GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York
By: LI YU
JESSICA JEAN HU
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel: (212) 637-2734/2726

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *et al.* *ex rel*. RAHIMI and SCHULTE, Plaintiffs, v. WALGREENS BOOTS ALLIANCE, INC., Defendant.	15 Civ. 5686 (PAC) **COMPLAINT-IN-INTERVENTION OF THE UNITED STATES**

The United States, by its attorney, Geoffrey S. Berman, the United States Attorney for the Southern District of New York, alleges for its complaint-in-intervention as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by plaintiff-intervenor the United States of America (the "Government") against defendant Walgreens Boots Alliance, Inc. ("Walgreens") to recover damages and civil penalties arising from Walgreens's violations of the False Claims Act (the "FCA"), 31 U.S.C. § 3729 *et seq*., in connection with dispensing insulin pens, such as the Lantus Solostar and Levemir Flextouch brands, to beneficiaries of federal healthcare programs.

2. When pharmacies like Walgreens seek reimbursement from federal healthcare programs for insulin pens dispensed to program beneficiaries, they are required to submit accurate data concerning, among other things, the days of supply for each prescription

filled.[1] In pharmacy practice, days of supply mean the number of days that the amount of insulin being dispensed should last if the patient used the insulin strictly according to her prescriber's directions for use. Having accurate days-of-supply data is critical to federal healthcare programs because these programs rely on the days-of-supply data reported by pharmacies like Walgreens to decide whether to pay for a refill or to deny a refill claim as premature. *See infra* ¶¶ 32–48.

3. From January 2006 until December 2017, Walgreens routinely submitted false insulin pen claims to four federal healthcare programs — Medicare, Medicaid, TRICARE, and the workers' compensation program administered by the U.S. Department of Labor (collectively, the "relevant federal programs"). These fraudulent submissions resulted from two practices at Walgreens in relation to how it dispensed insulin pens to beneficiaries of the relevant federal programs and sought reimbursement from the programs for these insulin pens.

4. *First*, Walgreens's electronic pharmacy management system defined a box of insulin pens – typically containing five individual pens – as the minimum package size. In other words, Walgreens pharmacists were not able to dispense fewer than a full box of insulin pens at a given time.

5. *Second*, if dispensing a full box of insulin pens would exceed the maximum days of supply limit for insulin established by payors like Medicaid or Medicare, Walgreens would falsely report that the days of supply for the box of pens equaled the applicable limit, instead of reporting the actual days of supply as calculated according to the standard pharmacy billing formula, which was higher and would have resulted in a denial of reimbursement by payors like

[1] A table of the brands of insulin pens relevant to this complaint-in-intervention, along with their associated national drug codes, is attached hereto as Exhibit A.

Medicaid.[2]

6. By engaging in these two practices, Walgreens submitted hundreds of thousands of false insulin pen claims, which *understated* days of supply, to the relevant federal programs. *See infra* ¶¶ 49–53, 62–69. Further, by under-reporting the days of supply data in insulin pen claims, Walgreens prevented the automated checks established by the relevant federal programs from identifying and denying premature refill claims. This, in turn, caused those programs to pay for more insulin than many beneficiaries actually needed. *See infra* ¶¶ 54–61. Finally, Walgreens's routine dispensing of unnecessary insulin pens led to a substantial waste of valuable medications and produced the potential for fraud and abuse involving insulin pens. *See infra* ¶¶ 70–79.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the Government's claims under the FCA pursuant to 28 U.S.C §§ 1331 and 1345.

8. This Court may exercise personal jurisdiction over Walgreens. Further, because Walgreens transacts business in this District and, in furtherance of the fraud alleged, submitted false claims in this District, venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and 1391(c).

THE PARTIES

9. Plaintiff is the United States of America. Through its agencies, the Government administers the relevant federal programs. More specifically, the U.S. Department of Health and Human Services ("HHS") administers the Medicare and Medicaid programs; the U.S. Department of Defense ("DOD") administers the TRICARE program; and the U.S. Department

[2] For example, if a box of Lantus Solostar pens represented a 75-day supply for a given Walgreens patient under the standard pharmacy billing formula, but the Medicaid program denied the claim for a 75-day supply due to its 30-day supply limit, Walgreens would resubmit that claim for the same box of pens as a 30-day supply.

of Labor ("DOL") administers workers' compensation programs for certain federal employees.

10. Defendant Walgreens is an Illinois corporation that operates a nation-wide pharmacy chain in the United States under the Walgreens brand. During all relevant times, Walgreens had its principal place of business in Deerfield, Illinois.

THE FALSE CLAIMS ACT

11. The False Claims Act was originally enacted in 1863 to address fraud on the Government in the midst of the Civil War, and it reflects Congress's objective to "enhance the Government's ability to recover losses sustained as a result of fraud against the Government." *See* S. Rep. No. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266.

12. As relevant here, the FCA establishes treble damages liability to the Government where an individual or entity:

> (A) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or
>
> (B) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, *id*. § 3729(a)(1)(B).

31 U.S.C. § 3729(a)(1)(A)-(B). In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.[3]

13. "Knowing," within the meaning of the FCA, is defined to include a defendant acting in reckless disregard or deliberate indifference of the truth or falsity of information, as well as actual knowledge of such falsity by defendant. *See id*. § 3729(b)(1).

THE RELEVANT FEDERAL HEALTHCARE PROGRAMS

14. ***Medicare Part D***. Medicare is a federal program that provides federally subsidized

[3] Under the FCA, as adjusted by applicable federal laws and regulations, civil penalties for violations occurring between September 29, 1999, and November 1, 2015, are $5,500 to $11,000, *see* 28 U.S.C. § 2461 (notes); 64 Fed. Reg. 47,099, 47,103 (1999); and civil penalties for violations occurring after November 1, 2015, are $10,781 to $21,563, *see* 82 Fed Reg. 9,131, 9,136 (2017).

health insurance for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq*. ("Medicare Program"). As relevant here, Part D of Medicare, which was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, provides prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Parts A or B are eligible to enroll in a prescription drug plan under Part D.

15. Under Medicare Part D, HHS, through its component the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. The Part D sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors, in turn, subcontract with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

16. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy, like a Walgreens location, to be filled. When the pharmacy dispenses drugs to that Part D beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through a pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the Part D sponsor (or the PBM) for the portion of the drug cost not paid by the beneficiary.

17. The Part D sponsor then is required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under Medicare Part D. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program. Submitting PDE claims data to CMS, which is necessary for CMS to

administer the Part D program and make payments to Part D sponsors for qualified drug coverage, is a condition of payment for CMS's provision of Medicare funds to Part D sponsors. *See* 42 C.F.R. § 423.322.

18. Under Medicare Part D, CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. *See* 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS then reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data submitted by the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled for Medicare beneficiaries under Part D. If CMS determines that it underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference; and if CMS determines that it overpaid the sponsor, it will recoup the overpayment from the Part D sponsor.[4] The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. *See* 42 C.F.R. § 423.315(a).

19. In order to receive Part D funds from CMS, the Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions. By statute, all contracts between a Part D sponsor and HHS must include a provision whereby the sponsor agrees to comply with the applicable requirements and standards of the Part D program as well

[4] After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. *See* 42 C.F.R. § 423.336.

as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112. Further, CMS regulations expressly require Part D sponsors to certify, in their contracts with CMS, that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA. *See* 42 C.F.R. § 423.505(h)(1).

20. Accordingly, all contracts entered into between CMS and Plan D sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729*, et seq.*)[.]" Further, CMS regulations also expressly require that all subcontracts between Part D sponsors and downstream entities – including pharmacies – contain language obligating the pharmacies to comply with all applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. § 423.505(i)(4)(iv).

21. ***Medicaid***. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). Among the states, FMAP is at least 50 percent and as high as 83 percent.

22. The Medicaid programs in all 50 states and the District of Columbia reimburse for prescription drugs. The majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw

down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). *See* 42 C.F.R. § 430.30.

23. ***TRICARE and DOL's Workers Comp Programs***. The Government, through DOD and DOL, administers the TRICARE and the workers' compensation programs for certain federal employees, respectively. More specifically, TRICARE provides healthcare benefits, including pharmacy benefits, for certain current and former members of the armed services and their dependents. *See* 10 U.S.C. § 1071 *et seq*. To qualify for TRICARE coverage, services, including pharmacy services, must be medically necessary. *See* 32 C.F.R. § 199.4(a). Similarly, the workers' compensation programs administered by DOL provide coverage for pharmacy services when they are medically necessary.

THE USE OF INSULIN PENS TO TREAT DIABETES

24. ***Insulin Therapy***. Insulin is a peptide hormone secreted by the pancreas that controls blood sugar levels. Patients with Type 1 and Type 2 diabetes often need insulin injections because they cannot generate enough insulin themselves.

25. To obtain the types of insulin pens at issue here from pharmacies like Walgreens, diabetic patients must obtain prescriptions from their physicians. When a physician prescribes insulin to a patient, the physician must provide directions specifying how frequently the patient should inject insulin and much insulin to inject each time.

26. The directions of use provided by physicians typically indicate the amount of insulin that patients need to inject in terms of a certain number of "units" of insulin. For example, the insulin prescription for a Medicaid beneficiary ("Patient A"), who has Type 2

diabetes and lives in Bronx County, New York, directs him to "inject 23 units [of Lantus insulin] subcutaneously every night at bedtime."

27. When they prescribe insulin, physicians emphasize to their patients the importance of following the prescribed directions for insulin usage. It is critical for patients to understand the importance of following their prescribed insulin regimen because, among other reason, overusing insulin can exacerbate the risk of hypoglycemia (*i.e.*, excessively low blood sugar level), which can lead to coma and other serious health consequences.

28. ***Insulin Pens***. Insulin pens are reusable devices (shaped like pens) that patients can use to inject themselves periodically with insulin. Each type of insulin pens relevant here consists of a syringe, which contains insulin solution, inside a hard plastic case.[5] These types of insulin pens are all designed and manufactured to allow diabetic patients to select the amount of insulin to inject by turning a dial at the end of the pen.

29. Since at least 2000, insulin pens have become a common way for diabetic patients to receive insulin therapy. During the relevant times, the most popular brands of insulin pens include Lantus Solostar, Humalog Kwikpen, Levemir FlexTouch, and Novolog FlexPen.

30. Each of these common brands of insulin pens contains 3 milliliters of insulin solution. Each milliliter of insulin solution, in turn, contains 100 units of insulin. In other words, each individual insulin pen contains 300 units of insulin.

31. For purposes of distributing insulin pens to wholesalers and pharmacies, the insulin manufacturers package the insulin pens in tamper-evident cartons that, in most cases, contain five individual pens each. Thus, a full carton of Lantus Solostar, Humalog Kwikpen or Levemir FlexTouch insulin pens provides 1,500 units of insulin.

[5] Insulin pens cartons do not include the needles that patients use to inject insulin. Instead, the needles are sold separately by pharmacies. Further, unlike the insulin pens, the needles for injecting insulin are *not* reusable and are intended to be discarded after each injection.

FEDERAL PROGRAMS RELY ON PHARMACIES LIKE WALGREENS TO REPORT ACCURATE DAYS-OF-SUPPLY DATA IN ORDER TO PROCESS REIMBURSEMENT CLAIMS

A. The Importance of Accurate Days of Supply Data for Pharmacy Claim Processing

32. To seek reimbursement from payors like Medicare for dispensing medications like insulin pens to patients covered by the payors, pharmacies like Walgreens are required to submit claims containing a standard set of data that have accepted definitions in the pharmacy billing context.

33. Payors, or the prescription benefit managers ("PBMs") acting on their behalf, rely on the accuracy of the claims data submitted by pharmacies to make reimbursements decisions.

34. Among the types of claims data that Walgreens must submit to payors to obtain reimbursement for insulin pens are the "quantity dispensed" and the "days of supply" fields. In the pharmacy billing context, "quantity dispensed" means the total amount of insulin dispensed to a patient when she fills her prescription; and "days of supply" mean the number of days that the quantity of insulin dispensed will last if the patient uses the insulin strictly according to the directions for use provided by her insulin prescriber.

35. Pharmacies follow a standard formula to calculate days of supply. Specifically, a pharmacist divides the total quantity of medication being dispensed to a particular patient by that patient's "daily dose," *i.e.*, the specific quantity of medication that the prescription directs the patient to take each day. Further, at the times relevant here, Walgreens's internal procedures recognized this formula as the standard for pharmacy billing purposes. For example, a 2014 Walgreens policy instructed its pharmacy staff to use this formula to calculate days of supply:

Total Quantity Dispensed / Daily Dose = Days Supply

36. To illustrate — the daily dose of insulin for Patient A (the Medicaid beneficiary living in the Bronx, *see supra* ¶ 26) is 23 units of insulin because Patient A's insulin prescription directed him to "inject 23 units [of Lantus insulin] subcutaneously every night at bedtime."

Thus, according to the formula, when Walgreens dispensed a box of Lantus insulin pens containing 1,500 units of insulin to patient A in October 2014, the days-of-supply for this fill was 65 days (*i.e.*, 1,500 units of insulin divided by 23 units of insulin per day = 65 days).

37. Executives and managers at Walgreens understood how important it was for Walgreens to accurately report days-of-supply data to payors. For example, a 2016 internal policy advised pharmacy employees at Walgreens that "ensuring an accurate [days of supply] is entered correctly is important for both third party billing and customer service reasons."

38. Payors and PBMs also regularly emphasize the importance of the requirement for pharmacies to accurately report the days-of-supply data in the claims they submit for reimbursement. For example, the pharmacy manual issued in 2008 by WHI Health Initiatives – a PBM controlled by Walgreens until 2010 – instructed participating pharmacies that the days-of-supply data they submitted "must be legible, accurate, and complete."

39. A key reason that payors and PBMs require pharmacies to report accurate days-of-supply data is that payors and PBMs typically rely on this data to decide whether to reimburse refill claims or to deny such claims as premature. Specifically, payors and PBMs typically calculate the date on which a prescription refill would be needed (the "refill due date") based on the date when a patient last filled a prescription and the days of supply reported by the pharmacy for that prior fill. Payors and PBMs also typically have automated processes that deny as premature refill claims too far in advance of the refill due dates.

B. The Relevant Federal Programs Required Pharmacies to Report Days-of-Supply Data Accurately in Their Reimbursement Claims

40. During the relevant times, Medicare Part D, Medicaid, TRICARE, and DOL's workers' compensation programs all required participating pharmacies like Walgreens to report accurate days-of-supply data accurately in the claims they submitted to these programs for reimbursement.

41. ***Medicare Part D***: Under Medicare Part D, for example, CMS regulations have required Part D sponsors to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," has provided in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for 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.
> …
> (3) 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 under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. . . .

42 C.F.R. § 423.505(k). Compliance with the regulatory requirement that PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under Medicare Part D.

42. In accordance with this regulatory requirement, and since the Part D program began, CMS has required each Part D sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"), which states:

> Pursuant to the contract(s) between the [CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D

> plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

All approved Part D sponsors who received payment under Medicare Part D after 2006 submitted these required Attestations in the same or similar format.

43. For pharmacies like Walgreens that participate in Medicare Part D, CMS regulations further provide: "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 on 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 obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

44. The pharmacy manuals and other published guidance issued PBMs that adjudicate pharmacy claims for Medicare Part D plans also have consistently indicated that PBMs rely on the days of supply submitted by the participating pharmacies to determine whether the PBMs would pay or deny claims. Finally, the Medicare Part D PBMs also conduct audits of pharmacy claims on an ongoing basis, and the accuracy of days of supply reporting has typically been one of the essential components of such audits.

45. ***Medicaid***. Similarly, pharmacies like Walgreens that participate in Medicaid have typically been required to sign enrollment agreements with their states Medicaid programs certifying compliance with the state and federal Medicaid requirements, including the requirement to submit accurate claims data. In New York, for example, pharmacies have been required to periodically sign a "Certification Statement for Provider Billing Medicaid," in which they certify that "ALL STATEMENTS, DATA AND INFORMATION TRANSMITTED ARE TRUE, ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE" and that "NO MATERIAL FACT HAS BEEN OMITTED[.]" (capitalization in original).

46. Like CMS in the Medicare Part D context, state Medicaid programs also have issued guidance to pharmacies like Walgreens explaining that Medicaid relies on the accuracy of the days-of-supply data submitted by pharmacies to decide whether to pay or deny refill claims. In 2008, for example, New York Medicaid issued an update notifying pharmacies that an "early refill edit will be implemented [to] deny drug claims when less than 75% of the previously dispensed amount, based on previously dispensed supply, has been used." That update further

explained that the "claim denial message will … specify the date that is the earliest the [refill] claim will be accepted for payment."

47. Further, like Medicare Part D PBMs, state Medicaid programs – or PBMs acting on their behalf – have regularly audited claims submitted by participating pharmacies to determine whether they accurately reported days-of-supply data.

48. Finally, TRICARE and the workers' compensation programs administered by DOL have similar requirements for participating pharmacies to submit claims that accurately report the days of supply for the quantities of medication being dispensed. *See*, *e.g.*, TRICARE Standard Handbook, at 20.

WALGREENS SYSTEMATICALLY UNDER-REPORTED THE DAYS OF SUPPLY FOR INSULIN PENS IN CLAIMS SUBMITTED TO THE RELEVANT FEDERAL PROGRAMS

A. Walgreens's Dispensing Practices for Insulin Pens Resulted in the Submission of False Claims and Under-reporting of Days-of-Supply Data to Federal Programs

49. From January 2006 until December 2016, Walgreens routinely submitted to the relevant federal programs false insulin pen claims that understated the days-of-supply for the insulin pens dispensed. These fraudulent submissions were the result of two practices in relation to how Walgreens dispensed insulin pens and billed the federal programs for these pens.

50. *First*, Walgreens configured its pharmacy management program – Intercom Plus – to designate a full box of insulin pens, instead of individual pens, as the "minimum quantity." In practice, this meant that pharmacists at Walgreens could *not* dispense individual insulin pens, even when a patient needed less than a full box — for example, a Walgreens pharmacist noted in an Intercom Plus entry in May 2015 that "[ano]ther pharmacy was dispensing 2 pens, we can only dispense in box of 5 pens," so the patient "loses 9 ml [*i.e.*, three pens worth of insulin]."

51. *Second*, because it often takes patients several months to use up a full box of insulin pens, and because payors like Medicare Part D plans and Medicaid often limit the maximum

days of supply for each fill to 30 days, Walgreens's full-box-only insulin pen dispensing practice frequently resulted in its insulin pen claims being denied by the payors because the days of supply exceeded the payors' limits. When this occurred, the practice at Walgreens was not to seek permission for an extended days of supply from the payor or to reduce the quantity of insulin being dispensed. Instead, pharmacists at Walgreens were trained to resubmit the claim for the same quantity of insulin, but to falsely under-report the days of supply to make it match the payor's limitation so that the claims would be paid.[6]

52. In New York, for example, certain Medicaid plans limit the days of supply for each fill of insulin to 30 days. Thus, even though a full box of Lantus insulin pens represented a 65-day supply for Patient A (the Medicaid beneficiary in the Bronx with a prescription to inject 23 units of Lantus insulin each night, *see supra* ¶ 36), Walgreens repeatedly submitted claims to Patient A's Medicaid plan falsely reporting these boxes of Lantus pens as 30-day supplies.

53. Further, during the relevant times, Walgreens configured its electronic pharmacy management system – Intercom Plus – to record and then automatically reuse the days of supply reported for the initial fill for a prescription for all subsequent refills. In practice, this meant that whenever Walgreens under-reported the days of supply for the initial fill of an insulin pen prescription, it would continue to falsely under-report the days of supply for all the subsequent refills for that prescription.

B. Falsely Under-Reporting Days-of-Supply Data for Insulin Pens Also Resulted in Walgreens Dispensing Premature Refills to Federal Program Beneficiaries

54. Beyond submitting individual false claims, the practice of under-reporting days of supply for insulin pens also led Walgreens to dispense, and bill the relevant federal programs for,

[6] The payor would not be aware that the resubmitted days of supply data Walgreens was in fact inaccurate because pharmacies do not provide the daily dose or the directions of use information to payors as part of pharmacy billing.

premature refills to program beneficiaries. There were two main causes for this result.

55. *First*, during the relevant times, the pharmacy management system used by Walgreens – Intercom Plus – relied on the reported days-of-supply data to track when Walgreens should send out refill reminders to patients. In practice, this meant that, whenever Walgreens falsely under-reported the days-of-supply data for a given prescription, Intercom Plus also sent out refill reminders to that patient prematurely.

56. In Patient A's case, for example, because Walgreens under-reported the days of supply for the boxes of Lantus insulin pens it dispensed to this patient, *see supra* ¶ 52, Patient A repeatedly received refill reminders from Walgreens every *30 days*, instead of every *65 days* as he should have if Walgreens had accurate reported the days of supply.

57. *Second*, under-reporting days of supply also obstructed the federal programs' ability to identify and deny premature refills because their tracking procedures – such as New York Medicaid's "early refill edit" procedure, *see supra* ¶ 47 – rely on the accuracy of days-of-supply data reported by Walgreens.

58. To illustrate, consider how Walgreens dispensed two boxes of Lantus insulin pens to Patient A on September 13 and October 10, 2014. If Walgreens had accurately reported to New York Medicaid that each box of Lantus pens represented a 65-day supply for Patient A, then Medicaid's "early refill edit" would have denied the October 10 refill claim as premature. Specifically, because Patient A had received a full box of Lantus pens on September 13, the "early refill edit" would have calculated that Patient A should not have used up 75% of that box by October 10. However, because Walgreens falsely under-reported the box of Lantus pens for Patient A as a 30-day supply, the "early refill edit" did not identify or deny the October 10, 2014 refill claim as premature. Instead, Medicaid was misled to approve and pay that refill claim.

59. Nor were the premature refills for Patient A limited to just October 2014. During the 3½-month period between August and November 2014, Walgreens dispensed four boxes of Lantus insulin pens to Patient A. The 20 Lantus pens in those boxes in fact represented an 8-month supply of insulin for this patient.

60. Similarly, in January, February, and March 2017, Walgreens dispensed three boxes of Levemir Flextouch pens each time to a Medicaid beneficiary in Waycross, Georgia ("Patient B"), even though Patient B's insulin prescription directed her to "inject 20 units of twice daily" (*i.e.*, 40 units total per day). Instead of reporting each fill of three boxes as a 112-day supply (*i.e.*, 4,500 units/40 units per day) for Patient B, Walgreens reported each as a 30-day supply. This, in turn, resulted in Walgreens dispensing nine full boxes of Levemir pens to Patient B in the span of three months, whereas these 45 Levemir pens represented almost a full year's supply for Patient B.

61. In short, the impact of Walgreens's practice of falsely under-reporting days-of-supply data for insulin pens was not limited to individual false claims or isolated instances of premature refills. To the contrary, these fraudulent submissions resulted in widespread and repeated premature refills for thousands upon thousands of federal program beneficiaries like Patient A and Patient B.[7]

C. Walgreens Knew That Its Pharmacies Were Falsely Under-Reporting the Days of Supply for Insulin Pens and That It Was Causing Premature Refills

62. As noted above, *see supra* ¶¶ 42–44, PBMs that adjudicate claims for Medicare Part D plans and Medicaid programs have issued guidance to emphasize the need for pharmacies to report days-of-supply data accurately in their reimbursement claims.

[7] In addition to impeding the ability of the federal programs' tracking procedures to deny premature refill claims, Walgreens's insulin pen dispensing and billing practices also prevented its own pharmacists from getting "refill too soon" warnings within Walgreens's own pharmacy system and advising patients to wait and get refills at appropriate intervals.

63. In 2012, for example, a national PBM ("PBM 1") updated its pharmacy manual to instruct pharmacies participating in Medicare Part D that if that PBM 1 rejected a claim for exceeding the maximum days-of-supply limit, then the pharmacy may call PBM 1 "to request an override." The manual further provided that "[a]ny claims resubmitted must be entered with the accurate quantity and days supply," and that the pharmacy "maintains responsibility to adhere to appropriate refill intervals."

64. PBMs also have regularly audited the claims submitted by pharmacies. During the relevant period, audit findings from multiple PBMs provided ample notice to Walgreens that it not only was regularly under-reporting the days of supply for insulin pens, but also that this practice frequently led to repeated premature refills on the same insulin pen prescriptions.

65. For example, in June 2014, Walgreens received a notice of audit findings from a national PBM ("PBM 2") seeking refunds for multiple claims in which a Walgreens pharmacy located in Iowa had reported "incorrect days [of] supply" for Lantus insulin pens and, thereby, causing refills to be dispensed prematurely.

66. In September 2014, PBM 2 issued another notice of audit findings concerning a premature refill of Novolog pens by a Walgreens pharmacy located in Minnesota.

67. Similarly, in October 2014, Walgreens received a notice of audit findings from PBM 2 seeking refunds for 10 instances where a Walgreens pharmacy located in Wisconsin had reported incorrect days-of-supply data for Humalog, Novolog, Lantus, and Levemir brands of insulin pens and dispensed premature refills of those types of insulin pens to patients.

68. The audit findings based on the under-reporting of days-of-supply data and premature refills of insulin pens at Walgreens were not limited just to PBM 2. In December 2014, for example, Walgreens received a set of audit results from PBM 1 that sought refunds for,

among other things, a premature refill of the Novolog brand of insulin pens to a patient by a Walgreens pharmacy located in Florida.

69. Likewise, throughout 2015, Walgreens received a series of audit reports from a Midwest regional PBM that sought refunds because Walgreens had under-reported the days of supply for numerous insulin pen prescriptions and, in many cases, dispensed premature refills.

D. Walgreens's Submission of False Insulin Pen Claims and Dispensing of Premature Refills Led to Waste and Created the Potential for Other Fraud and Abuse

70. To participate in federal programs like Medicare Part D and Medicaid, Walgreens has been required to implement training for its pharmacy employees on their obligations to recognize and avoid fraud, waste, and abuse when they dispense medications to federal program beneficiaries.

71. As part of the waste, fraud, and abuse training at Walgreens, pharmacists learned that examples of waste include instances where a pharmacy repeatedly dispenses premature refills to a patient and causes the patient to have to discard the unnecessary medications. Yet, during the relevant times, the practice at Walgreens to regularly under-report the days of supply for insulin pens led to many such instances of waste involving insulin pens.

72. For example, in the case of a Medicaid beneficiary with Type 2 diabetes living in Brooklyn ("Patient C"), Walgreens repeatedly under-reported the days of supply for Humalog and Lantus insulin pens it dispensed to this patient between 2014 and 2017. This, in turn, led to Patient C receiving automated refill reminder calls from Walgreens for the all the types of medications she used.

73. When Patient C or her children went to pick up the refills, Walgreens placed boxes of Humalog and Lantus pens – which the patient did not need because she had not used up her previous insulin pen fills – in the same bag along with Patient C's other medications. Over time, Patient C accumulated a number of unused boxes of Lantus and Humalog insulin pens. So

Patient C eventually discarded those unused boxes of insulin pens – which cost approximately $400 per box – by taking them to a medication disposal site.

74. Another Medicaid beneficiary ("Patient D"), who lives in the Bronx and filled her insulin pen prescriptions at a Walgreens location until early 2017, had a very similar experience.

75. Patient D's doctor initially prescribed 10 units of Lantus insulin per day for her in 2014 and increased it to 20 units per day in 2015. The Walgreens location, however, repeatedly dispensed full boxes of Lantus insulin pens to Patient D, falsely reported these as 30-day supplies, and also sent her monthly refill reminders.

76. Because Patient D typically had extra Lantus pens left over from her prior fills when Walgreen refilled her Lantus pen prescriptions, she regularly threw away the leftover Lantus pens, which cost approximately $100 each.

77. Beyond sheer waste, Walgreens's practice of routinely reporting false days-of-supply data for insulin pens also created the potential for other fraud or abuse.

78. According to Walgreens's own training, it is a type fraud or abuse for patients to resell prescription medications using online platforms like Craig's List or eBay. Yet, during the relevant times, there frequently were postings on these online platforms for the resale of insulin pens individually or in full boxes. In a number of cases, the postings contained photographs of boxes of insulin pens that still had labels showing that they had been dispensed by Walgreens.

79. In short, by under-reporting the days of supply, Walgreens not only submitted false claims relating to thousands upon thousands of federal program beneficiaries, but also caused waste and created the potential for other fraud and abuse involving insulin pens.

FIRST CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment

(31 .S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A) (Supp. 2009))

80. The Government incorporates by reference paragraphs 1 through 79 above as if fully set forth in this paragraph.

81. The Government asserts claims against Walgreens under Section 3729(a)(1) of the FCA, 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

82. As a result of its improper dispensing practices in connection with the sale of insulin pens to beneficiaries of the relevant federal programs, Walgreens knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

83. By reason of the false or fraudulent insulin pen claims that Walgreens knowingly presented, or caused to be presented, for payment or approval, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements

(31 U.S.C. § 3729(a)(2) (2000) and, as amended, 31 U.S.C. § 3729(a)(1)(B) (Supp. 2009))

84. The Government incorporates by reference paragraphs 1 through 79 above as if fully set forth in this paragraph.

85. The Government asserts claims against Walgreens under Section 3729(a)(2) of the FCA, 31 U.S.C. § 3729(a)(2) and, as amended, 31 U.S.C. § 3729(a)(1)(B) (Supp. 2009).

86. As a result of its improper dispensing practices in connection with the sale of insulin pens to beneficiaries of the relevant federal programs, Walgreens made, used, or caused to be made or used, false records or statements that were material to getting false or fraudulent claims paid by the relevant federal programs.

87. By reason of these false records or statements, the Government has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the Government, requests that judgment be entered in its favor as follows:

(a) on the First and Second Claims for relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(1) and 3729(a)(2) and, as amended, 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B)), a judgment against Walgreens for treble the Government's damages, in an amount to be determined at trial, plus a civil penalty in the maximum applicable amount for each violation of the FCA by Walgreens;

(b) an award of costs incurred by the Government against Walgreens pursuant to 31 U.S.C. § 3729(a)(3); and

(c) such further relief as is proper.

Dated: New York, New York
January 10, 2019

GEOFFREY S. BERMAN
United States Attorney

By: */s/ Li Yu*

LI YU
JESSICA JEAN HU
Assistant United States Attorneys
United States Attorney's Office, Civil Division
86 Chambers Street, 3rd Floor
New York, NY 10007
Tel: (212) 637-2734/2726
Email: li.yu@usdoj.gov
jessica.hu@usdoj.gov
Attorneys for the Government

Exhibit A

Insulin Pen Brands Relevant to the Complaint-in-Intervention

Brand Name	National Drug Code
APIDRA	00088250205
HUMALOG	00002771227
HUMALOG	00002879759
HUMALOG	00002879859
HUMALOG	00002879959
HUMALOG	00002751659
HUMALOG	00002872559
HUMALOG	00002879459
HUMULIN	00002880359
HUMULIN	00002882427
HUMULIN	00002880559
LANTUS	00088221905
LANTUS	00088222052
LANTUS	00088222060
LEVEMIR	00169643910
LEVEMIR	00169643810
NOVOLOG	00169369619
NOVOLOG	00169633910
NOVOLOG	00169330312
TOUJEO	00024586903
TRESIBA	00169255013
TRESIBA	00169266015