncover” about what “support services” the PBM Defendants supply to their clients).

This failure, too, warrants dismissal. Courts have consistently held that where a relator asserts that a defendant has violated the FCA by paying or receiving compensation in excess of FMV without disclosing that compensation, the relator “must allege a benchmark of FMV against which Defendants’ [compensation arrangements] . . . can be tested.” *United States ex rel.*

Schaengold v. Mem'l Health, Inc., No. 4:11-cv-58, 2014 WL 7272598, at *11 (S.D. Ga. Dec. 18, 2014) (bracket and internal quotation marks omitted); *see also United States ex rel. Schubert v. All Children's Health Sys., Inc.*, No. 8:11-cv-1687, 2013 WL 6054803, at *11 (M.D. Fla. Nov. 15, 2013); *United States ex rel. Dennis v. Health Mgmt. Assocs., Inc.*, No. 3:09-cv-484, 2013 WL 146048, at *13 (M.D. Tenn. Jan. 14, 2013); *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253, 2012 WL 2871264, at *7 (S.D. Fla. July 12, 2012).

Relator offers no such comparative benchmark here, nor does he allege what the FMV payment should have been for any specific contract. To the contrary, the SAC admits that CMS has “purposely not defin[ed] methods for BFSF FMV assessment in the Part D program” and that as a result “each drug manufacturer must determine its own process based upon acceptable practices in the private marketplace.” SAC ¶ 653.

Relator attempts to salvage this assertion by claiming that “the appropriate ‘arm’s length’ compensation to the PBM Defendants for providing manufacturer services should be very modest, even for ‘complex’ specialty drugs.” *Id.* In support, Relator points to a statement by an entity he identifies as Diplomat Pharmacy—“the largest remaining independent specialty pharmacy”—made in an SEC filing: “[W]e incur significant costs in providing these services and receive minimal service fees in return.” *Id.* ¶¶ 668, 671 (emphasis omitted). But Diplomat Pharmacy is not a PBM akin to any of the Defendants in this case. It is, the SAC acknowledges, a specialty pharmacy and, in this role, provides a different scope and type of services than the PBM Defendants provide. *See id.* ¶¶ 668–69. Even as to the service it does provide, it avers it is undercompensated as it incurs “significant costs.” *Id.* ¶ 671. In addition, Diplomat’s statements do not relate to services provided in connection with the Part D program. Even as to the services Diplomat provides, the SAC lacks any actual description of how much Diplomat charges for its

services or how those fees compare to the service fees received by the PBM Defendants. The SAC never offers a particularized allegation of the services at issue under any Part D contract; what the FMV of those services was for even a single one of the drugs at issue; or whether or why any particular payments by particular Defendants for particular services under particular contracts exceeded FMV.¹⁹

c. Relator Lacks Any Particularized Allegations that the PBM Defendants' Service Fees Were Not Properly Reported to CMS.

Relator equally fails to plead that any PBM Defendant's service fees were not properly reported to CMS. In a plan sponsor's Part D DIR reports to CMS, the plan sponsor is required to report as a price concession any portion of a service fee that exceeded FMV. *See, e.g.*, SAC ¶ 30. ("As per [CMS] regulations, 'service fees' in excess of FMV should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D. In turn, the plan sponsor should report 'service fees' in excess of FMV to CMS in its [DIR] report as a 'discount,' leading to lower Part D 'negotiated' drug prices."). In other words, CMS regulations *permit* fees to be set at above FMV, so long as the difference is reported to CMS as a discount (and thus inures to CMS's benefit by lowering its costs). Relator's FCA theory depends on establishing not only that any service fees charged by the PBM Defendants were excessive, but also that these excessive fees—through the actions of the PBM—were not reported to CMS as required under Part D DIR guidance and regulations and thus led to the submission of false claims by the plan sponsors. Relator fails to plead any such allegations, with particularity or otherwise.

Relator offers only a vague and cursory allegation that "[t]he Defendants are intentionally not doing so"—i.e., not reporting service fees in excess of FMV to the government. *Id.* But he

¹⁹ Even if the "cost approach" were the only acceptable method for determining FMV in the Part D context, as Relator suggests, *see* SAC ¶¶ 460, 471, Relator still never describes what an FMV payment for the PBM Defendants' services on any of the drugs in question would be using the "cost approach" method.

alleges *zero* facts to support this crucial aspect of his case. For this reason, too, Relator's claims fail Rule 9(b).²⁰

3. Relator Also Fails to Present Particularized Allegations About Supposed Catastrophic Coverage Payment Waivers.

Relator's catastrophic coverage theory fails under Rule 9(b) for the same reasons as his service fees theory, and the Court should readily dispose of these allegations for failure to satisfy Rule 9(b). As discussed above, this theory depends on Relator's claim that the Manufacturer Defendants forgave unspecified debts allegedly owed by the PBM Defendants' affiliated Part D plan sponsors in connection with expensive drugs that trigger "catastrophic coverage" requirements, and then failed to report those forgiven amounts to the government as discounts or rebates. *See, e.g.*, SAC ¶¶ 395–444. Like his allegations about the service fees, however, Relator fails to plead any particularized allegations to support the key factual components of that theory. This theory, as well, is purely speculative.

First, Relator offers no particularized allegations that any catastrophic coverage payments were actually owed by any of the PBM Defendants, nor that any of the Manufacturer Defendants has ever forgiven any such debts, let alone as to any of the drugs at issue in this suit or in relation to a Part D contract or subcontract. Instead, he merely hypothesizes that (a) the PBMs are more profitable than his analysis of their SEC disclosures suggests that they should be, and (b) receiving massive debt forgiveness from the Manufacturer Defendants (apparently, in addition to excessive service fees) must be the explanation. *See, e.g.*, SAC ¶¶ 413–21. Based on that speculation,

²⁰ While *qui tam* relators can sometimes plead a viable FCA complaint even in circumstances where they do not have access to the actual claims documents the defendants submitted to the government, the Second Circuit has held that to do so, the relator must still allege that he has reason to know that the false statements or claims were made and point to "reliable indicia that lead to a strong inference that claims were actually submitted." *See United States ex rel. Chorchos v. Am. Med. Response, Inc.*, 865 F.3d 71, 89 (2d Cir. 2017) (citation and internal quotation marks omitted). Relator has none of that here. He is not, as in *Chorchos*, a corporate insider who has seen fraud first-hand but simply lacks access to the specific billing documents on which the fraud was consummated. *See, e.g., id.* at 84–85.

Relator alleges that “[w]e concluded that the Manufacturer Defendants, *in many instances*, are ‘forgiving’ the PBM Defendants for this ‘catastrophic exposure’ in order to further the ‘service fee’ pricing scheme.”²¹ *Id.* ¶ 352 (emphasis added); *see also id.* ¶ 422 (“We concluded that, *in many instances*, manufacturers are fraudulently excusing the PBM Defendants from their 15% ‘catastrophic’ cost-sharing exposure . . .”). Relator does not claim to have ever seen or heard about any document reflecting forgiven “catastrophic coverage” debt. Nor does he offer any explanation for his leap from his (unsupported) speculation that the Manufacturer Defendants are forgiving debts “in many instances,” *id.* ¶¶ 352, 422, to his conclusion that they have forgiven debt owed by PBM Defendants. Without such particularized allegations to connect his amorphous hypotheses to the claims he is actually pursuing here, he cannot satisfy Rule 9(b).

Second, Relator has not identified any instances in which such forgiveness occurred but was not properly reported to CMS under the Part D program. As with his service fee theory, particularized pleading of those facts is necessary because—as he acknowledges—there is nothing wrong with debt-forgiveness so long as it is properly reported to CMS on the designated forms as a rebate or discount. *See id.* ¶ 432 (“If the Manufacturer Defendants are commonly ‘forgiving’ the PBM Defendants from their Part D ‘catastrophic’ exposure, these amounts should be properly reported as discounts via DIR reports to CMS . . .”). The most Relator can say is that “*we expect discovery to uncover* wide-ranging ‘cost sharing’ reporting and financial fraud for Gleevec and other extreme-priced ‘specialty’ oral cancer drugs.” *Id.* ¶ 433 (emphasis added). That amounts to a concession that he filed his SAC “as a pretext for discovery of unknown wrongs,” *Madonna*, 878 F.2d at 66, which Rule 9(b) forbids.

²¹ Relator refers throughout his SAC to an undefined “we.” *See, e.g.*, SAC ¶¶ 21, 23, 75. As he is the only Relator in this case, the PBM Defendants presume he drafted his complaints with the expectation (now proven to be mistaken) that the U.S. government and various state governments would be joining his crusade and has simply failed to modify his pleadings to reflect that he is alone in propounding the “conclusions” in his SAC.

4. Relator Fails to Allege Scienter.

The Supreme Court has emphasized that the scienter requirement under the FCA is a “rigorous” one and that complaints may be dismissed at the pleading stage for failure to allege it adequately. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016). To survive a motion to dismiss, a *qui tam* relator must allege facts sufficient to establish a strong inference that the defendant acted “knowingly.” 31 U.S.C. § 3729(b)(1)(A) (2012). Although knowledge may be alleged generally, “under Rule 9(b), the proponent of an FCA claim must allege facts that give rise to a strong inference of fraudulent intent.” *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 694 (S.D.N.Y. 2018) (emphasis in original); *see also Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994), *superseded by statute on other grounds, as recognized in Norguard Ins. Co. v. RCJ Constr. Servs. Corp.*, No. 14-cv-432, 2018 WL 1178034, at *3 (E.D.N.Y. Jan. 19, 2018). Despite including 923 paragraphs in the SAC, Relator fails to allege any facts giving rise to a “strong inference” that the PBM Defendants had knowledge of the alleged wrongdoing. Relator offers only speculative inferences of a supposed industry-wide “secretive” scheme paired with his own conclusory say-so that the PBM Defendants acted “intentionally” or “knowingly.” SAC ¶¶ 30, 808–09. His threadbare SAC falls well short of establishing the critical scienter element of an FCA claim. *Accord, e.g., Grubea*, 318 F. Supp. 3d at 695 (granting motion to dismiss because complaint lacked “particularized information” as to scienter). The SAC should accordingly be dismissed.

5. Relator Fails to Make Specific Allegations Against Any of the PBM Defendants, in Violation of Rule 9(b).

Relator consistently aggregates entirely separate companies, with entirely separate postures vis-à-vis manufacturers and Part D, under the rubric “PBM Defendants.” *See* SAC ¶¶ 1, 147. Relator does not distinguish conduct purportedly attributable to any one of the PBM Defendants

(Aetna, Cigna, Humana, CVS Health, Express Scripts, or UnitedHealth Group), each of which are large corporations with wide-ranging business operations and functions and disparate organizational structures. *See* SAC ¶¶ 141–46. Relator’s generalized and undifferentiated allegations against all PBM Defendants as a group are neither credible nor legally sufficient and, on this basis alone, should be dismissed. *Kermanshah v. Kermanshah*, 580 F. Supp. 2d 247, 258 (S.D.N.Y. 2008) (“[A] complaint alleging fraud against multiple defendants must state the allegations specifically attributable to each individual defendant.”); *United States ex rel. Corp. Compliance Assocs. v. N.Y. Soc’y for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 Civ. 292 (PKC), 2014 WL 3905742, at *19 (S.D.N.Y. Aug. 7, 2014) (dismissing claims under Rule 9(b) where relators’ causes of action made blanket allegations against all three defendants collectively and failed to set “forth *separately* the acts complained of by *each defendant*” (emphasis in original) (internal quotation marks omitted)). Without identifying each Defendant’s conduct, Relator’s claims must fail.

B. Relator’s Anti-Kickback Statute (AKS) Theory Fails for the Same Reasons as His FCA Theory, and for Several Other Reasons.

Relator also alleges that the PBM Defendants engaged in criminal conduct in violation of the AKS. While a violation of the AKS can serve as a predicate for an FCA violation, to survive a motion to dismiss, Relator would need to allege plausibly and specifically the elements of both the AKS and the FCA.²² Relator alleges that “[t]he PBM Defendants . . . receive fraudulent ‘service fees’, as ‘kickbacks’, for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies.” SAC ¶ 79. Relator asserts throughout the SAC the conclusory mantra

²² The AKS makes it a crime to: (1) knowingly and willfully, (2) offer or pay, (3) any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person, (4) to induce such person, (5) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service, (6) for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A). For a further discussion regarding the AKS, *see* Mem. of Law in Support of Manufacturer Defendants’ Jt. Mot. to Dismiss Borzilleri’s SAC, at 9–10.

that purported “service fee” payments must have been “kickbacks” because they exceeded FMV for the services rendered. *See, e.g., id.* ¶¶ 332, 634, 639, 646, 648, 673. As a result, according to Relator, “[v]irtually all Part D submissions for reimbursement pertaining to the Manufacturer Defendant drugs over the past 12 years-plus have been ‘tainted’ by kickbacks and have been false claims.” *Id.* ¶ 87. Relator also appears to allege that manufacturers’ supposed forgiveness of “catastrophic coverage” debts was also exchanged for formulary placement of their drugs. *Id.* ¶¶ 79, 81, 395–437.

Relator’s AKS claim can be easily rejected, on the same basic grounds that necessitate dismissal of his FCA claims. He has failed to allege with particularity: (1) any of the supposed services provided in exchange for “service fees” on which his whole theory of liability is based; (2) why these services were “not necessary” or were a “sham”; (3) the FMV of the services; (4) the amount actually paid for the services; (5) why the amount paid exceeded FMV and by how much; or (6) whether service fees should have been or were reported to Medicare Part D. For these reasons alone, his AKS theory fails.

Relator’s AKS theory suffers additional fundamental flaws, however. First, the AKS requires proof that the Manufacturer Defendants paid (or were solicited to pay) “service fees” to the PBM Defendants to “induce” illegal referrals of Part D business. 42 U.S.C. § 1320a-7b(b)(1), (b)(2)(A); *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App’x 890, 894 (5th Cir. 2013) (“[A]ctual inducement is an element of the AKS violation . . . and [relator] must provide reliable indicia that there was a kickback provided in turn for the referral of patients.”). All Relator appears to allege is that the service fees (which Relator hypothesizes must have been excessive) must have been intended to secure favorable formulary placement. But he does not allege any particular facts even suggesting that this actually occurred between any Defendants, let

alone in the Part D Program. It is at least equally plausible that any service fees were paid in exchange for legitimate services provided by PBMs.

Second, even if Relator had alleged that a drug manufacturer paid above-FMV service fees with the intent to sway formulary decisions, Relator makes no plausible allegation that any PBM Defendant “*knowingly and willfully*” participated in any such conduct. *See* 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added). Relator cannot adequately allege knowledge or willfulness under the AKS without plausibly setting forth facts showing that the Defendants knew their conduct was unlawful. *Bryan v. United States*, 524 U.S. 184, 196 (1998) (holding that willfulness requires that the defendant had “knowledge that the conduct is unlawful”); *United States v. Bishop*, 740 F.3d 927, 932–33 (4th Cir. 2014); *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013) (an AKS violation requires proof that the defendant “acted with the intent to do something that the law forbids” (internal quotation marks omitted)). Here, Relator uses the word “willful” just *once* in a 191-page pleading. SAC ¶ 170(2).

C. The SAC Fails to State a Claim for Conspiracy to Submit False Claims.

To allege conspiracy under the FCA, a plaintiff must plausibly allege “(1) an unlawful agreement by the defendant to violate the FCA, and (2) at least one overt act performed in furtherance of that agreement.” *United States ex rel. Scharff v. Camelot Counseling*, No. 12-CV-3791, 2016 WL 5416494, at *9 (S.D.N.Y. Sept. 28, 2016) (quotation omitted).²³ Although Count II of the SAC purports to allege an FCA conspiracy, Relator has failed to meet these essential pleading requirements, in addition to other deficiencies of the SAC discussed above. There is no particularized allegation of an agreement between any Defendants (or anyone else, for that matter)

²³ 31 U.S.C. § 3729(a)(3) (2006) imposed liability on anyone who “conspire[d] to defraud the Government by getting a false or fraudulent claim allowed or paid.” Now, 31 U.S.C. § 3729(a)(1)(C) imposes FCA liability on anyone who “conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G).”

to violate the FCA. Relator makes only the conclusory statement that “Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims.” SAC ¶ 815. This is clearly insufficient under both Rule 12(b)(6) and Rule (9)(b). *See, e.g., United States ex rel. Piacentile v. Amgen, Inc.*, No. 04-CV-3983, 2018 WL 4409838, at *13 (E.D.N.Y. Sept. 17, 2018) (dismissing conspiracy claim under Rule 12(b)(6) where relator failed to “specify ‘the defendants’ who allegedly participated in the alleged conspiracy” and failed to alleged defendants “shared the objective of getting claims paid by the Government”); *Ladas*, 824 F.3d at 27 (upholding dismissal of FCA conspiracy claim where complaint failed “to identify a specific statement where [defendants] agreed to defraud the government”); *Camelot Counseling*, 2016 WL 5416494, at *9 (dismissing conspiracy claim where complaint failed to allege agreement to violate the FCA).

Relator also does not make any plausible factual allegations of an “overt act” in furtherance of an agreement to violate the FCA, let alone with the sufficient particularity demanded by Rule 9(b). As elsewhere in the SAC, Relator relies on a boilerplate allegation, without any facts, that defendants “took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.” SAC ¶ 815. This summary allegation does not stave off dismissal, *see Iqbal*, 556 U.S. at 678, and falls well short of meeting the heightened pleading requirements of Rule 9(b). *See Ladas*, 824 F.3d at 27. Without plausible and particularized allegations of facts supporting violations of § 3729(a)(1)(C) or § 3729(a)(3) (2006), the Court should dismiss Count II.

D. The Ancillary State Law Claims Fail to Allege Any Plausible Claims Under Any State FCA.

Relator's state law claims, Counts 5 through 32, are subject to the same Rule 12(b)(6) and (9)(b) pleading standards applicable to his federal claims, *see, e.g., United States ex rel. Blaum v. Triad Isotopes, Inc.*, 104 F. Supp. 3d 901, 912–13 (N.D. Ill. 2015), and they are premised on the same thin factual allegations he offers to support his federal FCA counts. Therefore, this Court should dismiss all analogous state FCA counts for the same reasons outlined above.²⁴

E. Relator's Common Law Claims for Unjust Enrichment and Common Law Fraud Must Be Dismissed Because Relator Lacks Standing to Bring Them on Behalf of the Government.

Relator does not have standing to bring common law claims here, because the FCA does *not* “give relators the right to assert common law claims on behalf of the United States.” *United States ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 451 (S.D.N.Y. 2001) (internal citation omitted). Therefore, Count 33 and Count 34 must be dismissed with prejudice.

II. RELATOR'S FCA CLAIMS ARE PRECLUDED BY THE STATUTE'S PUBLIC DISCLOSURE BAR.

The FCA's “public disclosure” bar prevents “‘parasitic lawsuits’ based upon publicly disclosed information in which would-be relators ‘seek remuneration although they contributed nothing to the exposure of the fraud.’” *United States ex. rel Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993) (quoting *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992)). That is precisely what Relator is doing here—indeed, he blatantly pleads that his allegations are based on various public disclosures cited in the SAC.

²⁴ Alternatively, the Court could dismiss the federal FCA claims and decline to retain supplemental jurisdiction over Relator's state law claims. *See Ruotolo v. Fannie Mae*, 933 F. Supp. 2d 512, 527 (S.D.N.Y. 2013) (“[N]othing [] separates this case from the usual case where courts typically decline to exercise jurisdiction over state law claims when all federal claims are dismissed before trial.”).

The Affordable Care Act (ACA) amended the public disclosure bar effective March 2010. Thus, to the extent the Relator alleges false claims made between 2006 and March 23, 2010, the pre-ACA version governs. *See, e.g., United States ex rel. Amico v. Deutsche Bank AG*, No. 15-CIV-9551 (CM), 2017 WL 2266988, at *4 n.4 (S.D.N.Y. May 8, 2017) (“Public disclosure” bar is not retroactive.). As to post-March 2010 false claims, the amended version controls. *See, e.g., United States ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.*, 295 F. Supp. 3d 186, 195 (E.D.N.Y. 2018) (noting that every federal court of appeals to consider the issue has held that “the pre-2010 version of the public disclosure bar applies to any conduct that occurred prior to the amendment and that the post-2010 version applies to any conduct that occurred after the effective date of the 2010 amendment” (internal quotation marks, alterations, and citation omitted)).

Under either version, the Court must perform a two-step analysis and determine: (1) whether the allegations in the complaint are “substantially similar” to the allegations contained in prior “public disclosures,” and, if so, (2) whether the suit may nonetheless go forward because the relator is an “original source” of the information on which he bases his allegations. *United States ex rel. Ping Chen v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 296–97 (S.D.N.Y. 2013). “Public” is defined broadly. *See Kreindler*, 985 F.2d at 1158 (deciding that discovery material in a lawsuit is public). Relator’s SAC should be dismissed with prejudice in its entirety because prior public disclosures are substantially similar to the allegations in the SAC and Relator is not an original source. *See* 31 U.S.C. § 3730(e)(4)(A).²⁵

²⁵ Pre-ACA, prior public disclosures deprived the court of subject-matter jurisdiction and required dismissal pursuant to Rule 12(b)(1), whereas after the 2010 amendments, such public sources instead constitute failure to state an FCA claim and thus justify Rule 12(b)(6) dismissal. *See Chorchos*, 865 F.3d at 80; *United States ex rel. JDJ & Assocs. LLP v. Natixis*, No. 15-cv-5427 (PKC), 2017 WL 4357797, at *5 (S.D.N.Y. Sept. 29, 2017).

A. Factual Allegations and Fraud Inferences Substantially Similar to Those in Relator’s SAC Were Publicly Disclosed Before He Filed This *Qui Tam* Action.

Whether a prior disclosure involved allegations “substantially similar” to those made in the operative *qui tam* complaint depends on whether the “information conveyed could . . . at least have alerted law-enforcement authorities to the likelihood of wrongdoing.” *Ping Chen*, 966 F. Supp. 2d at 298 (quoting *United States ex rel. Springfield Term. Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)). Claims that are even partly based on public disclosures are deficient under the statute. *See, e.g., Kreindler*, 985 F.2d at 1158. The same is true where the relator’s “independent investigation” or analysis of publicly-disclosed material forms the basis for his allegations. *See, e.g., id.* at 1158–59; *JDJ*, 2017 WL 4357797, at *11 (“[C]ombining publicly available information with specialized expertise is not sufficient to overcome the first step of the public disclosure bar”); *United States ex rel. Alcohol Found. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 461–62 (S.D.N.Y. 2002) (applying public disclosure bar where relator gathered information from articles published by third parties and obtained a unique “perspective” by “spending hundreds of hours compiling facts into a ‘mosaic’”). So long as the “material aspect[s] of [the] alleged scheme” appeared in prior public disclosures, the FCA claim fails. *Ping Chen*, 966 F. Supp. 2d at 298.

As demonstrated below, Relator’s allegations regarding PBMs’ and drug manufacturers’ “service fees” involve a long-disclosed subject of public (and government) scrutiny.

2011 OIG Report. In March 2011—more than four years before Relator filed this *qui tam* action—the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) released a report entitled, “Concerns with Rebates in the Medicare Part D Program.” *See* Ex. H, OIG Report OEI 02-08-00050, “Concerns with Rebates in the Medicare Part D Program” (Mar. 2011). In all material respects, Relator’s SAC contemplates the same potential for fraud as the

OIG recognized in its report. Indeed, Relator cites that very OIG report as support for his suspicions. See SAC ¶¶ 227–30. The OIG Report described the results of OIG’s examination of administrative fees received by PBMs, noting that: (a) PBMs were receiving “fees from drug manufacturers,” (b) in exchange for “services that the PBM provided to the manufacturer, such as negotiating rebates, calculating rebate amounts, and distributing rebates to sponsors,” and (c) the fees “were generally based on a fixed percentage of [Wholesale Acquisition Cost (WAC)].” Ex. H at ii, 18–19. A majority of the PBMs receiving such fees “did not pass them on to the sponsors” and, “[a]s a result, the sponsors did not report the fees to CMS and therefore they were not passed on to the [Medicare Part D] program,” all because the “PBMs considered these fees to be bona fide service fees, which CMS does not consider price concessions if they are at fair market value.” *Id.* at 19. OIG concluded that reporting of such fees to CMS “may be inaccurate[]” and *recommended an assessment of “whether these fees should actually be considered rebates.” Id.* (emphasis added). That same spring, OIG’s Semiannual Report to Congress noted that some PBMs “collected fees from drug manufacturers that were not always passed on to the Part D program.” Ex. I, OIG, Semiannual Report to Congress, Oct. 1, 2010–Mar. 31, 2011, at I-16. Two years later, in OIG’s Fall 2013 Semiannual Report to Congress, it was publicly disclosed that OIG had begun undertaking reviews of BFSFs. Ex. J, OIG, Semiannual Report to Congress, Apr. 2013–Sep. 2013, at 95–96 (App’x B).

These OIG reports, which squarely qualify as administrative “report[s], . . . audit[s], or investigation[s],” 31 U.S.C. § 3730(e)(4)(A), publicly disclosed the inference of fraud that Relator postulates and asks the Court to draw in this case—i.e., that the PBM Defendants received service fees based on a percentage of sales price (namely, WAC) and did not pass those fees on to Medicare Part D, and that that conduct amounted to “inaccurate” reporting and wrongful retention of those

funds if they did not constitute BFSFs. Ex. H at 18–19. These OIG reports vividly demonstrate the government’s awareness of the potential fraud alleged by Relator and are quintessential public disclosures that bar Relator’s claims. *See* 31 U.S.C. § 3730(e)(4)(A).

Other Pre-2015 Public Disclosures. OIG’s reports were not the first or only public disclosures that pondered whether service fees paid by drug manufacturers to PBMs might be improperly reported. Both Relator’s conclusory inferences and the raw materials from which he draws them were a subject of open discussion dating back to the early 2000s.²⁶

- September 1, 2002, Managed Care, *When Success Sours: PBMs Under Scrutiny* (Ex. K), at 4: “PBMs receive other payments from manufacturers that are not rebates and which are paid separately. These include *administrative fees for services rendered in connection with rebate agreements*. . . . Halbert told analysts that administrative fees don’t exceed 3 percent of the *amount spent for the branded drugs covered by the fees*. . . . *The company retains . . . the administrative fees paid by the drug makers.*”
- Spring 2003, Journal of Health Law, *The Spotlight on PBMs: Federal Enforcement of the Anti-Kickback Statute on the Pharmaceutical Benefit Management Industry*, 36 J. HEALTH L. 213, 218 (Ex. L): “PBMs . . . typically receive both an administrative fee and a rebate from drug manufacturers. . . . As noted in a HCFA report, ‘[r]ebates and *administrative fees are commonly paid as a percent of the drug’s wholesale acquisition cost (WAC)—which represents the manufacturer’s sale price.*’”
- January 28, 2005, 70 Fed. Reg. 4194, 4308–4309 (Medicare Prescription Drug Benefit Final Rule) (Ex. M): “In the preamble to the proposed rule, we said that to the extent the administrative fees paid to Part D plans (or their subcontractors, such as PBMs) are above the fair market value of the services rendered, this differential will be considered a price concession. . . . [A]s fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not *masked as administrative fees.*”
- September 8, 2005, News Release, U.S. Attorney’s Office, *AdvancePCS to Pay \$137.5 Million to Resolve Civil Fraud and Kickback Allegations* (Ex. N), at 1: “The civil settlement resolves claims under the False Claims Act . . . arising from (1) *payments made by pharmaceutical manufacturers to AdvancePCS in the form of excessive administrative fees* and over-priced products and services agreements as an improper

²⁶ The sources referenced here properly may be considered by the Court on this Motion. With respect to false claims alleged to have been made prior to March 2010, the Court’s inquiry is jurisdictional and thus it may look beyond the SAC. As to false claims alleged to have been made after March 2010, this Court can and should take judicial notice of these public disclosures. *See, e.g., Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) (“[I]t is proper to take judicial notice of the *fact* that press coverage, prior lawsuits, or regulatory filings contain[] certain information, without regard to the truth of their contents”); *Ping Chen*, 966 F. Supp. 2d at 294.

reward for favorable treatment of the manufacturers' drugs in connection with the contracts." *See also* Dep't of Health & Human Servs. & Dep't of Justice, Health Care Fraud & Abuse Control Program, Annual Report for FY 2005 (Aug. 2006) (Ex. O), at 7–8 (describing AdvancePCS settlement).

- January 2007, Congressional Budget Office (CBO), *Prescription Drug Pricing in the Private Sector* (Ex. P), at 12: "Manufacturers also make other types of payments to PBMs in addition to rebate payments. For example, *manufacturers commonly pay a fee to PBMs for the service of administering formularies. Such fees are frequently equal to about 3 percent of wholesale list prices.*"
- March 6, 2009, Business Wire, *State of Maryland's CVS Caremark Contract Audit Reveals More than \$10 Million in Potential Overpayments, Undisclosed Rebates, Improper Drug Switching, According to CtW* (Ex. Q), at 1: "In 2006, the United States Office of Personnel Management . . . [determined CVS's predecessor, AdvancePCS,] kept \$13 million in administrative fees that should have been considered drug rebates and returned to the federal agency."
- January-February 2013, Specialty Pharmacy Times, *Why We Care About Bona Fide Service Fees* (Ex. R), at 1–2: "Bona Fide Service Fees (BFSFs) is one of the most important industry terms today, with a dramatic impact across pharmaceutical manufacturers, . . . specialty pharmacy and specialty distributors, and GPOs, as well as CMS and oversight agencies such as the [OIG] and [DOJ]. . . . *The price that the government reimburses for pharmaceutical products under . . . Medicare . . . is impacted by the fees the manufacturer pays to trading partners and how those fees are treated. If a fee is considered a legitimate administrative fee, or a BFSF, it is excluded from statutory pricing calculations that the manufacturer submits to the government, which in turn defines the 'Government Price.'* *If the price is a price incentive (not an excluded BFSF), it also affects pricing. Therefore, the treatment of fees moves pricing and reimbursement up or down. . . . If the government pays more than it thinks it should for pharmaceutical products under these programs, it can apply the False Claims Act, which is legal action related to the pharmaceutical manufacturer submitting incorrect data which causes the government to pay more than it should. . . . [T]he treatment of fees impacts all of the statutory pricing. . . .*"
- October 7–8, 2013, CBI Conference, *Fair Market Value of Bona Fide Service Fees: Ensure Accuracy of Reported Government Pricing and Compliant Documentation Practices*: An industry conference conducted by CBI on the subject of "[a]pproaches to determining fair market value (FMV) and bona fide service fees (BFSF)," which "continue to be a challenge due to limited guidance . . . [and] heavy government scrutiny," was open to anyone who paid the registration fee. (Ex. S) All presenters' presentation materials were subsequently available online for purchase as a "Compendia." (Exs. T, U). According to Relator, "[a]ll key components of the fraud were verified via presentations . . . at the conference." SAC ¶ 460.

CBO reports, DOJ press releases, and articles published in BusinessWire and various healthcare industry and academic publications clearly constitute “news media.” *See, e.g., Ping Chen*, 966 F. Supp. 2d at 291, 297–98 (“news media” extends “to ‘smaller’ or ‘professionally specialized’ reader bases”); *cf., e.g., Alcohol Found.*, 186 F. Supp. 2d at 463 (“news media” encompasses published information in “scholarly or scientific periodicals”). Likewise, a written presentation, advertised and available online (even for a fee), counts as a public disclosure under the broad definition of “news media.” *See, e.g., United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (collecting cases finding that public or promotional websites, legal notices, and advertisements count as “news media”); *cf., e.g., Patriarca*, 295 F. Supp. 3d at 200 (public disclosure not impacted by required “annual subscription fee” to access journal); *United States ex rel. Brown v. BankUnited Trust 2005-1*, 235 F. Supp. 3d 1343, 1354–56 (S.D. Fla. 2017) (public disclosure not impacted by procedural necessity of filing formal requests to obtain materials). Thus, notwithstanding Relator’s dramatic characterizations of a conference that he attended, organized by CBI, as a conspiratorial meeting solely of “industry expert[s]” and “insider[s],” SAC ¶¶ 446, 452, the written presentations from that conference (which Relator describes in SAC ¶¶ 452–89) are public disclosures because they were available for online sale to the public. *See Patriarca*, 295 F. Supp. 3d at 200. These sources publicly disclosed both the “essential elements” of the supposed scheme, from which readers could infer the potential fraud, and the “crux of the alleged fraud” itself. *See Ping Chen*, 966 F. Supp. 2d at 298–99 (internal quotation marks and citation omitted).

Moreover, it is irrelevant that these public sources did not identify each of the specific PBM Defendants because, as Relator admits, PBMs are a concentrated group of readily-identifiable major players. SAC ¶ 15. Where the methodology of the supposed fraud and the types of entities

involved have been generally aired in prior disclosures, a relator cannot reap a *qui tam* recovery merely by performing the straightforward task of using public information to name particular defendants. *See, e.g., In re Natural Gas Royalties*, 562 F.3d 1032, 1043 (10th Cir. 2009); *United States v. Emergency Med. Assocs. of Ill., Inc.*, 436 F.3d 726, 728–29 (7th Cir. 2006) (application of the public disclosure bar was “not [even] a close question” where “since the mid-1990s” there had been “public allegations that Medicare was being billed for services provided by residents as if attending physicians had actually performed the services” and the relator had merely asserted that false-claims theory against specific defendants).

This principle is particularly applicable when the government itself has ready access to documents from which it could identify particular participants in an industry-wide practice. *See, e.g., United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999) (barring FCA claims where prior complaint alleged the same general scheme against different defendants because the government “presumably would have ready access to documents identifying [the] contractors” and “could easily identify the contractors at issue” itself); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 569–72 (10th Cir. 1995) (dismissing FCA claims when prior disclosures necessarily implicated a group of unnamed laboratories because “the government has already identified the problem and has an easily identifiable group of probable offenders”).

The public documents identified disclose the possibility of PBMs receiving fees that might not be BFSFs and failing to pass them along as price concessions to plan sponsors and ultimately CMS. Further, the PBM market contains just a handful of “readily identifiable” companies, and the government—not Relator—was well positioned to consult Medicare Part D submissions already in its possession to identify any particular PBMs that may have engaged in the “service fee” practices described in the public disclosures between 2002 and 2013. Therefore, Relator’s

claims are barred unless he is an “original source” of his allegations. 31 U.S.C. § 3730(e)(4). He is not.

B. Relator Is Not an “Original Source.”

With respect to Relator’s pre-2010 claims, Relator is only an “original source” if he had “direct and independent knowledge” of that information. 31 U.S.C. § 3730(e)(4) (2006). As to post-2010 claims, relator must have had “knowledge that is independent of and *materially adds to* the publicly disclosed allegations or transactions,” 31 U.S.C. § 3730(e)(4)(B) (2010) (emphasis added). To be “direct,” Relator must have “knowledge obtained from actually viewing source documents, or first-hand observation of the fraudulent activity,” *Ping Chen*, 966 F. Supp. 2d at 300, which is not the case where a public disclosure or a “third party is ‘the source of the core information’ upon which the *qui tam* complaint is based,” *United States v. N.Y. Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (internal citation omitted). The “original source” rule differentiates “between those individuals who . . . simply stumble upon a seemingly lucrative nugget and those actually involved in the process of unearthing important information about a false and fraudulent claim.” *Ping Chen*, 966 F. Supp. 2d at 299. Additionally, under both the pre- and post-ACA versions of the statute, Relator must also have “voluntarily provided the information to the Government *before* filing an action.” *N.Y. Med. College*, 252 F.3d at 120; *Ping Chen*, 966 F. Supp. 2d at 299. Relator is not an original source for three reasons.

First, the SAC gives no indication that Relator voluntarily shared his information with the government *before* initiating this *qui tam* suit in October 2015, which dooms his FCA claims. *See, e.g., Phipps*, 152 F. Supp. 2d at 454; *A1 Procurement, LLC v. Hendry Corp.*, No. 11-cv-23582, 2013 WL 12061864, at *8 (S.D. Fla. June 24, 2013) (rejecting “original source” solely on this basis).

Second, Relator here falls well short of possessing the “independent” knowledge necessary to qualify as an “original source” under either version of the statute. Relator is an “investment fund manager and physician” who has worked as a “professional healthcare industry investment analyst for 25+ years.” SAC ¶ 132. He was never employed by any Defendant and did not have any “business relationship with [Defendants] through which [he] gained insider information.” *JDJ*, 2017 WL 4357797, at *10; *accord, e.g., Amico*, 2017 WL 2266988, at *5 (“Amico could not have had direct and independent knowledge of the Defendants’ RMBS fraud because he never worked for Deutsche Bank. . . . [E]ven if Amico had worked for Deutsche Bank, he admits that the allegations underlying the Complaint are based on knowledge he derived from third-party sources, including public records.”). Thus, Relator cannot claim “direct” or “independent” knowledge of the scheme he now alleges. To the contrary, Relator concedes in his Rhode Island *qui tam* complaint that he “is *not an insider* at any of the Defendants, but rather an industry expert who has filed this case based upon extensive expertise, investigation and supporting factual evidence.”²⁷ First Am. Compl. ¶ 92, ECF No. 6, *United States ex rel. Borzilleri v. Bayer AG, et al.*, No. CV-14-03 (D.R.I. filed May 1, 2014) (hereafter “RI Am. Compl.”). Relator’s job, until he was recently fired for improper trading linked to his serial *qui tam* actions, entailed collecting and evaluating publicly available information about healthcare companies. By his own admissions, that is all he has done in this case.²⁸

²⁷ Relator’s 2014 Rhode Island *qui tam* complaint may be properly considered by this Court at least as to Relator’s pre-2010 allegations and claims, because the pre-ACA “public disclosure” bar is a *jurisdictional* barrier. *E.g., Hamm v. United States*, 483 F.3d 135, 137 (2d Cir. 2007) (“In resolving the question of jurisdiction, the district court can refer to evidence outside the pleadings” (internal quotation marks and citation omitted)); *see also supra* note 3.

²⁸ To be sure, in exceptional circumstances a non-insider may conduct such beneficial first-hand observations and investigations as to render himself an “original source.” *See, e.g., United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1017–18 (7th Cir. 1999) (relator alleging fraud conducted extensive first-hand observational tracking of whether city bussing practices lived up to public descriptions of those practices). But Relator falls far from that tree in this case.

Third, under the current version of the statute, Relator’s SAC does not “materially add” to the existing public record. Stitching together facts and reiterating inferences already set out in publicly available documents adds nothing at all to the state of knowledge preceding Relator’s *qui tam*. Relator’s allegations that he had limited *oral* and supposedly *private* conversations and conferences with “insiders” do not assist him as they reveal that even his non-published information was still patently second-hand. *See, e.g.*, SAC ¶¶ 128(a)–(c), 445–89. At best, the facts Relator learned in those conferences and conversations merely confirmed what the OIG and others already had noted years earlier: a significant number of PBMs were (a) calculating their administrative service fees based on drugs’ list prices and (b) keeping the fees for themselves. *See infra* Part II.A. Not only is that practice proper, but also these are hardly facts that materially add to the prior public record.

Relator’s own “speculation and conjecture” does not satisfy the “original source” requirement for him to proceed with a *qui tam* action notwithstanding prior public disclosures. *United States ex rel. Morgan v. Express Scripts, Inc.*, No. 2:05-cv-1714, 2013 WL 6447846, at *13 (D.N.J. Dec. 9, 2013). Relator epitomizes the tag-along, opportunistic litigant that Congress intended to discourage when it established the original source doctrine. This Court should dismiss Relator’s FCA claim on public disclosure grounds.

III. THE COURT SHOULD DISMISS RELATOR’S SAC UNDER THE FCA’S FIRST-TO-FILE RULE BECAUSE IT IS RELATOR’S SECOND-FILED ACTION PLEADING THE SAME ALLEGATIONS AGAINST THE SAME PBM DEFENDANTS.

This case presents a straightforward application of the first-to-file bar. As Relator concedes, his allegations merely repackage—and often directly parrot—claims he previously asserted in a near-identical *qui tam* suit filed in the District of Rhode Island in early 2014. This is

a transparent attempt to hedge his bets by proceeding simultaneously in separate jurisdictions. The FCA does not allow or reward this strategy.

When an FCA *qui tam* action has been filed, “no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.”²⁹ 31 U.S.C. § 3730(b)(5). This “first-to-file” rule aims to encourage meaningful whistleblowing while avoiding the “dilution of ‘copycat actions that provide no additional material information’” to the Government regarding a potential fraud. *Wood*, 899 F.3d at 169–70 (quoting *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011)). It seeks to deter and prevent “opportunistic suits,” *United States ex rel. LaCorte v. SmithKline Beecham Clin. Labs., Inc.*, 149 F.3d 227, 233 (3d Cir. 1998), recognizing that “[a] later-filed complaint that mirrors the essential facts as the pending earlier-filed complaint does nothing to help reduce fraud of which the government is already aware,” *United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 36 (1st Cir. 2013). There is no dispute that the Rhode Island matter was pending when this action was filed.

The first-to-file rule applies whenever a later-filed FCA case alleges the “same material elements of fraud” as the pending earlier-filed claim, “even if the allegations incorporate additional or somewhat different facts or information.” *Wood*, 899 F.3d at 169 (quoting *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 121 (D.C. Cir. 2015)). What matters is whether the “essential facts” are sufficiently the same that the government would have had notice, based on the earlier-filed claim, “to initiate an investigation into allegedly fraudulent practices.” *Heineman-Guta*, 718

²⁹ After the passage of the ACA, the first-to-file bar no longer deprives a court of subject-matter jurisdiction, but rather constitutes a failure to state a viable claim. *United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 86 (2d Cir. 2017). Nevertheless, this defect in Relator’s SAC cannot be cured by amendment or supplement, and thus dismissal—rather than leave to amend—is the appropriate course. *Wood*, 899 F.3d at 172–73; *United States ex rel. Shea v. Verizon Comm’ns, Inc.*, 160 F. Supp. 3d 16, 30 (D.D.C. 2015) (“No matter how many times Plaintiff amends his Complaint, it will still be true that he ‘br[ought] a related action based on the facts underlying the [then] pending action.’” (quoting 31 U.S.C. § 3730(b)(5) (alteration in original))).

F.3d at 36–37. The first-to-file rule is “‘designed to be quickly and easily determin[ed], simply requiring a side-by-side comparison’” of the allegations in the two actions. *United States ex rel. Wood v. Allergan*, 246 F. Supp. 3d 772, 791 (S.D.N.Y. 2017), *rev’d on other grounds*, 899 F.3d 163. That comparison is dispositive in this case.

In early 2014, Relator filed a sealed *qui tam* complaint in the District of Rhode Island. On May 1, 2014, he amended that complaint, asserting federal false claims, federal AKS, and state false claims counts. *See* RI Am. Compl. As here, Relator summarized his Rhode Island allegations in a “Summary of Fraud Allegations,” alleging that the “Manufacturer Defendants of multiple sclerosis (MS) drugs have made fraudulent overpayments of ‘Bona Fide Service Fees’ (BFSFs) far in excess of the legally-required ‘Fair Market Value’ (FMV) to the PBM Defendants, as part of a nationwide collusive scheme in the Medicare Part D program.” *Id.* ¶ 10; *see also id.* ¶ 85 (“The cornerstone of this complaint pertains to the handling in Medicare Part D of ‘Bona Fide Service Fees’ (BFSFs) . . .”). More than 17 months later, on October 6, 2015, Relator filed this *qui tam* action under seal in this Court. *See* ECF No. 1. Even after multiple amendments, his SAC alleges the exact same theory and material facts that he pleaded in Rhode Island—i.e., that “Manufacturer Defendants of brand drugs have and continue to make fraudulent overpayments of illegitimate ‘Bona Fide Service Fees’ (BFSFs) far in excess of legally-required ‘Fair Market Value’ (FMV) to the PBM Defendants, as part of a nationwide collusive price inflation scheme in the Medicare Part D program.” *See* SAC ¶ 26.

Relator’s two *qui tam* actions are not merely “related,” as prohibited by the statute; the claims in this case derive from Relator’s Rhode Island claims and directly parrot them in all material respects. In both suits, Relator pleads that PBMs now make the majority of their compensation through service fees from manufacturers that far exceed FMV and are not properly

reported to the government. *Compare* RI Am. Compl. ¶¶ 10, 12, 22, 26, 28–31, 36–47, 59, 83, 95, 167, 242, 252, *with* SAC ¶¶ 13, 26, 35, 59–60, 86, 161–64, 170, 632, 646, 673. And in both cases, Relator asserts an ancillary theory that drug manufacturers have improperly forgiven PBMs’ debts associated with “catastrophic coverage” rules and then failed to report that debt-forgiveness. *See, e.g.*, RI Am. Compl. ¶¶ 50–58; SAC ¶¶ 32, 33, 347, 352.

The *only* difference between this case and the Rhode Island *qui tam* action is that Relator swaps out the alleged drugs at issue, focusing on multiple sclerosis drugs in Rhode Island and on medications that treat cancer, diabetes, and rheumatoid arthritis in this case. For purposes of the first-to-file rule, this distinction is immaterial. Indeed, Relator’s earlier-filed Rhode Island *qui tam* allegations were rife with references to drugs treating cancer, rheumatoid arthritis / inflammatory conditions, and diabetes, including those manufactured by the Manufacturer Defendants named in this case. *See, e.g.*, RI Am. Compl. ¶¶ 10, 75–77, 124, 285 & Exs. 17–19, 23, 26, 34, 46. In the SAC, in fact, Relator explicitly recognizes that the various drug categories are part and parcel of one broad alleged fraud. *See* SAC ¶¶ 8–9 (“The pricing abuse among ‘old’ blockbuster and new drugs has been particularly severe in the largest-spending US drug categories, including multiple sclerosis (MS), rheumatoid arthritis, cancer and diabetes,” and “[t]he latter three therapeutic categories are the focus of this *Qui Tam* action.”). In fact, Relator’s allegations of violations of state false claims statutes in this case have been cut-and-pasted from the Rhode Island pleadings without modification, such that they refer solely to states’ losses from overpayments on multiple sclerosis drugs. *See* SAC ¶¶ 614, 617, 620, 623, 626, 629, 632, 635, 638, 641, 644, 647, 650, 653, 656, 659, 661, 664, 667, 670, 673, 676, 679, 682, 685, 688, 691, 694, 697, 700, 707.

There can be no dispute that the two complaints are based on the “same essential facts” and that the Rhode Island complaint easily put the government on notice of the potential for fraud

relating to services fees. *See, e.g., Wood*, 246 F. Supp. 3d at 792 (concluding that where FCA and AKS claims were based on general practice of improperly distributing drugs through surgical kits, “[w]hether Allergan unlawfully distributed one drug or more than one drug through those customer care kits is of no moment; either way the [first-filed] Complaint contained enough material facts to alert the government to [the] potential fraud alleged here”) (internal quotation marks and citation omitted); *accord Heineman-Guta*, 718 F.3d at 37 (applying first-to-file bar where second complaint “described the same types of kickbacks” as had been disclosed in the first-filed complaint); *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1280 (10th Cir. 2004) (applying first-to-file bar where second-filed complaint raised “same essential claim” that defendant “employed various fraudulent techniques” to mismeasure natural gas it produced and then “avoid or decrease its obligation to pay royalties to the United States”). And the fact that Relator himself filed the prior *qui tam* that activates the first-to-file bar here in no way saves his claims. Courts routinely dismiss successive *qui tam* actions by the same relator. *See, e.g., United States ex rel. Shea v. Cellco P’ship*, 748 F.3d 338, 342–43 (D.C. Cir. 2014), *vacated and remanded on other grounds*, 135 S. Ct. 2376 (2015); *United States ex rel. Moore v. Pennrose Properties, LLC*, No. 3:11-cv-121, 2015 WL 1358034, at *15–18 (S.D. Ohio Mar. 24, 2015); *United States ex rel. Bane v. Life Care Diags.*, No. 8:06-cv-467, 2008 WL 4853599, at *7 (M.D. Fla. Nov. 10, 2008) (“Piecemeal litigation by a relator is not allowed under the FCA.”); *United States ex rel. Smith v. Yale-New Haven Hosp., Inc.*, 411 F. Supp. 2d 64, 74–75 (D. Conn. 2005).

In sum, this case presents one of the clearest-cut examples of a violation of the FCA’s first-to-file bar in the federal case law, and this case should be dismissed.

CONCLUSION

This Court should dismiss Relator's claims with prejudice as inadequately pleaded under Rules 12(b)(6) and 9(b) and incurably barred by prior public disclosures. Only if the Court's sole ground for dismissal is the FCA's first-to-file bar should the dismissal be without prejudice. Given Relator's status as a short-seller outsider, who does not—and cannot—rely on anything other than publicly available information, any prospective amendment would be futile to cure *any* of the dispositive defects raised in this Motion. *See AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 726 (2d Cir. 2010) (“Leave to amend may be denied on grounds of futility if the proposed amendment fails to state a legally cognizable claim or fails to raise triable issues of fact.”). Relator filed his initial complaint on October 6, 2015, and has already amended his complaint on two separate occasions over a two-year period. ECF Nos. 1, 58, 148. Accordingly, the Court should dismiss all Relator's claims with prejudice, or, alternatively, without prejudice if the Court relies *solely* on the first-to-file bar.

Dated: October 1, 2018

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, THE
STATE OF CALIFORNIA, THE STATE
OF COLORADO, THE STATE OF
CONNECTICUT, THE STATE OF
DELAWARE, THE STATE OF FLORIDA,
THE STATE OF GEORGIA, THE STATE
OF HAWAII, THE STATE OF ILLINOIS,
THE STATE OF INDIANA, THE STATE
OF IOWA, THE STATE OF LOUISIANA,
THE COMMONWEALTH OF
MASSACHUSETTS, THE STATE OF
MICHIGAN, THE STATE OF
MINNESOTA, THE STATE OF
MONTANA, THE STATE OF NEVADA,
THE STATE OF NEW JERSEY, THE
STATE OF NEW MEXICO, THE STATE
OF NEW YORK, THE STATE OF NORTH
CAROLINA, THE STATE OF
OKLAHOMA, THE STATE OF RHODE
ISLAND, THE STATE OF TENNESSEE,
THE STATE OF TEXAS, THE
COMMONWEALTH OF VIRGINIA, THE
STATE OF WASHINGTON, THE STATE
OF WISCONSIN AND THE DISTRICT OF
COLUMBIA, *ex rel.* JOHN R.
BORZILLERI, M.D.

Plaintiffs,

ABBVIE, INC., AMGEN, INC.,
BRISTOL-MYERS SQUIBB COMPANY,
ELI LILLY AND COMPANY,
NOVARTIS PHARMACEUTICALS
CORPORATION, PFIZER, INC.,
SANOFI-AVENTIS U.S. LLC, AETNA,
INC., CIGNA CORPORATION, CVS
HEALTH CORPORATION, EXPRESS
SCRIPTS HOLDING COMPANY,
HUMANA, INC. AND UNITEDHEALTH
GROUP, INC.

Defendants.

CIVIL ACTION NO. 15-Civ. 7881 (JMF)

RELATOR'S SECOND AMENDED
COMPLAINT PURSUANT TO THE
FEDERAL FALSE CLAIMS ACT [31
U.S.C. §3729 *et seq.*]; AND
SUPPLEMENTAL
STATE FALSE CLAIMS ACTS

JURY TRIAL DEMANDED

NATURE OF THE ACTION

1. John R. Borzilleri, M.D. ("Relator"), a physician and professional healthcare investment fund manager, brings this Qui Tam action on behalf of the United States, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, the State of Washington and the District of Columbia (the "Plaintiff States" and collectively with the United States, the "Government Plaintiffs"), for violations of the Federal False Claims Act, 31 U.S.C. §3729-33 ("FCA") et seq., as well as for violations of the following State False Claims Acts: the California False Claims Act, Cal Government Code §§12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310; the Connecticut False Claims Act, Conn. Gen. Stat. §17b-301b; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201 et seq.; the Florida False Claims Act, Fla. Stat. §§ 68.081 et seq.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §§49-4-168 et seq.; Hawaii False Claims Act, Haw. Rev. Stat. §§661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1 et seq.; the Indiana Whistleblower Reward and Protection Act, Indiana Code §5-11-5.5; the Iowa False Claims Act, Iowa Code §§ 685.1 through 685.7; the Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 et seq.; the Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§5A et seq.; the Michigan Medicaid False Claims Act, MCLS §§400.601 et seq.; the Minnesota False

Claims Act, Minn. Stat. §§ 15C.01 through 15C.16; the Montana False Claims Act, Mont. Code Anno. §§17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. §§357.010 et seq.; the New Jersey False Claims Act, N.J. Stat. §2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§27-14-1 et seq.; the New York False Claims Act, NY CLS St. Fin. §§187 et seq.; the North Carolina False Claims Act, 2009-554 N.C. Sess. Laws §§1-606 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws §§9-1.1-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-171 et seq.; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1 et seq.; the Washington Medicaid Fraud False Claims Act, Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214; the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§20.931; and the District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03 et seq. (hereafter referred to as the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts against the following Defendants, and their affiliates, subsidiaries, agents, successors and assigns: AbbVie, Inc., Amgen, Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Novartis Pharmaceuticals Corporation, Pfizer, Inc., and sanofi-aventis U.S. LLC (referred to collectively as the "Manufacturer Defendants"); as well as, Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Co, Humana, Inc., and UnitedHealth Group, Inc. (referred to collectively as the "Pharmacy Benefit Manager (PBM) Defendants").

INTRODUCTION

2. The United States now faces a national crisis regarding the cost of pharmaceuticals. The cost of treating the most severe and life-threatening medical conditions in the US, such as

cancer, multiple sclerosis, rheumatoid arthritis and many others, with brand name drugs is now typically 4-6 fold higher than it was twelve years ago. The cost increases coincide with the enactment of Medicare Part D in 2003 and its start in 2006.

3. Pharmaceutical spending has been the fastest growing segment of US healthcare sector, which now consumes about 17% of the US economy, double the share of most other developed economies.

4. The skyrocketing US drug costs are placing a severe burden across our society. On a personal level, with therapies, particularly of the “specialty” variety, routinely now costing \$70,000-\$200,000 or more a year per person, many patients and their families face heartbreaking choices or financial ruin, as they struggle to pay for life-saving drugs. Physicians and other dedicated health professionals strive to help their sickest and most vulnerable patients access life-saving therapies, as beneficiary out-of-pocket “cost-sharing” exposure rises along with the escalating drug prices.

5. The rising drug costs are placing a severe financial burden on American private industry and taxpayers. US businesses are forced to decrease benefits and/or increase premiums/cost-sharing for their employees to remain competitive with foreign competitors who have access to the same drugs at a fraction of the US cost.

6. Furthermore, US taxpayers are funding an ever-increasing portion of these escalating drug costs through government drug programs, especially Medicare Part D.

7. The majority of the vast increase in US drug costs over the past decade has not occurred due to a wave of innovative new drugs reaching the US market. Rather, the primary driver has been the “inexplicable” massive price increases for numerous “old” blockbuster drugs, many of which have faced plummeting clinical use and market share due to severe competition.

8. The vast price increases for these declining drugs could not occur in a properly operating competitive market. The fraudulent price inflation for these “old” blockbuster drugs set the stage for massive US launch prices for new drugs, especially of the “specialty” variety.

9. The pricing abuse among “old” blockbuster and new drugs has been particularly severe in the largest-spending US drug categories, including multiple sclerosis (MS), rheumatoid arthritis, cancer and diabetes. The latter three therapeutic categories are the focus of this Qui Tam action.

10. The Manufacturer and PBM Defendants continue to promulgate the “complexity” surrounding extreme US brand drug pricing.

11. The real cause of widespread sharp increases in the US prices of pharmaceutical drugs is a straightforward price collusion scheme between certain pharmaceutical companies (who set US drug prices) and the uniquely-American, dominant US Pharmacy Benefit Managers (PBMs, who administer access to prescription drugs for the vast majority of Americans).

12. The “Rosetta Stone” behind the brand drug pricing crisis is a secret and seismic shift in the financial compensation model between drug manufacturers and the leading PBMs, which has its origins in the Medicare Part D program.

13. Simply put, the PBM Defendants now make most of their compensation via “service fees” from drug manufacturers, not “rebates”, as is still widely-presumed. Legitimate “service fees” are called Bona Fide Service Fees (BFSFs) in Medicare Part D and other government drug programs.

14. As with the Defendants’ drugs, the “service fees” are often linked to massive drug prices and price increases, with no relation to legitimate “services” provided by the PBM Defendants and their specialty pharmacy subsidiaries.

15. The four largest PBM Defendants (Express Scripts, CVS Health, UnitedHealth Group and Humana) control drug access for more than 80% of Americans, including the Medicare Part D program where this scheme originated.

16. Two of the dominant PBMs, CVS Health and UnitedHealth Group, have secretive partnerships with two of the smaller US PBM operators, Defendants Aetna and Cigna, respectively. Both parties in these secretive arrangements are benefitting significantly from the “service fee” price collusion scheme outlined in this Complaint.

17. The PBM industry is a uniquely-American business, with a minimal presence outside this country. When Medicare Part D began, the US prices for the Defendant drugs were at parity with the costs in major European countries. Now twelve years later, US prices for these “old”, competitively-challenged Defendant brand drugs are routinely 4-8 fold higher domestically, due to massive unilateral US price increases.

18. European drug markets appear to be operating properly, while the US has been greatly distorted by this systemic, collusive “service fee” scheme.

19. In recent years, as the public outcry regarding US drug pricing has escalated, both the pharmaceutical and PBM industries have been increasingly “blaming” each other for egregiously profiting from high US drug prices. The deceitful rhetoric has included all sorts of unverifiable claims regarding rebates, discounts, gross/net drug prices, drug coupons, patient assistance programs, etc.

20. Noticeably absent from the discussion are any significant mention of “manufacturer service fees” or the Medicare Part D program, the true epicenter of massive US brand drug price inflation.

21. In fact, the one topic both the pharmaceutical and PBM industries agree on is that

Medicare Part D has been an astounding success and that its “private competition” model should be a template for all government drug programs. For instance, some corporate interests are pushing for Centers for Medicare and Medicaid (CMS) to expand the Part D “model” into the Part B program. We find this ironic because CMS’ own public data clearly indicates that drug price inflation in the Part D program has been far greater than in the Part B program.

22. This ongoing scheme represents among the most severe corporate violations of the public trust in the history of this nation. Many Americans have lost their lives, have lost access to life-savings drugs and have faced financial ruin due to this intentional wide-ranging fraud. The resulting harm has been particularly severe for the most vulnerable elderly and disabled Americans who depend upon the Medicare Part D program.

23. On a broader scale, the financial harm to the public is staggering. Just for the fourteen (14) Defendant drug products, we estimate fraudulent US drug sales of nearly \$114 billion over the past decade (about 30% attributable to Medicare Part D), with the scheme ongoing and escalating.

24. The scheme has placed the financial viability of both the Medicare Part D program and our overall health insurance market at risk of insolvency.

25. We remain staunch supporters of the pharmaceutical industry and the need for innovative new drug therapies. This Qui Tam case has nothing to do with that important issue. The primary offenders of this centralized scheme have been a select group of Defendant senior executives, not the dedicated scientists, researchers and other employees, working at these companies.

SUMMARY OF THE FRAUDULENT “SERVICE FEE” SCHEME

26. John R. Borzilleri, M.D. ("Relator") has ascertained that the Manufacturer

Defendants of brand drugs have and continue to make fraudulent overpayments of illegitimate “Bona Fide Service Fees” (BFSFs) far in excess of legally-required “Fair Market Value” (FMV) to the PBM Defendants, as part of a nationwide collusive price inflation scheme in the Medicare Part D program.

27. In Medicare Part D, PBMs were expected to negotiate in good faith with drug manufacturers to obtain “rebates” and lower drug costs for beneficiaries and taxpayers.

28. Instead, the Manufacturer and PBM Defendants entered into an intentional, secretive and fraudulent price inflation scheme, based upon “service fee” contracts, in gross violation of the False Claims Act (FCA) and the Anti-Kickback Statute (AKS).

29. In sharp contrast to drug rebates, BFSFs are the only major financial item excluded from Part D “negotiated price” calculations, thereby leading to higher drug reimbursement prices and greater revenues/profits for the Defendants.

30. As per Center for Medicare and Medicaid Services (CMS) regulations, “service fees” in excess of FMV should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D. In turn, the plan sponsor (almost always via its contracted PBM) should report “service fees” in excess of FMV to CMS in its Direct and Indirect Remuneration (“DIR”) report as a “discount”, leading to lower Part D “negotiated” drug prices. The Defendants are intentionally not doing so in order to advance the “service fee” scheme, to fraudulently increase Part D drug prices and maximize their fraudulent profits.

31. Arm’s-length negotiations between the Manufacturer and PBM Defendants would have prevented virtually all of the massive 4-6 fold US price inflation for the 14 Defendant brand drugs over the past decade-plus.

32. In recent years, as US “specialty” drug prices have become more extreme and

numerous, fraudulent abuse of plan sponsor Part D “catastrophic” cost-sharing requirements has become widespread to advance the “service fee” scheme.

33. The Manufacturer Defendants (and other biopharmaceutical companies) are routinely “forgiving” the 15% unlimited “catastrophic” cost-sharing exposure of the PBM Defendants, in their dominant roles as Part D plan sponsors. We will discuss this issue in more detail later in the Complaint.

34. BFSFs are payments from drug manufacturers to PBMs and other service vendors in Part D (and other government drug programs) for a wide array of support “services”, such as rebate administration, inventory management, drug shipping/delivery, reimbursement/financial assistance, patient education/clinical programs, drug adherence programs, phone support, data reports, etc.

35. The fraudulent Manufacturer Defendant “service fee” payments to the PBM Defendants are standardly calculated via secretive “percent of revenue” contracts, based upon inflated brand drug “list” prices and massive price increases, primarily using Average Wholesale Price (AWP) or the related Wholesale Acquisition Cost (WAC) from public databases.

36. AWP is also the basis for reimbursement for brand drugs in Medicare Part D. As per the US Department of Health and Human Services (HHS), the “negotiated price that the sponsors and beneficiaries pay pharmacies for the ingredient cost of the drug is usually based upon Average Wholesale Price (AWP) discounted by a specified percentage....” Office of Inspector General (OIG), OEI-03-7-00350, Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid, February 2009.

37. These “service fee” payments from the Manufacturer Defendants are linked contractually to massive drug prices, with no relationship to bona fide “support services” being

provided by the PBM Defendants and their specialty pharmacy subsidiaries.

38. In these “service fee” contracts, both Defendant parties are fraudulently inflating US drug “list” prices (and contractually-linked “service fees”), Part D reimbursement levels and their profits, with the additional drug costs largely passed on to taxpayers and patients in Medicare Part D.

39. Massive increases in “service fee” payments to the PBM Defendants have occurred despite a significant decline in actual “support services” being provided for many “old” Defendant “blockbuster” drugs, commensurate with their sharply declining clinical use and prescription volume.

40. According to the Part D regulations, legitimate BFSFs paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D should:

- a. Be paid only for legitimate “support” services, based upon clinical usage of the drug;
- b. Represent “reasonable compensation”, based upon the actual cost of providing the “service”;
- c. Be “commercially reasonable” and not be “distorted” by anticompetitive market factors;
- d. Be consistent with the “efficient distribution of drugs”, at affordable prices for patients.

41. All of these legal requirements for BFSFs are encompassed in the long-established Federal “Four-Part Test”, which all BFSFs must “pass” to be considered “bona fide” or “legitimate” in Medicare Part D and other government drug programs. 71 Fed. Reg. 69624, 69667-9.

42. All the Defendants in this Qui Tam case knew or should have known of the clear legal requirements for “legitimate” BFSFs.

43. The “Four-Part Test” requires that:

- a. The “itemized” service is actually performed for the manufacturer;
- b. The manufacturer actually needs the “service” and is not performing the service itself;
- c. The “service fee” is kept by the PBM (or other service providers, such as specialty pharmacies) and not shared with the payer client (otherwise the payment would simply be another form of drug discount); and,
- d. The “service fee” payment is paid at “Fair Market Value” (FMV), commensurate with an “arm’s length” transaction between unaffiliated parties.

44. In Part D and other government drug programs, drug manufacturers have the legal responsibility to ensure that BFSFs are legitimate and paid at FMV. However, both Defendant parties have extensive legal liability under both the Anti-Kickback Statute (AKS) and the False Claims Acts (FCA).

45. All of the above four components of the “Four Part Test” are commonly being fraudulently violated in the Part D contractual and financial arrangements between the Manufacturer and PBM Defendants.

46. However, the central focus of this case is the wide-ranging evidence of ongoing violations of the “Fair Market Value” (FMV) requirements regarding BFSFs.

47. The abuse has been most severe for the “old” Defendant drugs in declining clinical use, including Amgen’s Enbrel (rheumatoid arthritis/psoriasis, FDA-approved 1997), Novartis’ Gleevec (cancer, FDA-approved 2001), Sanofi’s Lantus (insulin for diabetes, 2000), Eli Lilly’s Humulin (insulin for diabetes, 1982), Pfizer’s Viagra (erectile dysfunction, 1998), Pfizer’s Celebrex (osteoarthritis/pain, 1998), Pfizer’s Premarin (hormone replacement/osteoporosis, 1942),

Pfizer's Pristiq (depression, 2008) and Pfizer's Relpax (migraine, 2002).

48. The other drug products targeted in this action are: AbbVie's Humira (rheumatoid arthritis/psoriasis, FDA-approved 2003), Novartis' Tasigna (cancer, 2007), Bristol-Myers Squibb's Sprycel (cancer, 2006) and Pfizer's Chantix (smoking cessation, 2006).

49. The Relator has also filed a separate Qui Tam action, in the US District Court of Rhode Island (CV-14-03-WES), alleging Part D "service fee" pricing fraud pertaining to the US multiple sclerosis (MS) drug market.

50. Following the government's non-intervention decision, the Relator filed a Second Amended Complaint in Rhode Island. The public health and fiscal harm is distinct for each Defendant drug product in both of these Qui Tam actions.

51. BFSFs were employed in other government drug programs, prior to the enactment of Part D. However, Part D was the catalyst for severe BFSF fraud for several key reasons.

52. First, as the first "private competition" federal drug program, Congress placed no limits on brand drug price increases in the program (in sharp contrast to Medicaid), presuming arm's-length negotiation by the PBM Defendants.

53. Second, assuming "manufacturer rebate" negotiations would remain the key target for "cost-savings" and PBM profits, Medicare requires their deduction from Part D "negotiated" prices and requires full disclosure.

54. Third, assuming BFSFs would be for legitimate "support services", CMS excludes these payments from Part D "negotiated" prices.

55. Compounding the situation, CMS placed few reporting requirements and no financial limits on the amounts of BFSFs in the Medicare Part D program.

56. Part D also insulates most beneficiaries from massive price increases because the

majority of drug costs associated with high prices are covered by taxpayers, via the program's subsidies. Most importantly, the Low-Income Subsidies (LIS) cover almost all routine costs for low income beneficiaries, while the Reinsurance Subsidies cover 80% of all extreme drug costs for all Part D beneficiaries above a modest annual limit (only \$5,000 in 2018).

57. Finally, the liberal use of financial assistance programs by drug manufacturers (often with the assistance of PBMs) has limited beneficiary out-of-pocket exposure for much of the past decade and aided in deflecting public scrutiny.

58. Driven by these factors, Part D led to a seismic and secretive shift in the US pharmaceutical market and the financial transactions between drug manufacturers and the dominant PBMs.

59. Prior to Medicare Part D, the PBM Defendants made virtually all their profits from the portion of rebates they "retained" in their negotiations with manufacturers.

60. After the arrival of Part D, the PBM Defendants began secretly making the vast majority of their profits from "service fee" payments from drug manufacturers.

61. Wide-ranging US brand drug patent expirations (leading to lower brand sales and fewer brand drug rebate opportunities), have been a key factor propelling the "service fee" scheme to its current stratospheric heights, now more than 15 years after Part D was enacted as part of the Medicare Modernization Act (MMA) of 2003.

62. With generic prescriptions now accounting for more than 90% of US drug prescription volume (up from about 50% when Part D began), both the Manufacturer and PBM Defendants became increasingly dependent on a narrower group of remaining brand drugs for revenues and profits.

63. Further violating the public trust and the law, the financial scheme has intentionally

been kept secret by the Defendants from virtually all affected and influential constituents, including patients and their families, physicians and other healthcare providers, taxpayers, client corporations, insurance plan clients, unions, pension funds, independent pharmacies, patient support organizations, investors, regulators, Congress and the Securities and Exchange Commission (SEC).

64. In April 2018, following the unsealing of our Qui Tam actions, the Relator filed a Whistleblower Complaint (via TCR) with the SEC regarding all the Defendants in both the Rhode Island and Southern District of New York (SDNY) Qui Tam actions. Separate from our Medicare Part D fraud allegations, failure to provide any significant financial disclosures regarding these “service fee” arrangements and their profit contribution represents a gross violation of the SEC “materiality” requirements.

65. The Part D program has been compromised by the near complete control of all key functional roles by the PBM Defendants. In Part D, the PBM Defendants, and their wholly-owned subsidiaries, provide all three of the key Part D functions (plan sponsor, PBM and specialty pharmacy functions) for the majority of Part D plans and beneficiaries.

66. Because CMS depends upon plan sponsors for Part D program oversight, combined ownership and vertical integration has been a key factor enabling this scheme, due to severe conflicts of interest, limited transparency and lax oversight.

67. Based upon the biopharmaceutical industry’s own recent incriminating public data, the Manufacturer Defendants are typically contractually paying the PBM Defendants (and their specialty pharmacy subsidiaries) about 8% of US high-cost brand “specialty” drug sales, based upon the massive “list” prices and 4-6 fold price increases. Pharmaceutical Research and Management Association (PhRMA) report, “Follow the Dollar”, November 2017.

68. Defendant “specialty” drugs, such as AbbVie’s Humira, Amgen’s Enbrel and Novartis’ Gleevec, typically target smaller patient populations, but at an extreme annual cost of \$70-200,000 or more for each patient.

69. In these contracts, after years of massive inflation, the PBM Defendants are receiving astounding “service fees” in the \$5,700 range per year for each US patient treated with Humira or Enbrel and in the \$12,000 range per year for each US patient treated with Gleevec.

70. Based upon this same industry report, the Manufacturer Defendants are typically paying the PBM Defendants about 4% of “traditional” US brand drug sales, based upon “list” prices, inclusive of massive 4-6 fold price increases.

71. Defendant blockbuster “traditional” brand drugs include Sanofi’s Lantus (diabetes), Eli Lilly’s Humulin (diabetes), as well as Pfizer’s Lyrica (neurologic pain), Viagra (erectile dysfunction) and Celebrex (osteoarthritis, pain).

72. Brand drugs categorized as “traditional” by industry typically target far larger patient populations, at a more modest cost, typically \$4,000-7000/patient/year in mid-2018, after the massive price inflation over the past decade.

73. The Part D financial fraud generated by this scheme is far greater for an individual “specialty” vs. “traditional” drug-treated patient. However, the aggregate and cumulative Part D financial fraud for the Defendant “traditional” drugs is also severe, due to their high-volume use.

74. Among “traditional” Defendant drugs, Sanofi’s Lantus, a long-acting insulin for the large diabetic population, has been the top-selling drug in Medicare Part D. Pfizer’s Lyrica has been among the top-spending Part D drugs in recent years, due to its wide use for diabetic neuropathy and fibromyalgia.

75. Diabetes is the top-spending brand drug category in both Part D and the private

insurance market. We conservatively estimate that approximately 30% of US diabetes drug spending is in the Medicare Part D program.

76. Regarding “specialty” drugs, the rheumatoid arthritis/psoriasis and cancer categories targeted in this action are among the top-spending drug segments in virtually all Medicare Part D and private insurance plans. AbbVie’s Humira and Amgen’s Enbrel are top-spending products in virtually all plans. We estimate about 30% of the use on these two “blockbuster” drugs is in Medicare Part D.

77. With the high prevalence of cancer in the elderly, the oral chronic myeloid cancer (CML) therapies, Novartis’ Gleevec, Novartis’ Tasigna and Bristol-Myers Squibb’s Sprycel, are heavily used in Medicare Part D. Gleevec was the second top-selling cancer drug on Medicare Part D prior to its early 2016 US patent expiration. We estimate that approximately 60% of US CML drug spending is in the Medicare Part D program.

78. In these collusive contractual “service fee” arrangements, the vast majority of the financial gains from the price increases accrue to the Manufacturer Defendants, as indicated by their SEC-reported US sales.

79. The PBM Defendants, in turn, receive fraudulent “service fees”, as “kickbacks”, for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies and the avoidance of long-established, effective, PBM cost-saving strategies (aggressive rebate negotiations, brand drug “therapeutic substitution” and “formulary restriction” programs, etc.).

80. PBM brand drug “therapeutic substitution” and “formulary restriction” programs are the long-standing mechanisms for the PBM Defendants to obtain brand drug price concessions from drug manufacturers during negotiations.

81. In these standard negotiating practices, the PBM Defendants demand significant

price concessions for placing a brand drug on its formulary and not implementing/enforcing additional restrictions on access, such as prior authorization requirements, high co-pays, high co-insurance, etc.

82. In a normal operating market, had standard PBM Defendant formulary and cost-savings practices been legitimately implemented, the vast majority of price increases for the Defendant drugs would not have occurred over the past twelve years. For products in declining use, price decreases might have been expected.

83. The PBM Defendant negotiating leverage for cost savings should be particularly strong for the “old” Manufacturer Defendant “blockbusters” in declining clinical use in crowded US brand therapeutic categories, including the rheumatoid arthritis, diabetes and CML cancer segments targeted in this action.

84. Furthermore, cost-savings negotiating tactics should be particularly effective in Part D, where the vast majority of the plans and beneficiaries utilize the PBM Defendants’ “national formularies”.

85. Under the False Claim Act, “kickbacks” in federal programs are, by law, also false claims for reimbursement. While “kickbacks” are a criminal offense, under the FCA, liability only has to be proved by a preponderance of the evidence. 31 U.S.C. § 3731(d) US ex. rel. Pasqua v. Kan-Di-Ki, LLC, 2:10-cv-00965 C.D. CA. (March 8, 2013).

86. Furthermore, both the Manufacturer and PBM Defendants have caused or directly submitted a myriad of false claims via the array of submissions required for reimbursement in the Medicare Part D program, including Prescription Drug Event (PDE) reports, Direct and Indirect Remuneration (“DIR”) reports, Part D annual plan bids, as well as financial data required for Part D subsidy reconciliation. (Direct, Low-Income and Catastrophic subsidies).

87. Virtually all Part D submissions for reimbursement pertaining to the Manufacturer Defendant drugs over the past 12 years-plus have been “tainted” by kickbacks and have been false claims.

88. Both Defendant parties, as well as their subsidiaries and their senior executives (Chief Executive Officer and Chief Financial Officer), must “expressly certify” compliance with the Anti-Kickback Statute (AKS) and the False Claim Act (FCA) to participate in Medicare Part D.

89. The wide-ranging legal liability for the PBM Defendants in Part D contrasts sharply with their historic limited exposure in the private insurance sector. Due to lack of fiduciary responsibilities under the Employment Retirement Income Security Act (ERISA), the PBM Defendants have successfully deflected a wide array of private lawsuits alleging abusive business practices over the past several decades.

90. Prior US Department of Justice PBM Defendant case settlements have already established negligence in the FMV of BFSFs as a basis for false claims and kickbacks. United States Settlement Agreement with Advanced PCS (now part of CVS Health), September 7, 2005. United States Settlement Agreement with Medco Health Solutions, October 23, 2006.

91. The states with Qui Tam statutes have been named as plaintiffs, due to severe harm caused by the scheme. States are required to fund about a third of the cost of their high-consuming “dual-eligible” population in the Medicare Part D program. Prior to Part D, these state beneficiaries received their drug benefits via state Medicaid programs. Due to price inflation protections on brand drugs in Medicaid, states are paying fraudulently higher drug costs (4-6 fold higher) for the Defendant products directly due to the Part D pricing scheme.

92. The cumulative and compounding harm to the public fisc from this decade-plus

systemic, ongoing pricing scheme is staggering. Overall, we estimate cumulative fraudulent US sales of about \$114 billion between 2006 and 2017 for the 14 Defendant drug products, with about 30% attributable to the Part D program.

93. Our US sales fraud estimates have nearly doubled since our initial SDNY Qui Tam filing in October 2015 due to ongoing, uniform and extreme Manufacturer Defendant price increases.

94. To enable the systemic pricing scheme, we estimate that the Manufacturer Defendants have paid the PBM Defendants fraudulent “service fees” of approximately \$7 billion between 2006 and 2017, with about 30% attributable to the Part D program.

95. Our direct “service fees” fraud estimates have more than tripled since our initial SDNY Qui Tam filing in October 2015, due ongoing severe price increases and the Defendant public disclosure of a higher “service fee” contract rate for “specialty” drugs (8% rather than the 4% rate used in our prior filing)

96. For the individual declining-use Defendant products, we estimate that “service fee” payments from the Manufacturer Defendants to the PBM Defendants have increased approximately 5-fold over the decade for each Defendant drug prescription, driven solely by the massive price increases.

97. Our investigation found no legitimate justification for massive increases in “service fees” paid for drugs products with sharply eroding clinical usage.

98. Our investigation failed to identify any legitimate PBM Defendant “support services” attributable to massive price increases, other than potential abusive patient financial support programs required to advance the scheme.

99. Using the Defendant’s own data from the November 2017 PhRMA report, the PBM

Defendants are receiving approximately 8-to-11 fold greater compensation, for high-cost “specialty” drugs, via “service fees” from the Manufacturer Defendants compared to their “retained” portion of “manufacturer rebates”.

100. Based on the PhRMA data, for “traditional” pharmaceutical products, the PBM Defendants are typically receiving about twice as much compensation from manufacturers via “services fees” relative to “rebates”.

101. According to the PhRMA, these manufacturer “service fees” now account for 90-100% of PBM Defendant profits from “specialty” drugs and about 70% of profits for “traditional” drugs.

102. To this day, the majority of independent pharmaceutical and PBM experts still cite “manufacturer rebates” as the primary source of PBM Defendant profits, despite it being invalid now for more than a decade.

103. The gross violation of the Part D regulations, as well as the FCA and the AKS, is even starker when considering “service fee” payments at the aggregate level and the plummeting prescription volume for key Defendant drugs.

104. For numerous of the declining-use Defendant products, we estimate that the Manufacturer Defendants are commonly paying the dominant PBM Defendants approximately four times as much in aggregate annual “service fees” for supporting half or less as many prescriptions and patients compared to a decade ago. In layman’s terms pertaining to “services”, think of paying someone four times as much money to paint half of your house.

105. The “service fee” fraud has been particularly severe for “specialty” oral cancer drugs, including the Defendant products for CML; namely Novartis’ Gleevec and Tasigna, as well as Bristol-Myer’s Squibbs’ Sprycel.

106. With negotiated “manufacturer rebates” minimal for oral cancer “specialty” drugs, the PBM Defendants are receiving vast “service fees”, tied to vast drug prices and price increases, while providing minimal value for beneficiaries and payer clients.

107. As per Express Scripts’ CEO, Tim Wentworth: “Alternatively, in oral oncology, for example, rebates are practically nonexistent. Only 2 out of the 88 products pay rebates, yet prices have gone up 100% over five years. You can’t blame rebates for that.” Express Scripts Fourth Quarter 2016 Earnings Conference Call, February 15, 2017.

108. As such, the PBM Defendants are receiving massive “service fees” on the Manufacturer Defendant CML drugs and other extreme-priced oral “specialty” cancer drugs, with the virtually full “list” prices and price increases passed on to taxpayers and beneficiaries in Medicare Part D.

109. Using the standard PhRMA “8%” contract rate, after 5-fold inflation to the \$150,000 cost/patient range prior to its US patent expiry, the PBM Defendants received about \$12,000 per year in “service fees” from Novartis for each Gleevec-treated Part D patient or about \$1,000 for each monthly prescription of 30 daily pills.

110. With minimal or no rebates, “service fee” abuse has been severe for a wide array of other US oral cancer “specialty” drugs. Other top-spending, long-marketed and fast-inflating oral cancer drugs include: Celgene’s Revlimid (multiple myeloma, the top-selling cancer drug in Medicare Part D, AWP \$225,000/year), Bayer’s Nexavar (renal cell/liver cancer, AWP \$136,000 patient/year) and Roche’s Tarceva (lung cancer, AWP \$123,000 patient/year).

111. Among “traditional” oral drugs, Pfizer has employed the price inflation/“service fee” model for many declining-use “traditional” “blockbuster” oral drugs, such as Lyrica (neurologic pain), Viagra (erectile dysfunction), Premarin (hormone replacement/osteoporosis)

and Celebrex (osteoarthritis, pain).

112. The majority of the prescriptions for these straightforward oral “traditional” brand drugs are simply filled at a local pharmacy or routinely shipped to patients by mail, similar to any generic drug prescription.

113. At the 4-8% contract rates, the PBM Defendants’ absolute profit from an individual Defendant drug is obviously modest relative to the profits generated for the Manufacturer Defendants.

114. When this scheme is applied across numerous massively-inflating “blockbuster” US brand drugs and major therapeutic categories, the overall profits for the PBM Defendants are truly astounding.

115. The staggering profit benefit for the PBM Defendants is reflected in the SEC-reported financial statements of Express Scripts, the largest US PBM and the only major public stand-alone PBM.

116. Despite declining revenues and prescription volume over the past 5 years, Express Scripts’ annual profits have nearly tripled. In 2013, Express Script’s reported revenues of \$104 billion and net income of \$1.8 billion. In 2017, Express Scripts reported revenues of \$100 billion and net income of \$4.5 billion.

117. Escalating manufacturer “service fee” payments, tied to massive brand drug prices and price increases, has been the primary driver of Express Script’s remarkable profit growth in recent years, despite severe competition from and market share losses to other leading PBM Defendants.

118. A substantial 30% decrease in Express Scripts’ Selling, General and Administrative (S,G&A) spending over the 5 years, from \$4.6 billion in 2013 to \$3.3 billion in 2017, has been a

major contributor to the company's profit growth.

119. Express Scripts' sharply declining S,G&A spending trends indicate that escalating "support services" have not been provided to drug manufacturers as the "fee" payments have accelerated in recent years.

120. In fact, Express Scripts S,G&A trends indicate that the PBM is getting paid a lot more money by the drug manufacturers, in aggregate, for doing considerably less legitimate "support" work.

121. Besides Express Scripts, all the other PBM Defendants have also reported remarkable profit growth over the past 5 years. However, because of their more diversified business models, and their limited financial disclosures, we are unable to assign profits specifically to their PBM/specialty pharmacy subsidiaries.

122. For all the PBM Defendants, we expect discovery to determine that the manufacturer "service fee" scheme has been a primary driver of both their PBM and overall corporate profit growth over the past decade.

123. The evidence of this systemic "service fee" scheme is overwhelming. This pharmaceutical/PBM collusive "service fee" scheme is the "Rosetta Stone" behind virtually all instances of "inexplicable" massive US brand drug price inflation over the past decade. In fact, this scheme, with its origins in Medicare Part D, is the only viable explanation.

124. The systemic scheme, which began with the large biopharmaceutical and PBM companies, has also been aggressively employed by an array of smaller companies. Notable examples include Mallinckrodt's Acthar Gel, Mylan's Epipen, Turig's Daraprim, as well as the broad product portfolios of Valeant and Horizon Pharmaceuticals.

125. The major pharmaceutical and PBM corporations have done a remarkable job of

keeping media and other investigative efforts focused on these few small “bad actors”.

126. Notably, the aggregate US patient and financial harm of just one of the “blockbuster” products in this case, driven by the same scheme, dwarfs that of these combined small companies.

127. For example, even after its 5,000% price increase, the annual US sales of Turig’s Daraprim were only approximately \$10 million.

128. The Relator’s first hand and investigative evidence of the “service fee” scheme is extensive and conclusive. The evidence includes:

- a. In October 2013, the Relator attended a conference at which 50-60 directly-involved “corporate insiders” discussed the scheme openly. Representative “insider” quotes from the conference include: a) compensation for service providers from manufacturers had “shifted from rebates to fees”; b) “fees were the key to government pricing”; c) service fee agreements were the “main source of income”; d) service vendors “all want percent of revenue deals”; e) the contracts are not being “refreshed” for price increases; and f) manufacturers need to “consider whether percent of sales can be consistent with FMV as prices rise”.
- b. In December 2014, a pharmaceutical CEO discussed the details of the scheme with the Relator in a private investor meeting. Key quotes include: a) “well, PBMs don’t make their money off rebates anymore, PBMs make their money through service fees”; b) to put through big price increases, you just have to “play ball with them”, via service fee contracts.
- c. The Relator has verified the scheme in private discussions with an array of highly-experienced independent PBM consultants.

- d. Public disclosure of PBM Defendant client contracts, and related public commentary, verify the scheme. Several instructive Express Scripts and CVS Health PBM client contracts are discussed later in this Complaint.
- e. Recent public commentary from PBM Defendant senior executives verify the industry's reliance on the "service fees", rather than rebates for profits.
- f. For the first time, the pharmaceutical industry itself, via its closely-controlled lobbying organization, the Pharmaceutical Research and Management Association (PhRMA), publicly corroborated the scheme in a November 2017 report. The CEOs of most of the Manufacturer Defendants are current board members of PhRMA.
- g. The PBM Defendants also corroborated the "service fee" scheme in the US rheumatoid arthritis market, in a June 2017 report from the PCMA, the PBM industry's closely-controlled lobbying organization.

JURISDICTION AND VENUE

129. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. The Relator is the original source of the investigation and allegations in this Complaint.

130. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in this District, have appointed a registered agent for service of process in this District, and

/or transact business in this District.

131. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

PARTIES

132. Plaintiff/Relator John R. Borzilleri, M.D. ("Relator"), an investment fund manager and physician, is a resident of Cutchogue, New York. He has been a professional healthcare industry investment analyst for 25+ years. The Relator is a licensed physician in the State of New York, with an MBA degree from Columbia University.

133. Defendant AbbVie, Inc. ("AbbVie") is a Delaware corporation, with its U.S. headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. On January 1, 2013, Bayer became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories of 100 percent of the outstanding common stock of AbbVie to Abbott's shareholders. AbbVie focuses on anti-inflammatory conditions, infectious disease, and hormone replacement. AbbVie reported worldwide revenue \$28.2 billion in 2017. Pertaining to this case, AbbVie markets Humira in the United States for the treatment of rheumatoid arthritis, psoriatic arthritis, psoriasis, Crohn's disease, ulcerative colitis and ankylosing spondylitis. In 2017, Humira accounted for 65% of AbbVie's global sales.

134. Defendant Amgen, Inc. ("Amgen") is a Delaware corporation, headquartered at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and markets human therapeutics in the oncology, inflammatory, cardiovascular and

renal disease categories. Amgen reported worldwide sales of \$22.8 billion in 2017. Pertaining to this case, Amgen markets Enbrel in the United States for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis. Enbrel accounted for 27% of Amgen's global product sales in 2017.

135. Defendant Bristol-Myers Squibb Company ("Bristol-Myers Squibb") is a Delaware corporation, headquartered at 345 Park Avenue, New York, NY 10154. Bristol-Myers Squibb primarily generates revenues in the oncology, virology, cardiovascular, neuroscience, immunology, fibrosis and genetic diseases therapeutic areas. Bristol-Myers Squibb reported worldwide sales of \$20.8 billion in 2017, with 55% of sales in the United States. Pertaining to this case, Bristol-Myers Squibb markets Sprycel in the United States for the treatment of chronic myeloid leukemia. Sprycel accounted for 10% of Bristol-Myers Squibb's US revenues in 2017.

136. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation, headquartered at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly is a leading healthcare company focused on human pharmaceuticals and animal health. In its human pharmaceutical division, Eli Lilly focuses on the diabetes, oncology, neuroscience and cardiovascular therapeutic areas. Eli Lilly reported worldwide sales of \$22.9 billion in 2017, with 56% of sales in the United States. Pertaining to this case, Eli Lilly markets Humulin in the United States for the treatment of diabetes. Humulin accounted for 6% of Eli Lilly's global revenues in 2017.

137. Defendant Novartis Pharmaceuticals Corporation ("Novartis") researches, develops, manufactures and distributes medications. Novartis is owned, through a United States holding company, by Novartis International AG, a pharmaceutical manufacturer headquartered in Basel, Switzerland. Novartis' corporate headquarters in the United States are in East Hanover,

New Jersey. Novartis reported worldwide sales of \$49.1 billion in 2017. Related to this Complaint, Novartis markets Gleevec and Tasigna for the treatment of chronic myeloid leukemia (CML).

138. Defendant Pfizer, Inc. ("Pfizer"), a Delaware corporation, is headquartered in New York City at 235 East 42nd Street, New York, New York 10017. Pfizer focuses on therapies for cardiovascular/metabolic disease, immunology, inflammation, oncology and neuroscience. Pfizer reported worldwide revenues of \$52.5 billion in 2017. Related to this case, Pfizer markets Lyrica (neurologic pain), Viagra (erectile dysfunction), Celebrex (osteoarthritis/pain), Chantix (smoking cessation), Premarin (hormone replacement/osteoporosis), Pristiq (depression) and Relpax (migraines). The brand drugs targeted in this case accounted for approximately 30% of Pfizer's US pharmaceutical sales in 2017.

139. Defendant sanofi-aventis U.S. LLC ("Sanofi") is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-aventis U.S. LLC operates as a subsidiary of Sanofi. Sanofi manufactures and sells Lantus for the treatment of diabetes. In 2017, Lantus accounted for approximately 19% of revenues.

140. Defendants AbbVie, Inc., Amgen, Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Novartis Pharmaceutical Corporation, Pfizer, Inc. and sanofi-aventis U.S. LLC are collectively identified as the "Manufacturer Defendants" in this Complaint.

141. Defendant Aetna, Inc. ("Aetna"), headquartered in Hartford, CT, and its subsidiaries, is one of the nation's leading diversified health care benefits companies. Aetna's headquarters are located at 151 Farmington Ave, Hartford, CT 06156. Through annual contracts with CMS, Aetna offers HMO and PPO products for eligible individuals in certain geographic areas through the Medicare Advantage program. Aetna is a national provider of the Medicare Part

D Prescription Drug Program ("PDP") in all 50 states and Washington, D.C. to both individuals and employer groups. Aetna offers pharmacy benefit management services and specialty and mail order pharmacy services to its members. Aetna's pharmacy fulfillment services are delivered by Aetna Specialty Pharmacy ("ASP") and Aetna Rx Home Delivery®. ASP compounds and dispenses specialty medications and offers certain support services associated with specialty medications. In 2017, Aetna reported revenues of \$60.5 billion. In 2011, CVS Health began to perform the administration of selected functions for Aetna's retail pharmacy network contracting and claims administration; mail order and specialty pharmacy order fulfillment and inventory purchasing and management; and certain administrative services for Aetna. In December 2017, Defendant CVS Health announced an agreement to acquire Aetna, Inc.

142. Defendant Cigna Corporation ("Cigna"), headquartered in Bloomfield, CT, and its subsidiaries, is a global health services provider of medical, dental, disability, life and accident insurance and related products and services. Cigna's headquarters are located at 900 Cottage Grove Road, Bloomfield, CT 06002. Cigna's Medicare Part D plans are available in all 50 states and the District of Columbia. With a network of over 65,000 contracted pharmacies, Cigna Pharmacy Management is a comprehensive pharmacy benefits manager ("PBM") offering clinical integration programs and specialty pharmacy solutions. Cigna Pharmacy Management offers fast, cost-effective mail order, telephone and on-line pharmaceutical fulfillment services through our home delivery operation. Under a 2013 agreement, Catamaran Corporation (now part of Defendant UnitedHealth Group, Inc.) provides Cigna with access to their technology and service platforms, prescription drug procurement and inventory management capabilities, retail network contracting and claims processing services. Cigna reported revenues and net income of \$41.6 billion and \$2.23 billion, respectively, in 2017. In March 2018, Cigna announced an agreement to acquire Defendant

Express Scripts.

143. Defendant CVS Health Corporation ("CVS Health"), headquartered in Woonsocket, RI, and its subsidiaries, is the largest integrated pharmacy health care provider in the United States. CVS Health's headquarters are located at One CVS Drive, Woonsocket, RI 02895. CVS Health's Pharmacy Services Segment provides a full range of PBM services to our clients consisting primarily of employers, insurance companies, unions, government employee groups, managed care organizations ("MCOs") and other sponsors of health benefit plans and individuals throughout the United States. In addition, through our SilverScript Insurance Company ("SilverScript") subsidiary, CVS Health is a national provider of drug benefits to eligible beneficiaries under the Federal Government's Medicare Part D program. The Pharmacy Services Segment operates under the CVS Caremark® Pharmacy Services, Caremark®, CVS Caremark®, CarePlus CVS/pharmacy®, RxAmerica®, Accordant®, SilverScript® and Novologix® names. CVS Caremark participates in the administration of the drug benefit added to the Medicare program under Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA, Medicare Part D") through the provision of PBM services to its health plan clients and other clients that have qualified as Medicare Part D prescription drug plans ("PDP"). CVS Health reported revenues and net income of \$184.8 billion and \$6.6 billion, respectively, in 2017. In December 2017, CVS Health announced an agreement to acquire Defendant Aetna, Inc.

144. Defendant Express Scripts Holding Company ("Express Scripts"), headquartered in St. Louis, MO, and its subsidiaries, is the largest PBM company in the United States, offering a full range of services to our clients, which include managed care organizations, health insurers, third-party administrators, employers, union-sponsored benefit plans, workers' compensation plans and government health programs. Express Scripts headquarters are located at One Express

Way, St. Louis, MO 63121. Through its licensed insurance subsidiaries (i.e., Express Scripts Insurance Company ("ESIC"), Medco Containment Life Insurance Company and Medco Containment Insurance Company of New York), Express Scripts operates as Part D PDP sponsors offering PDP coverage and services to clients and Part D beneficiaries. Express Scripts, through our core PBM business, provide Part D-related products and services to other PDP sponsors, MA-PDPs and other employers and clients offering Part D benefits to Part D eligible beneficiaries. Express Script's specialty pharmacy subsidiary, Accredo Health Group ("Accredo®"), is focused on dispensing infused, injectable, inhaled and oral drugs that require a higher level of clinical services and support compared to what typically is available from traditional pharmacies. Express Scripts reported revenues and net income of \$100 billion and \$4.5 billion, respectively, in 2017. In March 2018, Defendant Cigna announced an agreement to acquire Defendant Express Scripts.

145. Defendant Humana, Inc. ("Humana"), headquartered in Louisville, KY, and its subsidiaries, is a leading health care company that offers a wide range of insurance products and health and wellness services. Humana's headquarters are located at 500 West Main Street, Louisville, KY 40202. During 2017, 79% of Humana's total premiums and services revenue were derived from contracts with the federal government. Most Humana Medicare Advantage plans offer the prescription drug benefit under Part D as part of the basic plan, subject to cost sharing and other limitations. Humana offers stand-alone prescription drug plans, or PDPs, under Medicare Part D, including a PDP plan co-branded with Wal-Mart Stores, Inc., or the Humana-Walmart plan. Humana, Inc. reported revenues and net income of \$52.8 billion and \$2.45 billion, respectively, in 2017.

146. Defendant UnitedHealth Group, Inc., ("UnitedHealth") headquartered in Minnetonka, MN, and its subsidiaries, is a diversified health and well-being company.

UnitedHealthcare provides health care benefits to a full spectrum of customers and markets. UnitedHealth Group's headquarters are located at 9900 Bren Road East, Minnetonka, MN 55343. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits for Medicare beneficiaries and retirees. UnitedHealthcare Community & State manages health care benefit programs on behalf of state Medicaid and community programs and their participants. UnitedHealth's Optum division is a health services business serving the broad health care marketplace, including payers, care providers, employers, government, life sciences companies and consumers, through its OptumHealth, OptumInsight and OptumRx businesses. UnitedHealthcare Medicare & Retirement provides Medicare Part D benefits to beneficiaries throughout the United States and its territories through its Medicare Advantage and stand-alone Medicare Part D plans. OptumRx is UnitedHealth's full service Pharmacy Benefit Manager (PBM) subsidiary. UnitedHealthcare Medicare & Retirement offers two standalone Medicare Part D plans: the AARP Medicare Rx Preferred and the AARP Medicare Rx Saver plans. In 2015, UnitedHealth acquired the PBM Catamaran Corporation. UnitedHealth Group, Inc. reported revenues and net income of \$201.2 billion and \$10.6 billion, respectively, in 2017.

147. Defendants Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc. and UnitedHealth Group, Inc., are collectively identified as the "PBM Defendants" in this Complaint.

BACKGROUND INFORMATION

A. The Medicare Program

148. Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare and

Medicaid Services (“CMS”). There are four major components to the Medicare program:

- a) Part A, the hospital insurance benefits program.
- b) Part B, the supplemental medical insurance benefits program, which generally pays for a percentage of certain medical and other health services, including physician services.
- c) Part C, the Medicare Advantage program, which allows CMS to contract with public and private entities to provide, at a minimum, Medicare Part A and B benefits to certain Medicare beneficiaries.
- d) Part D, the voluntary prescription drug benefit program.⁴² U.S.C. § 1395w-101, et seq.

B. The Medicare Part D Program

149. Part D was established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, which set up a voluntary prescription benefits program for Medicare enrollees. Part D became effective January 1, 2006. Unlike Parts A and B, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D “sponsors” to administer prescription drug plans. Part D benefits are provided by a Part D plan sponsor, which is either a prescription drug plan (“PDP”), a Medicare Advantage organization plan (“MA-PD”), or a Program of All-Inclusive Care for the Elderly (“PACE”).

150. A Part D sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month (“PMPM”) cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. From the bids, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. If the Part D plan sponsor’s bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium.

151. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary’s Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug

has been purchased and dispensed through a document called a Prescription Drug Event (“PDE”) record, which includes the amount paid to the pharmacy.

152. As a condition for receiving its monthly payment from CMS, a Part D Plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. 42 C.F.R. § 423.505(k)(1). If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must “similarly certify” that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. 42 C.F.R. § 452.505(k)(3).

153. Part D Plan sponsors must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

154. Part D Plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with PBMs and specialty pharmacies. PBMs can provide a variety of services to sponsors to help manage their prescription drug benefit. These services include processing prescription drug claims, contracting with pharmacies, managing formularies, as well as negotiating rebates with drug manufacturers. PBMs can be compensated for these services in a variety of ways, including receiving a fixed payment per claim or retaining a percentage of sponsors’ rebates.

155. PBMs can also be directly compensated by drug manufacturers via designated

"bona fide service fees" (BFSFs) for a wide array of product-related "services", such as inventory management, patient education, phone support, shipping, reimbursement assistance, data reports, etc., which would have otherwise been performed by the manufacturer. Legitimate BFSFs, paid at FMV, are excluded from government "negotiated price" calculations.

156. CMS has established a unique bid and reimbursement process in the administration of Part D with plan sponsors. Under Medicare Part D, plan sponsors are required to submit bids to CMS in the first week of June for the following calendar plan year. The bids are based upon the sponsor's estimate of its anticipated monthly drug costs for Part D beneficiaries in the plan, as well as administrative costs and expected profit. OIG Report, Medicare Part D Reconciliation Payments for 2006 and 2007, OEI-02-08-00460, September 2009. CMS uses the submitted data to determine individual plan premium rates and monthly subsidy payments made to plan sponsors for the following calendar plan year. The monthly subsidy payment schedule of Part D is designed to help plans effectively manage "cash flow" during a plan year as actual drug costs accrue.

157. The plan sponsor bid cost estimates and related monthly subsidy payments consist of four distinct tranches. First, the sponsor must provide a cost estimate for the "basic" Part D benefit for a beneficiary of "average" health in the plan, for which it receives monthly "Regular Subsidy" payments. According to CMS, the "Regular Subsidy" monthly payments for Part D plans across the US are relatively similar since the amounts are based upon national beneficiary cost averages, with modest adjustments for age and health status in each particular plan.

158. Second, the plan sponsor must provide an estimate of the benefit cost for low-income (LIS) beneficiaries (approximately 30% of overall Part D enrollment) in the plan for the following calendar year, for which CMS provides monthly "Low-Income (LIS) Subsidy" payments. LIS beneficiaries are low-income elderly and disabled people, who commonly are

afflicted with severe chronic medical conditions that often necessitate treatment with high-priced specialty drugs. Other than small copayments, CMS covers virtually all cost-sharing requirements for LIS beneficiaries in Medicare Part D.

159. Third, the sponsor must estimate the cost of providing “catastrophic” drug coverage for Part D beneficiaries whose annual out-of-pocket spending exceeds the annual maximum threshold (\$3,600 in 2006, rising to \$5,000 in 2018). For “catastrophic” drug costs, CMS covers 80% of the estimated costs via monthly “Reinsurance Subsidy” payments; with plan sponsors and non-LIS beneficiaries responsible for 15% and 5% of spending over the threshold, respectively. In Part D, the use of high-priced specialty drugs is the primary driver of crossing the annual “catastrophic” spending threshold. In contrast to “Regular Subsidy” payments, monthly “LIS Subsidy” and “Reinsurance Subsidy” payments among plans can vary widely, depending upon the enrollment and health status characteristics of a particular plan.

160. Starting in 2011, CMS added the “Gap Discount Subsidy” as part of the ACA legislation, which requires drug manufacturers to provide price discounts to all Part D beneficiaries in the so-called “donut hole” coverage window. In plan bid submissions, plan sponsors must estimate the amount of manufacturer “donut hole” discounts for the following calendar year, for which CMS provides monthly “Gap Discount Subsidy” payments. Since CMS hired a Third Party Administrator (TPA), Palmetto GBA, to administer the Gap Discount program, the “Gap Discount Subsidy” payments appear to be “pass through” amounts from manufacturers to plan sponsors.

161. Part D plan sponsors must provide detailed information to CMS in order to track performance, reconcile subsidy payments and to aid in the detection/prevention of fraud. In administering Part D, plan sponsors are required to submit a “Prescription Drug Event” (“PDE”) record for each prescription for all covered drugs dispensed to enrollees. The PDE includes more

than 50 different fields of data, including end-user pharmacy drug cost data. Notably, the PDE does not provide drug costs paid by PBMs to drug manufacturers.

162. In addition, sponsors must submit quarterly and year-end DIR ("Direct and Indirect Remuneration") reports to CMS to disclose any rebates or price concessions, which almost entirely come from manufacturers via PBM negotiations for the vast majority of plans.

163. Both the PDE and DIR data are "self-reported", with apparently limited CMS oversight or verification. Medicare Part D - Prescription Drug Event Reconciliation Process, A-18-08-30102, June 1, 2010. For the vast majority of Part D plans, the PDE and DIR reports are prepared by contracted PBMs, with limited controls by either CMS or unaffiliated plan sponsors.

164. Both "Low-Income Subsidy" and "Reinsurance Subsidy" plan sponsor payments undergo a reconciliation process after each plan year. In the case of "Low-Income Subsidy" payments, CMS guarantees full reimbursement of any unforeseen LIS cost-sharing requirements. In reconciliation, the cost-sharing responsibilities for excess "catastrophic" drug spending are the same as during the bid process. Namely, CMS covers 80% of unlimited excess costs, with the plan sponsor and beneficiary responsible for 15% and 5% (for non-LIS beneficiaries only), respectively.

165. As part of the 2003 MMA legislation, the drug benefit for many of the highest cost, most-severely ill beneficiaries "dual eligibles" beneficiaries were transferred, without recourse, from state Medicaid programs to Medicare Part D. "Dual eligibles" are low-income elderly and disabled beneficiaries eligible for both Medicaid and Medicare benefits. Former State "dual eligibles" account for about two-thirds of Part D LIS beneficiaries which, in turn, have historically accounted for the majority (up to 70% in early program years) of Part D premium-priced "specialty" drug spending.

166. By law, each State is required to fund a significant portion of Medicare Part D spending for their respective "dual eligible" beneficiaries via "phased-down contribution" or "clawback" payments to CMS paid on a monthly basis. In the program years 2006 through 2014, State "clawback" payments accounted for 32-37% of Part D LIS Subsidy costs each year. Furthermore, the State Part D financial responsibilities are legally tied to Federal Medicaid matching transfers. As such, if any State fails or refuses to pay its CMS-determined "clawback" payments, the same amount will be deducted from its scheduled Federal Medicaid matching funds. Overall, States made cumulative "clawback" payments to CMS of \$61.8 billion for the years 2006 through 2014.

167. Prior to Medicare Part D, State "dual eligible" beneficiaries received their outpatient drug benefit via State Medicaid programs. Medicaid requires additional manufacturer rebates for brand price increases greater than inflation (CPI-Urban), whereas Medicare Part D provides no such protection.

168. The Part D regulations clearly indicate that plan sponsors, as well as PBM/specialty pharmacy subcontractors, are liable under the False Claims Act for fraudulent data submissions to CMS due to their express requirement to "certify" compliance with regulations as a prerequisite for participation and payment. In addition, the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO) must individually expressly "certify" compliance. The provision of C.F.R. § 423.505, entitled "Certification of data that determines payment" states:

- a) General rule. *"As a condition of receiving a monthly payment under subpart G of this part (or fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness*

of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies."

- b) Certification of claims data. "The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based upon best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of Federal reimbursement."*
- c) Certification of bid submission data. "The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and assumptions related to projected reinsurance and low-income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265."*
- d) Certification of allowable costs for risk corridor and reinsurance information. "The Chief Executive Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement."*

DETAILS OF THE FALSE CLAIMS/KICKBACK VIOLATION PATHWAY

169. **For the Manufacturer Defendants:**

- 1) The Manufacturer Defendants knowingly made fraudulent overpayments of "*Bona Fide Service Fees*" ("*BFSFs*") far in excess of the legally-required "*Fair Market Value*" ("*FMV*") to the PBM Defendants, as well as their subsidiaries and partners, in the Medicare Part D program.
- 2) These fraudulent FMV BFSF payments are straightforward "*kickbacks*" by Manufacturer Defendants to the PBM Defendants to enable the massive price increases, to gain formulary access and to obviate standard PBM cost-savings practices that would lead to far lower Defendant drug prices in highly-competitive US markets.
- 3) By statute and law, "*kickbacks*" are also direct false claims according to the False Claims Act.
- 4) According to 31 U.S. code 3729, anyone who "*knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval*" faces liability. The Manufacturer Defendants have "*caused*" the PBM Defendants to submit a wide array of false claims to federal and state governments for reimbursement, including PDE reports, DIR reports, annual plan sponsor bids, and data required for annual reconciliation of Part D subsidies.
- 5) As per the regulations, "*service fees*" in excess of FMV should be reported by the drug manufacturer to the plan sponsor. In turn, the plan sponsor (usually via its contracted PBM) should report the excessive "*service fees*" to CMS in its DIR report as a "*discount*", leading to lower Part D drug prices. The Defendants are intentionally not

doing so in order to advance the “*service fee*” scheme, to fraudulently increase Part D drug prices and maximize their fraudulent profits.

- 6) The minimal direct Part D reporting requirements regarding BFSFs for the Manufacturer Defendants has been a central factor abetting the fraudulent scheme. As such, we view this fraud as primarily as “*fraud of exclusion*”, especially pertaining to Direct and Indirect Remuneration (“*DIR*”) reports.
- 7) As per the law, the Manufacturer Defendant legal liability regarding BFSFs is independent of its Part D reporting requirements, or lack thereof.
- 8) The “*express certification*” requirements of the Manufacturer Defendants, as well as their participating subsidiaries, against violation of the AKS and the FCA also clearly establishes liability.
- 9) For each Defendant, the CEO and CFO must also “*expressly certify*” compliance with applicable laws, including the AKS and the FCA.

170. For the PBM Defendants:

- 1) The fraudulent Manufacturer Defendants FMV BFSF overpayments to the PBM Defendants are “kickbacks” (i.e., “payments for referral”) and a violation of the Anti-Kickback Statute (“AKS”).
- 2) The willful receipt of these “*kickbacks*” is a criminal offense by all Defendant parties because the Part D regulations require all participants, including manufacturers, plan sponsors, PBMs, specialty pharmacies, and other First Tier, Downstream and Related Entities (FDRs), to “*expressly certify*” compliance with all relevant laws, including the AKS and FCA.

- 3) The PBM Defendants, in their role as PBMs, specialty pharmacies and plan sponsors, have directly submitted a wide array of false claims for reimbursement, including PDE reports, DIR reports, annual plan sponsor bids, and data required for annual reconciliation of Part D subsidies.
- 4) Virtually all Part D submissions impacting reimbursement for the Defendant drugs, for most of the past 12 years, are fraudulent and tainted by the systemic scheme.
- 5) Due their "*express certification*" requirements and coordination of the scheme, the Defendant CEOs and CFOs of these corporations may also be accountable for the AKS and FCA violations.

DETAILS REGARDING THE STATE FALSE CLAIMS VIOLATIONS

171. In Medicare Part D, each State is responsible for funding a significant portion of the drug costs of their "dual eligible" beneficiaries (i.e., low-income elderly and disabled individuals who qualify for both Medicaid and Medicare benefits) whose drug benefit was transferred from Medicaid to Medicare Part D as part of the MMA legislation.

172. The States pay their mandatory portion of Part D drug spending via monthly transfers, known as "Phase Down" or "Clawback" payments. By law, these State "Clawback" payments cover 35-40% of Part D LIS Subsidy costs each year of the Part D program.

173. Driven by the massive Part D drug price inflation for "specialty" drugs, directly resulting from this "service fee" scheme, State annual Clawback" payments have increased sharply since the start of Medicare Part D. As per the Medicare Trustee reports, State "Clawback" payments have increased from \$5.5 billion in 2006 to \$10.0 billion in 2016, with cumulative State payments of \$80.7 billion through the latter year. State "Clawback" payments are forecasted to be \$12.0 billion in 2018 and \$22.5 billion by 2026. 2017 Medicare Trustees Report, July 2017.

174. Due to the brand price inflation statutes in Medicaid, these State “dual-eligibles” would have access to “old” Manufacturer Defendant drugs at a fraction of the cost, if not for the Part D pricing scheme.

175. The “old” Manufacturer Defendants drugs in this case, including Amgen’s Enbrel, Eli Lilly’s Humulin and Pfizer’s Viagra, are currently available at 80-90% discounts to the prices in Medicare Part D.

176. As such, the “kickbacks” and federal false claims submissions related to the Manufacturer Defendant drugs have led directly to widespread financial fraud at the State level.

THE RECENT INCRIMINATING PhRMA INDUSTRY REPORT

177. In a November 2017, nearly four years after our initial Qui tam filing, the Pharmaceutical Research and Manufacturers Association (PhRMA), the leading pharmaceutical lobbying organization, released a report, entitled “Follow the Dollar”.

178. While the purpose of the report was to shift blame for severe US drug prices towards its collusive PBM Defendant partners, the document definitively incriminates both parties in the systemic “service fee” scheme.

179. In the report, PhRMA, for the first time, disclosed average contract terms for “service fees” between biopharmaceutical manufacturers and the dominant PBM Defendants.

180. Of note, the individual “service fee” contracts between the Manufacturer and PBM Defendants remain a closely guarded secret, obtainable by the non-insider Relator only via discovery.

181. PhRMA is funded and controlled by the major biopharmaceutical companies. Current board members of PhRMA include Jeffrey R. Stewart (President, US Commercial Operations for Defendant AbbVie), Robert A. Bradway (CEO of Defendant Amgen), Olivier

Brandicourt (CEO of Defendant Sanofi), Vasante Narasimhan (CEO of Defendant Novartis), Ian Read (CEO of Defendant Pfizer) and David Ricks (CEO of Defendant Eli Lilly).

182. In the November 2017 report, PhRMA disclosed that the PBM Defendants and their specialty pharmacy subsidiaries receive an average of 8% of the “list” (WAC) drug price, inclusive of all price increases, for each US private insurance patient treated with a high-cost “specialty” drug in the US, such as the rheumatoid arthritis (Humira and Enbrel) and cancer (Gleevec, Tasigna, Sprycel) drugs in this case.

183. For “traditional” US pharmaceutical products, such as Defendant Pfizer’s products, the PBM Defendants typically receive 4% of the “list” WAC price as “service fees” from drug manufacturers.

184. Furthermore, straightforward calculations from the report indicate that the PBM Defendants currently garner about 90-100% of their profits for “specialty” brand drugs from these manufacturer “service fees”, with almost all of the remainder from “retained” manufacturer “rebates”.

185. For “traditional” brand drugs, the PBM Defendants obtain about 70% of profits from “service fees”, with almost all of the remainder from “retained” manufacturer “rebates”.

186. To this day, the majority of independent pharmaceutical and PBM experts still publicly cite “manufacturer rebates” as the primary source of PBM Defendant profits, despite the claim being false for more than a decade.

187. As per the report, overall compensation from drug manufacturers, from combined “fees” and “rebates”, accounts for 98% of PBM Defendant profits for each “specialty” drug treated patient in the US private insurance market.

188. Notably, the “8% of sales” “specialty” contract rate, disclosed by PhRMA, is

double the conservative 4% contract terms estimate in our prior Qui Tam Complaints.

189. Based upon this disclosure, and ongoing massive Defendant drug price inflation, we have greatly escalated our estimates for the direct “service fee” fraud payments to the PBM Defendants related to the “specialty” drugs in this case; namely Amgen’s Enbrel, AbbVie’s Humira, Novartis’ Gleevec, Novartis’ Tasigna and Bristol-Myers Squibb’s Sprycel.

190. These private insurance calculations from the PhRMA report likely significantly understate the contribution of manufacturer “service fees” to PBM Defendant profits in the private insurance market, but especially regarding Medicare Part D.

191. In the report, PhRMA claimed that 20% of the “manufacturer fees” are “passed on” to private insurance clients. However, our discussions with highly-experienced independent PBM consultants uniformly indicate that these “manufacturer service fees” are virtually never shared with private insurance clients.

192. In fact, the PBM consultants stated that they had never negotiated a client contract with a leading PBM, in which ANY “manufacturer fees” were shared with one of their private insurance clients. Furthermore, the PBM consultants stated that they had never seen or reviewed a single “service fee” contract between a PBM and a drug manufacturer.

193. This PBM consultant feedback is consistent with PBM Defendant CVS Health’s public disclosures. Regarding a Maryland state contract discussed in detail later in the Complaint, CVS Health publicly admitted that it “does not disclose to its clients detailed information regarding service fees (from manufacturers) received and does not share those fees with its clients.” Before the Maryland State Board of Contract Appeals, Docket Nos. MSBCA 2544, 2548 & 2565, March 2007.

194. In its report, PhRMA estimated overall rebates of about 25% from manufacturers

off “list” prices and that the PBM/specialty pharmacy typically keeps about 20% of the amount.

195. However, in recent public commentary, the senior management of both Express Scripts and CVS Health stated that the company’s keep only about 10% of overall manufacturer rebates. They further stated that for large private insurance clients, they often don’t keep any rebates.

196. As stated by Express Script’s CEO, Tim Wentworth: “It’s important to understand how rebates flow. We retain 10% of rebates for our services and administrative fees, and 90% flows straight through to the plans.” Forbes Healthcare Summit, New York City, November 30, 2017.

197. Since BFSFs cannot be “passed on” in government drug programs, the PhRMA report’s claim of sharing 20% of “legitimate” fees with private clients is irrelevant in the Part D program.

THE RECENT INCRIMINATING PCMA INDUSTRY REPORT

198. In June 2017, the Pharmaceutical Care Management Association (PCMA), the leading PBM industry lobbying organization, released a report, entitled “Increasing Prices Set by Drugmakers Not Correlated with Rebates”.

199. The purpose of the report was to shift blame for severe US drug prices towards the biopharmaceutical industry. However, combined with the above PhRMA report, the PCMA report definitively incriminates both Defendant parties in the “service fee” scheme.

200. PCMA is funded and controlled by the dominant PBM Defendants. Current board members of PCMA include Tim Wentworth (CEO of Defendant Express Scripts), William Fleming (President, Health Services for Defendant Humana), Chris Hocevar (President, Strategy, Segments and Solutions for Defendant Cigna), Randy Hyun (President Pharmacy Management for

Defendant Aetna), John Prince (Chief Executive Officer of the OptumRx PBM subsidiary of Defendant UnitedHealth Group) and Jon Roberts (Executive Vice President and Chief Operating Officer of Defendant CVS Health).

201. First, the report corroborated that the PBM Defendants standardly “retain” only a small portion of “manufacturer rebates”; only in the 10% range, and less for many larger private insurance clients.

202. As per Mark Merritt, the President and CEO of the Pharmaceutical Care Management Association (PCMA), in the press release accompanying the report: “PBMs are hired by America’s largest, most sophisticated, health purchasers to reduce costs by, among other things, promoting generics and negotiating rebates and discounts on brand-name drugs. Typically, PBMs pass along 90 percent or more of these savings to plans, which use them to cut premiums, out-of-pocket costs and other expenses. Many health purchasers require PBMs to pass through 100 percent of rebates.” PCMA Press Release, June 12, 2017.

203. In their analysis of the “Top 200 Brand Drugs”, the PCMA found no correlation between increasing drug prices and the magnitude of “manufacturer rebates”

204. In fact, PCMA reported that “Drugmakers raise prices even when rebates are low in major drug categories”.

205. Specific to this case, PCMA reported that “rheumatoid arthritis drugs (DMARDs) have high price increases, yet rebates on these drugs are low”.

206. As per PCMA, between 2011 and 2016, despite a 125% increase in WAC cost, “rebate levels for these drugs was only 11%” throughout the six year period.

207. In this action, our fraudulent sales estimates for the rheumatoid arthritis drugs, AbbVie’s Humira and Amgen’s Enbrel, are severe due to their wide use and massive uniform price

increases.

208. We estimate cumulative fraudulent US Humira and Enbrel sales of \$32 billion and \$19 billion, respectively, since 2006, with about 30% in Medicare Part D.

209. In concluding the report, PCMA even proposed a rationale for the vast manufacturer price increases: “Perhaps to counter shrinking prescription volume for brand drugs”.

210. The PCMA report makes no mention of PBM Defendant compensation from drug manufacturers related to the vast “specialty” drug price increases - from “rebates”, “service fees” or any other sources.

211. The straightforward math from the PhRMA and PCMA reports verifies the fraudulent participation of both Defendant parties in the “service fee” scheme.

212. With the PBM Defendant only keeping about 10% of low (11%) manufacturer Humira and Enbrel discounts, PBM Defendant compensation from “retained” rebates has remained very low despite massive price increases.

213. On the other hand, PBM Defendant compensation from “service fees”, which are typically all kept by the PBM, has secretly and intentionally skyrocketed along with the massive price increases.

SECRETIVE PBM DEFENDANT PARTNERSHIPS

214. Inter-relationships of the PBM Defendants also increase complexity and decrease transparency. The PBM Defendants United Healthcare, Humana, Express Scripts and CVS Health have full ownership of the PBMs/specialty pharmacies servicing the Part D plans. However, various secretive partnerships among the PBM Defendants further increase concentration and limit disclosure regarding PBM practices in both Part D and the private insurance sector.

215. In plans sponsored by Defendants Aetna and Cigna, pharmacy benefits are provided

via long-term contractual arrangements with CVS Health, and UnitedHealth Group, respectively. UnitedHealth Group took over the Cigna contract upon its acquisition of the PBM Catamaran in 2015.

216. Recent merger announcements will further increase the concentration, and decrease transparency, in the US PBM/specialty pharmacy marketplace. In December 2017, CVS Health announced its intention to acquire Aetna, Inc. In March 2018, Cigna announced its intention to acquire Express Scripts. These transactions will only escalate already severe systemic “service fee” and US drug pricing abuse.

217. According to SEC filings and management commentary, Aetna and Cigna appear to have maintained a significant amount of control over PBM functions in their contractual arrangements with larger PBM Defendants, especially regarding key formulary decisions and manufacturer contract negotiations.

218. As such, Defendants Aetna and Cigna are knowingly participating in and benefiting from the “service fee” scheme in these contractual arrangements. However, public disclosure regarding these contractual arrangements between the PBM Defendants has been minimal. Close scrutiny of the financial terms and transactions related to these secretive arrangements will be a key part of case discovery. Following is a review of the limited public disclosure regarding the PBM Defendant partnerships.

219. According to the July 27, 2010 press release, Aetna stated: “Aetna and CVS Caremark today announced they have entered into a 12-year contract to provide Pharmacy Benefit Management (PBM) services that will further enhance value and services for Aetna's customers and members. Aetna will retain its PBM and manage clinical programs, protocols and oversight of its pharmacy benefit operations...In addition, CVS Caremark will manage purchasing,

inventory management and prescription fulfillment for Aetna's mail-order and specialty pharmacy operations." The impact on this contractual arrangement of the proposed CVS Health acquisition of Aetna remains unclear.

220. As per its 2014 10-K filing, Cigna states: "In June 2013, we entered into a ten-year pharmacy benefit management services agreement with Catamaran Corporation. Under this agreement, we utilize Catamaran's technology and services platforms, retail network contracting and claims processing."

221. Catamaran's 2014 10-K further states: "The two organizations are partnering on sourcing, fulfillment and clinical services. The partnership combines Cigna's significant clinical management and customer engagement capabilities with Catamaran's innovative technology solutions, while seeking to leverage the two companies' scale of network choice and efficient procurement to deliver value to Cigna's clients and members."

222. Most indicative of Cigna's ongoing central PBM role, Catamaran stated: "The gross profit percentage related to the Cigna contract is significantly lower than historical gross profit percentages due to the related transaction volume." The lower profits for UnitedHealth/Catamaran suggest that Cigna is actively participating in the "service fee" scheme, the primary source of PBM profits.

223. In contrast, the long-term contract between Express Scripts and Anthem is apparently financially unfavorable for the latter. We suspect that Express Scripts is gaining most of the financial benefit from manufacturer "service fees" in this contract. At present, Express Scripts and Anthem are in litigation and the latter has already announced its intention not to renew the partnership. Due to these developments, we have removed Anthem as a Defendant in this Qui Tam case.

224. Catamaran was acquired by PBM Defendant UnitedHealth Group in 2015, with minimal disclosure regarding any impact on the prior Cigna partnership. With no transparency, the impact of the proposed acquisition of Express Scripts by Cigna on the existing UnitedHealth PBM contract remains unclear.

PBM PART D PROFITS: SECRET MANUFACTURER FEES, NOT REBATES

225. The secretive reliance of the PBM Defendants on the “service fee” scheme, rather than manufacturer rebates, for profits has been verified by data from both the federal government and the Defendants themselves.

226. In fact, this key, still secretive, financial discovery was the starting point of the Relator’s fraud investigation more than five years ago. We summarize here and provide more details later in the document.

227. First, a 2011 Office of Inspector General (OIG) report documented that PBMs “retained” minimal “manufacturer rebates” in Medicare Part D in the program’s first three years of operation (2006-2008), despite the onset of severe systemic brand drug price increases. “Concerns with Rebates in the Medicare Part D Program”. OIG HHS Report, OEI-02-08-00050, March 2011.

228. As per the OIG report, in Medicare Part D for the year 2008, PBMs “retained” only \$24 million (less than 1%) of overall \$6.5 billion of drug manufacturer rebates. (Emphasis added)

229. As such, by definition, the PBMs were being compensated in Part D via a pathway other than “manufacturer rebates”, which was the intent of the legislation and remains the current public presumption.

230. Besides “rebates”, BFSFs (i.e., “service fees”) are the only other mechanisms for large financial payments from drug manufacturers to the PBM Defendants in Medicare Part D.

231. With minimal retention of Part D rebates, “services fees” became secretly and knowingly the primary source of profits for the PBM Defendants in the program.

232. Second, more recently both Express Scripts and CVS Health have disclosed that they keep only about 10% of aggregate “manufacturer rebates”, which, like “service fees”, are standardly contractually-based on AWP or WAC prices.

233. Third, CMS’ own data documents that Medicare Part D “manufacturer rebates” have averaged about 10-15% of AWP “list” prices annually since the inception of the program. Medicare Trustee Reports. The modest Part D rebates contrast with the unverifiable large rebate claims of the Manufacturer and PBM Defendants in recent years.

234. As per another government report, the “manufacturer rebate rate” for high-cost “specialty” drugs (including the Defendant rheumatoid arthritis and CML cancer drugs) has commonly been far less than the 10-15% aggregate rate in Medicare Part D. GAO-10-242, 2010; Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier”.

235. The low level of “manufacturer rebates” for several of the major “specialty” drug therapeutic categories in our Qui Tam actions was recently verified by the PBM Defendants themselves.

236. As per the previous section, the PBM Defendants themselves, via the PCMA report, verified the low level (11%) of “manufacturer rebates” for the US rheumatoid arthritis “specialty” category, including AbbVie’s Humira and Amgen’s Enbrel, despite ongoing massive price increases.

237. Indicative of the systemic “service fee” scheme, in addition to the rheumatoid arthritis category, the PCMA report also verified the low level of “manufacturer rebates” in the

US multiple sclerosis (MS) category.

238. According to PCMA, for six long-marketed US MS drugs, despite a 125% price increase over the period, “the weighted average rebate level for these drugs for the 2011-2016 period was 7%.”

239. Based upon government data and the PBM Defendants own public disclosures, the PBM Defendants are making very little profit for “manufacturer rebates”

240. Assuming an average 10% “manufacturer rebate” and the PBM Defendant publicly-stated 10% rebate “retention rate”, the PBM Defendants are keeping only about 1% of AWP-based drug product sales, on average, as “rebate” compensation.

241. In sharp contrast, the PBM Defendants are secretly obtaining far greater compensation (and the vast majority of their profits) in Part D via manufacturer “service fees”, routinely linked to massive, anti-competitive drug prices and price increases.

242. Using the straightforward math from the PhRMA and PCMA reports, the PBM Defendants now secretly receive, on average, 8-to-11 times as much compensation from manufacturer “service fees” compared to “retained manufacturer rebates” for high-cost “specialty” drugs. Of course, the PBM Defendant compensation for any particular “specialty” brand drug will depend upon specific contractual terms.

243. Based upon the same PhRMA report, the PBM Defendants typically receive at least twice as much compensation from manufacturer “service fees” compared to “rebates” for “traditional” brand drugs (assuming a higher 20% rebate rate). Of course, the PBM Defendant compensation for any particular “traditional” brand drug will also depend upon specific contractual terms.

244. The comparative contractual dynamics of US “specialty” and “traditional” brand

drugs is consistent with “specialty” drugs being the primary driver of massive Part D spending and fraudulent pricing over the past decade.

245. With ongoing massive price increases, the absolute PBM “service fee” compensation has skyrocketed relative to “rebates”, especially for extreme-priced “specialty” drugs.

246. We use a Defendant “specialty” rheumatoid arthritis drug, Amgen’s Enbrel, to illustrate the astounding economics for both Defendant parties in this collusive “service fee” scheme.

247. The annual US patient AWP cost for Amgen’s Enbrel has increased from about \$18,493 at the start of Part D in 2005 to about \$70,343 in mid-2018, despite declining clinical usage of the drug. See **Exhibit 1**. US Enbrel annual prescriptions have declined about 20% over this timeframe.

248. Assuming a stable 10% manufacturer rebate rate, the full annual Enbrel “manufacturer rebate” increased from \$1,849/patient in 2006 to \$7,034/patient in 2018. The PBM Defendants keep about 10% of the full rebate each year, or about \$185/patient in 2006 and \$703/patient in 2018, a \$518 absolute and 4-fold increase. See **Exhibit 1**.

249. The absolute increase in PBM Defendant compensation via Amgen “service fees”, relative to “retained rebates”, has been magnitudes greater.

250. Using the “8% of sales” PhRMA average “specialty” contract rate, the annual PBM/specialty pharmacy “service fee” payment from Defendant Amgen would be \$1,479 for each Enbrel-treated patient in 2006, rising to \$5,627 per patient in 2018, a \$4,148 absolute and 4-fold increase.

251. The PBM/specialty pharmacy compensation from Defendant Amgen “service fees”

for each US Enbrel-treated patient is 8-fold higher than from “retained “manufacturer rebates”, both in 2005 and 2018. See **Exhibit 1**.

252. “Service fees” from Amgen account for about 90% of PBM Defendant profits from Enbrel, with “retained” rebates comprising virtually all of the remainder.

253. Of course, the “service fee” financial benefit for the PBM Defendants from the scheme pales in comparison to the gains for Amgen from the massive price increases.

254. The net annual US revenues to Amgen for each Enbrel-treated patient (after rebates and fees) rises from about \$15,164 in 2006 to \$57,681 in 2018, a \$42,517 absolute and 4-fold increase. See **Exhibit 1**.

Exhibit 1**Medicare Part D: PBM Defendant "Service Fee" vs. "Rebate" Compensation
Amgen's Enbrel**

	<u>2006</u>	<u>2018</u>	<u>Change</u> <u>2006-2018</u>
AWP Cost/Patient/Year (\$)	\$18,493	\$70,343	\$51,850
Estimated Amgen Rebate Rate	10%	10%	
Total Amgen Rebate (\$)	\$1,849	\$7,034	
PBM Defendant Rebate Retention Rate	10%	10%	
PBM Defendant "Retained" Rebates (\$)	\$185	\$703	\$518
PBM Defendant "Service Fee" Rate	8%	8%	
PBM Defendant "Fee" Retention Rate	100%	100%	
PBM Defendant "Retained" Fees (\$)	\$1,479	\$5,627	\$4,148
Amgen US Revenue/Enbrel Patient (\$)¹	\$15,164	\$57,681	\$42,517

¹Excludes some other potential revenue offsets, especially drug assistance programs.

Source: Redbook/Truven, CMS, PhRMA.

255. Since PBM Defendant “manufacturer rebates” for oral cancer “specialty” brand drugs are absent or minimal in most instances, the “service fee” scheme is particularly severe for the oral CML therapies.

256. We use Novartis Gleevec to illustrate the surging economics for both Defendant parties fueled by massive price increases.

257. The annual US AWP patient cost for Novartis’ Gleevec has increased from about \$38,572 in 2006 to the \$147,788 in 2015, just prior to its early 2016 US patent expiration.

258. In this illustration, we assume no “manufacturer rebates” for Gleevec, with all PBM Defendant compensation via “service fees”. Of note, the GAO report mentioned previously (GAO-10-242, 2010) disclosed that Novartis provided no Part D rebates for Gleevec for the years 2006 through 2008, despite large price increases.

259. Using the “8% of sales” PhRMA average “specialty” contract rate, the annual PBM/specialty pharmacy “service fee” payment from Defendant Novartis would be \$3,086 per Gleevec-treated patient in 2006, rising to \$11,823/patient in 2015, a \$8,737 absolute and more than 4-fold increase.

260. The “service fee” gains for the PBM Defendants paled in comparison to the financial gains for Novartis from the massive Gleevec price increases.

261. The net annual US revenues to Novartis for each Gleevec-treated patient (after rebates and fees) rises from about \$35,486 in 2006 to the \$135,965 range in 2015, an absolute \$100,479 increase and more than 3-fold higher. See **Exhibit 2**.

262. Similar financial dynamics apply to the newer Defendant CML drugs, Novartis’ Tasigna and Bristol-Myers Squibb’s Sprycel, as well as many other extreme-priced oral cancer “specialty” drugs.

Exhibit 2**Medicare Part D: PBM Defendant "Service Fee" vs. "Rebate" Compensation
Novartis' Gleevec**

	<u>2006</u>	<u>2015</u>	<u>Change</u> <u>2006-2015</u>
AWP Cost/Patient/Year (\$)	\$38,572	\$147,788	\$109,216
Estimated Novartis Rebate Rate	0%	0%	
Total Novartis Gleevec Rebate (\$)	\$0	\$0	
PBM Defendant Rebate Retention Rate	10%	10%	
PBM Defendant "Retained" Rebates (\$)	\$0	\$0	\$0
PBM Defendant "Service Fee" Rate	8%	8%	
PBM Defendant "Fee" Retention Rate	100%	100%	
PBM Defendant "Retained" Fees (\$)	\$3,086	\$11,823	\$8,737
Novartis US Revenue/Gleevec Patient (\$) ¹	\$35,486	\$135,965	\$100,479

¹Excludes some other potential revenue offsets, especially drug assistance programs.

Source: Redbook/Truven, CMS, PhRMA.

263. For "traditional" brand pharmaceutical drugs, such as Defendant Pfizer's portfolio, the absolute increase in "service fees" is less for each prescription relative to "specialty" drugs. However, the aggregate fraud is also severe due to the far higher prescription volume for these products.

264. We use Pfizer's Premarin, a menopausal hormonal therapy, to illustrate the financial dynamics of a "traditional" brand drug for the Defendant partners. Estrogen replacement products are among the most widely-prescribed drugs in the US market.

265. In recent years, we estimate that approximately 450,000 Americans were treated with Premarin, compared to about 115,000 with Amgen's Enbrel and 25,000 with Novartis' Gleevec.

266. The AWP cost of a daily Premarin tablet increased from \$1.28 in early 2006 to \$6.43 in mid-2018, a five-fold increase.

267. The annual US AWP Premarin cost/patient has thereby increased from \$467 in 2006 to \$2,347 in 2018, despite plummeting clinical usage.

268. Annual US Premarin prescriptions have decreased about 60-70% over the past decade, due to escalating safety concerns and wide-ranging competition.

269. Assuming a stable 20% "manufacturer rebate", the full Premarin annual "manufacturer rebate" from Defendant Pfizer increased from \$102/patient in 2006 to \$469/patient in 2018. The PBM Defendants keep 10% of the full rebate each year, or about \$10/patient in 2006 and \$47/patient in 2018, a \$37 absolute increase, nearly a 5-fold increase. See **Exhibit 3**.

270. The increase in PBM Defendant compensation from Pfizer via "service fees", relative to "retained rebates", has been far greater.

271. Using the "4% of sales" PhRMA average "traditional" contract rate, the PBM Defendant annual "service fee" payment from Defendant Pfizer would be \$20 for each Premarin-treated patient in 2006, rising to \$94 per patient in mid-2018, a \$73 absolute increase and 5-fold more.

272. Based upon these estimates, the PBM Defendant compensation from Pfizer "service fees" for each US Premarin-treated patient is about twice as much relative to from "manufacturer rebates", both in 2006 and 2018. See **Exhibit 3**.

273. "Service fees" from Pfizer account for about 70% of PBM Defendant profits from

Premarin, with “retained” rebates comprising almost all of the remainder.

274. As with high-cost “specialty” drugs, the “service fee” financial benefit for the PBM Defendants from the scheme pales in comparison to the gains for Pfizer from the massive price increases.

275. The annual net US revenues for Pfizer from each Premarin-treated patient (after rebates and fees) rises from about \$389 in 2006 to the \$1,783 range in 2018, an absolute \$1,394 increase and also nearly 5-fold higher. See **Exhibit 3**.

Exhibit 3

Medicare Part D: PBM Defendant "Service Fee" vs. "Rebate" Compensation Pfizer's Premarin

	<u>2006</u>	<u>2018</u>	<u>Change 2006-2018</u>
AWP Cost/Patient/Year (\$)	\$512	\$2,345	\$1,834
Estimated Pfizer Rebate Rate	20%	20%	
Total Pfizer Premarin Rebate (\$)	\$102	\$469	
PBM Defendant Rebate Retention Rate	10%	10%	
PBM Defendant "Retained" Rebates (\$)	\$10	\$47	\$37
PBM Defendant "Service Fee" Rate	4%	4%	
PBM Defendant "Fee" Retention Rate	100%	100%	
PBM Defendant "Retained" Fees (\$)	\$20	\$94	\$73
Pfizer US Revenue/Premarin Patient (\$)¹	\$389	\$1,783	\$1,394

¹Excludes some other potential revenue offsets, especially drug assistance programs.

Source: Redbook/Truven, CMS, PhRMA.

DETAILS OF THE FRAUDULENT “SERVICE FEE” SCHEME

276. This long-standing, centralized fraudulent pricing scheme, which began from the outset of Medicare Part D, originated from the unique financial incentives regarding rebates and BFSFs incorporated into the program.

277. In Part D, all rebates and discounts provided by drug manufacturer are deducted from “negotiated prices” and serve to lower program and beneficiary drug costs. In sharp contrast, BFSFs are the only major financial item excluded from “negotiated price” determinations in Part D.

278. These shifting disclosure and financial incentives in Part D, which began now more than 15 years ago, were seismic for both the pharmaceutical and PBM industries. However, prior to our Qui Tam Complaints, the public and most health care experts remained unaware.

279. Compounding the abuse, CMS places no restrictions on the amount of BFSFs in Part D and initially placed no BFSF reporting requirements on manufacturers and PBMs, despite documented government concern regarding potential fraudulent abuse.

280. As stated by CMS in 2012: “We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at ‘fair market value’ for bona fide services.” Federal Register, Vol 77, No 22, February 2, 2012.

281. Without sufficient regulatory controls or oversight, nor Part D protection from brand drug price inflation (unlike with Medicaid), the Defendant parties have advanced this BFSF scheme to a staggering magnitude in the first 12-plus years of the program’s existence.

282. Further indicative of long-standing collusion and intent, our investigation determined that the Defendants quickly and secretly first began transitioning to the “service fee” model in the private health insurance market, starting in 2003 with the legislative passage of Medicare Part D, three years before it went into effect in January 2006.

283. This seismic profit model transition is reflected in the 2003-2011 10-K filings of Medco Health Solutions, the largest US PBM prior to its 2012 merger with PBM Defendant Express Scripts. The Medco filings are discussed in greater detail later in the Complaint.

284. According to the Part D regulations, legitimate patient and product support-related BFSFs paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D should be based upon drug and patient utilization.

285. As per the Code of Federal Regulations (CFR) at Sections §423.514 and §423.514 entitled "Reporting requirements for pharmacy benefit manager data": "Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan". (Emphasis added)

286. Rather than linking BFSF payments to drug/patient utilization and legitimate FMV assessment, both the Manufacturer and PBM Defendant parties have violated the FCA and the AKS, with illegitimate BFSF payments in Part D based primarily upon massive, anti-competitive price increases.

287. There are few, if any, "legitimate" or "bona fide" services solely related to a drug's price or massive drug price increases, with the possible exception of patient financial assistance programs (PAPs). Of course, the meteoric increase in financial assistance programs has been essential for advancing this price inflation scheme and deflecting public scrutiny.

288. Part D regulations and legal case precedents have established that all BFSF payments must be paid at "fair market value" (FMV) commensurate with an "arm's length

transaction between unrelated parties”.

289. By law, drug manufacturers bear the primary legal responsibility for the legitimacy of BFSFs, based upon the “Four-Part Test”. 71 Fed. Reg. 69624, 69667-9.

290. By law, in Part D any “service fee” amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in “excess” of FMV must be reported to CMS as “price concessions/discounts” in DIR (i.e., “Direct and Indirect Remuneration”) reports. When doing so, CMS will apply the “discount” to Part D “negotiated prices”, thereby lowering drug prices for beneficiaries and taxpayers.

291. As stated by CMS in 2011: “In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4.” Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated June 6, 2011.

292. A lack of direct BFSF reporting requirements for drug manufacturers, PBMs and specialty pharmacies in Part D has played a key part in maintaining the secrecy of this long-standing scheme.

293. As such, we anticipate that a review of Defendant CMS Part D financial filings may not be of much value in the investigation of these allegations. For instance, with an array of inter-related subsidiaries, the PBM Defendants have many paths to obscure “fee” fraud from regulators.

294. The regulatory reporting deficiencies regarding BFSFs, especially pertaining to drug manufacturers, do not diminish the clear legal liability of the Defendant parties. According to the Part D regulations, manufacturer liability regarding the FMV determination of BFSFs is

unrelated to any CMS reporting or direct disclosure responsibilities.

295. Upon request from government authorities, particularly in a fraud investigation, drug manufacturers must provide detailed information about BFSFs, including the “itemized” services provided for individual drug products, the related payments and a legitimate FMV determination.

296. Given the Part D BFSF reporting deficiencies and the sophistication of the Defendants, a detailed review of all financial transactions between the Manufacturer Defendants and a given PBM Defendant for a particular drug product, at the corporate level, will be required in a thorough investigation.

297. As a condition of both participation and reimbursement in Medicare Part D, the Defendant corporations, their subsidiaries, as well as Chief Executive Officer (CEO) and Chief Financial Officer (CFO), must “expressly certify” against violation of both the FCA and the AKS.

298. In addition to direct “kickback” and false claims allegations, broad “express certification” adds an additional and substantial layer of liability for all the Defendants.

299. The CFR at § 423.505 (4) states: “The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and assumptions related to projected reinsurance and low-income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.”

300. In § 423.505 (4), the CFR further states: “The Chief Executive Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in §

423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this is information will be used for the purposes of obtaining Federal reimbursement."

301. The legal liability of the PBM Defendants, either in their Part D role as plan sponsors or FDRs, has already been established by a prior Qui Tam case, the United States of America, ex. rel. Anthony Spay v. CVS Caremark Corporation.

302. The Spay case definitively established PDE submissions as a "claim for payment". Civil Action 09-4672, US District Court Eastern District of Pennsylvania.

303. As per the Spay Court Order: "The defendants' contracts with the sponsor required them to submit PDEs directly to CMS. Relying on CMS program instructions that stated that PDEs "will enable CMS to make payment," the court held that when the defendants submitted PDEs to CMS they 'clearly' were submitting 'claims' under § 3729(a)(2)."

304. Per the Spay Court Order: "the court ruled that these false statements rendered the claims false because defendants were required by 42 C.F.R. § 423.505(k)(3) to certify that the PDEs submitted to CMS were accurate, complete and truthful, and to acknowledge that the data in the PDEs would be used to obtain federal reimbursement."

305. The Defendant "percent of revenue" BFSF contracts linked to massive price increases fall outside the protection provided by either the "Group Purchasing Organization (GPO)" or the "Personal Services and Management Contracts" Safe Harbors. §1001.952.

306. These Safe Harbors require both FMV compensation and detailed disclosure to both CMS and private payers. Neither requirement has been met in these typically "secretive" BFSF

manufacturer/PBM contract arrangements.

307. The BFSF fraud among high-cost “specialty” drugs has been exacerbated by the increasing dominance of PBM Defendant centralized mail order specialty pharmacies. While the “Any Willing Pharmacy” (CFR at §423.120 (a) (8)) provision prohibits rote exclusion of independent pharmacies from Part D networks, CMS regulations do allow the PBM Defendants to offer “preferred” financial terms to their wholly-owned specialty pharmacies.

308. The PBM Defendants claim the rise of their “narrow networks” lead to lower drug prices for beneficiaries. However, the real PBM incentive for “narrow networks” is to capture the tremendous profit stream from the “service fees” associated with extreme-priced “specialty” drugs.

309. The dominance of the PBM Defendant mail order pharmacies has led to increased concentration of US “specialty” drug volume, further decreasing transparency regarding Manufacturer/PBM Defendant financial transactions.

310. Within these wholly-owned specialty pharmacies, the PBM Defendants have proprietary visibility/discretion over all pharmaceutical transactions, while limiting transparency for CMS and private payers. This unique position provides the PBM Defendants with numerous pathways to obscure the fraudulent BFSFs and other financial transactions with the Manufacturer Defendants.

311. Centralized specialty pharmacies, dominated by the PBM Defendants, now account for most of the prescription volume for the large-spending “specialty” drug categories targeted for severe BFSF fraud in the Relator's Qui Tam filings.

312. According to IMS, 86% of US multiple sclerosis drug prescriptions were dispensed by specialty pharmacies in 2014, up from 73% in 2010. In the anti-TNF inflammatory drug category, in which Defendant AbbVie's Humira and Defendant Amgen's Enbrel compete, 76% of

US prescriptions were dispensed by specialty pharmacies in early 2015, up from 54% in 2009. In the oral chronic myeloid leukemia (CML, cancer) category, in which Defendant Novartis' Gleevec competes, 70% of US prescriptions were dispensed by specialty pharmacies in 2014, up from 49% in 2009.

313. Driven by massive price inflation and "service fee" incentives, manufacturers and their PBM partners have little, if any, incentive to compete on price and/or aggressive rebates for market share.

314. Instead, the true battle behind the scenes is for the terms of "service fee" agreements between manufacturers and PBMs/specialty pharmacies as ALL products in major US brand drug therapeutic categories vastly-inflate in lockstep.

315. The dominant PBM/specialty pharmacies have considerable negotiating leverage with manufacturers, to obtain rebates and prevent price increases, in the wide-distribution, long-standing, top-spending drug categories at the center of this case, namely rheumatoid arthritis, diabetes and the CML segment of the cancer market.

316. Rather than using their leverage to garner savings for taxpayers and beneficiaries in Part D, the PBM Defendants have employed it to gain egregious "service fee" payments.

317. Beyond the Defendant products in crowded drug categories, an increasingly intense battle regarding "service fees" between manufacturers and PBMs/specialty pharmacies has also been underway in recent years regarding more unique "specialty" drugs, which typically face less competition.

318. Notable unique, extreme-priced, high revenue-generation, "specialty" drugs include AbbVie's Imbruvica (leukemia), Roche's Esbriet (pulmonary hypertension) and various other small population, extreme-cost "specialty" drugs.

319. For these “unique” products populations, manufacturers increasingly seek “limited distribution” specialty pharmacy networks. In some instances, the manufacturer may use an “exclusive” specialty pharmacy.

320. In these situations, the manufacturers have strong negotiating leverage with the PBM Defendants and smaller PBM/specialty pharmacy operators, such as Diplomat Pharmacy. To maximize profits, manufacturers seek to pay “service fees” to only a limited number of PBM/specialty pharmacies.

321. Prior to Part D, “limited distribution” drug arrangements were primarily employed for drugs that carry major safety risks, as per the FDA’s Risk Evaluation and Mitigation Strategy (REMS) program. However, without any regulatory restrictions and the aberrant “service fee” incentives, “limited distribution” arrangements are now increasingly employed primarily for financial reasons.

322. Both the manufacturers and PBM/specialty pharmacies in these arrangements have a strong incentive to aggressively increase prices at the expense of their payer clients.

323. Certain “limited distribution” arrangements suggest a potential for severe “service fee”-related pricing abuse, especially for products of little clinical value and/or those dependent upon severe price increases for US-centric revenue growth. Both partners in this arrangement may be perversely motivated to vastly increase drug prices and use, rather than to prevent inappropriate spending for clients.

324. Over the past decade, the sole distribution arrangement with Express Scripts for Mallinckrodt/Questcor’s Acthar suggests a high likelihood of severe “service fee” abuse. The arrangement between Questcor and Express Scripts was signed coincidentally with an announced massive Acthar price increase in 2007, just after the start of Part D.

325. Acthar is an unusual product which gained a broad “grandfathered” label from the FDA, for a wide array of autoimmune indications, prior to the 1960’s when the agency began requiring clinical trial proof for approval. Most expert physicians see little clinical utility for Acthar beyond a rare pediatric seizure condition.

326. Regardless, Questcor (later acquired by Mallinckrodt), with help from a dedicated “marketing” team from Express Scripts, turned the product into a billion dollar blockbuster by serially promoting Acthar for a variety of these clinically-unproven medical uses.

327. Other older “unique” specialty products that offer the potential for “service fee” abuse include Jazz Pharmaceutical’s Xyrem (narcolepsy) and Mylan’s Epipen (emergency allergic treatment). The primarily US-based revenue growth for both of these products has also been driven, in large part, by massive price increases.

328. Prior US Department of Justice PBM Defendant case settlements have already established negligence in the FMV of BFSFs as a basis for false claims and kickbacks.

329. On September 7, 2005, a Settlement Agreement was entered between the United States, Advanced PCS (now part of PBM Defendant CVS Health) and three Relators. In the Settlement, AdvancePCS paid the sum of \$137.5 million to resolve allegations brought forth by the US government.

330. As per the Advance PCS Settlement document: “The United States alleges that...AdvancePCS allegedly solicited and/or received payments of (a) administrative fees from pharmaceutical manufacturers for services related to the negotiation and administration of rebate contracts with those manufacturers, and (b) fees for products and services agreements from pharmaceutical manufacturers...”

331. The Advanced PCS settlement document further states: “The United States also

alleges that to the extent that the payments exceeded the value of the above-referenced services and products, AdvancePCS knowingly caused false claims to be made to OPM and false Medicare claims to be made to HHS. In addition, the United States alleges that AdvancePCS knowingly caused false Medicare claims to be made to HHS in connection with soliciting and/or receiving kickbacks in the nature of payments exceeding the value of the above-referenced services and products.”

332. Our investigation also indicates a high likelihood of “sham” BFSF payments (i.e. FMV equal to zero) from the Manufacturer Defendants to the PBM Defendants for services that are not actually being provided.

333. All the PBM Defendants make extensive claims regarding “clinical support” they are providing to physicians and patients, especially regarding “specialty” drugs. Common clinical support services highlighted by the PBM Defendants include injection training, patient consultations regarding drug efficacy/safety, input regarding drug selection and drug adherence programs.

334. However, extensive Relator interviews with specialist physicians uniformly indicate that the vast majority of clinical “support services” are actually being provided by office medical staff or directly by drug manufacturers, not the PBM Defendants or their affiliated specialty pharmacies.

335. The dominant role of centralized mail order pharmacies for the distribution of “specialty” drugs indicates that the PBM Defendants are greatly overstating their “clinical support services”. Simply put, even for patients newly-started on “specialty” drugs, the PBM Defendants typically have minimal, if any, in-person contact.

336. Furthermore, for the vast majority of patients that are stable on chronic drug

therapy, potential PBM/specialty pharmacy “services”, beyond simply mailing the prescription, are scant. Our discussions with both expert physicians and “specialty” drug-treated patients verify these findings.

337. The potential for “sham” “service fee” payments may be even greater for oral drugs, including the oral CML “specialty” drugs and Pfizer’s “traditional” products in this case. For many of these chronically-administered oral drugs, our investigation suggests few legitimate “support services” are being provided by the PBM Defendants (via their remote specialty pharmacies) for the vast majority of patients, beyond simply filling and mailing the prescription.

338. While the majority of the fraudulent drug costs enabled by the Part D BFSF scheme have been borne by US taxpayers at the federal level, state drug spending fraud has also been severe.

339. Prior to 2006, low-income seniors and disabled individuals who qualified for both Medicare and Medicaid received outpatient drug benefits through state Medicaid programs. When Medicare Part D was implemented in 2006, these “dual eligible” beneficiaries began receiving drug coverage under Medicare Part D, without recourse.

340. Due to their compromised health, these “dual eligibles” accounted for 50% of Medicaid drug costs and the majority of extreme-priced “specialty” drug spending prior to the transfer, despite only comprising 13% of the Medicaid enrollment in 2005. OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.

341. By law, each state is required to fund about a third of Medicare Part D spending for their respective “dual eligibles” via “clawback payments” to CMS. From 2006 through 2016, states made cumulative “clawback” payments of \$80.7 billion to CMS. 2017 Medicare Trustees Annual

Report, July 2017.

342. Medicaid requires additional manufacturer rebates for all annual brand price increases greater than inflation (CPI-Urban) whereas Medicare Part D provides no such protection. After many years of severe price increases, the Medicaid net cost for many brand drugs, especially older “specialty” drugs, is now a fraction of the Part D price.

343. The Relator obtained propriety information indicating that the Medicaid 2013 net cost for long-marketed “specialty” and “traditional” US brand drugs are now commonly 80-90% below the cost in Part D.

344. In its most recent comparison of Medicaid and Medicare Part D rebates, the Office of Inspector General (OIG) concluded that “the inflation-based additional rebate, meant to protect Medicaid from large drug increases in drug prices, was the primary reason that Medicaid rebates were higher than Part D rebates”. OIE-03-10-00650, Medicaid Rebates For Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.

345. From the same report: “for the 200 brand-name drugs with the highest Part D expenditures in 2012, rebates accounted for 47 percent of Medicaid expenditures, whereas rebates totaled 15 percent of Part D expenditures.”

346. If state “dual eligibles” had remained within Medicaid, their brand drug costs would now be a fraction of the cost in Medicare Part D. A significant portion of state “clawback” payments since the start of Part D have been driven by the “service fee” fraudulent pricing scheme.

347. Our investigation also indicates fraudulent abuse of the essential Part D plan sponsor “catastrophic” cost-sharing requirements. In Part D, plan sponsors (i.e., the insurance entities) are required to pay 15% of all drug costs above a very modest annual threshold (\$3,600

in 2006, rising to \$5,000 in 2018).

348. This “cost-sharing” exposure was expected to motivate plan sponsors to negotiate aggressively with manufacturers to get favorable prices for high cost “specialty” drugs. However, this essential cost-control mechanism has broken down because, in practice, the PBM Defendants (and their wholly-owned subsidiaries) surprisingly serve as the plan sponsor, PBM and specialty pharmacy for the majority of Part D plans and beneficiaries.

349. After more than a decade of massive price inflation, the PBM Defendants (in their function as plan sponsor) are responsible for about \$10,000 of “catastrophic” annual drug costs for each US Part D autoimmune patient treated with Amgen’s Enbrel or AbbVie’s Humira.

350. At its final \$150,000 annual price in late 2015 (just prior to its February 2016 patent expiry), plan sponsors would be responsible for approximately \$20,000 in “catastrophic” cost-sharing for each Part D leukemia patient treated with Defendant Novartis’ Gleevec.

351. The dominant PBM Defendants have similar or even greater “catastrophic” cost-sharing exposure for many other Part D beneficiaries treated with high cost “specialty” drugs, especially for cancer and hepatitis C.

352. We concluded that the Manufacturer Defendants, in many instances, are “forgiving” the PBM Defendants for this “catastrophic” exposure in order to further the “service fee” pricing scheme.

353. Without this cost-sharing “forgiveness”, massive plan sponsor “catastrophic” exposure for the PBM Defendants would have led to legitimate price negotiation with the Manufacturer Defendants, preventing most, if not all, of the Defendant drug price inflation. The potential abuse of Part D “catastrophic” cost-sharing requirements appears aided by minimal Defendant CMS reporting requirements.

STAGGERING FRAUD FOR FOURTEEN DEFENDANT BRAND DRUGS

354. While the “service fee” business model is now employed systemically, this case focuses on a select group of older US “blockbuster” drugs in which the scheme has been advanced to a staggering degree.

355. For most of the Defendant drugs, the decade-plus long “service fee” scheme has yielded an astounding 4-6 fold increase in prices, despite plummeting clinical use, prescription volume and market share.

356. The 14 Defendant brand drugs are: AbbVie’s Humira (arthritis/inflammatory conditions, FDA-approved 2003); Amgen’ Enbrel (arthritis/inflammatory conditions, 1997), Novartis’ Gleevec (cancer, 2001), Novartis’ Tasigna (cancer, 2007), Bristol-Myers Squibb’s Sprycel (cancer, 2006), Sanofi’s Lantus (insulin for diabetes, 2000), Eli Lilly’s Humulin (insulin for diabetes, 1982), as well as Pfizer’s Lyrica (neuropathic pain, 2004), Viagra (erectile dysfunction, 1998), Celebrex (osteoarthritis/pain, 1998), Chantix (smoking cessation, 2006), Premarin (hormone replacement/osteoporosis, 1942), Pristiq (depression, 2008) and Relpax (migraine, 2002).

357. The extreme divergence between pricing and volume trends for these drugs is clearly indicated in **Exhibit 4**.

Exhibit 4**Massive Defendant Product Price Inflation
Eroding or Slowing Patient Use**

<u>Product (US Approval)</u>	2006	2018	2006-18	Percent Change in	
	Annual	Annual		US Treated Patients ^{3, 4}	
	Patient Cost	Patient Cost	Change in	2006-16	2010-16
	<u>AWP (\$) ^{1, 2}</u>	<u>AWP (\$) ^{1, 2}</u>	<u>AWP</u>		
Enbrel (Amgen, 1997)	\$18,493	\$70,343	3.8x	-22%	-11%
Humira (AbbVie, 2003)	\$20,920	\$69,235	3.3x	207%	82%
Gleevec (Novartis, 2001)	\$48,050	\$147,788	3.1x	19%	-6%
Tasigna (Novartis, 2007)	\$83,238	\$198,854	2.4x	-	387%
Sprycel (Bristol, 2006)	\$64,496	\$188,516	2.9x	-	209%
Lantus (Sanofi, 2000)	\$1,405	\$5,903	4.2x	79%	28%
Humulin (Eli Lilly, 1982)	\$660	\$3,257	4.9x	-47%	-34%
Lyrica (Pfizer, 2004)	\$1,517	\$6,512	4.3x	59%	8%
Viagra (Pfizer, 1998)	\$550	\$3,879	7.1x	-58%	-42%
Celebrex (Pfizer, 1998)	\$1,220	\$5,282	4.3x	-40%	-20%
Chantix (Pfizer, 2006)	\$1,402	\$6,278	4.5x	-	-14%
Premarin (Pfizer, 1942)	\$512	\$2,347	4.6x	-	-57%
Pristiq (Pfizer, 2008)	\$1,494	\$5,092	3.4x	-	-29%
Relpax (Pfizer, 2002)	\$879	\$3,587	4.1x	-	-18%

¹ From Redbook/Truven Analytics Pricing Database.

² Patient cost estimates based upon average FDA-approved maintenance dose.

³ IMS Health National Prescription Audit (NPA) database and our estimates.

⁴ Gleevec data through 2015, prior to February 2016 US patent expiration;
Celebrex data through 2014, prior to 2015 US patent expiration.

358. As per **Exhibit 4**, the clinical usage of all but 5 of the Defendant drugs (Humira, Sprycel, Tasigna, Lantus and Lyrica) has been in significant decline.

359. Despite the eroding clinical use, and counter to any competitive market rationale,

all these Defendant products have had massive price increases instituted by the manufacturer over the past decade.

360. None of the manufacturers has disclosed any unique factors, such as drug shortages, which could have contributed to the price increases.

361. For the 5 products with rising clinical use over the decade, vast price increases have occurred despite escalating competition from a variety of new clinically-similar drugs.

362. Further suggestive of severe anticompetitive activity, price inflation has been virtually uniform and lockstep for all drugs in the major therapeutic categories in which the Defendant products compete.

363. In the rheumatoid arthritis, diabetes and CML cancer categories, all new drugs reaching the US market over the past decade have been launched at a parity or above the prices of fast-inflating older drugs. Thereafter, all manufacturers continue to increase prices aggressively in lockstep, as the “service fee” scheme advances.

364. We provide specific details regarding the pricing trends for the Defendant products and the therapeutic categories later in the Complaint.

365. The PBM “savings” opportunity, via aggressive rebate and price negotiations, should be considerable in top-spending US therapeutic brand drug categories crowded with numerous clinically-similar drugs - i.e., such as the rheumatoid arthritis, cancer and diabetes categories at the center of this case.

366. As the scrutiny of US drug pricing has escalated, drug manufacturers have increasingly argued that they are not receiving much of the financial benefit from vast AWP “list” price increases.

367. Statements of this nature are simply untrue regarding the Manufacturer Defendant

brand drugs targeted in this case. Based on their own SEC-reported financial statements, these Manufacturer Defendants have received vast US revenue and profit gains from the massive price increases over the past decade-plus.

368. The divergent pricing trends for brand drug prices in the US and Europe clearly indicates the role of both Medicare Part D and PBMs in this domestic price inflation scheme. Of note, the PBM industry is a uniquely American industry, with a minimal presence outside of this country.

369. Prior to the arrival of Medicare Part D, the cost of the Defendant brand drugs were approximately at parity among the US and major European countries.

370. Now, more than 12 years after the arrival of Part D (administered by PBMs), the cost for these drugs is typically 4-8 fold higher in the US compared to major European countries. Massive price inflation has occurred in the US, while prices for these “old” drugs have change little in Europe.

371. For instance, as of the spring of 2017, the annual US cost of AbbVie’s Humira and Amgen’s Enbrel was more than 4-fold higher than in Europe. The annual US cost of Sanofi’s Lantus (long-acting insulin) was 7-8 fold higher compared to Europe. Joseph Cruz, April 6, 2017.

372. The annual US cost of Pfizer’s Lyrica was nearly 5-fold higher compared to major European nations. Biostrategies Analytics, March 18, 2017.

373. For these declining and competitively-challenged Defendant drug products, stable European prices indicate a properly functioning marketplace. In sharp contrast, the US market has become distorted by the systemic and fraudulent “service fee” scheme between drug manufacturers and the dominant PBM Defendants.

374. In **Exhibit 5**, we provide the contribution of price increases and utilization to SEC-

reported US sales for the 8 Defendant products that have been available since the 2006 start of Medicare Part D.

375. Most of these brands are top-spending drugs both in the private insurance market and Medicare Part D. Humira is now the top-spending drug both in the US and worldwide. Enbrel and Gleevec have been among the top 10 Part D US drugs in terms of spending for most plans over the past decade. Until recently, Lantus was the top-spending single drug in Medicare Part D.

Exhibit 5

Manufacturer Defendant US Product Sales: 2005-2017 Driven by Massive Price Increases

	2005 Reported US Sales (\$mil)	2017 Reported US Sales (\$mil)	2017 Sales at 2005 Prices (\$mil)	Reported US Sales Growth 2005-2017	Growth Without Price 2005-2017
Enbrel (Amgen)	\$2,470	\$5,206	\$1,892	111%	-23%
Humira (AbbVie)	560	12,361	3,809	2107%	580%
Gleevec (Novartis) ¹	524	2,533	696	383%	33%
Lantus (Sanofi)	846	4,046	1,775	378%	110%
Humulin (Eli Lilly)	411	885	173	115%	-58%
Lyrica (Pfizer) ²	717	3,463	1,165	383%	62%
Viagra (Celebrex) ³	796	1,148	265	44%	-67%
Celebrex (Pfizer) ⁴	1,577	1,735	951	10%	-40%
Total Revenues	\$7,901	\$31,377	\$10,726	297%	36%
Total Ex Humira	\$7,341	\$19,016	\$6,917	159%	-6%

¹ US Gleevec sales in 2015, prior to early 2016 patent expiry.

² 2006 Pfizer product US sales.

³ Viagra 2016 US sales, prior to 2017 patent expiry.

⁴ Celebrex 2014 US prior to 2015 patent expiry.

Source: Company Reports, Truven/Redbook and our estimates.

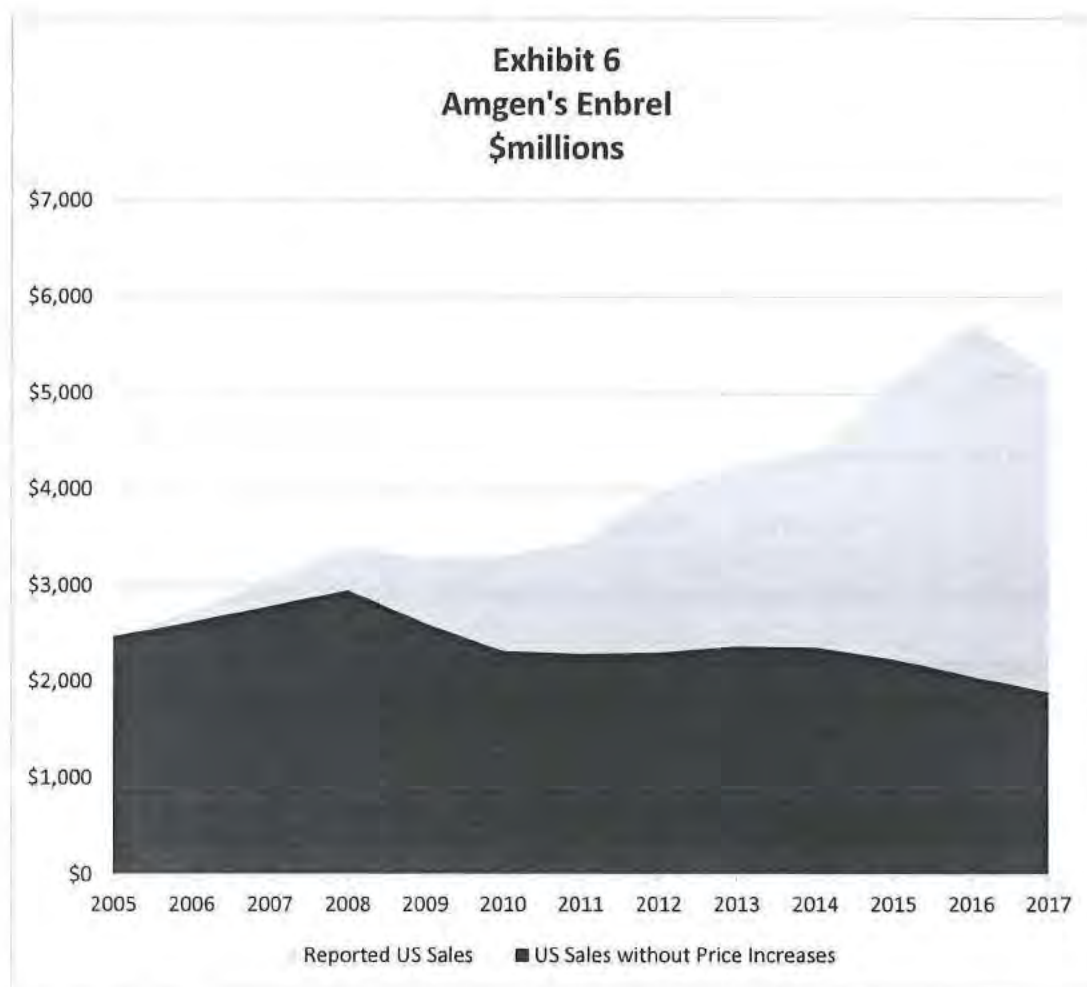
376. Based upon reported sales, public pricing data and documented utilization trends, we calculate that nearly 90% of the SEC-reported annual US revenue increase, between 2005 and 2017, for these eight major Defendant products has been driven by price increases.

377. Overall, we calculate that US sales for these 8 products would only have increased from about \$7.9 billion in 2005 to about \$10.7 billion in 2017, based solely on prescription volume.

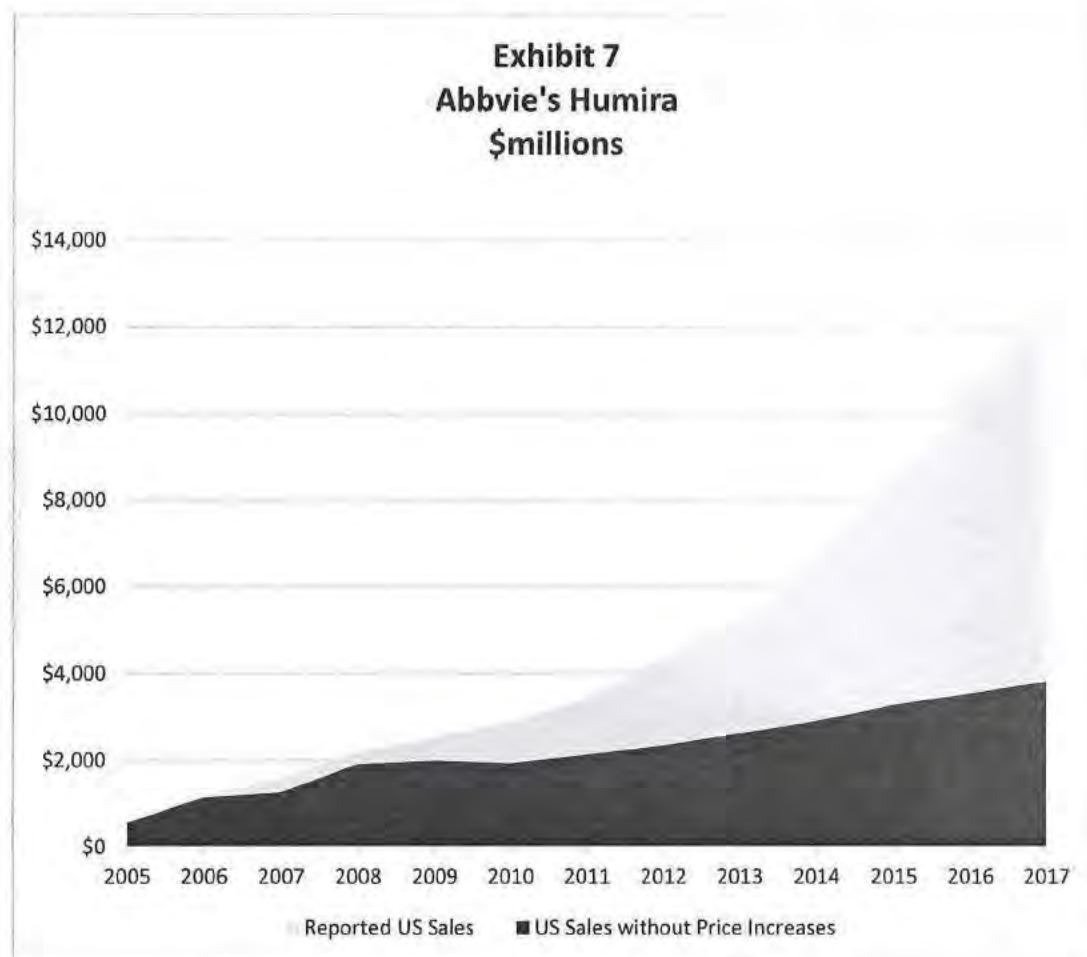
378. Instead, driven by massive price increases, the SEC-reported US sales for these products has more than tripled to \$31.4 billion in 2017.

379. The staggering, cumulative US public harm over the past decade-plus is well-illustrated by the graphic contribution of price and volume to SEC-reported US sales for the major Defendant drugs.

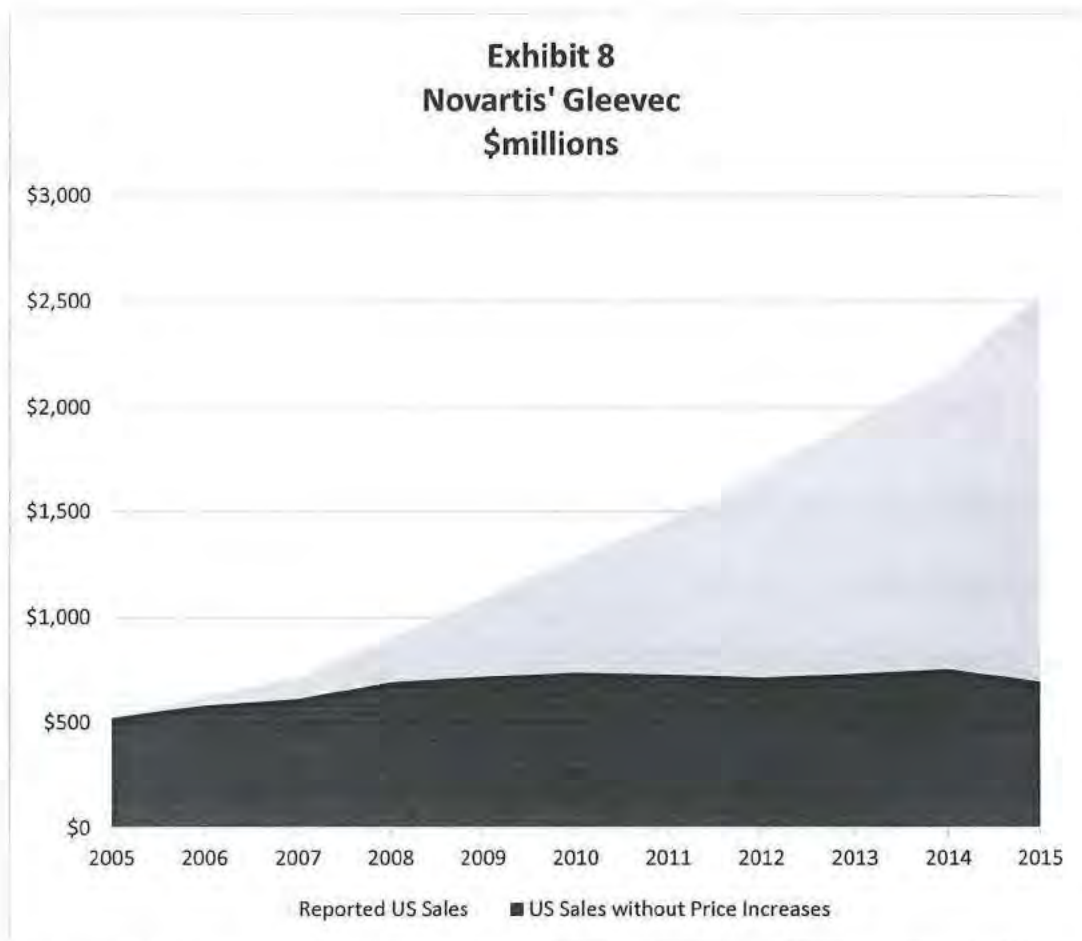
380. For Amgen's Enbrel, SEC-reported US sales increased from \$2.5 billion in 2005 to \$5.2 billion in 2017. The AWP annual US patient cost of Enbrel has increased from about \$17,600 in 2005 to \$70,000 in mid-2018. US annual prescriptions for Enbrel have decreased approximately 20% over this period. Without price increases, US annual Enbrel sales would have decreased to the \$1.9 billion range in 2017. See **Exhibit 6**.



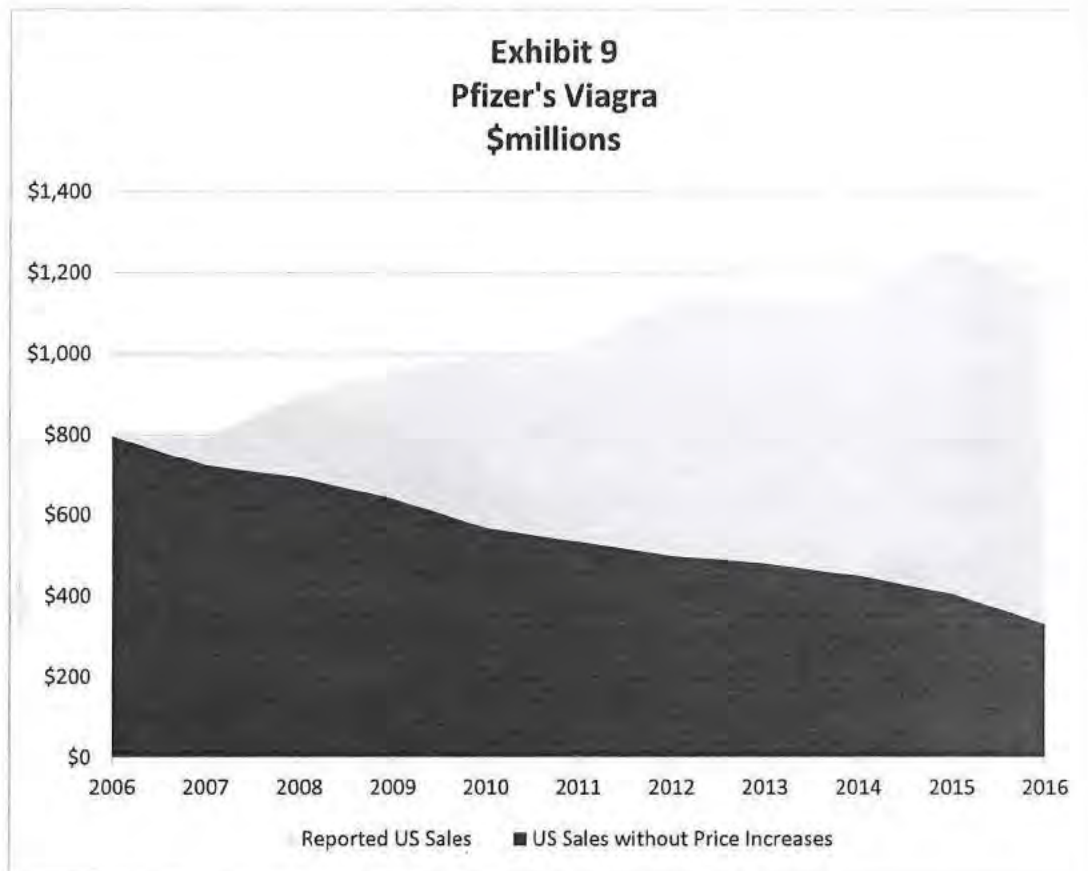
381. The absolute financial harm from vast price increases has been greatest for AbbVie's Humira due to its wide use and volume growth. Humira SEC-reported US sales have increased from about \$560 million in 2005 to \$12.4 billion in 2017. Humira is now the top-selling drug both in the US and worldwide. Over this time period, US Humira prices have increased in lockstep with Amgen's Enbrel, with an AWP patient/year cost of about \$69,235 in mid-2018. Without price increases, US Humira sales would have only been in the \$3.8 billion range in 2017, only about a third of the reported sales level. See **Exhibit 7**.



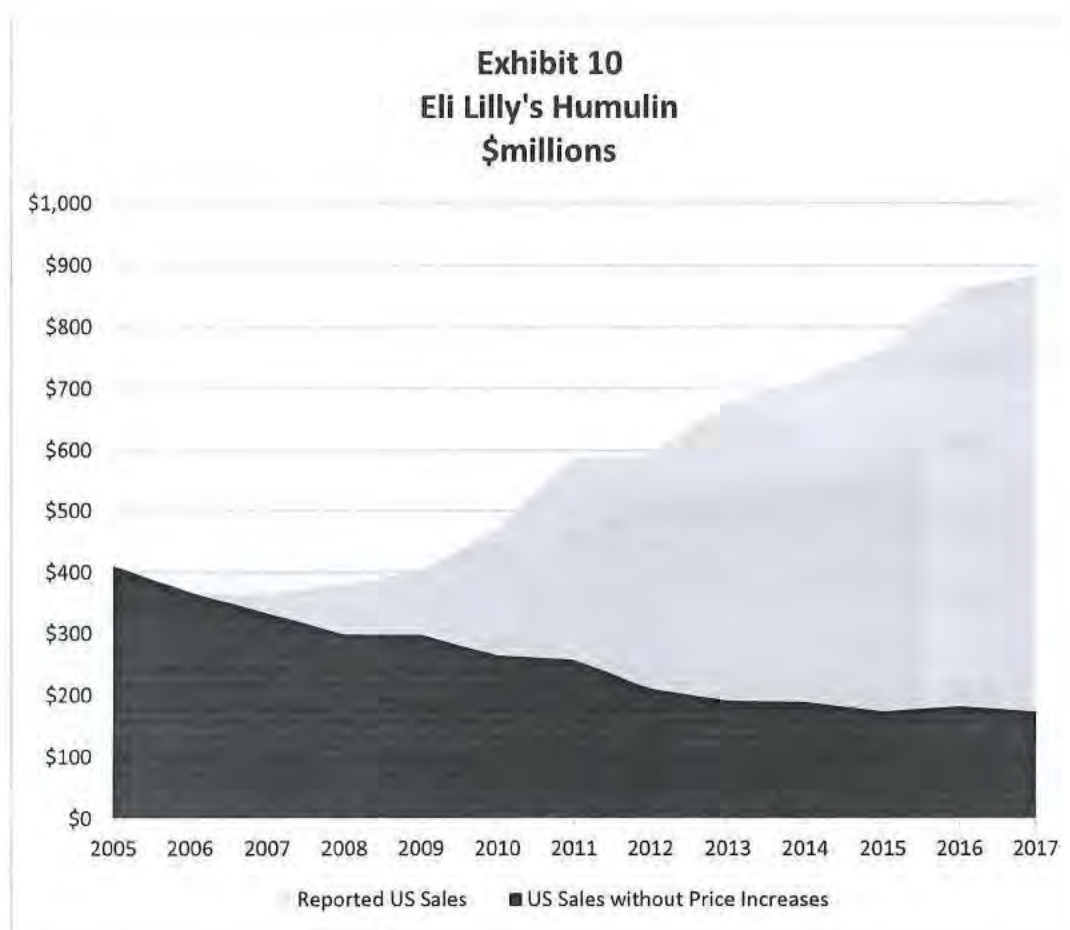
382. Novartis' Gleevec provides a startling example of pricing abuse in the US cancer market. SEC-reported US Gleevec sales rose from \$524 million in 2005 to \$2.5 billion in 2015, just prior to its early 2016 US patent expiration. Since the start of Part D, Gleevec's annual US prescriptions grew a modest 20%, but were in decline since 2010. The AWP annual patient cost of Gleevec has increased from about \$35,200 in 2005 to \$147,800 in 2015. Without price increases, 2015 US Gleevec sales would have only been in the \$700 million range. See **Exhibit 8**.



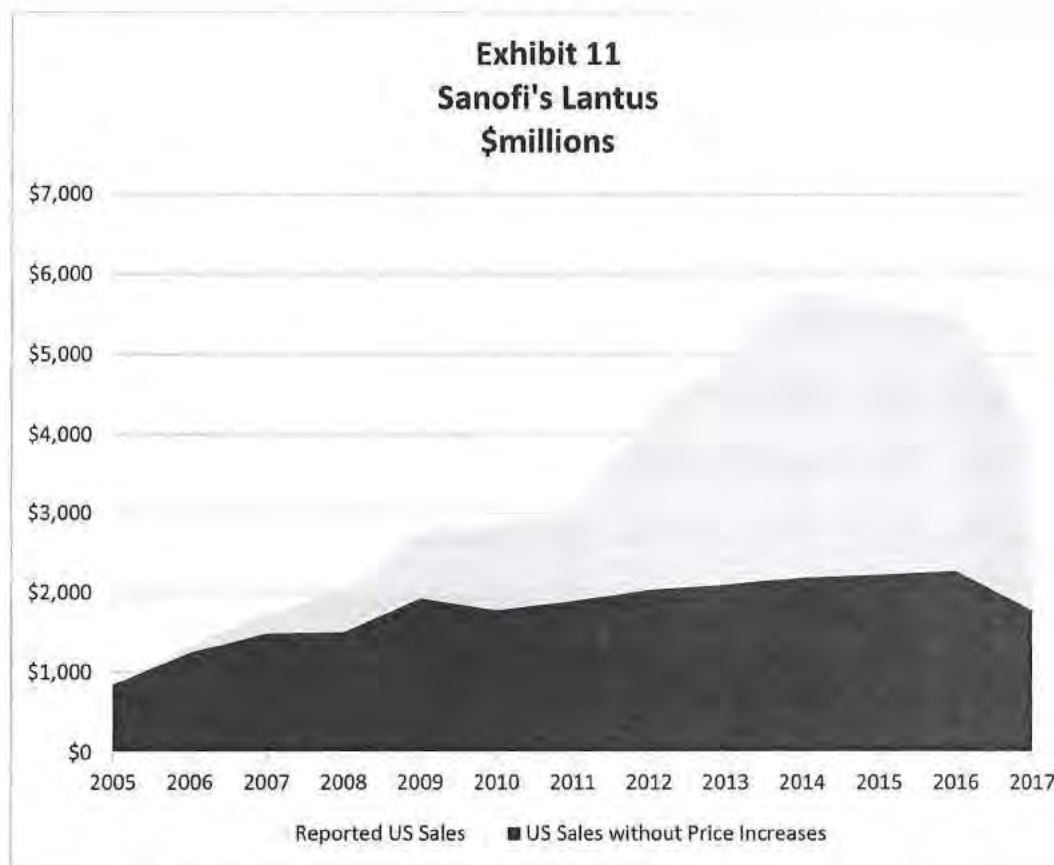
383. For Pfizer's Viagra, SEC-reported US sales rose from \$796 million in 2005 to \$1.15 billion in 2016. The AWP cost of each Viagra pill has increased from about \$11.46 in 2005 to \$80.82 in mid-2018. US annual prescriptions for Viagra have decreased approximately 40% over this period. Without price increases, US Viagra sales would have fallen to the \$330 million range in 2016. Viagra's US patent expired in late 2017. See **Exhibit 9**.



384. For Eli Lilly's Humulin, SEC-reported US sales increased from \$411 million in 2005 to \$885 million in 2017. The AWP annual US patient cost of Humulin (for a 50 unit daily dose) has risen from about \$606/patient in 2005 to the \$3,260 range in mid-2018. US annual prescriptions for Humulin have decreased approximately 40% over this period. Without price increases, US Humulin sales would have fallen to the \$175 million range in 2017. See **Exhibit 10**.



385. For Sanofi's Lantus, SEC-reported US sales increased from about \$850 million to a peak of about \$5.8 billion in 2014, before decreasing to about \$4.1 billion in 2017 as scrutiny and competition in the insulin category escalated. These US sales amounts include Sanofi's Toujeo, a concentrated version of Lantus, which was FDA-approved in February 2015. The AWP annual US patient cost of Lantus (for a 50 unit daily dose) has risen from about \$1,318/patient in 2005 to the \$5,606 in mid-2018. Without price increases, 2017 US Lantus/Toujeo sales would have been in the \$1.8 billion range in 2017, less than half of the reported amount. See **Exhibit 11**.



386. In **Exhibit 12**, we summarize the estimated “service fee” and US sales fraud, by Defendant product for the 2006-2017 period. The fraud estimates are truly staggering due to the magnitude of massive price increases and the cumulative/compounding impact of this long-standing scheme.

387. For the 14 Manufacturer Defendant products targeted in this Complaint, we estimate nearly \$114 billion of cumulative fraudulent US drug sales have been enabled by the scheme between 2006 and 2017, with the fraud ongoing and escalating. We estimate that 30% of this fraud has occurred in Medicare Part D.

388. Our estimates for fraudulent Manufacturer Defendant US product sales are nearly double those from our prior October 2014 SDNY Qui Tam filing, due to ongoing, severe and

lockstep price increases for the Manufacturer Defendant brand drugs

389. We further estimate that this sales fraud has been enable by approximately \$7.0 billion in fraudulent “service fee” payments from the Manufacturer Defendants to the PBM Defendants over the past decade and more. Our direct “service fee” fraud estimate is calculated using the PhRMA disclosed “service fee” contract rates of 8% and 4% “of “list” price revenues, for “specialty” and “traditional” Defendant products, respectively.

390. Our estimates for direct fraudulent “service fee” payments from the Manufacturer Defendants to the PBM Defendants have more than triple since our initial October 2014 Qui Tam filing, primarily due to the higher “8% service contract” rate for “specialty” drugs, disclosed by PhRMA. Our prior filing utilized a conservative “4% of sales” “service fee” contract rate for all Defendant drugs.

Exhibit 12**Staggering Cumulative Financial Harm: 2005-2017****Direct "Service Fee" and US Sales Fraud**

(\$ million)

	Direct "Service Fee" <u>Fraud (\$mil)¹</u>	US Sales <u>Fraud (\$mil)</u>	Estimated Part D Market <u>Share (%)</u>
Enbrel (Amgen)	\$1,528	\$19,105	30%
Humira (AbbVie)	2,585	32,308	30%
Gleevec (Novartis)	542	7,436	60%
Tasigna (Novartis)	113	1,023	60%
Sprycel (Bristol-Myers)	199	2,514	60%
Lantus (Sanofi)	855	21,384	30%
Humulin (Eli Lilly)	165	4,124	30%
Lyrica (Pfizer)	395	9,885	30%
Viagra (Pfizer)	227	5,670	20%
Celebrex (Pfizer)	170	4,262	35%
Chantix (Pfizer)	61	1,525	15%
Premarin (Pfizer)	109	2,725	30%
Pristiq (Pfizer)	51	1,264	25%
Relpax (Pfizer)	17	421	15%
Total	\$7,017	\$113,647	

1 Using 8% PhRMA "specialty" drug average "service fee" contract rate.

Source: Corporate reports, PhRMA, Redbook/Truven, our estimates.

391. Our cumulative estimates of US sales fraud for the individual Manufacturer Defendant drugs are similarly staggering.

392. As the top-selling product in the US and worldwide, the US sales fraud estimate is greatest for AbbVie's Humira, at more than \$32 billion between 2006 and 2017. Close behind are the fraud estimates for Enbrel and Lantus, at \$19 billion and \$21 billion, respectively.

393. However, the sales fraud estimates are also large for other Defendant drugs, due to their severe fraudulent price inflation over more than a decade.

394. In this action, we seek restitution for the massive overpayment of Part D drug costs and “service fees” generated by this systemic price collusion scheme, plus treble damages.

EVIDENCE OF SEVERE PART D CATASTROPHIC “COST-SHARING” FRAUD

395. The escalating “service fee” scheme for extreme-priced “specialty” drugs has also fueled severe financial fraud regarding essential Part D plan sponsor “catastrophic” cost-sharing requirements.

396. The evidence of “catastrophic” abuse has particularly escalated in the recent years, with the annual patient cost of “specialty” drugs now routinely in the \$70-200,000 or more price range.

397. In Part D, taxpayers (via the Part D “Reinsurance Subsidies”) cover 80% of all drug costs for any beneficiary crossing a modest annual “catastrophic threshold”, which was \$3,600 in 2006 and rose to \$5,000 in 2018.

398. For extreme-priced “specialty” drugs, typically with an annual treatment cost now in the \$70-200,000 range (\$5,000-16,700 or more per month), most treated Part D patients now cross the “catastrophic threshold” in the first 1-2 months of each calendar year.

399. In order to incentivize aggressive price negotiation with manufacturers, Part D requires plan sponsors to cover an unlimited 15% of all “catastrophic” spending for beneficiaries.

400. This “cost sharing” requirement is the central Part D mechanism to incentivize cost control and legitimate negotiation with drug manufacturers regarding extreme-priced “specialty” drugs in the program.

401. However, as noted previously, since the PBM Defendants serve all three key

functions (plan sponsor, PBM and specialty pharmacy) for the majority of Part D plans and beneficiaries, this “independent” plan sponsor function has been compromised.

402. The failure of this essential cost-control mechanism is indicated by the vast increase in Part D “catastrophic” spending in recent years.

403. Massive unanticipated “catastrophic” over-spending has been the primary driver of accelerating Part D spending in recent years. In 2016, Part D “catastrophic” spending was \$34.8 billion, up more than 3-fold just since 2010 and from only \$6 million in 2006.

404. “Catastrophic” spending accounted for less than 15% of Part D spending in 2006, rising to 38% of program spending in 2016. According the 2017 Medicare Trustees Report, “catastrophic” spending is forecasted to be \$42.1 in 2018 and more than \$80 billion by 2026, remaining the primary driver of Part D spending growth.

405. The “catastrophic” overspending in recent years has been fueled by the massive inflation of older “specialty” drugs, as well as the broad Part D use of new hepatitis C therapies and extreme-priced cancer drugs.

406. In a properly-functioning marketplace, this excess spending should have placed an extreme financial burden on Part D plan sponsors, including the dominant PBM Defendants.

407. A MedPAC report from June 2015 indicated that plan sponsors had under-forecasted Part D “catastrophic” spending by more than \$6 billion in 2013 (or by more 50%) of the actual “catastrophic” spending of \$19 billion for the year. MedPAC Report to Congress: Medicare and the Health Care Delivery System, June 2015, Chapter 6, “Sharing Risk in Medicare Part D”,

408. Consistent with their dominant plan sponsor role in the Part D program, in the MedPAC report 70% of the unforeseen “catastrophic” spending was attributed to the four largest

PBM Defendants, Express Scripts, CVS Health, UnitedHealth Group and Humana.

409. At the 15% cost-sharing rate, the \$6 billion in excess Part D “catastrophic” spending in 2013 corresponds to unforeseen plan sponsor additional “cost-sharing” exposures of more than \$900 million just for that single year for all plan sponsors and about \$630 million for the four largest PBM Defendants.

410. Furthermore, the bid, premium and actual “catastrophic” spending data suggest a further marked acceleration in unforeseen plan sponsor “cost-sharing” for 2014 and 2015.

411. Aggregate plan sponsors forecasted a 40% increase in Part D “catastrophic” spending between 2013 and 2015. The actual 2015 “catastrophic” spending came in at \$33.2 billion, 73% higher than 2013.

412. We estimate Part D plan sponsors (i.e., primarily the PBM Defendants) underestimated combined 2014 and 2015 “catastrophic” spending by another \$10 to \$20 billion.

413. This additional program spending led to an estimated \$1.5 to \$3.0 billion in unforeseen “cost sharing” expenses for aggregate Part D plan sponsors for 2014 and 2015 combined, with the four largest PBM Defendants responsible for about \$1.1 to \$2.1 billion.

414. Despite this large unforeseen “cost-sharing” burden, all the PBM Defendants have reported robust financial results for 2013-2015 and none has indicated significant financial challenges in Part D.

415. This fact is inconsistent with both the huge financial burden faced by the PBM Defendants from the “catastrophic” over-spending and the typically low operating profit margins (5-6% range) for Part D plan sponsors in their annual bids submitted to CMS.

416. In reality, the massive “catastrophic” cost over-runs should have reeked financial havoc among PBM Defendants in Part D, but it never materialized.

417. To put the magnitude of this unforeseen plan sponsor cost-sharing burden in perspective, the Part D plan bids for all sponsors across the nation in 2007 included "expected profits" of only \$1.07 billion. GAO Report OEI-02-08-00460, Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.

418. Based upon the 2015 plan bids (average \$130/beneficiary) and annual enrollment (39.2 million people), we estimate aggregate Part D profits in the \$3.0-3.5 billion range for aggregate US Part D plan sponsors for 2015.

419. There is no mathematical possibility that the dominant PBM Defendants could handle these massive unforeseen 2013-2015 "catastrophic" cost-sharing requirements (approximately \$2.4 to \$3.9 billion), without severe disruption to their financial performance and the overall Medicare Part D program.

420. This amount of unforeseen "catastrophic" cost-sharing would have negated virtually all Part D profits for the three year period.

421. The only way the PBM Defendants could avoid the tremendous dislocation from this unforeseen "cost sharing" exposure is through another secretive fraudulent financial arrangement with drug manufacturers.

422. We concluded that, in many instances, manufacturers are fraudulently excusing the PBM Defendants from their 15% "catastrophic" cost-sharing exposure (in their role as plan sponsors), in order to advance the now pervasive "service fee" pricing scheme.

423. We will Novartis' Gleevec to illustrate the scale of potential plan sponsor "cost-sharing" fraud. See **Exhibit 13**.

424. The annual AWP cost/patient of Gleevec increased from about \$38,572 in 2006 to the \$147,788 in 2015, prior to its early 2016 US patent expiration. In 2015, Gleevec was the second

top-spending cancer drug in Part D (after only Celgene's Revlimid).

425. In Part D, in 2006, the plan sponsor would be responsible for 15% of all Gleevec costs above the \$3,600 threshold, or about \$5,246 in annual costs, payable to the manufacturer, Defendant Novartis.

426. After the massive price increases, the PBM Defendants (in their role as plan sponsor) would be responsible in 2015 for nearly \$21,463 in "cost-sharing" for each Part D Gleevec-treated patient above the modest \$4,700 threshold that year.

427. With these dynamics, it would appear mathematically impossible for the dominant PBM Defendants to pay the escalating plan sponsor Gleevec "cost-sharing" burden driven by the massive price increases.

428. The 15% plan sponsor "cost-sharing" burden would be nearly twice as much as the "service fees" received from a standard "8% of revenue" "specialty" drug contract, leading to considerable losses for the PBM Defendant.

429. With apparently minimal, if any, "rebates" for Gleevec and other oral cancer "specialty" drugs, Novartis "service fees" for Gleevec are the sole source of PBM Defendant profits related to the product.

430. Beyond Gleevec and the other Defendant CML drugs, we suspect widespread abuse of the Part D plan sponsor "catastrophic" cost-sharing requirements for a wide array of extreme-priced oral "specialty" cancer drugs.

431. Just a few of the numerous other fast-inflating oral cancer "specialty" drug candidates for severe "service fee" and "catastrophic" abuse include: Celgene's Revlimid (myeloma, Part D's top-spending cancer drug, AWP \$225,000 patient/year), Johnson & Johnson's Imbruvica (leukemia, AWP \$178,000 patient/year), Bayer's Nexavar (renal cell/liver cancer, AWP

\$136,000 patient/year), Roche's Tarceva (lung cancer, AWP \$123,000 patient/year) and Tesaro's Zejula/Clovis' Rubraca/Astra Zeneca's Lynparza (PARP inhibitors for ovarian cancer, AWP \$215-300,000 patient/year).

Exhibit 13

Medicare Part D: "Catastrophic" Cost-Sharing Fraud Novartis's Gleevec

	<u>2006</u>	<u>2015</u>	<u>Change 2006-2015</u>
AWP Cost/Patient/Year (\$)	\$38,572	\$147,788	\$109,216
Annual Part D Catastrophic Threshold (\$)	\$3,600	\$4,700	
Drug Costs Above Catastrophic Threshold (\$)	\$34,972	\$143,088	\$108,116
PBM/Plan Sponsor Catastrophic Cost Sharing (%)	15%	15%	-
PBM/Plan Sponsor Catastrophic "Cost Sharing" (\$)	\$5,246	\$21,463	\$16,217
PBM "Service Fees"/Gleevec Patient (\$ @ 8%)	\$3,086	\$11,823	\$8,737

Source: Redbook/Truven, CMS, PhRMA.

432. If the Manufacturer Defendants are commonly "forgiving" the PBM Defendants from their Part D "catastrophic" exposure, these amounts should be properly reported as discounts via Direct and Indirect Remuneration ("DIR") reports to CMS, serving to lower program "negotiated" drug prices.

433. However, with Part D reimbursement based on AWP "list" prices, we expect discovery to uncover wide-ranging "cost-sharing" reporting and financial fraud for Gleevec and

other extreme-priced “specialty” oral cancer drugs.

434. These “forgiven” costs are another form of “kickbacks” and false claims required to advance the pervasive “service fee” pricing scheme.

435. Due to very limited public disclosure by either CMS or the Defendants, we have not attempted to estimate the magnitude of potential Part D plan sponsor “catastrophic” cost-sharing fraud.

436. However, in recent years, the Part D “cost-sharing” financial fraud likely exceeds that from direct “service fee” payments for many extreme-priced “specialty” drugs.

437. The underestimation of “catastrophic” spending in annual plan sponsor bids leads to artificially low Part D beneficiary premiums, which are beneficial to the both the PBM and Manufacturer Defendants.

438. Low Part D premiums are a key marketing tool for the PBM Defendants and have contributed to accelerating enrollment in recent years.

439. Both Defendant parties gain political capital from low Part D premiums. The Defendants, politicians and related parties frequently cite the low premium levels as indicative of Part D’s success in controlling spending, while largely ignoring the exploding “catastrophic” Part D cost increases in recent years.

440. Of course, in a properly-functioning program, the Defendant strategy falls apart if the Part D plan sponsors were actually bearing their share of the vast “catastrophic” excess spending.

441. Key Part D regulatory shortfalls have contributed to fraudulent abuse of the Part D plan sponsor “cost-sharing” cost-control mechanism. If Part D plan sponsors were truly independent entities, “catastrophic” risk-sharing would force legitimate, aggressive price

negotiations with manufacturers by the PBM Defendants.

442. Second and surprising to us, Medicare Part D does not require separate reporting and accounting (in PDE or any other CMS submissions) of the plan sponsor 15% “catastrophic” cost-sharing requirement, despite it being the primary mechanism for controlling high-cost “specialty” drug spending.

443. These regulatory shortfalls regarding plan sponsor “catastrophic” cost-sharing shrouds this important issue in secrecy that requires full investigation in the public interest.

444. With “specialty” drugs now the primary driver of both the biopharmaceutical and PBM industries, the apparent failure of the plan sponsor “catastrophic” cost-sharing mechanism now threatens the long-term viability of the Part D program.

EVIDENCE OF THE “FEE” SCHEME – DIRECT INSIDER COMMENTARY

445. Dr. Borzilleri obtained confirmation of Defendant intentional participation in the fraudulent systemic “service fee” scheme from his attendance at a one-of-kind conference specifically focused on the topic. On October 7-8, 2013 in Philadelphia, PA, Dr. Borzilleri attended a two-day conference entitled, “Fair Market Value of Bona Fide Service Fees”.

446. Consistent insider commentary over the two-day conference verified all key aspects of the fraudulent “service fee” arrangements between the Manufacturer and PBM Defendants.

447. The conference presenters and attendees were acutely aware that “service fee” contracts were routinely structured as a “percent of revenues”, inclusive of massive price increases. Furthermore, manufacturers and PBMs continue to structure contracts in this manner despite clear legal FMV risks and repeated legal/consultant advice against the practice. Detailed commentary from the conference is provided in the next section.

448. In December 2014, Dr. Borzilleri obtained corroboration of the BFSF scheme

during a "one-on-one" meeting at an investor conference with James Schoeneck, the former CEO of Depomed, a mid-capitalization biopharmaceutical company. Depomed marketed Gralise for the treatment of neurologic pain, which competed directly with Defendant Pfizer's Lyrica.

449. When asked about the competitive justification for coincident severe Gralise and Lyrica price increases, Mr. Schoeneck casually stated "well, PBMs don't make their money off of rebates anymore". He said, the "PBMs make their money off of service fees" and you just have to "play ball with them" to get a contract. He then stated that the typical contract required paying "3-4% of revenues", which would include the price increases".

450. Depomed had just recently announced the successful negotiation of contracts with the three-leading stand-alone PBMs at the time, Express Scripts, CVS Health and Catamaran for both private insurance and Part D formulary access for Gralise. Catamaran was acquired by Defendant UnitedHealth Group in 2015.

451. Both Pfizer's Lyrica and Depomed's Gralise are characterized as "traditional" pill drugs in PBM drug formularies, not high-cost "specialty" therapies. The "3-4% of sales" "service fee" contract rate (inclusive of price increases), quoted by Mr. Schoeneck, is consistent with the "traditional" drug rate disclosed by the PhRMA in its November 2017 report.

DETAILED COMMENTARY FROM "FMV OF BFSF INDUSTRY CONFERENCE"

452. Dr. Borzilleri obtained definitive confirmation of the "service fee" scheme from his attendance at an industry expert conference focused specifically on the topic. The two-day conference, sponsored by CBI, was entitled "Fair Market Value of Bona Fide Service Fees". The event was held in Philadelphia on October 7-8, 2013.

453. CBI describes itself as "the leading provider of market-driven, unbiased conferences for the pharmaceutical, biotechnology, medical device and healthcare industries."

454. The conference was attended by senior corporate government program staff from the biopharmaceutical and drug distribution industries, as well as representatives from leading consulting and law firms that advise industry regarding BFSFs and FMV. Of particular note was the absence of CMS or any other government agencies at the conference.

455. Key staff from the Defendants were in attendance, including Amgen, AbbVie, Bristol-Myers Squibb, Pfizer, Sanofi and Express Scripts. Also present were representatives from other leading drug manufacturers and service providers, including Johnson and Johnson, Glaxo, Astellas, Gilead, Mylan, Otsuka and Diplomat Specialty Pharmacy.

456. The legal and consulting firms, which gave most of the presentations and led discussions, are the leading firms among a narrow group of pharmaceutical and PBM industry advisors with dedicated BFSF and FMV healthcare practices. As per their corporate websites, these firms advise the majority of top pharmaceutical and biotechnology companies regarding compliance with government regulations.

457. Besides CIS, consultant firm presenters included representatives from Huron Consulting and Navigant Consulting.

458. On the legal front, presenters included representatives from King & Spalding, Reed Smith, Hogan Lovells and Sidley Austin. See **Exhibit 14** for a list of conference presenters and attendees.

Exhibit 14**"First Ever" Fair Market Value of Bona Fide Service Fees Conference****October 7-8, 2013, Philadelphia, PA*****Presenter/Attendee List***

<u>Name</u>	<u>Title</u>
<u>Presenters (in chronological order)</u>	
Tom Evigan	Senior Director, Commercial Contracting at Compliance Implementation Systems (CIS)
John Shakow	Partner, King & Spalding
Mark Linver ¹	Managing Director, Huron Consulting Group
Stephanie Gilson	Assistant General Counsel, Johnson & Johnson
Christopher Jackson	Corporate Attorney, Otsuka American Pharmaceuticals, Inc.
Donna White	Senior Director, Contracts and Compliance at Cornerstone Therapeutics
Joseph Metro	Partner, Reed Smith LLP
Mark Dewyngaert, Ph.D.	Managing Director, Huron Consulting Group
Michael Hepburn ²	Senior Director, Government Contract Compliance at Janssen Pharmaceuticals, Inc.
Doris Chern ²	Senior Manager, Pricing Strategy and FMV at Janssen Pharmaceuticals, Inc.
Jim Abrams	Director, Government Pricing and Reporting at Mylan Pharmaceuticals
Trevor L. Wear	Senior Associate, Sidley Austin, LLP
Julie DeLong, CFA	Director, Valuation and Financial Risk Management at Navigant Consulting, Inc.
Isabel P. Dunst	Partner, Hogan Lovells US LLP
John Moose, MBA, CPA, ABV	Project Leader, Huron Consulting Group
<u>Other Attendees</u>	
Sajid Saeed	Director Fee-for-Service, Glaxo Smithkline
Greg Haverkamp	Senior Manager of Government Contracts and Compliance, Novo Nordisk
Mitzi Cole	Strategic Pharmaceutical/Biotechnology Legal Counsel, Pfizer
Cynthia Bass	Associate General Counsel, Sanofi US
Cheryl Allen	VP Development/Industry Relations, Diplomat Specialty Pharmacy
Allyson Behm	Senior Corporate Attorney - Regulatory, Astellas

Jason Carter	Senior Manager, Government Analytics & Compliance, Roche/Genentech
Josh Parker	Director, Product Marketing, Express Scripts/Accredo Health
Lyndsay Nahf	Director, Central Consultancy Group, AbbVie
Linda Ozark	STAR Project Manager, Marketing Operations Systems, AbbVie
Jill Thompson	Senior Counsel and Assistant Secretary, NPSP Pharmaceuticals
John Walsh	Director Trade Account Management, Pfizer
Christine Morse	Senior Attorney, Novo Nordisk
Jamie Rowe	Senior Category Manager, Amgen

¹ Mark Linver did not attend the conference; his presentation was given by his colleague, Mark Dewyngaert

² Janssen Pharmaceuticals is a division of Johnson & Johnson

Source: CBI conference agenda and attendee poster from conference, Corporate websites.

459. At the conference, Dr. Borzilleri directly heard extensive commentary from the “insider” conference presenters, which fully corroborated the “service fee” allegations outlined in this Complaint. Dr. Borzilleri noted considerable trepidation among the presenters and audience regarding legal exposure throughout the two-day conference.

460. All key components of the fraud were verified via presentations, candid discussions and direct quotes at the conference, namely:

- a. "Service fees", rather than manufacturer rebates/discounts, have become the primary vehicle for manufacturer compensation of PBMs/specialty pharmacies;
- b. The standard contract terms between manufacturers and service vendors utilize "percent of revenue" terms; without adjustment even for severe price increases, despite broad awareness of FMV fraud risk.
- c. The experts recognize that the majority of "service fees" should legitimately be valued via the straightforward "Cost Approach" to FMV assessment, but it is rarely

being done;

- d. The large service vendors, including the PBMs, are using their considerable negotiating leverage to preserve "percent of revenue" service contracts with manufacturers.

461. In the first few minutes of his opening statements, Tom Evegán of CIS, the Chairman of the conference, stated that "fees were the key to government pricing" and the majority of compensation to service providers from manufacturers had "shifted from rebates to fees".

462. On the second day, Mr. Dewyngaert, a senior consultant from Huron Consulting, stated that "service fee agreements" accounted for a "substantial pool of money" and were the "main source of income" for service vendors.

463. A key presenter was John Shakow, from the law firm King & Spalding. Mr. Shakow disclosed that he was a defense lawyer in the Streck Qui Tam case, which included allegations of "service fee" abuse in the Medicaid program.

464. After providing background on the history of BFSFs and potential legal risks, Mr. Shakow stated that he was "not a fan" of "percent of revenue" contracts and that manufacturers need to "consider whether percent of sales can be consistent with FMV as prices rise". He stated it was "a lot easier to have a fixed fee per unit of service", which would make him "less worried regarding the impact of price increases".

465. Mr. Shakow went on to say that "percent of revenue" arrangements "may bear no relation to the value of service unless (the service is) price-based". He expected that "percent of revenue" deals will be "challenged in the future".

466. Mr. Shakow emphasized that the manufacturer's handling of fees must be able to "withstand review/auditing by an independent party, which can determine the same FMV", as well

as "justify the FMV to an outside party brought in by the government". He stated that the government will "look beyond the agreement and evaluate the true nature of the fees, via emails, communications, interviews and sworn testimony", in its search for "intent".

467. In their joint presentation, Isabel P. Dunst, a partner at Hogan Lovells and Julie DeLong, the Director of Valuation and Financial Risk Management at Navigant Consulting, offered somewhat contrasting viewpoints regarding valuation methodologies. Ms. Dunst stated that she "did not recommend percent of sales" contracts to her manufacturer clients, while Ms. DeLong indicated more flexibility.

468. Ms. DeLong stated that she "can value anything" and was comfortable "translating per unit fees to percentage of revenue". Ms. DeLong elaborated, stating that "some want to be paid in different ways" and that she could "translate FMV into a dollar amount per month or year, as well as a percent of revenues". During this discussion, Ms. Dunst stated that she hoped "the conference was not being recorded".

469. Ms. DeLong further stated that the FMV was a "snapshot in time" and "percent of revenue" deals had greater risk when linked to fast-rising "list" prices.

470. An audience member then asked about the proper FMV handling of fees for a \$100 versus a \$1,000 prescription with the same number of pills. Ms. Dunst, of Hogan and Lovells, replied that a "real problem was developing with percent of revenue" contracts. We view this commentary as particularly relevant for fast-inflating, extreme-priced oral "specialty" drugs, which may not require significant legitimate support services.

471. Numerous presenters stated the "Cost Approach" is the most legally-justifiable FMV methodology for the vast majority of services provided for manufacturers by service vendors. In the "Cost Approach", the payment is determined by a straightforward determination

based upon the staffing, time and resources required to provide a specific service.

472. In his discussion of contracting processes, John Moose of Huron Consulting stated that the negotiating parties must recognize that "most of the value of services comes from the connection with the patient" and that a "dollar amount per activity is the easiest to justify".

473. Julie DeLong and Isabel P. Dunst specifically discussed the topic of FMV for services provided for "specialty" drugs. Ms. Dunst stated that she "does not view the specialty channel any differently from other channels" regarding the handling of fees and FMV.

474. If a particular "specialty" service is "core" to the business model of the specialty pharmacy and "they are already doing it", the manufacturer "should not be paying for it". Ms. Dunst and Ms. DeLong indicated that virtually all the specialty pharmacy services are patient/unit based and should be valued using the "Cost Approach".

475. Despite the uniform recommendation of the "Cost Approach" for FMV "fee" determinations, conference presenters repeatedly admitted that this methodology is rarely used in practice. Rather, "percent of revenue" contracts, inclusive of all price increases, remain the industry standard.

476. A definitive moment in the two-day conference came during the final presentation of the first day given by Jim Abrams, the former Director of Government Pricing and Reporting at Mylan Pharmaceuticals. Mylan's leading brand drug, Epipen (epinephrine for severe allergic reactions) has been a controversial product, with its vast US sales growth over the past decade driven by massive price increases.

477. Mr. Abrams took a simple poll of the audience. He asked attendees to raise their hands "if they were using a rigorous cost-plus approach to qualify fees" - only one person, among the 50-60 conference attendees, raised his hand.

478. John Moose of Huron Consulting specifically discussed the need for contract adjustments for rising drug prices. He stated that unless manufacturers put "adjustments in contracts for price changes", they "run the risk of paying too much". He stated that manufacturers need to "refresh" contracts for price increases and service changes, in order to maintain reasonable FMV determinations. Despite his expert recommendation, Mr. Moose then admitted that "he had not done any refreshes for service contracts".

479. In her presentation, Stephanie Gilson, the Chief Counsel at Johnson & Johnson, admitted that "percent of WAC (Wholesale Acquisition Cost), deals are often not updated by manufacturers".

480. The considerable negotiating leverage of large service vendors, especially the PBM Defendants, pertaining to "service fee" contracts was apparent at the conference.

481. Jim Abrams of Mylan polled the audience of largely manufacturers and consulting/legal advisors, asking for an indication of who had "engaged vendors to assess fee structure". Out of the 50-60 attendees, only 2 raised their hands.

482. Tom Evegán of CIS then commented that "very few vendors were willing to provide the data" and were "worried" about doing so. Mr. Evegán expressed concern since "manufacturers were looking for documentation since manufacturers were responsible if ever challenged".

483. Mr. Shakow further stated that "up to a few years ago few contracts gave specifics regarding fees" and this "could be trouble".

484. Numerous expert presenters emphasized the need for manufacturers to insist on broad "audit rights" in their contracts with large service vendors, while admitting little success with these requests.

485. Mr. Shakow stated that shifting away from "percent of revenue" service contracts was difficult for manufacturers because vendors "all want percent of revenue deals" and change required "getting partners to agree".

486. Mark Dewyngaert from Huron stated that "often partners (i.e. service vendors) will not allow cost plus" fee determinations.

487. Ms. Gilson stated Johnson & Johnson was "trying to work with intermediaries" in order to decrease their reliance on "percent of WAC" contracts, but were getting "strong pushback from service providers". She stated that to change these business practices may require either a "manufacturer industry initiative" or a "CMS mandate".

488. Finally, expert commentary indicated that the federal government has been struggling to address industry "service fee" practices. Ms. Gilson stated that the Office of the Inspector General (OIG) "has been looking at these practices", but really had little knowledge" and the "learning curve takes time". She further stated that the OIG auditors had only just "engaged" with J&J directly on this issue recently in the "second quarter of 2013".

489. An attendee agreed that the OIG was "behind industry" and asked Ms. Gilson when the government would be "dangerous enough to understand how industry works". Ms. Gilson responded that she thought "CMS was getting burned out because a lot of stakeholders were in their ear".

DEFENDANT PRODUCT/THERAPEUTIC CATEGORY REVIEW

A. Anti-Tumor Necrosis Factor (TNF) Category:

490. Self-injected anti-TNF specialty drugs are leading biologic therapies for several major inflammatory conditions, including rheumatoid arthritis (the largest market), Crohn's

disease, ulcerative colitis and psoriatic arthritis.

491. In the US, the anti-TNF market has long been dominated by two long-available products, Amgen's Enbrel (enterecept, FDA approval 1997) and AbbVie's Humira (adalimumab, FDA approval 2003). Both Enbrel and Humira act by blocking tumor necrosis factor (TNF), a cytokine that plays a key role in inflammatory processes and resulting joint damage.

492. Over the past decade, Humira has steadily been taking market share from Enbrel, primarily due to a modestly improved dosing schedule (a biweekly injection versus weekly for Enbrel) and a greater number of medical indications. Humira is approved for Crohn's disease and ulcerative colitis in the US, while Enbrel is not.

493. In recent years, two additional anti-TNF therapies, UCB Group's Cimzia (certolizumab, FDA approval 2008) and Johnson & Johnson's Simponi (golimumab, FDA approval 2009) have become available. Both of these new products offer clinical profiles similar to Enbrel and Humira, with dosing advantages over both of the older anti-TNF agents. The maintenance doses for both Cimzia and Simponi are given monthly.

494. An intravenous anti-TNF therapy, Remicade (infliximab, Johnson & Johnson, FDA approval 1998) is marketed in the US for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis and psoriatic arthritis. Remicade is not implicated in this case because it is reimbursed via Medicare Part B, not Part D.

495. In 2009, Johnson & Johnson also received approval for an infused version of Simponi, called Simponi Aria. This formulation is similarly reimbursed via Medicare Part B and not implicated in this case.

496. The FDA-approved prescribing information for these subcutaneous four anti-TNF therapies indicate very similar clinical profiles. All four provide very similar clinical benefits in

rheumatoid arthritis, as measured by standard American College of Rheumatology (ACR) criteria. The side effect profiles of the drugs are nearly identical, and all carry a "Black Box" safety warning from the FDA regarding the risk of rare severe infections and malignancies.

497. Medical experts consider the clinical profiles of these four subcutaneous anti-TNF therapies to be clinically-interchangeable. In fact, leading US medical organizations do not discern between the products in their clinical guidelines.

498. In its 2012 updated guidelines for the treatment of rheumatoid arthritis, the American College of Rheumatology states: "If a patient has moderate or high disease activity after three months of methotrexate monotherapy or DMARD combination therapy....the panel recommends adding or switching to an anti-TNF biologic, abatacept or rituximab." 2012 Update of the 2008 American College of Rheumatology Recommendations for Disease-Modifying Antirheumatic Drugs and Biologic Agents I the Treatment of Rheumatoid Arthritis, Arthritis Care & Research, Vol. 64, No. 5, May 2012, pp. 625-639.

499. The major US medical organization clinical guidelines for Crohn's disease also do not separate the three anti-TNF therapies that are approved for use. According to the American Gastroenterological Association Crohn's disease guidelines: "We recommend using anti-TNF-alpha drugs to induce remission in patients with moderately severe Crohn's disease who have not responded to standard therapies. As a group, the three anti-TNF-alpha drugs that are FDA-approved for the treatment of Crohn's disease (infliximab, adalimumab and certilizumab) are more likely than placebo to induce remission in patients with moderately severe Crohn's disease refractory to standard therapies." The AGA Institute Clinical Practice and Quality Management Committee, March 04, 2014.

500. These four anti-TNF drugs also compete for US patients with an increasing number

of non-TNF rheumatology drugs, with similar efficacy, that have been approved over the past decade, including Orencia (abatacept, Bristol-Myers, FDA approval 2005), Stelara (ustekimumab, Johnson & Johnson, 2009), Actrema (tocilizumab, Roche, 2010), Xeljanz (tofacitinib, Pfizer, 2012), Ilaris (canakinumab, Roche, 2013), Otezla (apremilast, Celgene, 2014) and Olumiant (Eli Lilly, baricitinib, 2018).

501. The availability of four clinically-similar subcutaneous anti-TNF drugs, as well numerous other new clinically-similar therapeutic options, provides the dominant PBM Defendants considerable negotiating leverage with manufacturer on behalf of taxpayers and beneficiaries in the Medicare Part D program.

502. Furthermore, the motivation for PBMs (to seek rebates/discounts and to prevent price increases) should be high since the anti-TNF category is among the top-spending drug categories for all insurance plans in the nation. AbbVie's Humira is the top-selling drug in the US and Enbrel is among the top-five spending drugs in many insurance plans.

503. However, contrary to normal competitive dynamics, vast and uniform price inflation has occurred among the anti-TNF and other rheumatology drugs. As in the US multiple sclerosis category, new therapies are standardly launched at nearly the same price as fast-inflating older products, with ongoing aggressive increases for all products.

504. The pricing trends are most incongruous for Amgen's Enbrel, for which severe price increases have occurred despite eroding use by physicians and patients. Based on IMS prescription trends, Amgen's disclosures and our estimates, the number of US patients treated with Enbrel has decreased by about 20% between 2006 and 2017.

505. Despite its eroding use and market share, the annual AWP annual cost/patient of Enbrel has increased four-fold, from about \$17,629 in 2005 to about \$70,343 in mid-2018. See

Exhibit 15.

Exhibit 15**US Anti-TNF Therapies****AWP Annual Patient Costs (\$)**

	<u>Humira</u>	<u>Enbrel</u>	<u>Cimzia</u>	<u>Simponi</u>
Company/US Launch	AbbVie (2003)	Amgen (1997)	UCB (2008)	J & J (2009)
2005	\$17,277	\$17,629	-	-
2006	20,920	18,493	-	-
2007	19,011	19,399	-	-
2008	20,920	21,347	\$19,874	-
2009	21,945	22,820	21,062	\$23,791
2010	24,149	25,111	22,978	24,933
2011	25,815	26,592	25,309	27,960
2012	29,500	30,389	30,301	31,951
2013	36,038	34,728	36,284	36,513
2014	41,956	42,820	39,876	42,896
2015	49,425	53,825	43,823	50,103
2016	58,222	59,154	50,353	54,562
2017	63,113	64,123	55,187	59,418
2018	\$69,235	\$70,343	\$57,836	\$64,706

Source: Redbook/Truven.

506. Amgen has reported large increases in US Enbrel sales over the past decade, entirely driven by frequent, large price increases. Reported US Enbrel sales have increased from \$2.47 billion in 2005 to \$5.2 billion in 2017. Without price increases, US Enbrel sale would be in the \$1.9 billion range in 2017. All of Enbrel's cumulative US sales gains of \$19.1 billion over the

past decade are caused by the fraudulent “service fee” scheme, with an estimated 30% attributable to Medicare Part D.

507. As a newer drug with modest advantages over Enbrel, volume growth for AbbVie’s Humira has been far stronger. US Humira sales have increased from \$560 million in 2005 to \$12.4 billion in 2017, with about two-thirds of the growth due to severe price increases. As such, the majority of Humira’s astounding cumulative US revenue gains of \$32.3 billion over the period are attributable to the scheme.

508. Indicative of anticompetitive activity, despite an intense battle for US market share, the cost of both Enbrel and Humira has increased in virtual lockstep (with large price increases often within days of each other) over the past decade. Furthermore, the pace of the price increases has accelerated in recent years, with both up 100% in unison just since the start of 2013.

509. Consistent with the “service fee” scheme, the combined market share for the newer anti-TNF drugs, Simponi and Cimzia, remains quite modest (in the 10% range) despite the widening AWP cost spread with Humira and Enbrel in recent years. See **Exhibit 15**.

510. In the scheme, both the manufacturers and PBMs are incented to preserve the vast profits stream from the market-leading “blockbusters”, Humira and Enbrel, rather than seek larger rebates and lower drug costs for their payer clients from newer competitors.

B. Chronic Myeloid Leukemia (CML) Category:

511. Chronic Myeloid Leukemia (CML) is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid (white blood) cells. CML is caused by the translocation of a specific gene (ABL) from one chromosome (9) to another (22). In the United States, the average age of diagnosis is 60-65 years old, with approximately 4,600 new cases per year.

512. Over the past 15 years, the long-term survival of CML patients has markedly improved with the arrival of breakthrough targeted oral therapies, called Tyrosine Kinase Inhibitors (TKIs). The first TKI drug, Novartis' Gleevec (imatinib), quickly gained wide use following its US approval in 2001.

513. Two additional major TKIs have been approved for the treatment of CML over the past decade, namely Bristol-Myer's Squibb's Sprycel (dasatinib, US approval 2006) and Novartis' follow-up therapy, Tassigna (nilotinib, US approval 2007).

514. In more recent years, two additional niche TKI CML therapies have been approved in the US, Pfizer's Bosulif (bosutinib) and Ariad's Iclusig (ponatinib). The use of these latter two agents is primarily restricted to the smaller refractory CML population.

515. Both Sprycel and Tassigna were initially approved for the treatment of CML patients refractory to Gleevec therapy, but gained expanded labelling for newly-diagnosed CML patients in 2010. According to their FDA-approved labels, both Sprycel and Tassigna have demonstrated superior clinical responses in short-term head-to-head trials vs. Gleevec.

516. According to the leading US CML medical organization, the Leukemia and Lymphoma Society (LLS), "Findings from studies of each drug (Sprycel and Tassigna) show faster complete cytogenetic response (CCyR) and molecular response (MR) than the response with Gleevec. These drugs may prove to be associated with better long-term outcomes." Leukemia and Lymphoma Society Chronic Myeloid Leukemia Information Booklet, Revised 2014, www.LLS.org.

517. However, the LLS document further states: "neither Sprycel nor Tassigna has been shown to result in longer survival" (than Gleevec). Pending long-term comparative survival data, all three TKIs remain viable first-line CML therapies.

518. The LLS also indicates that the tolerability of both Sprycel and Tasigna compares favorably to Gleevec. “In a one-to-one comparison with Gleevec, most side effects were reported less commonly in patients treated with Sprycel”. Similarly, “In a one-to-one comparison with Gleevec, most side effects were reported less commonly in patients treated with Tasigna”. Leukemia and Lymphoma Society Chronic Myeloid Leukemia Information Booklet, Revised 2014, www.LLS.org.

519. Both Sprycel and Tasigna have steadily gained market share from Gleevec over the past decade. Gleevec’s US total prescription share among these three leading CML drugs declined from 100% at the start of Part D to 85% at year-end 2010 and 65% at year-end 2014. The market shares for Sprycel and Tasigna reached 9% and 6%, respectively, in 2010 and 17% and 16%, respectively, in 2014.

520. Due to the competition from these two new TKI drugs, the clinical use of Gleevec has moderated considerably over the past decade. Based upon IMS data and our estimates, the number of US patients treated with Gleevec increased by about 20% between 2005 and 2015. However, between 2010 and 2015 (just prior to its February 2016 US patent expiration), US Gleevec-treated patients declined by about -6%.

521. In a properly-functioning US market, these competitive factors would be expected to limit price inflation for Gleevec and the other TKI drugs.

522. Furthermore, with the majority of CML patients in Medicare Part D (about 60%), the PBM Defendants, in their role as plan sponsors, should be highly-incented to negotiate aggressively with Novartis in order to limit their escalating “catastrophic” cost-sharing exposure as prices rise.

523. Despite these competitive factors, Novartis and Bristol-Myers Squibb have

benefited from staggering price increases for the their TKI drugs. The AWP cost/patient/year for Gleevec has increased from about \$36,000 in 2005 to nearly \$150,000 in 2015.

524. Furthermore, the magnitude of Novartis's Gleevec price increases counterintuitively accelerated starting in 2010, as the volume started to decline. See **Exhibit 16**.

Exhibit 16

US Chronic Myeloid Leukemia (CML) Therapies

AWP Annual Patient Cost (\$)

	<u>Gleevec</u>	<u>Sprycel</u>	<u>Tasigna</u>
<u>Company/US Launch</u>	Novartis (2001)	Bristol-Myers (2006)	Novartis (2007)
2005	\$35,734	-	-
2006	38,572	\$64,496	-
2007	41,619	76,739	\$83,238
2008	48,050	80,006	\$91,395
2009	55,395	92,411	105,420
2010	66,991	111,613	115,856
2011	77,305	115,074	119,448
2012	93,368	125,299	125,300
2013	101,772	129,058	129,686
2014	122,361	140,662	142,707
2015	147,788	151,211	151,269
2016	147,788	164,966	164,942
2017	147,788	176,348	180,941
2018	\$147,788	\$188,516	\$198,854

Source: Redbook/Truven.

525. Despite an intense battle for patients in a mature market, the AWP prices of Sprycel and Tasigna have vastly increased since their launch a decade ago.

526. Price inflation for Sprycel and Tasigna has continued in recent years despite wide availability and greater use of generic Gleevec. The AWP cost of Sprycel has increased from about

\$65,000/patient/year at launch in 2006 to \$150,000 in late 2015. The cost has increased another 25% to nearly \$190,000 patient/year in mid-2018.

527. Ongoing inflation has been even greater for Novartis' Tasigna. Its AWP price has increased another 30% since 2015, with an annual patient cost in the \$200,000 range in mid-2018.

528. Based upon its SEC-reported financial statements, Novartis has received large financial gains from these severe price increases.

529. Novartis reported an increase in US Gleevec sales from \$524 million in 2005 to \$2.5 billion in 2015. Without price increases, US Gleevec sales would have only been in the \$700 million range for 2015.

530. The cumulative financial impact of these anticompetitive Gleevec price increases on the Part D program and the private insurance market over the past decade is about \$7.4 billion. The vast majority of these Gleevec financial gains by Novartis have been driven by the fraudulent "service fee" scheme. We estimate that 60% of this fraud has been in Medicare Part D.

531. Novartis's reported US sales of Tasigna have increased from \$30 million in 2008 to \$810 million in 2017. We estimate that about 40% of this growth is attributable to vast price increases enabled by the scheme.

532. Without price increases, US Tasigna sales would have only been in the \$480 range in 2017. We estimate a cumulative fraudulent impact for Tasigna since launch at \$1.0 billion, with 60% attributable to Medicare Part D.

533. Bristol-Myers Squibb's reported US sales of Sprycel have increased from \$22 million in 2006 to \$1.1 billion in 2017. We estimate that about 60% of this growth is attributable to vast price increases enabled by the scheme.

534. Without price increases, US Sprycel sales would have only been in the \$460 range

in 2017. We estimate a cumulative fraudulent impact for Sprycel since launch at \$2.5 billion, with 60% attributable to Medicare Part D.

C. Diabetes Insulin Category:

535. The US diabetes therapeutic category includes four major brand categories; two oral segments and two injectable segments. The two major oral segments are DPP-4 inhibitors and SGLT-2 inhibitors. The two major injectable segments are GLP-1 agonists and insulins. Following an array of recent new product approvals, all four of these segments now have a wide array of clinically-interchangeable drugs that should afford considerable PBM Defendant negotiating leverage and cost-savings potential.

536. The insulin category is divided into short-acting and long-acting products. Short-acting products are typically used around meals, while long-acting versions provide baseline insulin levels throughout the day.

537. Within the short-acting sub-segment, newer insulin analogues (Eli Lilly's Humalog, Novo Nordisk's Novolog and Sanofi's Apidra) offer faster onset than long-marketed regular insulins, such as Eli Lilly's Humulin and Novo Nordisk's Novolin.

538. The dominant long-acting insulin product has been Sanofi's Lantus, with competition from Novo Nordisk's similar product, Levemir.

539. All insulins are administered as subcutaneous injections and require individualized patient dosing depending upon numerous factors, including age, weight, diet, and insulin sensitivity/resistance.

540. As with the other diabetes brand segments, severe and uniform AWP price inflation of virtually all insulin therapies suggests broad-based "service fee" fraud tied to price increases.

541. Despite complete clinical interchangeability, the average AWP cost/patient/year for

Eli Lilly's and Novo Nordisk's long-marketed Humulin (FDA approval 1982) and Novolin (FDA approval 1991), respectively, has increased approximately 5-fold since the start of Part D.

542. Based upon an estimated average daily dose of 50 units, the average AWP annual cost of therapy for Humulin and Novolin has increased in lock-step from the \$605-630 range in 2005 to \$3,000-3,250 range in mid-2018. See **Exhibit 17**. Many diabetic patients require far more than a 50 unit daily dose due to insulin resistance and/or greater body weight.

Exhibit 17

US Short-Acting Insulin Therapies

AWP Annual Cost of Therapy (\$)

Based upon 50 unit daily dose

Company/US launch	<u>Humulin R</u>	<u>Novolin R</u>
	Eli Lilly (1982)	Novo Nordisk (1991)
2003	\$534	\$557
2004	561	585
2005	606	631
2006	660	660
2007	723	723
2008	840	818
2009	890	899
2010	1,058	1,187
2011	1,428	1,436
2012	1,664	1,660
2013	1,989	1,985
2014	2,402	2,399
2015	2,810	2,794
2016	3,020	3,016
2017	3,257	3,016
2018	\$3,257	\$3,016

Source: Redbook/Truven.

543. In the long-acting segment, based on an average daily dose of 50 units, the annual

AWP cost/patient/year of both Sanofi's Lantus (FDA approval 2001) and Novo Nordisk's Levemir (FDA approval 2005) has increased nearly four-fold in lockstep from the \$1,400-1,500 range in 2006 to the \$5,900-6,100 range in mid-2018. See **Exhibit 18**. As with the short-acting insulins, many diabetics require far more than a 50 unit daily dose, due to insulin resistance and/or greater body weight.

Exhibit 18

US Long-Acting Insulin Therapies

AWP Annual Cost of Therapy (\$)

Based upon 50 unit daily dose

Company/Year Launch	<u>Lantus</u> Sanofi (2000)	<u>Levemir</u> Novo Nordisk (2005)
2003	\$978	-
2004	1,162	-
2005	1,318	-
2006	1,405	\$1,528
2007	1,545	1,582
2008	1,776	1,776
2009	1,883	1,883
2010	2,176	2,206
2011	2,500	2,492
2012	2,886	2,959
2013	4,189	4,189
2014	5,442	5,442
2015	5,442	5,891
2016	5,442	5,891
2017	5,606	5,891
2018	\$5,903	\$6,127

Source: Redbook/Truven.

544. While “service fee” fraud in the insulin market is widespread, this case targets two products in which Manufacturer Defendant SEC-reported US product revenues are most disparate

from underlying patient utilization trends; namely Sanofi's Lantus and Eli Lilly's Humulin. For these two products, the Manufacturer Defendants have garnered the majority of the illicit gains from the collusive price increases.

545. Over the past decade, driven primarily by repeated large price increases, Sanofi's Lantus grew to be the largest spending "non-specialty" and diabetes drug in both the private insurance market and Part D. Sanofi reported US Lantus sales of approximately \$850 million in 2005 rising to about \$5.8 billion in 2014, with about two-thirds of this growth due to price increases.

546. Without the massive price increases, 2014 US Lantus sales would have been in the \$2.2 billion range. The US sales of Lantus have decreased since 2014 due to the launch of a brand generic version, Eli Lilly's Basaglar, and category price moderation due to increased public/political scrutiny of the diabetes market.

547. Overall, we estimate that the scheme has resulted in unwarranted Lantus costs in excess of \$21.4 billion between 2006 and 2017, with an estimated 30% attributable to the Part D program.

548. The signs of pricing fraud with Eli Lilly's Humulin has been even more severe, although the absolute financial harm has been less, due to its smaller diabetes market share compared to Lantus.

549. Despite an estimated -60% decrease in the number of US treated patients, according to IMS data and corporate reports, Eli Lilly has reported an increase in annual Humulin US sales from \$411 million in 2005 to \$885 million in 2017.

550. Without the massive price increases, 2017 US Humulin sales would have been only in the \$175 million range. Over the past decade, we estimate cumulative US Humulin pricing fraud

of \$4.1 billion, with 30% attributable to Part D.

D. Defendant Pfizer Products:

551. In addition to the above three major therapeutic categories, we have also ascertained significant “service fee” pricing fraud for an array of Pfizer’s major US brand drug products.

552. The Pfizer products targeted in this Complaint are Lyrica, Viagra, Celebrex, Chantix, Premarin, Pristiq and Relpax. Except for Lyrica, the US prescription volume for all these products has eroded considerably in recent years.

553. However, counter to sluggish and/or falling prescription volume, Pfizer has reported strong US sales for all these brand products over the past decade, driven by massive price increases. In aggregate, these seven products accounted for \$6.8 billion of Pfizer’s 2017 US revenues, representing about 40% of US brand drug sales and 25% of overall US sales.

554. Pfizer has instituted twice yearly price increases in the 10% or more range for each of these products for each of the past five years. The majority of this price inflation and related US sales has been enabled by fraudulent “service fee” arrangements between Pfizer and the PBM Defendants.

555. As noted previously, we received direct confirmation of the scheme from the CEO of a smaller specialty pharmaceutical company, Depomed, Inc., which competed directly with Pfizer’s Lyrica in the neuropathic pain market.

556. Of note, all these targeted Pfizer drugs are “traditional” oral therapies, not “specialty” drugs. As “traditional” oral drugs, legitimate PBM Defendant “services” (beyond filling/shipping) are minimal for each of these products.

557. Pfizer’s Lyrica (pregabalin) received FDA approval for three indications in September 2004; namely neuropathic pain associated with diabetic peripheral neuropathy (DPN),

postherpetic neuralgia (PHN) and as adjunctive therapy in the treatment of partial seizures in adults. Lyrica later received approval for treating fibromyalgia in June 2007.

558. Lyrica is structurally-related to gabapentin, a widely-used generic drug; both drugs share a similar mechanism of action. Lyrica offers a modest improvement in dosing (2-3 times a day vs. 3-4 times a day for gabapentin) and a greater number of approved indications.

559. Within the medical community, many physicians consider Lyrica to offer relatively minor clinical advantages compared to generic gabapentin, especially considering the extreme cost differential. The availability of other therapies for neurologic pain has also negatively impacted Lyrica's clinical use.

560. With these market dynamics, US prescription trends for Lyrica have been sluggish in recent years. According to IMS, total prescriptions growth for Lyrica has increase an average of 1-2% in recent years, with the overall number of US patients treated up by about 8% between 2010 and 2016.

561. Despite sluggish use and strong competition, the AWP price for a 150mg pill of Lyrica has increased 4-to-5 fold from \$2.00 in 2006 to \$8.92 in mid-2018. See **Exhibit 19**.

562. Driven by these frequent severe price increases, Pfizer has reported robust US Lyrica sales growth, with SEC-reported US sales rising from \$717 million in 2006 to \$3.46 billion in 2017. Lyrica is Pfizer's top-selling US brand drug.

563. Without the massive price increases, Pfizer's 2017 US Lyrica sales would only be in the \$1.2 billion range, less than one-third of the reported number.

564. Overall, we estimate cumulative fraudulent US Lyrica sales of approximately \$9.9 billion between 2006 and 2017. We estimate that 30% of the fraud has occurred in Medicare Part D.

565. Pfizer's Viagra (sildenafil) was FDA-approved for the treatment of erectile dysfunction in 1998. Viagra is a phosphodiesterase-5 (PDE-5) inhibitor. In 2003, two additional PDE-5 drugs, Eli Lilly's Cialis (tadalafil) and Bayer's Levitra were launched in the US. More recently, a fourth PDE-5 drug, Endo Pharmaceutical's Stendra (avanafil) was approved by the FDA in 2012. Intense competition in this mature and crowded therapeutic category has negatively impacted the usage of both Viagra and Cialis.

Exhibit 19
Pfizer Products
AWP Price and US Prescription Trends

<u>Product</u>	<u>2006</u>	<u>2009</u>	<u>2012</u>	<u>2015</u>	<u>2018</u>	Price Change 2006- 2017	Change Prescriptions 2010-2016
<u>AWP Price/Pill (\$)</u>							
Lyrica	\$2.08	\$2.83	\$4.04	\$6.94	\$8.92	4.3x	8%
Viagra	11.46	17.49	26.72	45.45	80.82	7.1x	-42%
Celebrex	3.34	4.22	5.74	10.09	14.47	4.3x	-20%
Chantix	1.92	2.35	3.69	5.76	8.60	4.5x	-14%
Premarin	1.40	1.85	2.85	4.35	6.43	4.6x	-57%
Pristiq	-	4.29	5.90	10.14	13.95	3.4x	-29%
Relpax	18.32	23.82	33.92	45.45	74.73	4.1x	-18%

Source Redbook/Truven and IMS.

566. According to IMS, the annual US prescription volume for Pfizer's Viagra has declined about -42% between 2010 and 2016.

567. Despite sharply eroding use, the AWP price of Viagra increased seven-fold from \$11.46, per 100 mg tablet, in early 2006 to \$80.82 in mid-2018. See **Exhibit 19**. Of note, indicative of anticompetitive activity, the vast price increases have been similar and in lockstep for the other

three marketed PDE-5 drugs.

568. Driven by these severe price increases, Pfizer's SEC-reported US Viagra sales increased from \$796 million in 2006 to \$1.15 billion in 2016. The US sales of Viagra are now in decline, following its December 2017 US patent expiration. Without the price increases, US Viagra sales would have only been in the \$300 million range in 2016.

569. All of Viagra's price-driven US sales growth has been enabled by fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Viagra fraudulent US sales of about \$5.7 billion between 2010 and 2017. We estimate that 20% of this fraud has occurred in Medicare Part D.

570. While not targeted in this Complaint, we also suspect severe "service fee" pricing fraud with Lilly's similar erectile dysfunction drug, Cialis.

571. Pfizer's Celebrex (celecoxib) was initially approved by the FDA as an anti-inflammatory/pain therapy in 1998. The product is currently approved for the treatment of osteoarthritis, acute pain, rheumatoid arthritis, dysmenorrhea and ankylosing spondylitis. Unlike the anti-TNF drugs, Celebrex is primarily for symptomatic benefit and is not "disease-modifying".

572. In its early years of launch, Celebrex's US prescription uptake was robust. However, over the past decade, use of the drug has eroded considerably due to rising safety concerns. The product's label now includes an FDA "black box" warning regarding increased cardiac events (including strokes and heart attacks) and gastrointestinal events (bleeding, ulcers and perforation). Celebrex lost patent protection in the US in 2015.

573. According to IMS, US Celebrex prescription volume was declining sharply even prior to its 2015 US patent expiration, with volume down about -40% between 2006 and 2014.

574. Despite sharply eroding use, the AWP price of Celebrex increased more than four-

fold from \$3.34 per 200 mg pill in early 2006 to \$14.47 in mid-2018. See **Exhibit 19**.

575. Driven by these price increases, Pfizer's SEC-reports US sales of Celebrex rose from \$1.577 billion in 2006 to \$1.735 billion in 2014, despite markedly eroding clinical use. Without the price increases, US Celebrex sales would have been in the \$950 million range in 2014.

576. All of Celebrex's price-driven US sales growth has been enabled by "service fee" fraudulent arrangements with the PBM Defendants. Overall, we estimate cumulative Celebrex fraudulent US sales of about \$4.2 billion between 2006 and 2016. We estimate that 35% of this fraud has occurred in Medicare Part D.

577. Pfizer's Chantix (varenicline) was FDA-approved as an aid to smoking cessation treatment in 2006. Due to limited efficacy and safety concerns, use of Chantix has been relatively modest. The FDA label for Chantix includes a "black box" safety warning regarding serious neuropsychiatric events, including agitation, depression and suicidal ideation. Chantix competes with an array of other prescription and over-the-counter smoking cessation therapies, including numerous nicotine products.

578. According to IMS, the annual US prescription volume for Chantix declined by 29% between 2010 and 2014, but has rebounded over the past several years. Overall, we estimate that Chantix US prescription volume has decreased about -14% between 2010 and 2016.

579. According to Red Book, the AWP price of Chantix increased 4-to-5 fold from \$1.92 per 1 mg tablet in early 2005 to \$8.60 in mid-2018. See **Exhibit 19**.

580. Driven by these large price increases and a recent usage rebound, Pfizer's SEC-reported US Chantix sales have increased from \$330 million in 2010 to \$789 million in 2017. Without the price increases, US Chantix sales would be in the \$290 million range in 2017.

581. Most of Chantix's price-driven US sales growth has been enabled by fraudulent

“service fee” arrangements with the PBM Defendants. Overall, we estimate cumulative Chantix fraudulent US sales of about \$1.5 billion between 2010 and 2017. We estimate that 15% of this fraud has occurred in Medicare Part D, since quitting smokers are often younger in age.

582. Pfizer’s Premarin (conjugated estrogen) is one of the longest-marketed US brand products, available since 1942. Pfizer began marketing Premarin following its 2009 acquisition of Wyeth Pharmaceuticals. Premarin is FDA-approved for the treatment of vasomotor symptoms due to menopause, vaginal atrophy and the prevention of osteoporosis.

583. Due to its complex formulation derived from horse urine, AB-rated, fully-substitutable generic versions of Premarin have yet to reach the US market, despite numerous development attempts.

584. In 1995, the combination hormonal product, Prempro (conjugated estrogen/medroxyprogesterone) was approved in the US. The progesterone component of Prempro decreases the uterine cancer risk associated with unopposed estrogen therapy.

585. Over the past decade the use of Premarin/Prempro, and the many other estrogen formulations available in the US, has declined sharply due to health and safety concerns. All estrogens now carry an FDA “black box” safety warning regarding cancer and cardiovascular risks.

586. According to IMS, combined annual US prescriptions for all Premarin/Prempro formulations has declined by about -57% just between 2010 and 2016, with more erosion back to 2006.

587. Despite sharply eroding use, the AWP price of all Premarin formulations has increased five-fold from \$1.28 per pill in early 2006 to \$6.42 in mid-2018. See **Exhibit 19**.

588. Driven by these severe price increases, Pfizer reported stable US Premarin sales,

despite severe erosion in clinical use. Pfizer's SEC-reported US Premarin sales were \$949 million in 2010, which modestly declined to \$921 million in 2017. Without the price increases, US Premarin sales would have fallen sharply to the \$360 million range in 2017.

589. All of Premarin's price-related US sales growth has been due to fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Premarin fraudulent US sales of nearly \$2.725 billion between 2010 and 2017. We estimate that 30% of this fraud is attributable to Medicare Part D.

590. Pfizer's Pristiq (desvenlafaxine) was FDA-approved for the treatment of depression in 2008. Pristiq is a serotonin and norepinephrine reuptake inhibitor (SNRI). The usage of Pristiq has been moderate since launch due to the availability of a wide array of generic antidepressants offering similar clinical profiles. Former similar major US antidepressant brands that are now generically-available include Prozac, Zoloft, Paxil, Lexapro, Cymbalta and Effexor.

591. According to IMS, the annual US prescription volume for Pristiq has declined by about -29% between 2010 and 2016.

592. Despite declining use in a largely generic marketplace, the AWP price of a 50mg pill of Pristiq has increased more than three-fold from \$4.09 per 50 mg pill in 2008 to \$13.95 in mid-2018. See **Exhibit 19**.

593. Driven by these price increases, Pfizer's SEC-reported US sales of Pristiq increased from \$405 million in 2010 to \$578 million in 2016. Without the price increases, US Pristiq sales would be in the \$275 million range in 2016. US Pristiq sales declined sharply in 2017, following its US patent expiration.

594. All of Pristiq's price-driven US sales growth has been enabled by fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Pristiq

fraudulent US sales of about \$1.26 billion between 2010 and 2016. We estimate that 25% of this fraud has occurred in Medicare Part D.

595. Pfizer's Relpax (eletriptan) was FDA-approved for the acute treatment of migraines in 2002. Relpax acts as a serotonin receptor agonist. The usage of Relpax has been modest since launch due the availability of numerous other similar serotonin migraine therapies.

596. In recent years, patient usage of Relpax has eroded due to the availability of generics for the three former market-leading serotonin therapies, Glaxo's Imitrex (sumatriptan, 2009 patent expiry), Merck's Maxalt (rizatriptan, 2013 patent expiry) and Astra Zeneca's Zomig (zolmitriptan, 2013 patent expiry).

597. According to IMS and our estimates, the annual US prescription volume for Relpax has declined by about -24% between 2010 and 2016.

598. Despite eroding use, the AWP price of Relpax increased four-fold from \$18.32, per 20 mg pill, in early 2006 to \$74.73 in mid-2018. See **Exhibit 19**.

599. Driven by these price increases, Pfizer's SEC-reported US sales of Relpax have increased from \$189 million in 2010 to \$226 million in 2016. Without the price increases, US Relpax sales would be in the \$145 million range in 2016.

600. All of Relpax's price-driven US sales growth has been enabled by fraudulent "service fee" arrangements with the PBM Defendants. Overall, we estimate cumulative Pristiq fraudulent US sales of about \$420 million between 2010 and 2016. We estimate that 15% of this fraud has occurred in Medicare Part D.

LONG-STANDING PATTERN OF DEFENDANT SECRECY AND DECEIT

601. Avoiding the detection of a scheme of this magnitude and duration requires extreme secrecy and lack of transparency, which must be stringently coordinated at the executive suite

level.

602. Both the Manufacturer and PBM Defendants uniformly refuse to disclose any information in their SEC filings regarding their mutual financial arrangements, including contracts, rebates, “service fees” or any other transactions.

603. Specific to this scheme, we have found no discussion of BFSFs in any of the Defendants’ SEC filings over the past decade, since the arrival of Medicare Part D. Failure to disclose this material information has enabled this scheme and led to severe financial and medical harm.

604. The extreme lack of financial disclosure in the PBM industry is legendary in the investment world and central to the pricing scheme. The PBM SEC disclosures regarding their source of profits are scant and often misleading.

605. For instance, the following is the only comment from Express Scripts in its 2015 10-K regarding its drivers of gross profit growth: “This increase is also due to better management of ingredient costs and formulary, as well as cost savings from the increase in the aggregate generic fill rate, partially offset by lower claims volume”.

606. Similar to Express Scripts, none of the other three dominant PBMs, CVS Health, UnitedHealth Group and Humana, provides detailed disclosure of its sources of profits from prescription drugs.

607. Furthermore, the PBM Defendants provide minimal, if any, disclosure of the profit contribution of “specialty” drugs and Medicare Part D, the key growth driver in recent years.

608. With little verifiable financial information in the public domain, the senior executives from the Manufacturer and PBM Defendant intentionally disseminate a wide array of deceitful, misleading and inaccurate information in order to deflect attention from their collusive

scheme. Key topics of deceit include drug rebates, price increases, Medicare Part D, patient assistance programs (PAPs) and drug coupons.

609. Both drug manufacturers and PBMs effectively utilize their closely-controlled trade organizations, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Pharmaceutical Care Management Association (PCMA). These organizations are funded by industry, with numerous senior executives from the Defendants serving as board members.

610. We will highlight a couple examples of coordinated misinformation, which are indicative of the long-standing, nationwide collusive scheme.

611. A repeated strategy is the use of spurious and unverifiable internal or “paid consultant” research. For instance, in April 2016, the PhRMA and individual drug manufacturers aggressively utilized “research” from IMS that indicated that net price increases realized by US drug manufacturers declined sharply in 2015 to only 2.8%, despite average AWP price increases of 12% for the year. IMS Institute for Health Informatics, March 2016.

612. The pharmaceutical manufacturers, including executives of the Defendants, have widely attributed this net pricing decline to aggressive “rebate/discount” negotiations by PBMs, despite the data being counter to a wide array data indicating far higher pricing and lower manufacturer rebate trends (including the CMS data for Medicare Part D).

613. However, the footnotes of the IMS report indicate that their “cost savings” calculations included manufacturer patient assistance programs (PAPs) and “service fees”, thereby intentionally exaggerating the “calculated discounts” to payers and beneficiaries.

614. The PAP impact was included at “retail” prices, rather than the far lower true manufacturing cost of the drugs.

615. Since PBM “service fees” are nearly universally not shared by the PBM Defendants

with payer clients, their inclusion in the “discount” calculations is intentional deceit.

616. The PBM industry and the PCMA routinely use similar deceitful tactics. In November 2011, the PCMA paid a consulting firm, Visante, to generate a report regarding drug coupons, an increasingly controversial topic. Many experts report that drug coupons cause patients to inappropriately use expensive brand drugs. How Copay Coupons Could Raise Prescription Drug Costs by \$32 Billion Over the Next Decade. November 2011.

617. Not surprisingly, the “paid” research concluded that drug manufacturers were fully to blame for the abuse of drug coupons and that PBMs could do little about it since they did not have access to the prescription claims data. This conclusion is inaccurate and deceitful for extreme-priced “specialty” drugs, which now account for the majority of money spent on coupon programs.

618. The PBM Defendants dominate the specialty mail order pharmacy market, which now accounts for 80% of US “specialty” drug prescription volume. As such, the PBMs have full access to all claims data for their administered “specialty” prescriptions and could stop the use of coupons at any time in the interest of their private insurance clients.

619. Over the past several years, as US pricing scrutiny has escalated, the collusive pharmaceutical and PBM industries are increasingly “blaming” each other for drug massive drug price increases that have resulted from their mutual scheme. The manufacturers claim that they are keeping only small portion of price increases, while the PBMs are taking extraordinary profits through their “murky” and nontransparent business practices.

620. The PBMs, in turn, state that they have no control over drug pricing. Of note, both Defendant parties continue to focus on “rebates” as the key issue, while assiduously avoiding discussion of “service fees”.

621. Regardless of the recent escalation in the deceitful “adversary” rhetoric,

manufacturers and PBMs have been, in reality, working closely together for the past two decades.

622. In the decade before Part D, PBMs made the majority of their profits from manufacturer rebates. Since Part D, PBMs have made the largest portion of their profits in collusive pricing scheme regarding manufacturer “service fees”.

PART D REQUIREMENTS FOR “BONA FIDE SERVICE FEES (BFSFs)”

623. Indicative of the secrecy of this scheme, we have been unable to locate any public record of legislative discussion of BFSFs prior to Congressional passage of Part D into law. In fact, BFSFs are not even mentioned in the 416-page Medicare Modernization Act (MMA) of 2003, which enacted the Part D program. PUBLIC LAW 108-173, DEC. 8, 2003.

624. In addition, BFSFs are only cursorily mentioned in the subsequent Code Federal Regulations (CFR) governing the Part D program, in Sections §423.514 and §423.501.

625. Section §423.514 of the CFR establishes the exclusion of BFSFs, in sharp contrast to manufacturer rebates, from Part D “negotiated price” calculations.

626. In Section §423.514, among other reporting requirements, the regulations state: “Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan”.(Emphasis added)

627. Section §423.501 of the CFR states: “Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in

part to a client or customer of an entity, whether or not the entity takes title to the drug".

628. According to CMS, all BFSFs must pass the "Four-Part Test" in order to "qualify" for exclusion from Medicare Part D "negotiated price" calculations. 71 Fed. Reg. 69624, 69667-9. The first three parts of the test are:

629. the "itemized" service is actually performed;

630. the manufacturer would otherwise perform or contract for the service in the absence of the service contract, and;

631. the fee is not passed on in whole or in part to a client (i.e., it is kept by the PBM Defendant or other service providers).

632. However, the "Achilles Heel" facing both the Manufacturer and PBM Defendant in this scheme is the final criteria of the "Four-Part Test", which requires that all BFSFs be paid at "Fair Market Value" ("FMV") commensurate with an "arm's length" transaction between unaffiliated parties.

633. The CMS regulations regarding the handling of BFSFs and the legal requirements of FMV in Medicare Part D have been unequivocally in place since the start of the program in 2006. Furthermore, since at least 2007, the handling of BFSFs and FMV has been virtually identical in the Medicaid, Medicare Part B and Medicare Part D drug programs.

634. In the Part D regulations, CMS places the legal onus on the drug manufacturers to justify that the fees represent "Fair Market Value" ("FMV") for the services rendered. However, as mentioned previously, both the Manufacturer and PBM Defendant are liable under the FCA and the AKS for the fraudulent BFSFs and excessive drug costs in Medicare Part D.

635. CMS states: "manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their

payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination." (Emphasis added) 77 Fed. Reg. at 5332.

636. CMS has purposely kept its guidance regarding FMV vague due to concerns about potential fraud. CMS reiterated its position in its February 2012 proposed rule: "We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define 'fair market value' at this time." Federal Register, Vol 77, No 22, February 2, 2012.

637. CMS has made it clear that it considers all payments to service vendors, other than BFSFs, to be price discounts/concessions that must be included in Part D "negotiated price" calculations.

638. Per the Medicare Part D DIR ("Direct and Indirect Remunerations") Reporting Requirements for 2010 Payment Reconciliation, dated June 6, 2011: "CMS considers all remunerations received directly or indirectly from pharmaceutical manufacturers, with the exception of bona fide service fees (BFSFs), to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor."

639. By law, any "service fee" amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in "excess" of FMV must be reported to CMS as price concessions (i.e., "Direct and Indirect Remuneration") which serve to lower drug costs in Medicare Part D.

640. As per CMS in 2011: "In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other

amount and fair market value must be reported as DIR in column DIR #4." Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated June 6, 2011.

641. Legal precedent (*American Lithotripsy Society v. Thompson*, 215 F Supp. 2d 23 (200), US District Court, District of Columbia) has established that payments in excess of FMV are "payments for referral" and a violation of the Anti-Kickback Statute (AKS).

642. In 2006, CMS enacted regulations clarifying BFSFs. The regulations expressly re-affirmed that "service fee" payments must be for legitimate services rendered and thus not related to the price of the drug. Fed. Reg. 69624, 69668 (Dec 1, 2006) (relevant sections codified at 42. C.F.R. 414.802, 414.804).

643. In its 2007 final rule, CMS added that BFSFs should be "associated with the efficient delivery of drugs". In the rule, CMS interprets this standard to "encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69667-6.

644. The AKS requires that transactions be "commercially reasonable". 69 Fed. reg. 16,093 (March 26, 2004) According to the statute's theory, most business transactions must be "commercially reasonable" or there would be no reason for them to occur.

645. Of note, the AKS considers "commercial reasonableness" of a financial transaction to be a separate and distinct determination compared to FMV. The AKS states: "If compensation is based upon comparables, assurance is required that the markets are not "distorted", and that compensation is "commensurate with the skill level and experience reasonably necessary to perform the contracted service". *OIG Supplemental Compliance Program for Hospitals*, p 4866-67.

646. In this scheme, the broad use of “percent of revenue” contracts, linked to massive price increases has corrupted and “distorted” the US pharmaceutical market. As per the AKS, a Defendant following these practices simply because others are doing it is not a viable defense. Each Defendant is individually responsible for ensuring, separately and distinctly, the appropriate levels of “commercial reasonableness” and FMV in its business transactions.

647. The AKS separately requires that, in any compensation arrangement, the payment must represent “reasonable compensation”. 26 C.F.R. 1.162-7 (b) (3) (2004). The typical 7 to 8-fold increase in “service fee” compensation per patient for the “old” Defendant drugs, driven by massive price increases, fails this requirement by a wide margin.

648. We have determined that the large “service fees” paid, per patient per year, by the Defendant Manufacturers to the PBM Defendants for both oral “specialty” and “traditional” drug products represents excessive compensation far outside of FMV.

649. Although CMS has increased BFSF reporting requirements in recent years, the data still has important limitations. First, virtually all BFSF and DIR reporting is still done by the plan sponsor “insurance” legal entity in Part D and are only reported at the “aggregate” level (not by individual product).

650. To this day, CMS does not require direct reporting of BFSFs, or their FMV justification, by drug manufacturers. Furthermore, CMS apparently does not require direct reporting of BFSFs by PBM or specialty pharmacy legal entities operating in Part D. As such, the PBM Defendants could potentially conceal fraudulent BFSFs in their legally-separate, but wholly-controlled PBM and specialty pharmacy subsidiaries.

651. Given the varied opportunities to obscure illegal “service fee” payments, we anticipate an investigation of these fraud allegations must include a review of all economic

transfers between the Manufacturer and PBM Defendant, starting with their contractual arrangements. We would seek to obtain all forms of economic transfer from the manufacturers to the PBMs and their affiliates, including BFSFs, discounts, free goods, cost-sharing offsets, etc.

652. The CMS “Four-Part Test” requirement for manufacturers to “itemize” BFSFs by individual product and service is an important consideration in this case. Upon request by the government, such as in a fraud investigation, the Manufacturer Defendants must produce documentation of individual services actually provided by PBM Defendants for specific products and the FMV assessment methodology used to assign appropriate value.

REVIEW OF FAIR MARKET VALUE (FMV)

653. With CMS purposely not defining methods for BFSF FMV assessment in the Part D program, each drug manufacturer must determine its own process based upon acceptable practices in the private marketplace.

654. Although FMV assessment in the business world is designed to provide flexibility, a review of the topic reveals remarkable consistency in recommended approaches across both private and government entities.

655. The definition of FMV provided by the American Society of Appraisers has been generally accepted by both private industry and government agencies: “The price expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm’s length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts”. American Society of Appraisers Business Valuation Standard Glossary, Approved June 2005, Copyright 2005, American Society of Appraisers.

656. In the private sector, generally accepted valuation principles employee three

primary approaches to FMV assessment: the "Income", "Market" or "Cost" Approaches.

657. Using the "Income Approach", the FMV payment would be based upon the amount and timing of cash flows generated by the business, asset or service.

658. The "Income Approach" is typically not relevant for "services" provided by healthcare professionals (i.e., including PBM "service fee" agreements with manufacturers) because "these services cannot, and should not be, directly associated with cash flow." Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.

659. In the "Market Approach", FMV is determined by looking at the market prices of similar services. As such, a manufacturer may decide to determine the FMV of a "service fee" arrangement with a PBM/specialty pharmacy based upon the financial terms of competitor manufacturer/vendor relationships.

660. A "percent of revenue" arrangement is the most common form of "Market Approach" FMV methodology. However, some Manufacturer and PBM Defendant may utilize other contract terms, such as flat fees and lump sum payments, in abusive "service fee" arrangements, particularly if they seeking to avoid legal issues pertaining to "percent of revenue" arrangements.

661. The "Market Approach", including "percent of revenue" constructs, carries significant risk under the AKS.

662. These concerns were summed up in a 1992 letter from the OIG to the IRS: "Merely because another buyer may be willing to pay a particular price is not sufficient to render the price to be paid fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to

result from the purchase." Letter from D. McCarty Thorton, Associate General Counsel, Office of Inspector General (HHS) to T. J. Sullivan, Technical Assistant, off of the Associate Chief Counsel, Employee Benefits and Exempt Organizations, December 22, 1992.

663. In the "Cost Approach", the FMV of the service is based upon the specific cost of providing the service, plus a reasonable profit. In this methodology, the FMV should not exceed the cost to obtain substitute service from a third-party in an "arm's-length" transaction.

664. Our investigation and expert commentary clearly indicate that the straightforward "Cost Approach" is the most appropriate and accurate way to assess the FMV of "service fees" paid by manufacturers to PBMs and specialty pharmacies. First, FMV experts clearly state that FMV payments should be determined for a "service and not a person". Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.

665. In a September 2012 presentation, consultants from Huron Associates stated: "Once a fair market value range for an activity is determined, the amount should be multiplied by the volume of that activity for each type of service and added together to arrive at a fair market value range for the contract." Huron Life Sciences Presentation, "Determining the Bona Fide Nature of Fee-for-Service Arrangements", 9/27/12.

666. In the same presentation, Huron Life Sciences described the particulars of the appropriate "Cost Approach" for "bona fide" services. The "price for a bona fide service" can be thought of as an amount that covers:

- a) *"the direct cost of the service;*
- b) *the overhead associated with delivering that service;*
- c) *the cost of assets used up in the delivery of the service; and,*
- d) *a reasonable return on the assets employed in the delivery of that service".*

667. The appropriateness of the “Cost Approach” was verified by a wide array of industry experts at FMV of BFSF conference attended by Dr. Borzilleri in October 2013.

DIPLOMAT PHARMACY SEC FILINGS: TRUE LOW FMV OF “SERVICE FEES”

668. The SEC filings of the largest remaining independent specialty pharmacy, Diplomat Pharmacy, Inc., verify that the appropriate “arm’s length” compensation to the PBM Defendants for providing manufacturer services should be very modest, even for “complex” specialty drugs.

669. According its public disclosures, Diplomat provides services for all the Defendant “specialty” drugs in this case. However, in comparison to the larger PBM Defendants, Diplomat has apparently historically lacked the negotiating leverage with drug manufacturers that would enable favorable “percent of revenue” service contract arrangements.

670. Despite offering specialty pharmacy services to manufacturers which they claim to be equal to, if not superior to, the PBM Defendants, Diplomat disclosed, in its Form S-1 filed with the SEC in July 2014 for its Initial Public Offering (IPO) that the company received minimal compensation from manufacturers for these “services”.

671. As per page 18 of the S-1, Diplomat states: “We also provide a significant amount of direct and indirect services for the benefit of our pharmaceutical manufacturer customers and our patients in order to get access to specialty drugs, and our failure to provide services at optimal quality could result in losing access to existing and future drugs. In addition, we incur significant costs in providing these services and receive minimal service fees in return.” (Emphasis added)

672. While Diplomat and likely other smaller specialty pharmacies, receive minimal compensation, the larger PBM Defendants are receiving large and escalating “percent of revenue” “fee” payments, tied to massive price increases, for the same Manufacturer Defendant “specialty”

drugs.

673. This wide discrepancy, between the PBM Defendants and smaller “arm’s length” operators, indicates that the appropriate FMV “service fee” payments to the PBM Defendants should be a fraction of what they are currently receiving.

"PERCENT OF REVENUE" CONTRACTS NOT PROTECTED BY SAFE HARBORS

674. Our investigation indicates that “percent of revenue” Part D BFSF contractual arrangements between the Manufacturer and PBM Defendant are not protected by Office of Inspector General (OIG) Safe Harbors regarding “kickbacks”.

675. The relevant OIG Safe Harbors in this matter pertain to Personal Services and Group Purchasing Organizations (GPOs).

676. On April 18, 2003, the OIG issued a document in the Federal Register entitled “OIG Compliance Program Guidance for Pharmaceutical Manufacturers” In the document, OIG states: “In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value, for legitimate, reasonable, and necessary services” (Emphasis added). Further details are provided in the “Personal Services and Management Contracts Safe Harbor”. §1001.952.

677. The April 2003 OIG Pharmaceutical Manufacturer guidance states: “Any rebates or other payments by drug manufacturers to PBMs that are based on or otherwise related to, the PBM’s customers’ purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO Safe Harbor at 42 CFR 1001.952(j).”

678. GPOs are organizations that act as purchasing intermediaries that negotiate contracts between health care providers (primarily hospitals) and vendors of medical products and

services, including manufacturers, distributors and other suppliers.

679. The GPO Safe Harbor appears to be the only federal mechanism potentially affording specific protection for “service fee” contracts structured as a “percent of manufacturer revenues”, albeit with significant limitations.

680. According to the April 2003 guidance, “That safe harbor (GPO) requires, among other things, that the payments be authorized in advance by the PBM’s customer and that all amounts actually paid to the PBM on account of the customer’s purchases be disclosed in writing at least annually to the customer.” This information must be disclosed to the Secretary of Health and Human Services (HHS), upon request.

681. With consent of the entity (i.e., payer client), the GPO Safe Harbor states: “participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.”

682. In violation of the GPO Safe Harbor, in most instances, neither the manufacturer nor PBM Defendant is disclosing the contracts or amounts of “service fees” to either private insurance clients or CMS.

683. In addition, in many contractual arrangements, the PBM Defendants garner manufacturer “service fees” far in excess of the 3% GPO limit.

684. The Safe Harbor states that the GPO can neither be “wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity.” Since the PBM Defendants wholly-own the PBM, specialty pharmacy and plan sponsor subsidiaries in most instances in Part D, the GPO Safe Harbor cannot apply in these predominant situations.

685. In February 2016, with the release of the AMP final rule and its related public commentary, CMS definitively stated that BFSFs are not protected by the GPO Safe Harbor. 42 CFR Part 447. While the AMP rule pertains to Medicaid, the regulatory requirements for BFSFs are identical in all government drug programs, including Part B and Part D.

686. As per the government reply below, drug manufacturers must determine the legitimacy of “service fee” arrangements via the Four-Part test, including a FMV determination.

687. As per page 5180 of the February 2016 AMP rule document: “Comment: A few commenters urged CMS to rely on the GPO safe harbor associated with the federal anti-kickback statute as it defines which fees would qualify as bona fide. The commenter stated that the final rule should state that a fee satisfying the anti-kickback statute safe harbor requirement meets the fair market value prerequisite and is a bona fide service fee”.

688. CMS Response: “We believe that to adopt a categorical exclusion of administrative fees if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination as to whether or not the fee is bona fide because it would mean that the manufacturer has not evaluated the details of the specific arrangements regarding the services being performed. Additionally, we do not agree that we should adopt the safe harbor provisions associated with the federal anti-kickback statute as part of this rule as it does not address bona fide service fee determinations for purposes of determining included and excluded transactions related to a manufacturer’s determination of AMP and best price.”

PBM CLIENT CONTRACT INDICATE ‘SERVICE FEE’ FRAUD

1) EXPRESS SCRIPTS:

689. While manufacturer/PBM “service fee” contracts remain closely guarded by the

Defendants and outside the public domain, we have located several PBM/payer client relationships that indicate the fraudulent drug pricing scheme between the Defendant parties.

690. Our investigation has determined that PBM/payer client contract terms are highly standardized across the PBM industry, both in the private insurance market and Medicare Part D.

691. A good example is the April 2012 PBM contract between Express Scripts and the Oklahoma City Municipal Facilities Authority. Express Scripts, Inc., Pharmacy Benefit Management Agreement, signed December 10, 2012.

692. The Oklahoma City contract states: "In addition, ESI (Express Scripts) provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price (AWP) or (ii) 5.5% of the wholesale acquisition cost (WAC) of the products."

693. Express goes on to highlight other fee opportunities from manufacturers in the Oklahoma City contract. The PBM contract further states: "In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These services are not part of the formulary rebate and

associated administrative fees."

694. As such, the actual service fee payments from some manufacturers to Express Scripts may be considerably higher than the "4.5-5.5% of sales" range stated in the previous paragraph.

695. Further increasing Express Scripts' manufacturer "service fee" opportunity, the Oklahoma contract excludes both "specialty" drugs and its own specialty pharmacies from general contract terms.

696. Exhibit A-1 of the contract states: "Specialty products will be excluded from any price guarantees set forth in the Agreement. In no event will the Mail Service Pharmacy or Participating Pharmacy pricing terms specified in the Agreement, including, but not limited to, the annual average ingredient cost discount guarantees, apply to Specialty Products dispensed by Curascript". (i.e., a wholly-owned specialty pharmacy subsidiary of Express Scripts)

697. The contract further states that Express Scripts' wholly-owned specialty pharmacy subsidiaries can make separate "service fee" arrangements with manufacturers. As per the Oklahoma contract: "ESI has several licensed pharmacy subsidiaries, including our specialty pharmacies. These entities may maintain product purchase discount arrangements and/or fee-for-service arrangements with pharmaceutical manufacturers and wholesale distributors. These subsidiary pharmacies contract for these arrangements on their own account in support of their various pharmacy operations. Many of these subsidiary arrangements relate to services provided outside the PBM arrangement and may be entered irrespective of whether the particular drug is on one of ESI's national formularies. Discounts and fee-for-service payments received by ESI's subsidiary pharmacies are not part of the PBM formulary rebates or associated administrative fees paid to ESI in connection with ESI's PBM formulary rebate programs."

698. With these numerous potential manufacturer "service fee" revenue streams, the PBM Defendants have the opportunity for vast, non-transparent compensation from manufacturers in both Part D and the private sector, especially for "specialty" drugs exhibiting severe price inflation.

699. In the Oklahoma City contract, Express Scripts directly admits its culpability to the "service fee" scheme. First, the contract states: "ESI and Sponsor shall comply with all applicable and existing federal, state and local laws, standards, codes, ordinances, administrative regulations and all amendments and additions thereto, pertaining in any manner to the work and/or services provided by this Agreement."

700. Second, under section 7.13 of the contract, entitled "Alignment of Interests", the agreement states: "ESI acknowledges and agrees (as represented by ESI's response to Sponsor's RFP (i.e., Request for Proposal) that its business model is to align its interests with those of Sponsor. ESI does not engage in any business with a pharmaceutical manufacturer that is designed to manipulate the price or cost of any Brand Drug or Generic Drug in a manner that adversely impacts the cost to Sponsor of providing pharmacy benefits to Members under this Agreement. In this regard, "adversely impacts" is intended to mean that Sponsor would be required to pay a higher price for a Brand Drug or Generic Drug than the market would otherwise provide if it were not for ESI's business arrangement with such pharmaceutical manufacturer."

701. In stark violation of this contract language, the client and CMS drug costs for a wide array of brand drugs have been exorbitantly escalated by the collusive fee arrangements between Express Scripts and drug manufacturers, linked to massive price increases.

702. As stated previously, the wide-ranging Part D liability for the PBM Defendants contrasts sharply with the situation in the private insurance market. Due to lack of ERISA fiduciary

responsibilities, the PBM Defendants have successfully fought of a wide array of private payer lawsuits over the past several decades.

2) CVS Health:

703. CVS Health client contracts also indicate fraudulent “service fee” arrangements with manufacturers based upon severe price inflation.

704. A clear example is CVS Health's May 15, 2008 agreement with the National Association of Counties. In a section entitled “Disclosure of Manufacturer Fees”, this contract states: “Caremark may receive fees or other compensation from Manufacturers, including, without limitation, administrative fees not exceeding three percent of the aggregate cost of the pharmaceutical products dispensed to participants, and fees for property provided or services rendered to a Manufacturer (which may include providing physicians clinical messages consistent with the Performance Drug List, as defined below). Caremark's specialty pharmacies may also receive fees from the Manufacturers for products and services provided ... The term Rebate as used in this Agreement does not include these fees and discounts which belong exclusively to Caremark or Caremark's mail order or specialty pharmacies, respectively.”

705. All reimbursement in the Nation Association of Counties contract was based upon discounts to the Average Wholesale Price (AWP), with no protection from price increases.

706. Caremark provided definitive commentary regarding its handling of manufacturer fees during the 2007 bidding process for a contract to manage pharmacy benefits for the Maryland State Employee and Retiree Health and Welfare Program.

707. In this contract, Maryland sought full “pass-through” to the State for all manufacturer compensation to the PBM, including rebates and “service fees”.

708. During the Maryland negotiations, the State asked CVS Health to confirm the

following contract provision: "The Contractor (i.e., PBM) selected shall not retain any revenue (attributable to the State's business) from pharmaceutical manufacturers or wholesalers, including, but not limited to data fees, access fees, market share fees, rebates, formulary access fees, administrative fees or marketing grants." Before the Maryland State Board of Contract Appeals, Docket Nos. MSBCA 2544, 2548, & 2565, March 2007.

709. Caremark replied in writing as follows: "Caremark agrees to the retail, mail, specialty, market share and rebated components. The following further explains Caremark's positioning on passing through service and data fees: Service fees that Caremark receive from pharmaceutical manufacturers include fees that Caremark may receive in connection with programs offered by Caremark, such as physician or participant education programs; compliance and persistency programs; and communications to healthcare professionals. These fees that are paid to Caremark are not paid to or allocated by Caremark on a client-specific basis. Rather, these fees are paid to reimburse Caremark for its service program offerings. For these reasons, Caremark does not disclose to its clients detailed information regarding service fees received and does not share those with its clients." (Emphasis added)

710. The Maryland Procurement Officer wrote that he "did not understand Caremark's response". He also stated that he found the response to be "purposely confusing" and interpreted Caremark's response to mean that "Caremark was holding back money that he wanted to get for the State".

711. Caremark did not provide greater clarity on these statements despite several requests. Maryland, in turn, awarded the Maryland contract to another vendor despite Caremark's being the lowest bid.

712. These CVS Health disclosures indicate that manufacturer "percent of revenue"

service fee contracts are set at a national level and not determined by the specific service needs of clients.

713. In the "County" contract, CVS Health certified that it "shall not violate the federal anti-kickback statute...with respect to the performance of its obligations under this agreement."

PHYSICIAN INTERVIEWS: LIMITED PBM DEFENDANT CLINICAL ROLE

714. Our discussions with physicians indicate that the clinical claims of the PBM Defendants greatly overstates their limited role in day-to-day patient care. As part of this investigation, Dr. Borzilleri conducted interview with 20-25 leading physicians in the multiple sclerosis, rheumatoid arthritis and cancer therapeutic areas.

715. In virtually all instances, the physicians indicated that the PBM Defendants primary role was to fill/deliver prescriptions and sometimes coordinate financial assistance. The need for patient financial assistance is now ubiquitous for "specialty" drugs after years of vast price inflation.

716. According to the physicians, for a patient newly-started on an injectable multiple sclerosis or anti-inflammatory "specialty" drug, their medical staff provides virtually all clinical support.

717. For the majority of stable patients chronically taking the long-marketed "specialty" drugs at the center of this case, the physicians reported minimal clinical involvement of PBMs/specialty pharmacies. One physician described the clinical claims of PBM/specialty pharmacies as a "gimmick to justify themselves."

718. In fact, numerous physicians stated that attempts at clinical intervention by centralized PBM/specialty pharmacy staff is often harmful, since the organizations typically have no in-person contact with these complex patients. One physician tersely stated, "If patients have a

problem with their CML (chronic myeloid leukemia) drug, they call me, not an 800 number at a PBM or a specialty pharmacy”.

719. Conversations with physician experts uniformly indicated that PBM/specialty clinical services were even more scant for most oral “specialty” drugs. These physician discussions indicate a particularly high risk of “sham” services with “percent of revenue” service agreements for oral “specialty” drugs, particularly those linked to massive price inflation, such as the CML therapies in this case.

720. Prior to Medicare Part D, “service fees” were primarily employed for complex “specialty” patients, not for those treated with “traditional” drugs. We expect discovery to uncover even less legitimate “support services” for the Defendant “traditional” drugs.

PART D ORIGINS OF THE “SERVICE FEE” SCHEME

721. Before Medicare Part D, the dominant PBMs made virtually all their profits from the portion of “rebates” they “retained” from their negotiations with manufacturers on behalf of their private insurance clients.

722. In the private sector, aggressive PBM “rebate” negotiations with manufacturers were essential for controlling drug costs and preventing severe price increases. As compensation, the PBM kept (i.e., “retained”) a significant, but often secretive, portion of these rebates.

723. Concerns regarding potential manufacturer/PBM collusion regarding “rebates” led to several major PBM lawsuits and settlements just as Medicare Part D was coming to fruition. On September 7, 2005, a Settlement Agreement was entered into between the United States, the PBM Advanced PCS and three Relators (Brown, Waite and Schulmann). In the settlement, AdvancePCS paid the sum of \$137.5 million to resolve allegations brought forth by the US government.

724. On March 24, 2004, Advance PCS became a wholly-owned subsidiary of Caremark

Rx, Inc. Subsequently, on March 22, 2007, Caremark Rx merged with CVS to form CVS Caremark (now renamed CVS Health), one of the largest PBM Defendants.

725. The Justice Department made a similar Settlement Agreement in 2006 with another PBM, Medco Health Solutions. Medco merged with PBM Defendant Express Scripts in April 2012.

726. Despite these and other legal matters, as well as widespread concerns about their business practices, last decade PBMs were charged with the central role of “negotiating” in good faith with drug manufacturers on behalf of beneficiaries and taxpayers in the then new Medicare Part D program.

727. Cognizant of the central role of “manufacturer rebates” in the private insurance sector, Congress legislated assuming similar dynamics in the Part D program. Congress expected PBMs to aggressively negotiate with manufacturers for rebates/discounts on behalf of Part D beneficiaries and to be compensated by “retaining” a portion of the savings.

728. Congress required full disclosure of “rebates”, including the portion kept by the PBMs, and their deduction from Part D “negotiated” prices in order lower drug costs for beneficiaries and the program. As such, compensation of PBMs by manufacturers via “rebates” in Part D would lead to lower drug prices and lower future industry profits, particularly regarding the competitively-challenged Defendant products.

729. Part D also requires full disclosure of brand drug pharmacy “price spreads”, thereby limiting another prior key source of revenues/profits for the dominant PBMs. The abuse of brand drug “price spreads” was the central focus of the wide-ranging Average Wholesale Price (AWP) litigation, which resulted in more than \$3 billion in pharmaceutical industry Qui Tam and RICO settlements.

730. In sharp contrast to rebates, legitimate BFSFs from manufacturer to PBMs (and other service providers) are the only major financial item excluded from government drug price calculations, including from Part D “negotiated” prices.

731. PBM compensation via BFSFs would lead to lower rebates and higher drug prices for both collusive partners. In fact, BFSFs became the only pathway for significant non-transparent payments between manufacturers and PBMs/specialty pharmacies in the Part D program.

732. By linking the “service fee” model to vast drug price increases, both manufacturers and PBMs could garner staggering profits. The vast majority of the rising drug costs would be borne primarily by taxpayers in Part D (via the program’s various subsidies) and by largely unaware clients in the private sector.

733. Obviously, this new business model is counter to the intent of the Part D program, which sought legitimate negotiation between PBMs and manufacturers and affordable drugs costs for beneficiaries and taxpayers.

734. It is not surprising that the Defendants quickly pursued their own self-interest by secretly switching from the “rebates” to the “service fee” business model with the arrival of Medicare Part D. What is surprising is the astounding magnitude to which they have advanced the scheme.

735. Our investigation indicates that both the design of Part D and industry competitive threats contributed to the Defendants’ aggressive pursuit of this fraudulent pricing scheme.

736. Most importantly, massive US brand drug patent expirations over the past decade decimated the prior largely secretive PBM “rebate”-based compensation model.

737. Starting around the time of Part D’s arrival, virtually all the top brand drugs in the former top-spending primary care therapeutic categories lost patent protection, including the

cholesterol lowering, anti-hypertensive, antidepressants, anti-ulcer and antihistamines drug segments. As a result, generics now account for 90+% of US prescription volume, compared to about 50% a decade ago.

738. These patent expirations left the biopharmaceutical industry, but especially the Manufacturer Defendants, increasingly dependent upon a small number of remaining brand drugs, many of which also faced severe competition from new entrants.

739. The PBM financial opportunity from manufacturer brand drug rebates, their prior primary source of profits, also plummeted along with the widespread patent expirations.

740. Unfortunately, to the extreme detriment of the American public, rather than accepting the sharply deteriorating competitive market reality, the senior executives at these Defendant companies intentionally chose a fraudulent path for their corporate and personal financial gain.

741. We suspect that the astounding stock-based compensation packages for these senior executives, most of whom have been employed for the duration of the scheme, has been a key factor driving the abuse to the current stratospheric heights.

742. The increasing reliance of the Defendants upon high-cost “specialty” drugs for revenue and profit growth has been a key driver of the escalating scheme. After the massive wave of traditional US patent expirations over the past decade, many of the few remaining brand drugs are extreme-priced and highly-profitable “specialty” drugs, such as the Defendant products for rheumatoid arthritis and cancer.

743. Furthermore, the lax Part D definition of “specialty” drugs, based solely on price without any criteria for complexity or legitimate support needs, helped advance the scheme.

744. Most of the long-marketed drug Defendant brand drugs were widely and

chronically self-administered successfully, at far lower prices, by patients long before the illicit shift to the “service fee” based PBM compensation model.

745. As such, the purpose of this shift in “compensation model” was clearly to generate profits for the collusive partners, not to provide better care or lower drug costs for Part D and its beneficiaries.

746. Primarily driven by massive price increases on older drugs, “specialty” drugs now account for about 35-40% of US drug spending (up from about 10-15% at the start of Part D), while accounting for only 1-2% of overall US prescription volume (but about 10-20% of the shrinking US brand drug volume).

747. This price collusion scheme has masked and offset a tremendous drug cost-savings opportunity over the past ten years for American taxpayers and private employers, but especially in the Medicare Part D program.

748. If not for the massive price increases for the relatively few remaining US brand drugs, especially of the “specialty” variety, American taxpayers, employers and employees would have benefited from a sharp erosion in drug costs over the past decade due to massive patent expirations.

749. These dynamics are clearly reflected in the spending trends for the Medicare Part D program itself. According to CMS’s own data, the average drug costs for the majority of relatively healthy Part D beneficiaries (i.e., those not needing extreme-priced “specialty” drugs) decreased by an astounding 43% (i.e., annual “Direct Subsidies” per beneficiary) between 2006 and 2014. Medicare Trustees Report, 2015.

750. Ironically, both the pharmaceutical and PBM industries frequently cite the Part D program as a glowing example of “free market” success and have recommended it as a “model”

for controlling drug spending in other segments of the US market.

PART D LEGISLATIVE HISTORY AND KEY GOVERNMENT DATA

751. When the Medicare Part D program began, both legislators and CMS expected private competition to generate significant cost savings for seniors and to hold down drugs prices.

752. In October 2003, as Congress was debating the Medicare Part D legislation, President George W. Bush claimed: "The best way to provide seniors with modern medicine, including prescription drugs coverage...is to give them better choices under Medicare. If seniors have choices, health plans will compete for their business by offering better coverage at more affordable prices." The White House, President Calls on Congress to Complete Work on Medicare Bill (Oct. 29, 2003).

753. In November 2003, Secretary of Health and Human Services, Tommy Thompson, stated: "Health insurance companies are going to get into this market...The pharmaceutical benefit managers (PBMs) who will be taking over purchasing of the drugs are going to be able to purchase in bulk with the pharmaceutical companies and hold down prices." (Emphasis added) The Big Story with John Gibson, Fox News Network (Nov. 26, 2003).

754. Key government officials actually suggested Medicare Part D drug cost savings would be even greater than in other federal drug programs, such as Medicaid.

755. While awaiting implementation of the program, in September 2004, Medicare Administrator Mark McClellan claimed that the private insurers would be able to obtain "the best" prices for seniors. He stated: "Our approach is expected to provide the best discounts on drugs, discounts as good or better than could be achieved through direct government negotiation." (Emphasis added) Testimony of Dr. Mark McClellan, Senate Finance Committee, Hearing on The

Medicare Prescription Drug Benefit, 109th Cong. (Sept. 14, 2005).

756. Legislative proponents and CMS clearly expected significant "negotiated" rebates/price concessions from drug manufacturers to be the primary method to limit elderly drug costs, to prevent severe brand drug price inflation and to compensate PBMs and other service vendors for their efforts in the Medicare Part D program.

757. Our investigation has found no public evidence of legislative debate regarding the role of "Bona Fide Service Fees" ("BFSFs") in Medicare Part D, with the issue remaining largely out of the public eye even now, more than a decade since the program's inception.

758. Counter to these expectations, considerable brand drug inflation in Medicare Part D commenced as soon as the program was implemented in January 2006.

759. According to CMS's own data reported in comments to a January 2010 General Accounting Office (GAO) report (GAO-10-242): "An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both specialty and non-specialty tier) between January 2006 and October 2009."

760. In addition, counter to the CMS expectations, the percentage rate of rebates in Medicare Part D have been modest compared to other federal drug programs. Since inception, manufacturer rebates have averaged about 10%, with a modest increase to the 15% range in recent years. Medicare Trustee Annual Reports.

761. Compared to Part D, manufacturer rebates in the Medicaid program have been far larger, averaging 34% of program spending for the years 2006 through 2009. OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.

762. The far larger rebate proportion in Medicaid is because its statutes, in sharp contrast

to Medicare Part D, require that manufacturers provide additional rebates to CMS for any revenues generated by brand drug price increases on marketed products greater than general inflation (CPI-U, Consumer Price Index-Urban).

763. With ongoing severe Part D price inflation, OIG's most recent comparison of Medicaid and Medicare Part D indicated further divergence in rebate trends. For the year, 2012, rebates for the top-spending 200 brand drugs in Medicare D were 15% of the program's spending versus 47% for Medicaid. OIE-03-10-00650, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.

764. In March 2011, the Office of Inspector General (OIG) of the Department of Health and Human Services released a report entitled "Concerns with Rebates in the Medicare Part D Program". OIG HHS Report, OEI-02-08-00050, March 2011. The OIG analysis was based on all Part D sponsor rebate reports and plan bid data for 2008, as well as an in depth review of six selected sponsors.

765. The OIG report disclosed that Medicare Part D sponsors reported receiving \$6.5 billion in drug manufacturer rebates in 2008, corresponding to approximately 10% of total gross Part D drugs costs of \$63 billion for the year.

766. However, central to these fraud allegations and contrary to legislative expectations, PBMs "retained" less than 1% or only \$24 million of the \$6.5 billion (Emphasis added) in total manufacturer rebates reported to CMS in plan sponsor "Direct and Indirect Remuneration" ("DIR") reports for 2008.

767. In addition, 61% of plan sponsors reported that PBMs retained no Part D rebates in 2008.

768. As such, counter to legislative and public expectations, PBMs received minimal rebate compensation from drug manufacturers in 2008. Of note, this OIG report is the only federal document we have been able to locate which discusses manufacturer rebates "retained" by PBMs in the Part D program.

769. Since BFSFs were, by law, the only significant payments excluded from Part D sponsor DIR reports in 2008, virtually all PBM compensation for that year, beyond the minimal reported "retained" rebates, came in the form of BFSFs from manufacturers.

770. Additional direct CMS data confirms both extreme price increases and very low level of rebates for many high-cost "specialty" drugs in Part D.

771. In January 2010, the General Accounting Office (GAO) released a report (GAO-10-242), entitled: Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier". The study analyzed "specialty" drug pricing and manufacturer price concession trends in the first three years of Part D, 2006 through 2008.

772. In the analysis, the GAO obtained "specialty" drug pricing and price concession data for 20 key specialty drugs from 7 large plan sponsors, which represented 51% of all Medicare Advantage Part D enrollment and 67% of standalone Part D enrollment in 2008.

773. In the report, the GAO identified ten chronic conditions commonly treated with "specialty" drugs; then selected two therapies for evaluation from each therapeutic category.

774. For all reviewed "specialty" drugs, the GAO found the level of discounts/rebates was below the 9-11% average in the Medicare Part D program throughout the 2006-2008 period. In addition, the Medicare Part D costs per patient had risen considerably for major "specialty" drugs, due to severe price inflation.

775. In the multiple sclerosis category, negotiated discounts for Biogen's Avonex were only 1.1-2.6% of list price, despite a 35% price increase over the two years. Discounts for Teva's MS therapy were modestly higher, at 6.2-8.0% of list price during the period, with a 26% increase in cost of therapy over the two years.

776. In the anti-TNF category, negotiated discounts for AbbVie's Humira were in the 6.1-8.2% of list price range, with 9% price inflation over the two years. For Amgen's Enbrel, negotiated discounts were lower, at 2.0-3.7% of list price, with 7% price inflation between 2006 and 2008.

777. In the cancer space, no negotiated discounts were provided in any year for Novartis' Gleevec and Roche's Tarceva (an oral drug for lung cancer), despite 24% and 13% price escalation, respectively, between 2006 and 2008.

778. The magnitude of price increases for the above noted "specialty" drugs and many other brand products has greatly accelerated since this dated GAO study.

MEDCO SEC FILINGS: LONG-STANDING, INTENTIONAL "SERVICE FEE" FRAUD

779. Prior to its 2012 merger with PBM Defendant Express Scripts, Medco Health Solutions was the largest independent PBM operating in the US.

780. As part of a 2004 settlement of a prior Qui Tam case and a related (OIG) Corporate Integrity Agreement, Medco provided unique and instructive financial disclosures in its 2003-2011 SEC 10-K filings regarding the burgeoning "service fee" scheme.

781. For the fiscal years 2003 through 2011, Medco disclosed both overall brand manufacturer rebates, as well as the amount of rebates the PBM "retained". Furthermore, Medco also provided disclosures regarding its "service fee" contractual arrangements with drug

manufacturers.

782. The 10-K disclosures indicate that Medco quickly and secretly began shifting away from a “manufacturer rebate”-based compensation model towards a primarily “service fee”-based model in the private insurance market upon the 2003 passage of the Medicare Part D legislation. Furthermore, the vast majority of the transition was complete by 2006 when Part D went into effect.

783. In 2003, Medco “retained” \$1.6 billion, or 54% of all brand rebates from manufacturers, which accounted for more than 100% of Medco’s gross profits for the year.

784. By 2006, Medco “retained” only \$670 million, or 20% of all brand rebates, which accounted for only 28% of surging gross profits for the year.

785. In 2011, Medco’s retained a similar magnitude of rebates (\$757 million), which represented only 16% of exploding operating profits for the year.

786. For Medco overall, gross profits rose 60% from \$1.5 billion in 2003 to \$2.4 billion in 2006 and then nearly doubled in the next five years to \$4.6 billion in 2011, despite a sharp drop in the contribution from “retained” manufacturer rebates.

787. These financial disclosures bluntly indicate that Medco was completely dependent upon manufacturer rebates for its profits at the time of Part D's legislative passage. In fact, in 2003, with “retained” manufacturer rebates, the remainder of Medco's operation, inclusive of its generic business, was unprofitable in 2003.

788. As the largest PBM in the US in 2003 by a wide margin, these Medco financials infer that manufacturer rebates were the dominant profit driver throughout the PBM industry in 2003.

789. In 2003, as the market leader, Medco had by far greatest generic procurement

negotiating leverage and the most efficient mail order operations.

790. If Medco's operations in 2003, excluding "retained" brand rebates, were unprofitable, smaller PBMs were either similarly dependent on manufacture brand rebates for profits or were minimally profitable at best.

791. Medco attributed its remarkable business transformation and profit growth between 2003 and 2011 to gains in its generic business.

792. Medco stated in its 2004 10-K: "the impact on profitability from the increase in generic utilization, particularly in mail order, more than offsets the impact from lower rebate retention on brand name prescriptions."

793. Medco suggested a wider range of profit contributors in its 2006 10-K, stating: "the gross margin effect of overall higher rebate sharing levels is partially mitigated by other elements of pricing including higher claims processing, administrative and other client service fees, higher generic dispensing rates, and increased specialty volumes."

794. In its final 2011 10-K prior to the Express Scripts merger, Medco reiterated its ongoing dependence on generics for profits: "Our future success will be largely dependent on our ability to drive mail-order volume and increased generic penetration rates in light of the significant brand-name drug patent expirations expected to occur over the next several years."

795. Medco never mentioned in its SEC filings a shift in compensation mechanisms for brand drugs from manufacturers towards "service fees" or any impact from Medicare Part D.

796. Based upon its own financial disclosures, Medco's claims regarding accelerating generic profitability between 2003 and 2011 would appear to be mathematically impossible.

797. Excluding "retained" brand drug rebates, Medco reported an astounding increase in its annual gross profits from a -\$71 million loss in 2003 to a \$3.9 billion profit in 2011.

798. With Medco's generic segment apparently unprofitable in 2003, the implied vast transformation in this business segment would appear unfeasible.

799. In reality, the only viable explanation for this profit transformation is the clandestine shift from a PBM compensation model based on brand manufacturer rebates to one based upon "service fees" (driven primarily by massive price increases), as a direct result of the Medicare Part D financial incentives.

800. With the increased brand "spread" and "rebate" transparency requirements in Part D, "service fees" became the only mechanism for large-scale "hidden" payments between drug manufacturers and PBMs. Medco secretly began the transition in the private insurance sector prior to the 2006 enactment of Part D, without any public disclosure.

801. There can be little doubt that other PBMs followed the lead of the market leader, Medco, in this secretive profit transition.

802. The Medco financial disclosures indicate a well-orchestrated, intentional systemic collusive scheme that has caused unimaginable public harm, now more than 13 years in duration.

803. Of note, Medco disclosed that its manufacturer "service fee" contracts with drug manufacturers were calculated as a "percent of revenues", inclusive of price increases.

804. Several of Medco's 10-Ks, including the 2006 document states: "Our contracts with manufacturers provide us with rebates and fees for prescription drugs through our mail-order and retail pharmacy networks, discounts for prescription drugs we purchase and dispense from our mail-order pharmacies, and performance-based fees associated with certain biopharmaceutical drugs. Rebates and fees are generally calculated as a percentage of the aggregate dollar value of a particular drug that we dispensed, based upon the manufacturer's published wholesale price for that drug".

805. In closing, the information in this Complaint all points to a singular conclusion. Namely, that the vast “inexplicable” price inflation for the Defendant brand drugs, and many others in the US marketplace, has been caused by this intentional, long-standing, secretive and collusive “service fee” scheme. After five-plus years of intensive investigation, we conclude that there is no other viable explanation.

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE

False Claims Act

31 U.S.C. §§3729(a)(1) and (a)(2)

(Against All Defendants)

806. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

807. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

808. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval, within the meaning of 31 U.S.C. §3729(a)(1).

809. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2).

810. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be

paid but for Defendants' unlawful conduct.

811. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

812. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT TWO

False Claims Act

31 U.S.C. §3729(a)(3)

(Against All Defendants)

813. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

814. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

815. By virtue of the acts described above, Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims, within the meaning of 31 U.S.C. §3729(a)(3). Defendants, moreover, took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

816. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

817. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every violation of 31 U.S.C. §3729(a)(3) as described herein.

COUNT THREE

Federal False Claims Act

31 U.S.C. §3729(a)(7)

(Against All Defendants)

818. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

819. This is a claim for penalties and treble damages under the Federal False Claims Act.

820. By virtue of the acts described above, including without limitation Defendants' overpayment of BFSFs in lieu of rebates, which would have reduced the ultimate cost reimbursed by the federal government under Medicare Part D, to Service Vendors, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

821. As a result, money was lost to the United States through the non-payment or non-transmittal of money from foregone discounts and rebates to which the United States was entitled and owed by the Defendants, and other costs were sustained by the United States.

822. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

823. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

COUNT FOUR

Federal False Claims Act

31 U.S.C. §§3729(a)(1) and (a)(2)

(Against All Defendants)

824. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

825. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

826. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment and/or approval, within the meaning of 31 U.S.C. §3729(a)(1) by paying BFSFs as illegal remuneration to Service Vendors (primarily PBMs and their specialty pharmacy subsidiaries in Medicare Part D) in order to induce purchase of Defendants' drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

827. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid and/or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2) by paying BFSFs as illegal remuneration to induce Service Vendors to purchase Defendants' drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

828. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

829. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

830. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT FIVE

California False Claims Act Cal

Gov't. Code §12651(a)(7)

(Against All Defendants)

831. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

832. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the "Bona fide Service Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of California via Federally-mandated, non-recourse "Clawback" payments for Defendants' drug costs in the Medicare Part D program.

833. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California, within the meaning of Cal Gov't. Code §12651(a)(7). The State of California has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIX

Colorado Medicaid False Claims Act

Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310

(Against All Defendants)

834. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

835. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Colorado via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

836. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Colorado. The State of Colorado has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVEN

Connecticut False Claims Act

Conn. Gen. Stat. § 17b-301b(a)(7)

(Against All Defendants)

837. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

838. During the Relevant Time Period, the Manufacturer Defendants and the PBM

Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Connecticut via Federally-mandated, non-recourse “Clawback” payments for Defendants drug costs in the Medicare Part D program.

839. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Connecticut, within the meaning of Conn. Gen. Stat. § 17b-301b(a)(7). The State of Connecticut has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHT

Delaware False Claims And Reporting Act

6 Del Code §1201(a)(7)

(Against All Defendants)

840. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

841. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Delaware via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

842. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Delaware, within the meaning of 6 Del. Code §1201(a)(7). The State of Delaware has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINE

Florida False Claims Act

Fla. Stat. Ann. §68.082(2)(g)

(Against All Defendants)

843. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

844. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Florida via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

845. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Florida, within the meaning of Fla. Stat. Ann. §68.082(2)(g). The State of Florida has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TEN

Georgia False Medicaid Claims Act

Ga. Code Ann. §49-4-168.1(7)

(Against All Defendants)

846. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

847. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Georgia via Federally-mandated, non-recourse “Clawback” payments for Defendants drug costs in the Medicare Part D program.

848. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Georgia, within the meaning of Ga. Code Ann. §49-4-168.1 (7). The State of Georgia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT ELEVEN

Hawaii False Claims Act

Haw. Rev. Stat. §661-21(a)(7)

(Against All Defendants)

849. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

850. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Hawaii via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

851. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Hawaii, within the meaning of Haw. Rev. Stat. §661-21(a)(7). The State of Hawaii has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWELVE

Illinois Whistleblower Reward

And Protection Act

740 Ill. Comp. Stat. §175/3(a)(7)

(Against All Defendants)

852. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

853. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Illinois via Federally-

mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

854. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Illinois, within the meaning of 740 Ill. Comp. Stat. §175/3(a)(7). The State of Illinois has thereby suffered actual damage s and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTEEN
Indiana False Claims and
Whistleblower Protection Act
IC 5-11-5.5-2(b)(6)
(Against All Defendants)

855. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

856. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

857. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Indiana, within the meaning of IC 5-11-5.5-2(b)(6).

The State of Indiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FOURTEEN
Iowa False Claims Act
Iowa Code §§ 685.1 through 685.7
(Against All Defendants)

858. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

859. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

860. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Iowa. The State of Iowa has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FIFTEEN
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 46:438.3(C)
(Against All Defendants)

861. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

862. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Louisiana via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

863. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Louisiana, within the meaning of La. Rev. Stat. § 46:438.3(C). The State of Louisiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIXTEEN

Massachusetts False Claims Law

Mass. Gen. Laws ch. 12 §5B(8)

(Against All Defendants)

864. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

865. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the Commonwealth of Massachusetts

via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

866. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts, within the meaning of Mass. Gen. Laws ch. 12 §5B(8). The Commonwealth of Massachusetts has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVENTEEN

Michigan Medicaid False Claims Act

§400.607(3)

(Against All Defendants)

867. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

868. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Michigan via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

869. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Michigan, within the meaning of §400.607(3). The State of Michigan has thereby suffered actual damages and is entitled to recover treble damages

and a civil penalty for each false claim.

COUNT EIGHTEEN

Minnesota False Claims Act

Minn. Stat. §§ 15C.01 through 15C.16

(Against All Defendants)

870. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

871. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Minnesota via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

872. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Minnesota. The State of Minnesota has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINETEEN

Montana False Claims Act

Mont. Code Ann. 17-8-403(1)(g)

(Against All Defendants)

873. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

874. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Montana via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

875. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Montana, within the meaning of Mont. Code Ann. 17-8-403(1)(g). The State of Montana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY

Nevada Submission of False Claims to State or Local

Government Act

Nev. Rev. Stat. Ann. §357.040(1)(g)

(Against All Defendants)

876. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

877. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program.

Intentional failure to do so led to fraudulent overpayment by the State of Nevada via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

878. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Nevada, within the meaning of Nev. Rev. Stat. Ann. §357.040(1)(g). The State of Nevada has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-ONE

New Jersey False Claims Act

N.J. Stat. §2A:32C-3(g)

(Against All Defendants)

879. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

880. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Jersey via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

881. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Jersey, within the meaning of N.J. Stat.

§2A:32C-3(g). The State of New Jersey has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-TWO

New Mexico Medicaid False Claims Act

N.M. Stat. Ann. § 27-14-3(a)(7)

(Against All Defendants)

882. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

883. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Mexico via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

884. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Mexico, within the meaning of N.M. Stat. Ann. § 27-14-3(a)(7). The State of New Mexico has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-THREE

New York False Claims Act

NY CLS St. Fin. §189(g)

(Against All Defendants)

885. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

886. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New York via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

887. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New York, within the meaning of NY CLS St. Fin. §189(g). The State of New York has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FOUR

North Carolina False Claims Act

2009-554 N.C. Sess. Laws §1-607(a)(7)

(Against All Defendants)

888. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

889. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of North Carolina via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

890. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of North Carolina, within the meaning of 2009-554 N.C. Sess. Laws §1-607(a)(7). The State of North Carolina has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FIVE

Oklahoma Medicaid False Claims Act

Okla. Stat. tit. 63, §5053.1B (7)

(Against All Defendants)

891. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

892. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Oklahoma via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D

program.

893. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Oklahoma, within the meaning of Okla. Stat. tit. 63, §5053.1B (7). The State of Oklahoma has thereby suffered actual damages and is entitled to recover treble Oklahoma damages and a civil penalty for each false claim.

COUNT TWENTY-SIX

Rhode Island State False Claims Act

R.I. Gen. Laws §9-1.1-3(7)

(Against All Defendants)

894. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

895. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Rhode Island via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

896. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Rhode Island, within the meaning of R.I. Gen. Laws §9-1.1-3(7). The State of Rhode Island has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-SEVEN

**Tennessee False Claims Act and
Medicaid False Claims Act**

**Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(1)(D)
(Against All Defendants)**

897. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

898. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Tennessee via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

899. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Tennessee, within the meaning of Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(1)(D). The State of Tennessee has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-EIGHT

Texas Medicaid Fraud Prevention Act

**Tex. Hum. Res. Code Ann. §36.002(12)
(Against All Defendants)**

900. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

901. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Texas via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

902. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Texas, within the meaning of Tex. Hum. Res. Code Ann. §36.002(12). The State of Texas has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-NINE
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(7)
(Against All Defendants)

903. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

904. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the Commonwealth of Virginia via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the

Medicare Part D program.

905. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Virginia, within the meaning of Va. Code Ann. §8.01-216.3(a)(7). The Commonwealth of Virginia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY

Washington Medicaid Fraud False Claims Act

Wash. Sess. Laws, Laws of 2012

Ch. 241 §§ 201 through 214

(Against All Defendants)

906. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

907. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Washington via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

908. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Washington. The State of Washington has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false

claim.

COUNT THIRTY-ONE

Wisconsin False Claims For Medical Assistance Act

Wis. Stat. §20.931(2)(g)

(Against All Defendants)

909. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

910. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Wisconsin via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

911. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Wisconsin, within the meaning of Wis. Stat. §20.931(2)(g). The State of Wisconsin has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-TWO

District of Columbia False Claims Act D.C.

Code Ann. §2-308.14(a)(7)

(Against All Defendants)

912. Relator repeats and realleges each and every allegation contained in the paragraphs

above as though fully set forth herein.

913. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the “Bona fide Service Fees” (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the District of Columbia via Federally-mandated, non-recourse “Clawback” payments for Defendants’ drug costs in the Medicare Part D program.

914. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia, within the meaning of D.C. Code Ann. §2-308.14(a)(7). The District of Columbia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-THREE

Unjust Enrichment

915. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

916. By virtue of their conduct, Defendants have been unjustly enriched at the expense of the United States. By obtaining money as a result of their violations of federal law, Defendants were unjustly enriched, and are liable to account and pay such amounts to be determined at trial.

917. By this claim, Relator demands a full accounting of all BFSFs (and interest thereon) incurred and/or paid by the Manufacturer Defendants to the PBM Defendants for services and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United

States.

COUNT THIRTY-FOUR

Common Law Fraud

918. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

919. Manufacturer Defendants made or caused to be made material and false representations concerning the calculation, for which they are responsible, of the BFSFs that were paid to the PBM Defendants for services that CMS requires be provided at FMV, which representations were made by Service Vendors for Services that CMS requires be provided at FMV, with knowledge of their falsity or with reckless disregard for the truth. The PBM Defendants then knowingly submitted false claims for payment to the United States to act upon those misrepresentations to the United States' detriment. The United States acted in justifiable reliance upon both the Manufacturer Defendants and the PBM Defendants misrepresentations by making payments on the false claims.

920. Had the Manufacturer Defendants and the PBM Defendants made truthful statements, the United States would not have made payments for excessive prices for the Defendants' drugs in Medicare Part D.

921. As a direct and proximate cause of Defendants' conduct, the United States has been damaged in an amount to be determined at trial.

PRAYERS FOR RELIEF

922. WHEREFORE, the Relator acting on behalf of and in the name of the United States of America, and on his own behalf, demands and prays that judgment be entered as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.*, and the Anti-Kickback Statute as set forth above;

B. That this Court enter judgment in favor of the United States against the Defendants jointly and severally in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not Eleven Thousand Dollars (\$11,000) for each false claim;

C. In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

D. In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to 31 U.S.C. § 3730(d) and in favor of the Relator against Defendants for reasonable expenses, attorneys' fees and costs incurred by the Relator;

E. In favor of the Relator and the United States and against the Defendants for all costs of this action;

F. In favor of the Relator and the United States and against the Defendants for such other and further relief as this Court deems to be just and equitable.

G. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Cal. Govt. Code §1651(a);

H. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310;

I. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Conn. Gen. Stat. § 17b-301b;

J. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of 6 Del. C. §1201(a);

K. That this Court enter judgment against Defendants in an amount equal to

three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of Fla. Stat. Ann. §68.082(2);

L. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of Ga. Code Ann. §49-4-168.1.

M. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Haw. Rev. Stat. §661-21(a);

N. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

O. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least \$5,000 for each violation of IC 5-11-55;

P. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil penalty of at least \$10,000 for each violation of Iowa Code §§ 685.1 through 685.7;

R. That at this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of La. Rev. Stat. §437 et. seq.;

S. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

T. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of MI Public Act 337;

U. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Minn. Stat. §§ 15C.01 through 15C.16;

V. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Mont. Stat. Ann. 17-8-401;

W. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

X. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of N.J. Stat. §2A:32C-3;

Y. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

Z. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of \$12,000 for each violation of NY CLS St. Fin. §189;

AA. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty or \$11,000 for each violation of 2009-554 N.C. Sess. Laws §1- 607(a);

BB. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Okla. Stat. tit. 63, §5053.1B;

CC. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants'

actions, plus a civil penalty of \$10,000 for each violation of R.I. Gen. Laws §9-1.1-3;

DD. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(l);

EE. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

FF. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of Va. Code Ann. §8.01-216.3(a);

GG. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Wis. Stat. §20.931(2);

HH. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Washington has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214;

II. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of \$10,000 for each violation of D.C. Code Ann. §2-308.14(a);

JJ. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

KK. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

LL. That Relator recovers such other relief as the Court deems just and proper.

JURY DEMAND

923. Plaintiff/Relator demands a trial by jury on all counts.

Dated: August 2, 2018

Respectfully Submitted,
RELATOR John R. Borzilleri, M.D.

_____/s_____
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