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Combating Health-Care Fraud

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Introduction

Susan Strawn

Civil and Criminal Health Care Fraud and Affirmative Civil Enforcement Coordinator

Executive Office for United States Attorneys

Welcome to the August 2022 edition of the Department of Justice Journal of Federal Law and Practice. This edition of the journal focuses on health-care fraud. The timing is fitting. September 30, 2021, around the time when work on this edition began, marked the end of the 25th year of the Health Care Fraud and Abuse Act Program (HCFAC), an important milestone in the fight against health-care fraud. The HCFAC Program supports the work of all the authors contributing to this issue, as well as their colleagues across the country.

The HCFAC Program was created as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), PL 104-191. To the public, HIPAA is better known for privacy and nondiscrimination rules. But HIPAA also created a number of health-care offenses and enforcement tools, including the “HIPAA subpoena,” 18 U.S.C. § 3486, and mandated that the Department of Justice (Department) and Department of Health and Human Services (HHS) coordinate closely to support efforts to investigate and prosecute health-care fraud. In order to further that goal, HIPAA provided a funding source, specifically requiring that amounts equaling recoveries from health-care fraud investigations (including civil, criminal, forfeitures, and administrative penalties) be deposited in or transferred to the Federal Hospital Insurance Trust Fund. Monies are then appropriated from the Trust Fund to the Health Care Fraud and Abuse Control Account (Control Account) in an amount the Attorney General and HHS Secretary annually certify are necessary to finance anti-fraud activities. Appropriations from the Control Account, along with other appropriations, fund attorneys, investigators, and litigation support, among other things, to combat health-care fraud.

The results of the Program are impressive. According to the annual HCFAC Reports delivered to Congress,¹ since 1997, over \$57 billion has been collected by the Department and the HHS Office of the

¹ *Health Care Fraud and Abuse Control Program Report*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://oig.hhs.gov/reports-and-publications/hcfac/> (last visited Aug. 23, 2022).

Inspector General in criminal, civil, and administrative health-care fraud matters. Of that, almost \$40 billion has been returned to the Medicare Trust Funds, an average of over \$1.5 billion per year. Many additional dollars were returned to Medicaid, Tricare, the Veteran's Administration, other federal programs, and private victims. In the same period, 13,628 defendants have been convicted of health-care fraud offenses, an average of 545 every year.

Yet, health-care fraud persists. Given the perennial nature of this scourge, the reader might be forgiven for asking, "What is new about health-care fraud?" The answer is "plenty." Like health care itself, health-care fraud evolves, finding new vulnerabilities or programs to exploit. Just as investigators follow stolen money to find the criminals, fraudsters follow legitimate money to transform into illicit profits. The COVID public health emergency resulted in the injection of massive amounts of money into health care, and fraudsters were quick to take advantage. While the Department will be dealing with pandemic-related fraud for years to come, in this issue Assistant United States Attorneys (AUSAs) Kenneth Coffin and Andrew Robbins tell the story of how they acted quickly and decisively early in the pandemic to shut down swindlers hawking phony COVID vaccines and cures to an anxious public.

Economic incentives to promote the widespread use of electronic health records (EHR) provided another new target for creative but malevolent practices. Civil Division Trial Attorney Nicholas Perros explores the resulting enforcement efforts in cases involving EHR, ranging from certification fraud to numerous insidious kickback schemes enabled by EHR. While paying kickbacks to program beneficiaries is not new, AUSA Ellen Bowden McIntyre and Civil Division Trial Attorney Jake Shields team up to explain recent schemes in this area. Investigations of these complex arrangements have resulted in settlements of over \$1 billion in the last decade.

The breadth and complexity of health-care fraud cases also provides fertile ground for significant legal developments. The last few years are no exception. Civil Division Trial Attorneys Ben Wei and Diana Cieslak expertly analyze False Claims Act (FCA) decisions since the 2016 Supreme Court decision in *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, and their impact on health-care fraud cases, while AUSAs Michael Castiglione, Austin Hall, Richard Hayes, and Bonnie Perlin pool their considerable talents to examine recent decisions addressing the issue of whether an anti-kickback

violation must cause the presentment of claims for liability to arise under the FCA.

In addition to articles exploring new schemes and legal issues, our accomplished contributors share the experience they have gained from recent battles in this practice area, and best practices they have developed. AUSAs Nathaniel Kummerfeld and Adrian Garcia, two of the toughest in the field, provide insights on how to try a complicated kickback case. AUSA Paul Kaufman advises on a key motion to advance parallel proceedings, which are often key to achieving the best result for the government. AUSA Dan Fruchter shares lessons learned from a three-week trial in 2019 involving the falsification of data in numerous clinical drug trials, a difficult area to investigate, but one where ensuring integrity is crucial to patient safety and the development of new medical treatments. Former AUSA and current Executive Office for United States Attorneys Assistant Director Denise Simpson and AUSA Nathaniel Kummerfeld provide advice on working with state and local partners to maximize resources and recoveries. AUSAs Davis Rhorer and Chase Zachary argue for a more robust use of civil penalties under the FCA. And of critical importance after the investigation is done and liability established, AUSA Daniel Meyler provides valuable advice on how to get the money when, as is often the case, the defendant has been purchased by a new entity.

With health-care spending accounting for almost 20% of the American gross domestic product in 2020,² the sector remains an inviting target for criminals and civil fraudsters. Enforcement plays a critical role in punishing and deterring fraud, as well as in returning money to the Medicare Trust Funds and other health-care programs. We hope that you find this edition valuable and inspiring in your practice as you pursue this important work.

Susan Strawn is the Civil and Criminal Health Care Fraud and Affirmative Civil Enforcement (ACE) Coordinator in the Executive Office for United States Attorneys, Legal Programs. She previously served as an Assistant U.S. Attorney in the Western District of Texas, where she handled ACE matters and served as Health Care Fraud Coordinator. Other Departmental positions have included serving as a Trial Attorney in the Civil Division's Office of Consumer Litigation

² *NHE Fact Sheet*, CNTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet> (last visited Aug. 23, 2022).

(now the Consumer Protection Branch), as a Special Assistant U.S. Attorney in the Economic Crimes Section in the District of Colorado, and as a Resident Legal Advisor for Kosovo for the Criminal Division's Office of Prosecutorial Development, Assistance and Training.

Containing the Chaos—How We Used Section 1345 to Stop Providers from Selling Fake Covid Cures

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I. Introduction

On January 21, 2020, the Centers for Disease Control and Prevention (CDC) confirmed the first case of the novel Coronavirus in the United States.¹ By March, the United States' first wave had started in earnest, and the nation was facing thousands of new cases each day. Hospitalizations and deaths rose precipitously. Hospitals in hard-hit areas struggled under the weight of the surge due to the lack of space, equipment, and protective gear. The virus moved across American communities with shocking ease. Confronted by the rapid spread of this deadly virus, lockdowns were imposed from New York² to California³ and everywhere in between.⁴

Dallas, Texas, was no different. On March 22, 2020, Dallas County Judge⁵ Clay Jenkins issued a shelter-in-place order, requiring that the people of Dallas County stay home unless they fit into certain narrow exceptions.⁶ As Civil AUSAs in North Texas, we dutifully stayed home

¹ Press Release, Ctrs. for Disease Control, First Travel-related Case of 2019 Novel Coronavirus Detected in United States (Jan. 21, 2020).

² N.Y. Exec. Order No. 202.6 (Mar. 18, 2020).

³ Cal. Exec. Order No. N-33-20 (Mar. 19, 2020).

⁴ See, e.g., Ill. Exec. Order No. 2020-10 (Mar. 20, 2020) (last visited Mar. 23, 2022).

⁵ County Judge is the surprising (and anomalous) title for the chief executive of a county in Texas.

⁶ CNTY. OF DALLAS, TEX., AMENDED ORDER OF COUNTY JUDGE CLAY JENKINS (Mar. 22, 2020), <https://www.dallascounty.org/Assets/uploads/docs/judge-jenkins/covid-19/03232020-AmendedOrder.pdf>.

with our families and turned to a form of involuntary remote work with which we would become all too familiar.⁷ At the time, we knew little about how long and hard the road ahead would be. But we did know that a pressing fear of the virus—and the unknown—had already pervaded our communities. We also knew that unscrupulous individuals would use this fear for their own personal gain.⁸

On March 20, 2020, Attorney General William Barr directed “all U.S. Attorneys to prioritize the investigation and prosecution of Coronavirus-related fraud schemes.”⁹ In a follow-up memorandum, Deputy Attorney General Jeffrey Rosen highlighted several troubling COVID-19-fraud schemes the Department of Justice (Department) had already identified, including fraudsters selling fake cures and immunity pills for COVID-19 (Covid) online.¹⁰ In response, United States Attorneys’ Offices (USAOs) across the country partnered with the Department’s Consumer Protection Branch¹¹ to

⁷ As we write this, the nation is recording hundreds of thousands of cases each day, and we are once more spending a good deal of time working from home.

⁸ “Anxiety, fear and the beguiling temptations of a vulnerable patient group provide the unscrupulous with incentives for lucrative quackery and exploitation.” Ian Freckleton QC, *Covid 19: Fear, quackery, false representations and the law*, 72 INT’L J.L. & PSYCH. 101611 at 2 (Sept.–Oct. 2020) (surveying historical “quackery and charlatanism” as a backdrop to contextualize “inappropriate representations about preventing, treating and curing COVID-19”).

⁹ Press Release, U.S. Dep’t of Just., Attorney General William P. Barr Urges American Public to Report COVID-19 Fraud (Mar. 20, 2020). Each U.S. Attorney was directed to appoint a Coronavirus Fraud Coordinator to direct the prosecution of Coronavirus-related crimes, among other responsibilities. *Id.*

¹⁰ Memorandum from Deputy Att’y Gen. Jeffrey Rosen to All Heads of L. Enf’t Components, Heads of Litigating Divs., and U.S. Att’ys, Department of Justice Enforcement Actions Related to COVID-19, at 1 (Mar. 24, 2020). In addition to listing reported schemes relating to Covid, the memorandum provides “specific authorities to punish wrongdoing related to COVID-19,” *id.* at 1, as well as “emphasize[s] the importance of state and local coordination.” *Id.*

¹¹ “The Consumer Protection Branch (‘CPB’) handles criminal and civil litigation and related matters arising under federal statutes that protect consumers’ health, safety, economic security, and identify integrity.” JUSTICE MANUAL Section 4-8.010.

identify and prevent individuals from preying on a frightened populace by selling fake Covid cures.

We were by no means the first, or the only, AUSAs to join with our colleagues at the Department to respond to this crisis.¹² But shortly after Attorney General Barr's directive, we were confronted with credible information that two different groups in our community were advertising and selling fraudulent Covid vaccines and cures online. The first, a Dallas chiropractor, was advertising and selling a Covid vaccine that he claimed would offer his patients 90% protection from the virus, prevent serious illness, or both. He promoted these cures directly to a concerned citizenry via social media on an almost daily basis. The second, an ozone-therapy provider, promised a worried public that treatment with a toxic gas would prevent or eradicate any case of Covid. The provider even encouraged individuals to disregard the newly imposed stay-at-home order to get this miracle treatment in person. In conjunction with our colleagues in the Consumer Protection Branch, we turned to the Anti-fraud Injunction Statute in 18 U.S.C. § 1345 to put an end to these predatory schemes. Relying on the Department's wealth of knowledge—and the contemporary work of our colleagues in the Western District of Texas—we worked to learn how we could use this statute to swiftly stop Covid fraud in its tracks.¹³ It was all done from the comfort of our homes during a lockdown.

In this article, we will provide a brief overview of the Anti-fraud Injunction Statute, including its unique combination of criminal substantive law with civil procedure.¹⁴ We will also discuss how we used this statute to respond to two different Covid-fraud schemes operating in Dallas in the early weeks of the pandemic. Finally, we will provide some practical advice on how to request and secure injunctive relief based on our experiences handling these two matters.

¹² Indeed, that honor belongs to our talented colleagues from the Western District of Texas. See Press Release, U.S. Dep't of Just., Justice Department Files Its First Enforcement Action Against COVID-19 Fraud (Mar. 22, 2020).

¹³ See *id.*

¹⁴ For a more thorough review of the statute see Jacqueline Blaesi-Freed, *Stop the Bleeding: Using Civil Injunctions Under 18 U.S.C. § 1345 to Stop Fraud*, 66 DOJ J. FED. L. & PRAC., no. 7, 2018, at 39 (hereinafter Blaesi-Freed). For additional discussion of the statute and its use in the seizure of assets, see James S. Alexander, *Alternative Remedies: Statutory Remedies Available to Seize and Restrain Assets*, 67 DOJ J. FED. L. & PRAC., no. 3, 2019, at 181.

II. The Anti-fraud Injunction Statute: a civil remedy for criminal conduct

The Anti-fraud Injunction Statute empowers the Attorney General and his or her designees to deploy a civil injunction to stop ongoing criminal conduct. This unique hybrid of civil and criminal law has created some degree of confusion and disagreement as to the proper evidentiary standard.¹⁵ It can also enmesh Civil AUSAs with substantive criminal law—or Criminal AUSAs with civil procedure. Given the acute nature of such actions, prosecutors may have to navigate this foreign landscape and its hidden landmines at a full-out sprint. We encourage all AUSAs considering such an injunction to reach out to folks who have done it before (yes, even us!) and to make sure there is at least one person from the other side of the house who is available to serve as a sounding board.

A. Legislative background

Congress passed section 1345 into law as part of the Comprehensive Crime Control Act of 1984 and initially authorized the government to seek injunctions for violations of certain fraud statutes, such as mail fraud or wire fraud.¹⁶ Congress enacted section 1345 to ensure that innocent people would not continue to be victimized by fraudulent schemes during the “months, if not years, before [a] case is ready for

¹⁵ See *infra* at 5–7.

¹⁶ Comprehensive Crime Control Act of 1984, Pub L. No. 98-473, tit. II, § 1205(a), 98 Stat. 1976, 2152 (1984). Congress subsequently expanded the scope of Section 1345 on multiple occasions. Under the Anti-Drug Abuse Act of 1988, Congress permitted the Department to seek injunctions to stop violations of 18 U.S.C. §§ 287 (related to the submission of false claims) & 371 (for conspiracy to defraud the United States), along with violations of Section 1001. See Pub. L. No. 100-690, tit. VII, § 7077, 102 Stat. 4406 (1988). In the Crime Control Act of 1990, Congress added certain banking law violations and allowed the Department to freeze assets of equivalent value before trial to prevent dissipation. See Pub. L. No. 101-647, tit. XXV, § 2521, 104 Stat. 4863, 4865 (1990); see also Ana Maria Martinez, Freezing Assets in Health Care Fraud Cases, 57 U.S. ATT’YS BULL., no. 1, 2009, at 33. And finally in 1996, Congress added health-care offenses to the list of violations that could be enjoined by Section 1345. See Pub. L. No. 104-191, tit. II, § 247, 110 Stat. 2018 (1996).

criminal prosecution.”¹⁷ The Department Handbook on the Crime Control Act explained that the fraud injunction provision was “to provide prosecutors with an effective tool to prevent the continuation of a fraudulent scheme during the pendency of the investigation.”¹⁸ Through section 1345, Congress sought to protect victims of fraud while investigations were ongoing.

B. Statutory text

Section 1345 permits the Department to request a temporary restraining order (TRO), preliminary injunction, and permanent injunction in a civil action to stop ongoing fraudulent schemes.¹⁹ The statute provides as follows:

(a)(1) If a person is (A) violating . . . this chapter or section 287, 371 (insofar as such violation involves conspiracy to defraud the United States or any agency thereof), or 1001 of this title; (B) committing or about to commit a banking violation (as defined in section 3322(d) of this title); or (C) committing or about to commit a Federal health care offense; the Attorney General may commence a civil action in any Federal court to enjoin such violation.

(b) The court shall proceed as soon as practicable to the hearing and determination of such an action, and may, at any time before final determination, enter such a restraining order or prohibition, or take such other action, as is warranted to prevent a continuing and substantial injury to the United States or to any person or class of persons for whose protection the action is brought. A proceeding under this section is governed by the Federal Rules of Civil Procedure, except that, if an indictment has been returned against the respondent,

¹⁷ S. REP. NO. 98-225, at 401–02, *reprinted in* 1984 U.S.C.C.A.N. 3182, 3539–40.

¹⁸ U.S. DEP’T OF JUST., HANDBOOK ON THE COMPREHENSIVE CRIME CONTROL ACT OF 1984 AND OTHER CRIMINAL STATUTES ENACTED BY THE 98TH CONGRESS 152 (1984).

¹⁹ *See* 18 U.S.C. § 1345.

discovery is governed by the Federal Rules of Criminal Procedure.²⁰

The statute covers any crime described in Chapter 63 of the U.S. Code, such as mail fraud, wire fraud, bank fraud, health-care fraud, and securities-and-commodities fraud.²¹ The inclusion of mail and wire fraud gives the statute a potentially broad reach, allowing the government to enjoin any such crimes involving the interstate use of mail or wires.²²

C. Hybrid discovery

Section 1345 proceedings are governed by the Federal Rules of Civil Procedure, unless and until an indictment is returned, at which point discovery is governed by the Federal Rules of Criminal Procedure.²³ Oftentimes, section 1345 cases are resolved quickly—typically through consent judgment or judgment by default—but there are exceptions. Traditional discovery remains possible in a section 1345 action and presents prosecutors with a host of issues that are outside the scope of this article. Sufficed to say, deploying section 1345 may secure an injunction against criminal conduct, but it will also open any criminal investigation to discovery under the Federal Rules of Civil Procedure.²⁴ Prosecutors must be aware that defense counsel could seek and obtain materials that would otherwise not be discoverable, such as investigative reports, reports of interviews, etc., and they can potentially do so mid-investigation even before their client has been charged.²⁵

²⁰ 18 U.S.C. § 1345(a)(1), (b). Additional statutory text, which is not excerpted herein, provides for the seizure or preservation of assets under certain circumstances. *Id.* at § 1345(a)(2).

²¹ *Id.* at § 1345(a)(1).

²² As explained further in note 16, *supra*, section 1345 now includes additional predicates beyond the fraud statutes.

²³ 18 U.S.C. § 1345(b).

²⁴ For more in-depth discussion of this potential morass, we once again refer the reader to Jacqueline Blaesi-Freed's superb article on section 1345. See Blaesi-Freed, *supra* note 14.

²⁵ Of course, the shifting rules cut both ways and the government may itself be able to obtain civil discovery from the defendant that would otherwise be unavailable under the rules of criminal procedure. See *id.*

D. Burden of proof—what’s the standard?

If civil procedure and substantive criminal law combined with the morphing discovery standards were not enough, prosecutors face still more complexity when it comes to the legal standards governing requests for injunctions under section 1345. Due to the relative paucity of cases—especially cases available on the various online legal databases—there are lingering questions about what the government must show to justify an injunction under section 1345. The questions can be broken down into two parts. First, what is the evidentiary standard appropriate for a TRO? Is it probable cause, preponderance of the evidence, or some hybrid of these two standards? Second, does the government need to meet the four traditional common law elements required to secure a civil injunction? Or does injunctive relief authorized by statute simply require the government to meet the statutory elements? Based on our survey of the available literature, we provide some likely answers below, but please be warned that there is continued uncertainty in this area.

1. Probable cause or preponderance of the evidence?

Courts have struggled to identify the proper burden of proof when confronted with requests for injunctive relief under section 1345. This pre-indictment request to enjoin allegedly criminal conduct can seem like an awfully big ask to some courts—especially when requested *ex parte*. The statute provides no clear answers. As we did in the two cases discussed below, the Department has long argued that a court should issue a TRO or preliminary injunction under section 1345 if the United States demonstrates probable cause that a violation of one of the predicate statutes is occurring or is likely to occur.²⁶ But some courts have applied a preponderance of the evidence standard.²⁷ Given the scarcity of cases addressing this issue, there is no clarity from the Supreme Court or the Courts of Appeals.²⁸

²⁶ *United States v. Livdahl*, 356 F. Supp. 2d 1289, 1294 (S.D. Fla. 2005); *see also United States v. Fang*, 937 F. Supp. 1186, 1197 (D. Md. 1996); *United States v. Dr. Ray L. Nannis, P.C. et al.*, Civil Action No. 20-cv-0940, 2020 WL 1920222 (Apr. 17, 2020).

²⁷ *See, e.g., United States v. Quadro Corp.*, 916 F. Supp. 613, 617 (E.D. Tex. 1996).

²⁸ For example, the Fifth Circuit has explicitly declined to decide “which standard of proof applies to a preliminary injunction pursuant to [section]

2. Prosecutors do not need to meet the four traditional requirements of injunctive relief . . . unless they do!

Traditionally, to obtain a temporary restraining order or preliminary injunction, the movant must show:

- (1) a substantial likelihood of success on the merits,
- (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.²⁹

But the anti-fraud injunction is not founded in equity or the common law. Section 1345 is a statutory injunctive remedy that Congress authorized the federal government to seek. Typically, “[t]he standard for a statutory injunction is different from the injunction standard for private litigants.”³⁰ In particular, the Department has consistently taken the position that “[w]hen an injunction is sought pursuant to statute and for the public good, it is not necessary to demonstrate that there is an inadequate remedy at law.”³¹

As such, to obtain a statutorily authorized injunction:

- it should be sufficient for the Government to show:
- (1) that the person or entity sought to be enjoined is engaged in, or is about to engage in, conduct that would violate [the relevant statutory provision]; and (2) that equitable relief is warranted to prevent continuing and substantial injury to the United States or to the public.³²

1345.” *United States v. Legro*, 284 F. App’x 143, 145 (5th Cir. 2008) (not precedential).

²⁹ *Bynum v. Landreth*, 566 F.3d 442, 445 (5th Cir. 2009) (quoting *Speaks v. Kruse*, 445 F.3d 396, 399–400 (5th Cir. 2006)).

³⁰ *United States v. Chung Prods. LP, et al.*, 941 F. Supp. 2d 770, 794 (S.D. Tex. 2013).

³¹ U.S. Dep’t of Just., *Handbook On The Comprehensive Crime Control Act Of 1984 and Other Criminal Statutes Enacted by the 98th Congress* 153 (1984).

³² *Id.*

Courts have generally agreed,³³ finding that where “an injunction is explicitly authorized by statute, proper discretion usually requires its issuance if the prerequisites for the remedy have been demonstrated, and the injunction would fulfill the legislative purpose.”³⁴ To put it more plainly, most courts agree with the Department that the traditional test for injunctive relief does not apply where the United States seeks an injunction pursuant to a federal statute authorizing injunctive relief that was enacted to protect the public interest.³⁵

In the context of section 1345, that means that once the government demonstrates by the applicable evidentiary standard that a defendant is violating one of the predicate statutes (for example, by committing wire fraud in violation of 18 U.S.C. § 1343), no specific finding of irreparable harm is necessary, no showing of the inadequacy of other remedies at law is necessary, and no balancing of the interests of the parties is required before the issuance of the injunction.

Sometimes courts require more before granting the injunction. Before an indictment, before the completion of an investigation, and sometimes before notice has been given to the opposing party, some courts are uneasy moving forward simply on the basis that the government has satisfied the statutory requirements of section 1345. For example, the government has been required to “demonstrate that the balance of the . . . equitable factors counsel in favor of granting the requested injunction,” mirroring the common law standard.³⁶ Some

³³ See, e.g., *United States v. Livdahl*, 356 F. Supp. 2d 1289, 1290–91 (S.D. Fla. 2005) (“[N]o specific finding of irreparable harm is necessary, no showing of the inadequacy of other remedies at law is necessary, and no balancing of the interests of the parties is required prior to the issuance of a preliminary injunction.”).

³⁴ *United States v. Grider*, No. 10-cv-0582-D, 2010 WL 4514623, at *2 (N.D. Tex. Nov. 2, 2010) (quoting *Donovan v. Brown Equip. & Serv. Tools, Inc.*, 666 F.2d 148, 157 (5th Cir. 1982)).

³⁵ See *United States v. Medina*, 718 F. Supp. 928, 930 (S.D. Fla. 1989) (“Where, as here, the statute was enacted to protect the public interest and itself authorizes injunctive relief, [t]he passage of the statute is in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained.”) (quoting *United States v. Diapulse Corp.*, 457 F.2d 25, 28 (2d Cir. 1972)).

³⁶ See, e.g., *United States v. Williams*, 476 F. Supp. 2d 1368, 1377 (M.D. Fla. 2007) (“[T]he United States must still demonstrate that the balance of the . . . equitable factors counsel in favor of granting the requested injunction”).

courts have even fashioned a novel burden-shifting approach. Under the burden-shifting rubric, after the government meets the statutory requirements, the defendant is given the opportunity to explain why the fraudulent conduct will not recur, allegedly rendering the injunction unnecessary.³⁷

In jurisdictions where the standard remains unsettled, AUSAs have successfully argued that the government has provided sufficient proof under any of the competing standards—thereby allowing the court to grant relief without needing to wrestle with determining the appropriate standard.³⁸

III. Case studies from the Northern District of Texas

In March and April 2020, Texas—like most states—watched as the number of Covid cases continued to rise, and the availability of ICU beds in major hot spots began to drop.³⁹ On March 19, 2020, Governor Gregg Abbot issued an executive order closing schools and non-essential businesses.⁴⁰ In his announcement, Governor Abbot urged,

³⁷ See, e.g., *United States v. Am. Therapeutic Corp.*, 797 F. Supp. 2d 1289, 1292 (S.D. Fla. 2011) (“Once the government establishes the existence of the statutory violation, the burden shifts to the defendants to show that there is no reasonable expectation that the wrong will be repeated.”).

³⁸ See Blaesi-Freed, *supra* note 14, at 50 n.36 (listing cases).

³⁹ Americans watched as case surges in Europe transformed doctors into wartime field surgeons—forced to triage patients in a desperate attempt to save those with the highest likelihood of surviving. See, e.g., Greta Privitera, *Italian doctors on coronavirus frontline face tough calls on whom to save*, POLITICO (Mar. 9, 2020, 10:38 PM), <https://www.politico.eu/article/coronavirus-italy-doctors-tough-calls-survival/>. Desperate to prevent a similar situation in the United States, various local governments sought to stave off the worst by implementing lockdowns and other measures to stop the surge.

⁴⁰ See Tex. Exec. Order No. GA-08 (Mar. 19, 2020). At the time, Texas had confirmed a mere 161 cases of Covid statewide. See Patrick Svitek, *Gov. Greg Abbott closes bars, restaurants and schools as he anticipates tens of thousands could test positive for coronavirus*, THE TEXAS TRIBUNE, (Mar. 19, 2020, 9:00 PM), <https://www.texastribune.org/2020/03/19/texas-restaurants-bars-closed-greg-abbott/>. As of February 5, 2022, the Texas Department of State Health Services reports that Texas has had 5,271,033 confirmed (cumulative) cases of Covid. See *COVID-19 Data*, TEX. DEP’T OF STATE HEALTH & HUM. SERVS.,

but did not mandate, Texans to stay at home.⁴¹ On March 22, 2020, Dallas County Judge Clay Jenkins ordered “all individuals anywhere in Dallas County to shelter in place” except for “certain essential activities and work.”⁴² In the midst of this public-health crisis and lockdown, two unrelated providers in the Northern District of Texas announced that they had the solution—treatments that would both prevent and cure Covid. Of course, they didn’t—no one did. As the Food and Drug Administration (FDA), CDC, and the World Health Organization made clear, there were no known treatments or cures for Covid in early 2020.

Shortly after discovery of these fraudulent claims, the USAO for the Northern District of Texas filed civil actions seeking TROs under section 1345. In two separate actions filed just one week apart, the USAO convinced two different judges to enter orders directing both providers to immediately remove any false claims regarding Covid and prohibiting them from advertising and selling their fake Covid cures to a worried public.

The following provides a summary of the investigations, legal actions, and ultimate relief the USAO obtained using section 1345 to inhibit Covid fraud.

A. The neighborhood chiropractor with the homeopathic Covid cure

On March 19, 2020, Dr. Ray Nannis—the owner of Optimum Wellness Solutions, a chiropractic clinic in Richardson, Texas⁴³—announced on Facebook that his new Corona-19 Homeopathic Vaccine remedy would soon be available to his patients.⁴⁴ Dr. Nannis claimed that his new treatment could provide up to 90% protection and urged everyone to “reserve your homeopathic [and come] in ASAP to pick up

<https://dshs.texas.gov/coronavirus/AdditionalData.aspx> (last visited Feb. 5, 2022).

⁴¹ Governor Abbot stated in his announcement that “[t]his . . . is not a shelter-in-place order.” See Greg Abbott, Governor, Tex., Governor Abbott Coronavirus News Conference (Mar. 19, 2020).

⁴² See CNTY. OF DALLAS, TEX., *supra* note 6, at 1.

⁴³ See App. in Support of Emergency Ex Parte Mot. at 1–2, *United States v. Dr. Ray L. Nannis, P.C. et al.*, No. 3:20-cv-00940 (N.D. Tex. Apr. 16, 2020), ECF No. 6 (hereinafter Nannis App.). Notably, Dr. Nannis made this false claim on the same day that Governor Abbot closed schools and non-essential businesses across the state. See *supra* note 40.

⁴⁴ Nannis App. at 2.

the remedies that will help protect yourself and your loved ones.”⁴⁵ Over the following weeks, Dr. Nannis—through regular social media posts—continued to advertise and sell a treatment that he claimed would prevent, mitigate, or otherwise treat Covid.⁴⁶ But as Dr. Nannis well understood, there was no known treatment or vaccine for Covid at that time.⁴⁷

Unbeknownst to Dr. Nannis, a United States Secret Service Special Agent—who had been tasked with investigating claims of Covid fraud—was among the viewers of Optimum’s public social media posts. The agent contacted Dr. Nannis by phone on March 30, 2020, and asked for additional information about the alleged homeopathic vaccine described on Optimum’s Facebook page.⁴⁸ Dr. Nannis told the agent that the vaccine should provide 90% protection from the Coronavirus—“more so than any other vaccine out there right now.”⁴⁹ Although he claimed that he could not technically describe the homeopathy as a cure due to the FDA, Dr. Nannis, nonetheless, stated that it was basically a cure “for all intents and purposes.”⁵⁰ He provided additional information about the treatment, including specific instruction on how to self-administer, and offered to sell this homeopathic remedy-*cum*-vaccine for \$95 per dose.⁵¹ Secret Service agents would later observe customers patronizing Optimum’s clinic in the midst of the lockdown.⁵²

In coordination with the Consumer Protection Branch, our office reviewed the social media posts and other evidence the Secret Service gathered. Dr. Nannis’s claims were false, and he knew he could not

⁴⁵ *Id.*

⁴⁶ *Id.* at 2–3 (for example, Dr. Nannis boasted in another social media post on April 1, 2020, that the drug can prevent Covid or “if you do get sick, it’s going to make it very very very minimal.”).

⁴⁷ See Emergency Ex Parte Mot. at 4, *United States v. Dr. Ray L. Nannis, P.C. et al.*, No. 3:20-cv-00940 (N.D. Tex. Apr. 16, 2020), ECF No. 5 (“[T]here are currently no vaccines to prevent or drugs to treat COVID-19 approved by the U.S. Food and Drug Administration.” (quoting *Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments> (last visited Apr. 4, 2022))).

⁴⁸ See *Nannis App.*, *supra* note 45, at 5–7.

⁴⁹ *Id.* at 6–7.

⁵⁰ *Id.* at 6.

⁵¹ *Id.*

⁵² *Id.* at 7.

make those claims. But what could we do to stop him? We had little information on the so-called Corona-19 Homeopathic Vaccine remedy, including whether the treatment itself posed a genuine risk of harm. We also believed that Dr. Nannis’s claims were not only false but also dangerous.⁵³ Covid-positive individuals might be tempted to travel to his office or avoid legitimate medical care. Allegedly immunized individuals might eschew precautions based on a false belief in this homeopathic remedy. Knowing that Dr. Nannis would continue to use Facebook and other platforms to sell these bogus treatments and vaccines unless the court intervened, we looked for a way to stop him from profiting off his fake cure.⁵⁴ Section 1345 presented the quickest and most effective pathway to an injunction. Given Dr. Nannis’s use of Facebook as his preferred platform to broadcast his false Covid claims to virtually anyone with access to the internet, we chose 18 U.S.C. § 1343, the wire-fraud statute, as the predicate offense for our section 1345 motion.⁵⁵

On the evening of April 16, 2020, the USAO filed a civil action alleging that Dr. Nannis was facilitating a predatory, ongoing wire-fraud scheme to exploit the Covid pandemic.⁵⁶ At the same time, we filed an emergency ex parte motion for a TRO and order to show cause why a preliminary injunction should not be issued.⁵⁷ In support

⁵³ Dr. Nannis had seemed to suggest that the treatment itself was harmless in social media posts by claiming, among other things, that he had given the treatment to his family (as well as himself).

⁵⁴ Indeed, on the day that we filed our complaint, Dr. Nannis posted a new video to Facebook announcing *another* Covid treatment available to patients of Optimum—this time, a “health tonic” with “amazing nanotechnology” that he claimed would boost the immune system, along with “proteolytic enzymes” that could “digest any virus.” *Id.* at 5.

⁵⁵ Arguably, other predicates—such as 18 U.S.C. § 1347 (health-care fraud), Section 1349 (conspiracy to commit fraud), or Section 1040 (fraud in connection with major disasters and emergencies)—were available based on the facts and circumstances of the investigation (but likely presented more risks than the well-worn path of wire fraud). Section 1343 is discussed in greater detail in the *Purity Health and Wellness Centers, Inc.* case summary that follows.

⁵⁶ See Compl., United States v. Dr. Ray L. Nannis, P.C. et al., No. 20-cv-00940-B (N.D. Tex. Apr. 16, 2020), ECF No. 1.

⁵⁷ See Emergency Ex Parte Mot. and App. in Support, United States v. Dr. Ray L. Nannis, P.C. et al., No. 3:20-cv-00940 (N.D. Tex. Apr. 16, 2020), ECF Nos. 5–6.

of the application, we attached the affidavit of the Special Agent and several exhibits concerning the social media posts. We argued that Optimum and Dr. Nannis had violated and were continuing to violate the wire-fraud statute by promoting a homeopathic treatment and vaccine for Covid even though there were no known or approved treatments or vaccines at that time. We requested the court take immediate, emergency action requiring Dr. Nannis to remove the existing social media posts and to prohibit Dr. Nannis from promoting this worthless and potentially dangerous treatment.

The court contacted us the next morning, April 17, 2020, and expressed some reservations about proceeding *ex parte*. The court wanted us to provide notice to Dr. Nannis and Optimum and suggested that we schedule a hearing the following week after the papers were served on the defendants. But we had requested emergency relief for a reason. The day after we filed our complaint, Dr. Nannis uploaded a new video marketing his miracle cure. Allowing Dr. Nannis to continue to knowingly sell and profit from a false Covid cure throughout the weekend and into the next week meant he could prey upon more individuals in the community. We urged the court to take up the motion that day on an *ex parte* basis or, at a minimum, to let us see if we could quickly affect service. Ultimately, the court agreed to schedule a hearing that day if we could complete service beforehand, which we did. That Friday afternoon, the court held a telephonic hearing with both the United States and Dr. Nannis appearing.⁵⁸ During the hearing, we argued that the court should issue an injunction under section 1345 because there was probable cause to believe that Dr. Nannis was violating and would continue to violate 18 U.S.C. § 1343. We further noted that while not required, the United States had provided substantial evidence demonstrating that Dr. Nannis's continued violations would cause irreparable harm.⁵⁹ The court agreed and issued a TRO that evening directing Dr. Nannis to stop promoting worthless and potentially

⁵⁸ Dr. Nannis appeared *pro se*.

⁵⁹ For example, we explained that Dr. Nannis's homeopathy—even if itself was not dangerous—could lead to public harm by: (i) encouraging symptomatic individuals to seek treatment and potentially cause community spread; and (ii) causing individuals to engage in higher risk behavior under the false belief that they were immunized.

dangerous treatments and required him to immediately remove all misleading internet posts.⁶⁰

One week later, Dr. Nannis agreed to entry of a judgment that permanently prohibited him from “offering to treat, cure, prevent, or otherwise mitigate the impact of . . . COVID-19” and required him to “remove, delete, and take down any representations regarding the same.”⁶¹

B. Wellness center claims ozone therapy treats and prevents Covid

Purity Health and Wellness Centers, Inc. (Purity) is a Wyoming corporation that offered purported ozone therapy treatments in Dallas, Texas.⁶² Ozone is a toxic gas.⁶³ On January 21, 2020—the day of the first confirmed case of Covid in the United States—Purity posted on its Instagram account that “you don’t have to worry [about the Coronavirus] if you do ozone.”⁶⁴ The next day, Purity doubled down, stating “CORONA VIRUS [sic] is here in the USA. The only prevention is ozone.”⁶⁵ In the ensuing weeks, numerous publicly available posts on their Instagram account echoed this claim that ozone could eradicate or prevent the coronavirus. At the time, there were “no known effective medical cure[s] or vaccine[s] for COVID.”⁶⁶

⁶⁰ *United States v. Dr. Ray L. Nannis, P.C., et al.*, Civil Action No. 20-cv-0940, 2020 WL 1920222, at *1–2 (N.D. Tex. Apr. 17, 2020) (“Even though a showing of irreparable harm is not necessary under Section 1345 in order to obtain injunctive relief, the Court has found that permitting Defendants to continue to perpetrate the alleged wire fraud would constitute irreparable harm.”).

⁶¹ *Agreed Mot. For Entry of J. Of Permanent Inj., United States v. Dr. Ray L. Nannis, P.C. et al.*, No. 20-cv-00940 (N.D. Tex. Apr. 27, 2020), ECF Nos. 13–15.

⁶² *App. in Support of Emergency Mot. For TRO and Order to Show Cause Why a Prelim. Inj. Should Not Issue at 2* (Dkt. No. 4), *United States v. Purity Health & Wellness Ctrs., Inc., et al.*, No. 20-cv-00985 (N.D. Tex. Apr. 22, 2020), ECF No. 4 (hereinafter *Purity App.*).

⁶³ *See List of Highly Hazardous Chemicals, Toxics and Reactives*, 29 C.F.R. § 1910.119, App. A.

⁶⁴ *Purity App.* at 2.

⁶⁵ *Id.*

⁶⁶ *Emergency Mot. for TRO and Order to Show Cause Why a Prelim. Inj. Should Not Issue at 2–3*, *United States v. Purity Health and Wellness Ctrs., Inc., et al.*, No. 20-cv-00985 (N.D. Tex. Apr. 22, 2020), ECF No. 3.

And there was certainly no evidence that treatment with a toxic gas could prevent or cure Covid.⁶⁷

Concerned about Purity's false and fraudulent claims, the Federal Bureau of Investigation's (FBI) Dallas Field Office launched an investigation. Using a confidential human source, the FBI contacted Purity by phone in early April of 2020. The source posed as a prospective customer who was curious about Purity's claims that ozone could prevent or cure Covid. The defendants told the source that ozone would cure the Coronavirus, while acknowledging that the FDA did not and would not approve their claims, American doctors never use ozone to treat patients, and treatment with ozone gas could be fatal. Defendants even told the confidential source to bring in a Covid-positive relation to their location for a treatment they described as medical, while also claiming that ozone would prevent any transmission of the virus.

In follow-up emails and calls with Juanita Allen, one of the general managers and owners of Purity, Allen stated that her team of doctors had recommended a certain ozone sauna treatment for the confidential source and her Covid-positive relation. After digesting this information, noting the continued flow of social media posts claiming that ozone therapy could prevent or cure Covid and observing customers continuing to patronize Purity, the USAO for the Northern District of Texas and the Consumer Protection Branch decided to try to stop these false and fraudulent claims using a section 1345 injunction. But first, we needed a predicate.

Considering the defendants' use of Instagram and Gmail, we evaluated whether we had sufficient evidence that the defendants were engaged in an ongoing scheme to violate 18 U.S.C. § 1343. That statute provides criminal penalties for anyone who, "having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises," uses an interstate wire or causes an interstate wire to be used "for the purpose of executing the scheme or artifice."⁶⁸ To establish wire fraud in the Fifth Circuit, the United States must show that: (1) "the defendant knowingly devised or intended to devise any scheme to defraud"; (2) "the scheme to defraud employed false material representations" or promises; (3) "the

⁶⁷ *Cf.* 21 C.F.R. § 801.415(a) ("Ozone is a toxic gas with no known useful medical application. . .").

⁶⁸ 18 U.S.C. § 1343.

defendant transmitted [or] caused to be transmitted by way of wire . . . communications, in interstate [or] foreign commerce, any writing[,] sign[,] signal[,] picture[, or] sound for the purpose of executing [the] scheme”; and (4) “the defendant acted with a specific intent to defraud.”⁶⁹

On the morning of April 22, 2020, the United States filed a complaint against Purity and its owner and general manager, Allen, for devising and executing a predatory wire-fraud scheme to profit from the pandemic by selling fake Covid cures.⁷⁰ We immediately followed up with an *ex parte* emergency motion for a TRO and order to show cause why a preliminary injunction should not be issued, supported by the affidavit of an FBI agent and several exhibits.⁷¹ We argued that Purity and Allen had violated and were continuing to violate the wire-fraud statute by representing that their ozone treatments could treat or cure Covid despite the daily, well-published reminders that there was still no known treatment or vaccine for Covid in March and April of 2020. They used social media and email to convey these false representations and request payment from a duped public. The need for emergent action was even more necessary because they were enticing citizens—including Covid-positive citizens—to join them in their offices protected only by the fiction of their miracle cure.

As with the case against Optimum and Dr. Nannis, the court responded swiftly, but did not want to issue the order on an *ex parte* basis. Dismissing our arguments that immediate action was necessary to protect the public, the court required that we serve notice of our application for TRO immediately. With the help of our colleagues in the FBI, we did so. We were confident in our case and evidence, and we were not worried about any potential opposition from Purity or its lawyers. We were worried about delay. If we could not serve them

⁶⁹ Fifth Circuit Pattern Jury Instructions § 2.57 (2019); *see also* *United States v. Mills*, 199 F.3d 184, 188 (5th Cir. 1999) (holding that wire fraud requires proof that “(1) that the defendant knowingly participated in a scheme to defraud; (2) that interstate wire communications were used to further the scheme; and (3) that the defendant intended that some harm result from the fraud.”).

⁷⁰ Compl., *United States v. Purity Health and Wellness Ctrs., Inc., et al.*, No. 20-cv-00985 (N.D. Tex. Apr. 22, 2020), ECF No. 1.

⁷¹ Emergency Mot. in Support of TRO, *United States v. Purity Health and Wellness Ctrs., Inc., et al.*, No. 20-cv-00985 (N.D. Tex. Apr. 22, 2020), ECF Nos. 3–4.

quickly, the scheme would continue. Fortunately, we had planned for this possibility after it had happened in our first case. We already had the documents printed, prepared, and in the hands of FBI agents waiting outside Purity's offices, and they were able to quickly serve the defendants that same day.

We immediately notified the court that we had provided notice to the defendants and requested that the court proceed to argument on the application for TRO. As with the Optimum matter, the court was reluctant to move so quickly. Pointing to the evidence in the application and the appendix in support, we urged the court to allow us to present our case given the continued danger that someone in the community would get defrauded, or worse, harmed. The court relented and set the telephonic argument for that afternoon. Shortly before argument, counsel for the defendants agreed to entry of a permanent injunction against the clients mirroring the proposed TRO and preliminary injunction we had submitted to the court. We apprised the court, filed the joint motions for entry of the agreed injunction, and the order was entered the next day.

IV. Conclusion

The Covid pandemic has proven, once again, that section 1345 is an effective and flexible tool that prosecutors can use to swiftly halt ongoing fraud to protect the innocent from harm. When confronting circumstances involving ongoing fraud—whether involving Covid or some other emergency—AUSAs should always consider section 1345 as an option.⁷² Although every situation is different, we want to conclude by sharing a few pieces of advice gleaned from our recent experiences.

⁷² Depending on the nature and timing of the fraud, prosecutors may also consider coordinating with the Federal Trade Commission (FTC) and seeking injunctive relief, civil penalties, or both through the since passed COVID-19 Consumer Protection Act (which is not addressed in this article). *See* COVID-19 Consumer Protection Act of the 2021 Consolidated Appropriations Act, Pub. L. No. 116-260, 134 Stat. 1182, 3275–76, Title XIV, § 1401(b)(1). The Act makes it unlawful, for the duration of the ongoing novel coronavirus public health emergency, for any person, partnership, or corporation to engage in a deceptive act of practice in or affecting commerce in violation of section 5(a) of the FTC Act, 15 U.S.C. § 45(a), that is associated with the treatment, cure, prevent, mitigation, or diagnosis of Covid. *Id.* at § 1401(b).

TROs and preliminary injunctions remain relatively rare. It is possible that your assigned judge has rarely seen, let alone granted, such a request. For that reason, regardless of the proper standard, we advise presenting as much compelling evidence as possible to convey the emergency nature of the situation. It may seem quaint, or even unhelpfully obvious, to advise AUSAs to put their best foot forward when requesting an injunction. But relying too heavily on the lower standards presented above could compel attorneys to act too swiftly or hold back evidence in light of the likelihood of oral argument and the possibility of discovery into an ongoing criminal investigation. Congress placed the power to issue section 1345 injunctions in the sound discretion of the trial courts.⁷³ In the context of the pandemic, the gravity of the situation seemed obvious to us and our colleagues. We thought the evidence was very clear. But even with what we thought was clear evidence of ongoing Covid fraud, we were required in each case to serve notice on the defendants. In both situations, we had to argue for immediate action following such notice in response to the natural restraint of the courts to act on an emergency or *ex parte* basis. To be fair, requesting even narrow injunctive relief on an emergency basis calls upon the power of the courts to stop potentially illicit commercial activity. Many courts view early requests for injunctive relief with skepticism. Regardless of the standards articulated above, we think any prosecutor considering a TRO under section 1345 should be prepared to explain why the court needs to act immediately and *ex parte* and to show the court that the evidence compels the conclusion that fraud is ongoing. While it might not always work out, we believe that explanation will put AUSAs in the best position to secure an injunction under section 1345.

⁷³ 18 U.S.C. § 1345(b) provides that the court “may” enter “a restraining order or prohibition, or take such other action, as is warranted” by the evidence and the injury. Note that courts have broad discretion to tailor an injunction to the specific facts and issues of the case. *See, e.g.,* *United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 761 (S.D.N.Y. 2015) (Section 1345 “provides the Court with the flexibility and the power to impose relief necessary to protect the public.”) (citing *United States v. Payment Processing Ctr., LLC*, 435 F. Supp. 2d 462, 464–68 (E.D. Pa. 2006) and *United States v. William Savran & Assocs.*, 755 F. Supp. 1165, 1182 (E.D.N.Y. 1991)).

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The False Claims Act and Electronic Health Records Technology

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I. Introduction

When my daughter was a toddler, one of her favorite games was performing medical exams on the family dog. To assume the role of physician, she collected her toy medical kit, the beleaguered subject, and a small plastic laptop to document the results. Though imaginary, these exams mirrored my daughter's real-life health-care experiences: A doctor is a person who sits in front of a computer and talks to you, only getting up to listen to your heart or perhaps give you a shot. Not so long ago, however, computers did not play such a significant role in the practice of medicine. Paper medical records, handwritten prescriptions, and faxed or even hand-delivered orders were commonplace. There were no personalized summaries to take home after an office visit, nor could you read your doctor's notes through an Internet portal. How has the computer so quickly come to be as linked to the practice of medicine—to one pediatric patient at least—as the stethoscope and syringe?

In 2009, Congress enacted a new law to incentivize health-care providers to integrate Electronic Health Record (EHR) technology into their practices. The result is widespread adoption of EHR technology. But the development of this federally subsidized industry has created novel issues about the regulation of companies that develop and offer EHR products. There have since been numerous settlements with EHR vendors under the False Claims Act (FCA) and the Anti-kickback Statute (AKS) that touch on a range of issues, from the functionality of EHR technology to the payment and receipt of kickbacks by EHR vendors. This article aims to provide an overview of how the government incentivizes health-care providers to adopt EHR technology and the requirements for receiving federal incentive payments. It then concludes with a review of significant enforcement

actions to date that illustrate how EHR technology has intersected with FCA enforcement.

II. Federal payments for EHR technology

Starting in 2009 with the enactment of the Health Information Technology for Economic and Clinical Health Act (HITECH Act),¹ the Centers for Medicare and Medicaid Services (CMS) have encouraged health-care providers to adopt and make meaningful use of EHR technology with certain base functionality. These incentives initially took the form of payments by Medicare and Medicaid to adopters of EHR technology. Today, many providers are subject to a combination of payment incentives for using EHR technology and penalties for failing to do so. Notably, these incentive programs are directed at health-care providers such as clinicians and hospitals, rather than the technology companies that develop and offer EHR technology. EHR vendors, nevertheless, play a significant role in the incentive programs. Their products must meet certain criteria and receive certification if their clients are to receive incentive payments. The vendors also benefit from a market motivated to purchase their products and from the money, paid to their clients, that helps offset the costs of acquiring their products.

The technical requirements for EHR technology to receive certification have evolved over time. Under the 2015 Edition Health IT Certification Criteria, an EHR must meet over 50 different criteria for certification. Although some functionality would be unnoticeable to the average person, other requirements have had a significant impact on the patient experience. Many readers will have unknowingly experienced some of the required functionality, such as the ability for patients to access health information electronically, transmit it to third parties, and send secure messages.² Other requirements include the abilities to electronically order drugs, tests, and imaging and to flag contraindications or drug interactions.³ Some criteria pertain to data portability—the ability to export patient data—which assists

¹ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

² 45 C.F.R. § 170.315 (2022); *see also Certification Criteria*, HEALTHIT.GOV, <https://www.healthit.gov/topic/certification-ehrs/certification-criteria> (last reviewed Oct. 4, 2021).

³ *See* 45 CFR § 170.315 (2022).

health-care providers in migrating to new EHR platforms.⁴ Also required are privacy and security features and the ability to track and report clinical quality measures.⁵

The criteria for certification are developed by the Office of the National Coordinator for Health Information Technology (ONC).⁶ To verify compliance, EHR technology must be certified by a third party approved by ONC, known as ONC-Authorized Certification Bodies or “ACBs.”⁷ The EHR vendor must attest to the ACB that its product meets the applicable criteria, and the EHR platform must undergo testing.⁸ EHR products that have been certified through this process are designated as Certified EHR Technology or “CEHRT.” The 21st Century Cures Act, enacted in 2016, created additional requirements to obtain and maintain certification.⁹ Under the Cures Act, it is a condition of certification that the EHR vendor not engage in information blocking, defined as a practice that the EHR vendor knows, or should know, is “likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.”¹⁰ In addition, the EHR vendor must not “prohibit or restrict any communication” about the usability, interoperability, or security of its health IT, among other topics.¹¹

Once an EHR platform is certified, health-care providers using it may elect to receive incentive payments through either Medicare or Medicaid. The providers must attest annually that they used CEHRT and that they satisfied certain objectives and measures that demonstrate that they made “meaningful use” of the technology.¹² The Stage 3 objectives applicable in 2019 and subsequent years include things such as making use of e-prescribing; clinical decision support; computerized orders for medication, labs, and diagnostic-imaging functionality; and giving patients electronic access to their health information.¹³ The provider must demonstrate compliance with these

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Certification Process*, HEALTHIT.GOV, <https://www.healthit.gov/topic/certification-ehrs/certification-process>.

⁸ *Id.*

⁹ 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

¹⁰ 42 U.S.C. § 300jj-52(a)(1); *see* 45 C.F.R. §§ 170.401–170.402.

¹¹ 45 C.F.R. § 170.403(a)(1).

¹² 42 U.S.C. § 1395w-4(o)(2).

¹³ 42 C.F.R. § 495.24(c)–(d).

objectives by meeting particular measures. For example, for electronic prescribing, more than 60% of permissible prescriptions must be transmitted electronically using CEHRT, unless an exemption applies (for example “eligible providers” who write fewer than 100 permissible prescriptions in the reporting period).¹⁴

Different incentive-payment structures are available depending on whether the provider is an “eligible hospital” or “eligible professional,” including certain physicians and other clinicians. Under the HITECH Act, “eligible professionals” could receive up to \$44,000 spread over 5 years from Medicare, ending in 2016, or up to \$63,750 over 6 years from Medicaid, ending after 2021.¹⁵ “Eligible hospitals” could qualify under Medicare or Medicaid for incentive payments of a \$2 million base amount adjusted based on the number of hospital discharges and a “transition factor.”¹⁶

In 2015, the government began reducing Medicare payments for health-care providers who did not make meaningful use of CEHRT, absent an exemption.¹⁷ The penalty was a reduction in an “eligible provider’s” total Medicare payments, and the penalty increased in subsequent program years.¹⁸ As a result, “eligible providers” who did not use CEHRT in 2015 would generally have received only 99% of the Medicare payments they would have been entitled to had they used CEHRT.

This arrangement of Medicare subsidies and penalties changed for “eligible professional[s]” with the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).¹⁹ MACRA consolidated several pre-existing Medicare incentive programs—including the Medicare EHR Incentive Program—into a single program called the Merit-based Incentive Payment System (MIPS). Under MIPS, CMS assesses MIPS-eligible clinicians in four

¹⁴ *Id.* § 495.24(d)(2)(i).

¹⁵ 42 U.S.C. § 1395w-4(o)(1)(B)(ii) (Medicare); CMS, MEDICAID ELECTRONIC HEALTH RECORD INCENTIVE PAYMENTS FOR ELIGIBLE PROFESSIONALS (2013), https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/mln_medicaidehrprogram_tipsheet_ep.pdf (Medicaid). For both Medicare and Medicaid, these figures were impacted by budget sequestration for certain program years.

¹⁶ 42 U.S.C. § 1395ww(n)(2)(A)(iii).

¹⁷ *Id.* § 1395w-4(a)(7).

¹⁸ *See id.* § 1395ww(n); *id.* § 1395w-4(a)(7)(A)(iii).

¹⁹ Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015).

performance categories: “Quality,” “[r]esource use,” “[c]linical practice improvement activities,” and “[m]eaningful use of certified EHR technology.”²⁰ Based on these four performance categories, CMS gives the MIPS-eligible clinician a “composite performance score” that it used to calculate a positive, neutral, or negative payment adjustment factor that is applied to the eligible clinician’s payments on claims for covered professional services under Medicare Part B in a subsequent year.²¹ In each payment year, in general, 25% of the composite performance score may be derived from the meaningful use of certified EHR category.²²

III. EHR enforcement trends

Several recent settlements have illustrated how FCA enforcement may intersect with EHR technology as well as the incentive programs discussed above. These settlements touch on both the functionality of EHR technology and the conduct that implicates the AKS, including the payment and receipt of remuneration by EHR vendors. Beyond this, EHR technology has other potential connections to FCA enforcement as new capabilities are developed which fraudsters may use to overbill federal health-care programs.

A. Certification fraud and functionality problems

As discussed in the previous section, to qualify for incentive payments, an EHR must meet certain certification criteria established by ONC. The vendor must also make attestations concerning the functionality of its product and that the EHR has been tested by a third party approved by ONC. In instances where a vendor attests that its EHR meets ONC certification criteria when it does not, it may be subject to liability under the False Claims Act, as two recent settlements illustrate.

The first came in May 2017, when the Department of Justice (Department) announced a settlement with eClinicalWorks (ECW), resolving allegations that ECW violated the FCA by fraudulently obtaining certification for its EHR platform.²³ The government alleged

²⁰ 42 U.S.C. § 1395w-4(q)(2)(A).

²¹ *Id.* § 1395w-4(q)(1)(A)(iii), (q)(6).

²² *See id.* § 1395w-4(q)(6), (q)(5)(E)(i)(IV), (E)(ii).

²³ Press Release, U.S. Dep’t of Just., Electronic Health Records Vendor to Pay \$155 Million to Settle False Claims Act Allegations (May 31, 2017).

that ECW's platform did not meet the requirements for certification due to several defects:

- ECW failed to use required standardized coding systems and vocabularies for drugs (RxNorm), laboratory tests (LOINC), and medical conditions (SNOMED-CT);²⁴
- ECW did not comply with data portability requirements intended to allow health-care providers to transfer patient data from ECW's platform to those of other vendors;²⁵
- ECW did not generate accurate audit logs;²⁶
- ECW failed to properly display diagnostic imaging orders;²⁷ and
- ECW did not reliably perform drug–drug interaction and drug–allergy checks.²⁸

Because these functionalities were required for certification, the government alleged that ECW's product was ineligible for EHR incentive payments under the HITECH Act.²⁹

To take one example in greater detail, the complaint alleged that ECW failed to use RxNorm, a standardized drug vocabulary that is used in e-prescribing.³⁰ RxNorm is important, because it designates particular drug formulations and dosages and helps ensure the accuracy of e-prescriptions.³¹ ECW allegedly did not use RxNorm in e-prescribing for several years after certification, despite having represented through its certification application that it had this functionality.³² The government contended that ECW concealed this limitation because it knew the scripts that were to be used for testing its e-prescribing functionality involved 16 particular drugs.³³ ECW then “hardcoded” these drugs into its software so that it would appear

²⁴ See United States' Complaint in Intervention at ¶¶ 38–55, *United States ex rel. Delaney v. eClinicalWorks, LLC*, No. 15-cv-095 (D. Vt. May 12, 2017), ECF No. 23.

²⁵ *Id.* at ¶¶ 60–64.

²⁶ *Id.* at ¶¶ 65–67.

²⁷ *Id.* at ¶¶ 68–71.

²⁸ *Id.* at ¶¶ 72–73.

²⁹ *Id.*

³⁰ *Id.* at ¶ 42.

³¹ *Id.* at ¶ 39–40.

³² *Id.* at ¶ 42.

³³ *Id.* at ¶ 43.

that the system was using RxNorm for all drugs, when in fact it was programmed for only the 16 test script drugs.³⁴

To meet the elements of alleging false or fraudulent claims or records, the complaint focused on ECW's attestations during the certification process as well as attestations by ECW users in claiming EHR incentive payments. According to the government's complaint, ECW falsely represented to the ACB during certification that its product satisfied the applicable criteria and standards and that it could meet those criteria and standards in the field.³⁵ In addition, the complaint alleged that ECW caused its users to unwittingly submit false claims for EHR incentive payments and false attestations that they had used CEHRT, when in fact they had not.³⁶

In February 2019, the government announced that it had resolved FCA allegations against a second EHR vendor, Greenway Health, concerning its EHR, Prime Suite. Like ECW, Greenway allegedly did not use RxNorm or SNOMED-CT standards, but evaded detection during product testing because of advanced knowledge of the test scripts that would be used for certification.³⁷ But the Greenway settlement also implicated another aspect of EHR incentive payments, namely the requirement that users make "meaningful use" of the EHR.³⁸

As discussed in Section II, to be eligible for EHR incentive payments, eligible professionals must submit annual attestations that they made "meaningful use" of the EHR and provide certain data to demonstrate meaningful use. In the 2014 Edition, one such measure was that eligible providers give patients "clinical summaries," an after visit summary of information about the visit, such as vital signs, the procedures that were performed, and the topics discussed during the visit.³⁹ To satisfy this measure, the provider was obligated to show that it provided clinical summaries for more than half of all office visits within three days.⁴⁰ Greenway's EHR platform allegedly miscalculated this metric such that some users appeared to meet the

³⁴ *Id.* at ¶ 44.

³⁵ *Id.* at ¶ 33.

³⁶ *Id.* at ¶¶ 76, 86–87.

³⁷ See Complaint at ¶¶ 46, 59, *United States v. Greenway Health, LLC*, No. 19-cv-20 (D. Vt. Feb. 6, 2019), ECF No. 1.

³⁸ *Id.* at ¶ 45–46.

³⁹ 75 Fed. Reg. 44358 (July 28, 2010).

⁴⁰ 42 C.F.R. § 495.20(d)(13)(ii).

objective when they did not.⁴¹ The complaint alleged that Greenway was aware of this problem for a period of years and understood that it was causing its users to obtain incentive payments to which they were not entitled.⁴² Even after implementing the correction, Greenway allegedly still provided inaccurate calculations to approximately 50 users so that they could continue to falsely attest to meeting the Clinical Summaries measure and receive incentive payments.⁴³

B. The Anti-kickback Statute and the unlawful marketing of EHR platforms

Recent settlements have also highlighted tactics that some EHR vendors used to sell and market their products. The ECW and Greenway settlements, in addition to addressing functionality issues, also resolved allegations that the vendors unlawfully promoted EHR sales by providing illegal remuneration in violation of the AKS.⁴⁴ ECW, for example, allegedly paid its current customers up to \$500 for each provider they referred who executed a contract with ECW, in addition to providing remuneration for site visits, consulting, and speaker fees.⁴⁵ Likewise, Greenway settled allegations that it paid users to host site visits and engage in other promotional activities in exchange for credits towards annual fees.⁴⁶ According to the Greenway complaint, users received a credit between \$750 and \$2,000 for referrals of physician groups that signed up for Greenway's products.⁴⁷ Both companies also allegedly provided things like iPads, gifts, and entertainment to encourage sales.⁴⁸

Following these settlements, in January 2021, athenahealth (Athena) entered into a settlement agreement with the Department to

⁴¹ See Complaint at ¶¶ 81–83, *United States v. Greenway Health, LLC*, No. 19-cv-20 (D. Vt. Feb. 6, 2019), ECF No. 1.

⁴² *Id.* at ¶¶ 83–113.

⁴³ *Id.* at ¶ 100.

⁴⁴ 42 U.S.C. § 1320a-7b(b).

⁴⁵ See *United States' Complaint in Intervention* at ¶¶ 79–85, *United States ex rel. Delaney v. eClinicalWorks, LLC*, No. 15-cv-095 (D. Vt. May 12, 2017), ECF No. 23.

⁴⁶ See Complaint at ¶¶ 113–15, 119, 122, *United States v. Greenway Health, LLC*, No. 19-cv-20 (D. Vt. Feb. 6, 2019), ECF No. 1.

⁴⁷ *Id.* at ¶¶ 122, 126.

⁴⁸ *Id.* at ¶ 127; *United States' Complaint in Intervention* at ¶ 83, *United States ex rel. Delaney v. eClinicalWorks, LLC*, No. 15-cv-095 (D. Vt. May 12, 2017), ECF No. 23.

resolve allegations that it offered and paid kickbacks to generate sales of its EHR product, athenaClinical. Unlike Greenway and ECW, this settlement did not involve allegations of certification fraud or functionality issues. The government alleged that three Athena programs violated the AKS.⁴⁹ First, the government alleged that Athena provided existing and potential clients with all-expense-paid “bucket list” trips to exclusive sporting, entertainment, and recreational events, including the Masters Tournament and the Kentucky Derby.⁵⁰ Second, the government alleged that Athena, like ECW and Greenway, paid existing clients for referrals of new practices that signed up for its EHR technology.⁵¹ In Athena, however, these payments were significantly higher: The government alleged that its clients received up to \$3,000 *per* physician successfully referred.⁵² Finally, Athena allegedly entered into “conversion deals” with other EHR vendors to cease offering their products and refer their clients to Athena.⁵³

In April 2021, a fourth EHR vendor, CareCloud, entered into a settlement to resolve allegations that it paid illegal kickbacks to generate sales of its EHR product.⁵⁴ Again, this was a kickbacks-only resolution with no allegations of functionality problems. The government contended that CareCloud offered and provided existing clients with credits, bonuses, and other remuneration to recommend its EHR product to prospective clients.⁵⁵ Existing clients who participated in the program were allegedly prohibited from providing negative information about CareCloud products to prospects, and prospects were not advised of the existence of the kickback arrangement with participating existing clients.⁵⁶

⁴⁹ See United States’ Complaint In Intervention at ¶ 3, United States *ex rel.* Geordie Sanborn, Cheryl Lovell, & William McKusick v. athenahealth, Nos. 17-cv-12125, 17-cv-12543 (D. Mass. Jan. 22, 2021).

⁵⁰ *Id.* at ¶ 4.

⁵¹ *Id.* at ¶ 5.

⁵² *Id.*

⁵³ *Id.* at ¶ 6.

⁵⁴ Press Release, U.S. Att’y Off. S. Dist. Fla., Miami-Based CareCloud Health, Inc. Agrees to Pay \$3.8 Million to Resolve Allegations that it Paid Illegal Kickbacks (Apr. 30, 2021).

⁵⁵ *Id.*

⁵⁶ *Id.*

C. Receipt of kickbacks by EHR vendors

EHR technology has implicated the AKS in a second way: In January 2020, the Department announced a settlement resolving civil and criminal charges that Practice Fusion solicited and received kickbacks from a major opioid manufacturer in exchange for using its EHR to influence providers to prescribe opioids.⁵⁷ In exchange for payments, Practice Fusion allegedly implemented clinical decision support (CDS) alerts in its EHR to increase drug prescriptions.⁵⁸ The government alleged that Practice Fusion “permitted pharmaceutical companies to participate in designing the CDS alert . . . and in some cases, even drafting the language used in the alert itself.”⁵⁹ In a criminal complaint, the government alleged that Practice Fusion had solicited nearly \$1 million from an opioid company to create an alert causing doctors to prescribe more extended-release opioids.⁶⁰ The CDS alert was ultimately designed with input from the opioid company’s marketing department.⁶¹

D. EHR technology as a kickback

EHR technology has yet another potential connection to kickbacks: EHR technology is itself a thing of value, and therefore may implicate the AKS and Stark law when someone provides free or discounted EHR services. The Department of Health & Human Services, Office of Inspector General and CMS have established a safe harbor under the AKS and an exception under the Stark law pertaining to the donations of interoperable EHR software.⁶² Under the AKS safe harbor, donations of EHR technology are excluded from the definition of “remuneration” under the AKS, provided certain criteria are met.⁶³ Among these criteria are that receipt of EHR donations cannot be a condition of doing business with the donor, and the donor cannot take into account the volume or value of referrals from the recipient in determining whether the recipient is eligible for an EHR donation or

⁵⁷ Press Release, U.S. Dep’t of Just., Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations (Jan. 27, 2020).

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² 42 C.F.R. § 1001.952(y); 42 C.F.R. § 411.357(w).

⁶³ 42 C.F.R. § 1001.952(y).

the amount or nature of the donation.⁶⁴ In addition, the recipient must cover at least 15% of the cost of the EHR.⁶⁵ There has been enforcement activity concerning donations of EHR technology. For example, in January 2019, the government announced a settlement with a pathology laboratory company, Inform Diagnostics, which allegedly provided subsidies to referring physicians for EHR systems and “free or discounted technology consulting services.”⁶⁶

E. Other FCA implications

A little over a decade after enactment of the HITECH Act, EHR technology continues to evolve and will undoubtedly continue to raise new legal questions and fact patterns as new functionality is added. Many EHR systems can easily copy patient notes from previous encounters or templates. Bad actors can potentially exploit this functionality to overbill the federal government for medical services. In an FCA settlement with MD2U holding company, a provider offering medical services in patients’ homes resolved allegations of providing medically unnecessary and “upcoded” services to the highest level E&M code possible.⁶⁷ While there is nothing especially novel about these sorts of allegations, it is significant that MD2U was alleged to have used an EHR that allowed providers to easily “copy and paste medical notes from prior visits.”⁶⁸ MD2U providers allegedly used this functionality to make it appear that it was “performing a significant amount of work during their patient encounters when in fact they were not.”⁶⁹ Although this settlement did not implicate wrongdoing by an EHR company, it, nevertheless, highlights another way that EHR functionality may intersect with FCA enforcement.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ Press Release, U.S. Dep’t of Just., Pathology Laboratory Agrees to Pay \$63.5 Million for Providing Illegal Inducements to Referring Physicians (Jan. 30, 2019).

⁶⁷ Press Release, U.S. Dep’t of Just., Louisville Based MD2U, a Regional Provider of Home-Based Care, and its Principal Owners Admit to Violating the Federal False Claims Act and Being Liable for Millions (July 7, 2016).

⁶⁸ *Id.*

⁶⁹ *Id.*

IV. Conclusion

In a little more than a decade after the enactment of the HITECH Act, EHR technology has come to occupy a central role in the health-care sector. EHR technology has the ability, for better or worse, to influence medical decision making and affect how medical services are billed to the government. The integrity of this technology is foundational for patients to receive safe, effective, and quality care. Because healthy competition between EHR vendors is vital, it is important that the marketplace for EHR technology is not distorted by kickbacks or other unlawful bribes. It is also critical for health-care providers to be able to choose freely between EHR platforms without fear of losing their patients' medical records. FCA enforcement ensures that EHR technology continues to serve these goals, while promoting patient safety and protecting taxpayer dollars.

About the Author

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Illegal Payment of Kickbacks and Other Unlawful Remuneration to Medicare Beneficiaries: Routine Copayment Waivers, Cost-Sharing Assistance Charities, and Free Items and Services

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I. Introduction

The payment of kickbacks and other unlawful remuneration in the health-care context is typically associated with prohibited remuneration payments to physicians and other health-care providers and suppliers in exchange for patient referrals. An often-overlooked area of unlawful remuneration is illegal payments to Medicare beneficiaries by health-care providers or suppliers to induce those beneficiaries to use services or products that are billed to Medicare.

The payment of unlawful remuneration to Medicare beneficiaries to influence their selection of health-care providers and suppliers is prohibited under several federal laws including the Anti-kickback Statute (AKS) and the anti-inducement provisions of the Civil Monetary Penalty Law (CMPL). In addition to potential criminal prosecution under the AKS and other statutes, the payment of such inducements can result in civil liability under the False Claims Act (FCA).

In fact, in the last decade, the Department of Justice (Department) has recovered well over \$1 billion in damages and penalties in FCA cases that involved allegations of the payment of unlawful remuneration to beneficiaries of federal health-care programs, including Medicare. Beyond the legal implications of unlawful remuneration, these illegal payments also harm the Medicare program and taxpayers by inappropriately increasing beneficiaries'

usage rates for high-cost items and services, which ultimately raises overall Medicare costs.

This article surveys the law prohibiting the payment of unlawful remuneration to Medicare beneficiaries, including highlighting guidance from the Office of Inspector General (OIG) for the Department of Health and Human Services on the issue. It will also explore several enforcement trends in the FCA context, specifically related to routine waivers of copayments or deductibles; cost-sharing assistance charities; and the provision of free items and services to Medicare beneficiaries.¹

II. Federal prohibitions on the offer or payment of remuneration to beneficiaries of federal health-care programs

The AKS criminalizes, among other things, the knowing and willful offer or payment of remuneration, “directly or indirectly, . . . in cash or in kind, to any person to induce such person” to buy or order a good, item, or service for which Medicare (or any other federal health-care program) may pay.² The offer or payment of any prohibited remuneration violates the AKS, not just the offer or payment of bribes or kickbacks.³ Under the CMPL, a person is subject to civil monetary penalties if they offer or transfer remuneration to a Medicare or Medicaid beneficiary knowing that this is likely to influence from whom the beneficiary obtains an item or service that may be billed to Medicare or Medicaid.⁴

Claims to Medicare that result from AKS violations explicitly trigger false claims liability under the FCA,⁵ without any requirement of a

¹ The AKS applies to all federal health-care programs, including, for example, Medicaid and TRICARE. See 42 U.S.C. § 1320a-7b. For simplicity’s sake, this article focuses solely on the AKS’s application to Medicare.

² 42 U.S.C. § 1320a-7b(b)(2).

³ *Pfizer, Inc v. United States Dep’t of Health & Hum. Servs.*, 42 F.4th 67, 76 (2d Cir. 2022) (“[T]he listed examples of ‘kickback, bribe, or rebate in the AKS do not limit the meaning of ‘any remuneration’; they are merely non-exhaustive examples”).

⁴ 42 U.S.C. § 1320a-7a(a)(5).

⁵ 42 U.S.C. § 1320a-7b(g); see *United States ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017) (“An AKS violation that results in a federal health care payment is a per se false claim under the FCA.”).

showing of materiality⁶ or need for the government to provide discovery on the issue.⁷ Damages are the full amount of every claim that results from or was tainted by the illegal remuneration,⁸ potentially including claims that were submitted a year or more after the illegal remuneration was offered or paid.⁹

Together, in most cases, these three statutes make the payment of remuneration to Medicare beneficiaries unlawful as a criminal, civil, and administrative matter.¹⁰ The Department enforces the AKS and FCA, while OIG enforces the CMPL. Thus, this article focuses on the illegal payment of unlawful remuneration to Medicare beneficiaries that violate the FCA with a predicate AKS violation, and does not specifically address the CMPL.

III. False Claims Act enforcement trends

A. Routine copayment waivers

It is well-established in federal case law that the routine waiver of Medicare beneficiaries' copayment obligations will, in most cases, violate the AKS and, thus, can result in civil liability under the FCA. Federal courts have held that the "waiver of patients' co-payments

⁶ United States *ex rel.* Goodman v. Arriva Med., LLC, 471 F. Supp. 3d 830, 840 (M.D. Tenn. 2020) (explaining that 42 U.S.C. § 1320a-7b(g) "requires the courts to treat the question of materiality . . . as resolved").

⁷ *Id.* at 842 ("Insofar as the production was ordered based on the premise that materiality might be factually contestable with regard to these claims, it was clear error.").

⁸ United States *ex rel.* Emanuele v. Medicor Assocs., No. 10-245, 2017 WL 4867614, at *9 (W.D. Pa. Oct. 26, 2017) ("[W]here the false claims at issue are based on illegal referrals or kickbacks, courts have typically awarded a full measure of damages . . .").

⁹ *E.g.*, United States *ex rel.* Fesenmaier v. Cameron-Ehlen Grp., Inc., No. 13-cv-3003, 2021 WL 101193, at *13 (D. Minn. Jan. 12, 2021) (holding that the government has "presented evidence that substantiates their use of a one-year taint period").

¹⁰ See 31 U.S.C. § 3730; 42 U.S.C. § 1320a-7b; 42 U.S.C. § 1320a-7a(c)(1).

and deductibles constitutes a kickback” under the AKS.¹¹ Thus, federal law “treat[s] the waivers as violations of the AKS.”¹²

This means that a provider typically will “violate[] the AKS by routinely waiving co-payments for Medicare patients.”¹³ Routine copayment waivers are problematic because “they amount to paying someone to choose one provider over another”¹⁴ and “artificially inflate[] the price that the government pays” for health-care services.¹⁵ Moreover, “[t]he creation of false records . . . are the necessary, foreseeable, and obvious consequence of offering to waive and actually waiving . . . patients’ copays.”¹⁶

A recent case from the Middle District of Tennessee provides a textbook example of how unscrupulous Medicare providers engage in unlawful routine copayment waivers and unreasonable collection efforts. In that case, the United States recovered collectively over \$161 million from Arriva Medical (Arriva), at one point the largest supplier of diabetic testing supplies to Medicare beneficiaries;¹⁷ Arriva’s two founders;¹⁸ and Arriva’s reimbursement consultant;¹⁹ which is the

¹¹ *United States ex rel. Riedel v. Bos. Heart Diagnostics Corp.*, 332 F. Supp. 3d 48, 68 (D.D.C. 2018); *see United States ex rel. STF, LLC v. Vibrant Am., LLC*, No. 16-cv-02487, 2020 WL 4818706, at *13 (N.D. Cal. Aug. 19, 2020) (“a benefit conferred directly on . . . patients in the case of [co-pay] waivers . . . support[s] a claim under the Anti-[k]ickback Statute and the FCA”). *See also* Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372-01 (Dec. 19, 1994).

¹² *United States ex rel. Goodman v. Arriva Med., LLC*, 471 F. Supp. 3d 830, 833 (M.D. Tenn. 2020).

¹³ *United States v. Chang*, No. 13-3772, 2017 WL 10544289, at *7 (C.D. Cal. July 25, 2017).

¹⁴ *Goodman*, 471 F. Supp. 3d at 833.

¹⁵ *United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1104 (7th Cir. 2014).

¹⁶ *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 501 (D.S.C. 2016).

¹⁷ *See* Press Release, U.S. Dep’t of Just., Mail-Order Diabetic Testing Supplier and Parent Company Agree to Pay \$160 Million to Resolve Alleged False Claims to Medicare (Aug. 2, 2021) [hereinafter *Arriva Press Release*].

¹⁸ Press Release, U.S. Dep’t of Just., Two Former Arriva Medical Executives Agree to Pay \$1 Million To Settle Diabetic Testing Supply Fraud Allegations (Apr. 24, 2019).

¹⁹ *See* Press Release, U.S. Dep’t of Just., Florida-Based Consultant Resolves Litigation For Allegedly Causing False Diabetic Supply Claims To Medicare (Feb. 14, 2022).

largest recovery ever in a beneficiary-kickback case against a Medicare Part B supplier. The settlement with Arriva resolved claims that were submitted to Medicare “as much as one year after th[e] Medicare beneficiaries became tainted by the offer or payment of kickbacks to them.”²⁰

As detailed in the press release announcing the Arriva settlement, with respect to the copayment waiver claim, the government alleged that Arriva “failed to send invoices” or “collection letters” to beneficiaries, or make “phone calls” to collect copayments.²¹ Instead, Arriva “systematically waived ‘small’ dollar copayments without informing beneficiaries of their copayment obligations,” and “automatically waived other unpaid copayments after sending no more than three invoices . . . and making no other collection efforts”—such as out-bound phone calls.²²

Arriva also waived copayments when customers complained that it “had advertised and otherwise indicated that [the diabetic testing] supplies would be free or at no cost.”²³

In recent years, the United States has had other significant recoveries against Medicare providers for routine copayment waivers,²⁴ which will likely continue to be a focus of the Department’s enforcement efforts.

B. Cost-sharing assistance charities

Another major area of focus for the Department’s FCA enforcement efforts in the Medicare-beneficiary-kickback context has been pharmaceutical manufacturers that fund purportedly independent foundations to subsidize beneficiaries’ cost-sharing obligations (including copayments and deductibles) for the manufacturers’ products with the intent to induce those patients to purchase those companies’ expensive prescription drugs.²⁵

²⁰ Settlement Agreement at 2, United States *ex rel.* Goodman v. Arriva Medical, LLC., No. 13-cv-00760 (M.D. Tenn. Aug. 10, 2021), ECF No. 202-1.

²¹ Arriva Press Release, *supra* note 16.

²² *Id.*

²³ *Id.*

²⁴ *See, e.g.*, Press Release, U.S. Dep’t of Just., Durable Medical Equipment Provider Lincare Pays \$5.25 Million to Resolve False Claims Act Allegations (Aug. 16, 2018); Press Release, U.S. Dep’t of Just., Pentec Health, Inc. to Pay \$17 Million to Settle False Claims Act Allegations (Feb. 4, 2019).

²⁵ This is separate from the direct funding of Medicare beneficiaries’ cost-sharing obligations by drug manufacturers, which in itself implicates the

In 2019 alone, the United States recovered more than \$624 million from drug manufacturers that were alleged to have “illegally paid patient copays [on] their own drugs through purportedly independent foundations that the companies in fact treated as mere conduits.”²⁶ As of September 2020, according to OIG, “the United States has settled enforcement actions totaling more than \$900 million against ten pharmaceutical manufacturers . . . and four foundations, for conduct solely involving the allegedly illegal use of foundations that operate[d] patient assistance programs as conduits for improper payments to patients.”²⁷

One of the concerns animating the government’s enforcement efforts is that, by paying beneficiaries’ cost-sharing obligations through charitable foundations, drug manufacturers “blunt the impact of patient cost sharing to induce patients to fill prescriptions for costly medications.”²⁸ This “removes a potential downward pressure on the price of the drugs” because the manufacturers have no incentive to reduce the drug’s price to induce sales.²⁹ This could lead to higher expenditures by Medicare for the implicated prescription drugs.

Moreover, as OIG has explained, “[c]ost-sharing subsidies can be very profitable for manufacturers.”³⁰ This is because as “long as the manufacturer’s sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit.”³¹ As OIG has concluded, “[t]hese profits

AKS. *See* Pfizer Inc. v. U.S. Dep’t of Health & Hum. Servs., No. 20-cv-4920, 2021 WL 4523676, at *15 (S.D.N.Y. Sept. 30, 2021) (“With regard to the Direct Program, the law is clear that absent an/ express carve-out, the Anti-[k]ickback Statute prohibits any remuneration intended to induce someone to purchase or receive a drug or medical service.”), *aff’d* 42 F.4th at 67 (rejecting challenge to an HHS-OIG advisory opinion that determined that a drug company’s direct copay assistance program “plainly would’ involve prohibited conduct under the AKS”).

²⁶ Press Release, U.S. Dep’t of Just., Justice Department Recovers over \$3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020).

²⁷ OIG Advisory Opinion No. 20-05, at 13, n. 31 (Sept. 18, 2020).

²⁸ *Id.* at 13–14.

²⁹ *Id.* at 14.

³⁰ Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005).

³¹ *Id.*

can be considerable, especially for expensive drugs for chronic conditions.”³²

Consequently, OIG has warned in the context of patient assistance programs operated directly by pharmaceutical manufacturers that such subsidies “present heightened risks under the anti-kickback statute.”³³ In fact, OIG has concluded that “the subsidies would be squarely prohibited by the statute[] because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product.”³⁴ This “present[s] all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries[] incentives to locate and use less expensive, equally effective drugs.”³⁵

Notwithstanding this, OIG has recognized that “pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, *bona fide* charitable assistance programs.”³⁶ To do so, “the independent charity . . . must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices.”³⁷ Not surprisingly, two key issues in charitable-foundation kickback cases are whether (1) the charitable foundation functioned as a conduit for the drug manufacturer’s subsidization of copayments for its own drugs; and (2) this was the manufacturer’s intent.

For example, in a recent decision from the District of Massachusetts, the court denied a defendant’s motion to dismiss the United States’ complaint where the “[t]he government allege[d] that [the drug manufacturer] Teva worked with [the charity] ACS to ensure that [Teva’s] donations . . . were used solely for [the manufacturer’s drug] Copaxone copay assistance.”³⁸ Specifically, “Teva worked closely with ACS to calculate the precise amount necessary to cover the copays of a specific number of Copaxone patients . . . [t]hen it coordinated the

³² *Id.*

³³ *Id.* at 70,624.

³⁴ *Id.* at 70,625.

³⁵ *Id.*

³⁶ *Id.* at 70,626.

³⁷ *Id.* at 70,627.

³⁸ *United States v. Teva Pharms. USA, Inc.*, 560 F. Supp. 3d 412, 417 (D. Mass. 2021).

timing of its donations . . . [to maximize] the likelihood that Teva’s donations would be disbursed to Copaxone patients.”³⁹ The District of South Carolina similarly sustained a relator’s complaint against a drug manufacturer where the relator alleged that “Defendant fraudulently correlated its charitable contributions [with the help of the charity] . . . to ensure its products were purchased.”⁴⁰ In both cases, the FCA plaintiff sufficiently alleged scienter.

One method that drug manufacturers and charities use to funnel copayment assistance to beneficiaries who use the manufacturer’s drug is to define the disease eligible for copayment assistance so narrowly that the copayment assistance effectively only covers that manufacturer’s drug. Consequently, OIG has warned that a “charity with narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding, either exclusively or primarily, the donors’ products or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors’ products.”⁴¹

This is exactly the factual scenario in the government’s FCA case against drug manufacturer Mallinckrodt in the Eastern District of Pennsylvania. In that intervened *qui tam* suit, the United States alleged that “Mallinckrodt limited its fund definition to MS exacerbation patients in order to prevent its donations from being used to cover copays for chronic MS drugs, or any drug other than [Mallinckrodt’s drug,] Acthar.”⁴² Consequently, according to the government’s complaint, “[f]rom its inception until 2014, the MS Acute Exacerbation Fund paid Medicare copays for Acthar and not for any other drug.”⁴³ The court concluded that these allegations were sufficient to allege that Mallinckrodt had unlawfully used the charity to fund beneficiary copayments for its own drug.⁴⁴ Earlier this year,

³⁹ *Id.* at 420–21.

⁴⁰ *United States ex rel. Vitale v. MiMedx Grp., Inc.*, 381 F. Supp. 3d 647, 659 (D.S.C. 2019).

⁴¹ Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120-01, 31,121 (May 30, 2014).

⁴² *United States ex rel. Strunk v. Mallinckrodt ARD LLC*, Nos. 12-175, 13-1776, 2020 WL 362717, at *2 (E.D. Pa., Jan. 22, 2020).

⁴³ *Id.*

⁴⁴ *Id.* at *6.

Mallinckrodt settled this and another FCA action involving the same drug with the United States for \$260 million.⁴⁵

In addition to the numerous cases that it has already settled, the Department has several copayment charity cases in active litigation, including the *Teva* case cited above. Thus, this will likely continue to be an area of enforcement focus and case law development.

C. Free items and services

The last and broadest area of the Department's FCA enforcement efforts involving kickbacks to beneficiaries concerns gifts of free items or services. As OIG and several courts have explained, by adding the broad phrase "any remuneration" to the AKS in 1977, Congress intended "to cover the transferring of *anything of value* in any form or manner whatsoever."⁴⁶ Subject to narrow exceptions that are largely not the subject of this article, the AKS and FCA bar the gift of free items and services to beneficiaries of federal health-care programs like Medicare.⁴⁷

The reason why these gifts are problematic, according to OIG, is that they can influence beneficiaries' choice of a Medicare provider or supplier.⁴⁸ "Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services."⁴⁹ These giveaways also favor large providers with more resources while disadvantaging small providers.⁵⁰

⁴⁵ Press Release, U.S. Dep't of Just., Mallinckrodt Agrees to Pay \$260 Million to Settle Lawsuits Alleging Underpayments of Medicaid Drug Rebates and Payment of Illegal Kickbacks (Mar. 7, 2022).

⁴⁶ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-kickback Provisions, 56 Fed. Reg. 35,952-01, 35,958 (July 29, 1991) (emphasis added); see, e.g., *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015) (not precedential) (endorsing "expansive understanding of remuneration as 'anything of value in any form whatsoever'" (citation omitted)).

⁴⁷ See *Jones-McNamara*, 630 F. App'x at 400 (not precedential); 42 C.F.R. § 1001.952 (listing safe harbors to AKS).

⁴⁸ Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55,855-01, 55,856, 55,856 n.1 (Aug. 30, 2002) ("in this Special Advisory Bulletin, the term 'provider' includes practitioners and suppliers").

⁴⁹ *Id.* at 55,856.

⁵⁰ *Id.*

1. Common free-items-or-services schemes

The types of free items or services unlawfully given to Medicare beneficiaries typically fall into several broad categories: (1) pharmacy gift cards and cash rebates, (2) free supplies and durable medical equipment, and (3) a catch-all category for other things of value.

Gift Cards and Cash Rebates

A common free-item kickback scheme involves pharmacies' providing discounts, discount cards, or cash rebates to Medicare beneficiaries. No safe harbor under the AKS protects these types of marketing incentive programs (for example, cash rebates).⁵¹ One district court found that Kmart pharmacies' practice of offering and giving cash gift cards, coupon promotions, and a loyalty promotion to federal-health-care-program beneficiaries may constitute illegal remuneration under the FCA.⁵² The Department also settled a FCA suit against Walgreens for \$50 million involving claims that the pharmacy gave discounts on drugs and a 10% rebate on Walgreen-brand products, including grocery items, to Medicare and other federal-health-care-program beneficiaries.⁵³

Free Supplies

Marketing of free items like supplies or durable medical equipment (DME) is a second category of enforcement efforts. As one court noted, suppliers "may not represent to a potential beneficiary that the DME is free."⁵⁴ That court upheld a criminal conviction for conspiracy to commit health-care fraud when the defendant told Medicare beneficiaries that they were entitled to free arthritis kits.⁵⁵ Another court found that relators had stated an FCA claim by alleging that

⁵¹ See 42 C.F.R. § 1001.952; United States *ex rel.* Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 81 (D. Mass. 2011).

⁵² United States *ex rel.* Yarberry v. Sears Holdings Corp., No. 09-CV-588, 2013 WL 12111729, at *5–6 (S.D. Ill. Nov. 20, 2013).

⁵³ Press Release, U.S. Dep't of Just., Manhattan U.S. Attorney Announces \$50 Million Settlement With Walgreens For Paying Kickbacks To Induce Beneficiaries Of Government Healthcare Programs To Fill Their Prescriptions At Walgreens' Pharmacies (Jan. 19, 2017).

⁵⁴ United States v. Turner, 561 F. App'x 312, 315 (5th Cir. 2014) (not precedential).

⁵⁵ *Id.* at 315–17.

telemarketers told beneficiaries that they “could receive free DME.”⁵⁶ And the \$160 million Arriva settlement discussed above was partly based on claims that Arriva was marketing “free” and “no cost” diabetic-testing meters in advertising and in customer-intake calls.⁵⁷

Free Giveaways

Another free-item category concerns miscellaneous giveaways. For example, in one case a court upheld a health-care-fraud conviction of a defendant who offered or gave away a combination of free items and services, including free neck pillows, a short massage, and free Subway sandwiches to Medicare beneficiaries.⁵⁸ In a more unusual case, another court determined that providing below-cost housing to Medicaid beneficiaries qualified as remuneration under the AKS when one purpose of the housing was to induce the beneficiaries to enroll in an outpatient drug program.⁵⁹ In fact, in the proposed rule change the defendant cited in that case, OIG explained that

one exception to the definition of “remuneration” for purposes of the beneficiary inducements [civil monetary penalty rules] incorporates exceptions to the anti-kickback statute and the safe harbor regulations. However, no parallel exception exists in the anti-kickback statute. Thus, the exceptions in section 1128A(i)(6) of the Act apply only to the definition of “remuneration” applicable to section 1128A.⁶⁰

2. Common defenses to free-items-or-services schemes

Defendants often raise three defenses in FCA suits alleging giveaways to beneficiaries: (1) a nominal value defense that the free items allegedly have a *de minimis* nature, (2) a chronic-condition defense, which asserts that beneficiaries with specific chronic conditions—such as HIV, diabetes, or kidney failure—need or benefit

⁵⁶ United States *ex rel.* Bumbury v. Med-Care Diabetic & Med. Supplies, Inc., 2014 WL 12279512, at *4, *8 (S.D. Fla. Dec. 23, 2014).

⁵⁷ Arriva Press Release, *supra* note 16.

⁵⁸ United States v. Choiniere, 517 F.3d 967, 970–73 (7th Cir. 2008).

⁵⁹ United States v. Narco Freedom Inc., 95 F. Supp. 3d 747, 756–58 (S.D.N.Y. 2015).

⁶⁰ *Id.* at 757 ((alterations in original) citing Medicare and State Health Care Programs, 79 Fed. Reg. 59,717-01, 59,724 (Oct. 3, 2014)).

from the free items, and (3) a financial-need defense, which posits that beneficiaries are presumptively needy and therefore should be permitted to receive free items in a blanket, non-individualized manner. But none of these defenses pass legal muster.

First, the nominal-value defense comes from the CMPL, not the AKS. And, as OIG has explained, “the anti-kickback statute does not have any exceptions for items or services of nominal value.”⁶¹ Under the CMPL, inexpensive non-monetary gifts of nominal value are permitted.⁶² Originally, OIG interpreted nominal value as meaning a retail value of “no more than \$10 per item, or \$50 in the aggregate per patient on an annual basis.”⁶³ But in 2016, OIG adjusted those figures for inflation to “no more than \$15 per item or \$75 in the aggregate per patient” annually.⁶⁴ Although some courts have erroneously concluded otherwise,⁶⁵ OIG has made clear that this nominal-value guidance “applies only with respect to the Beneficiary Inducements CMP and not to the Federal anti-kickback statute.”⁶⁶ Thus, assuming a court follows OIG’s guidance, this should not be a successful defense in an FCA case alleging kickbacks to beneficiaries.

Second, in the context of the CMPL, OIG has explicitly rejected the argument that beneficiaries with chronic conditions should somehow be allowed to receive kickbacks from providers. As OIG explained,

⁶¹ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368, 88,379 (Dec. 7, 2016).

⁶² H.R. Rep. No. 104-736 at 255 (1996) (Conf. Rep.).

⁶³ Health Care Programs: Fraud and Abuse; Revised OIG Civil Monetary Penalties Resulting from Public Law 104-191, 65 Fed. Reg. 24400, 24410–11 (Apr. 26, 2000).

⁶⁴ OIG General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016).

⁶⁵ See, e.g., *Miller v. Abbott Lab’sys*, 648 F. App’x 555, 561 (6th Cir. 2016) (not precedential) (“[OIG] has offered further guidance that items or services of nominal value are permitted under the AKS . . .”). *But see* *United States ex rel. Yarberry v. Sears Holdings Corp.*, No. 09-cv-588, 2013 WL 12111729, at *6 n.10 (S.D. Ill. Nov. 20, 2013) (“There does not appear to be any controlling authority on point as to whether CMP’s safe harbors apply to an FCA lawsuit . . . predicated upon an AKS violation.”).

⁶⁶ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors under the Anti-kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684, 77,791 (Dec. 2, 2020).

“there is no meaningful basis under the statute for exempting valuable gifts based on a beneficiary’s medical condition or the condition’s severity.”⁶⁷ Indeed, OIG recognizes that “providers have a greater incentive to offer gifts to chronically ill beneficiaries,” who likely generate more revenue for providers than other beneficiaries.⁶⁸ Although not directly applicable in the AKS context, the Department can pursue the same reasoning in a kickback case, where there is also no statutory basis for an exemption for the payment of remuneration to beneficiaries based on the severity of the beneficiaries’ medical conditions.

Third, as OIG explains, again in the context of the CMPL, “there is no meaningful statutory basis for a broad exemption based on the financial need of a category of patients.”⁶⁹ Similarly, the AKS contains no blanket statutory exception for the financial need of patients. In fact, although not discussed in this article, the AKS applies its anti-kickback rule to the Medicaid program, which necessarily includes low-income persons.⁷⁰ “The inclusion of Medicaid within the prohibition demonstrates Congress’[s] conclusion that categorical financial need is not a sufficient basis for permitting valuable gifts.”⁷¹ Further, the narrow exception for non-routine copayment waivers also supports this conclusion.⁷²

IV. Conclusion

Kickback payments and other unlawful remuneration to Medicare beneficiaries are AKS violations that should not be overlooked. This is a significant area of FCA enforcement for the Department, particularly in recent years, because these types of illegal remunerations corrupt the process by which Medicare beneficiaries choose health-care providers, often leading to the over-use of these providers’ products and services at the expense of the Medicare Trust.

⁶⁷ OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55,855-01, 55,857 (Aug. 30, 2002).

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

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Materiality in Health-Care Fraud Cases Post-*Escobar*

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I. Introduction

*Universal Health Services v. Escobar*¹ was the first case involving the substantive elements of the False Claims Act (FCA) that the Supreme Court had taken in nearly a decade.² It was not expected to address materiality. Instead, it was supposed to resolve the validity of the implied false certification theory of liability under the FCA.³ Indeed, the two questions the Court granted a writ of certiorari to resolve were (1) whether the implied certification theory of legal falsity is viable; and (2) if it was, whether that theory was limited to cases where the allegedly violated requirement is expressly labeled as a condition of payment.⁴ It was not until oral argument that the first hints emerged that the Court would even explore the issue of materiality.⁵ As we all now know, materiality was not just part of the decision, but arguably its most impactful portion.

¹ *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176 (2016).

² The last such case was *Allison Engine Co. v. United States ex rel. Sanders*, where the Court held, under a previous version of the FCA, that a defendant had to intend that a false record or statement be material to the government's decision to pay a claim. *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671–72 (2008).

³ See Ronald Mann, *Argument preview: Justices to consider whether False Claims Act permits qui tam suits for “implied” falsehood*, SCOTUSblog (Apr. 12, 2006), <https://www.scotusblog.com/2016/04/argument-preview-justices-to-consider-whether-false-claims-act-permits-qui-tam-suits-for-implied-falsehood/>.

⁴ Petition for a Writ of Certiorari, *Universal Health Servs. v. United States ex rel. Escobar*, 569 U.S. 176 (2016).

⁵ Ronald Mann, *Argument analysis: Justices display disparate views on implied fraud under False Claims Act*, SCOTUSblog, (April 20, 2016),

This article will discuss the impact of the *Escobar* decision on health-care-fraud cases. Part II will briefly recap the core elements of the decision. Part III will discuss how some of the key factors in assessing materiality have manifested themselves in health-care-fraud cases. Finally, Part IV will provide some general guideposts to dealing with materiality when litigating health-care-fraud cases.

II. The *Escobar* decision

At first or even second blush, the *Escobar* decision did not change the standard for when a violation is material. Indeed, the Court explained that “under any understanding of the concept, materiality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”⁶ In so doing, the Court articulated a definition that fit neatly under the natural tendency standard for materiality that had been part of the FCA since 2009.⁷ Under that standard, it is enough to show that a misrepresentation *could* have influenced the government’s payment decision, and not that the government *would*, or even likely would, have denied payment had it known the truth.⁸

The cases and common law sources relied upon by the decision make this point clear. For example, *Escobar* repeatedly cites to the Supreme Court’s prior decision in *Kungys*, which rejected the argument that materiality employed a standard of “more likely than not,” and indicated that something can be material even if it has less than a 30% chance of influencing the decision maker.⁹ Other authorities cited

<https://www.scotusblog.com/2016/04/argument-analysis-justices-display-disparate-views-on-implied-fraud-under-false-claims-act/>.

⁶ *Escobar*, 579 U.S. at 193 (quoting Williston on Contracts § 69:12) (cleaned up).

⁷ Fraud Enforcement and Recovery Act of 2009, Pub L. No. 111-21, 123 Stat. 1617.

⁸ *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 470 (5th Cir. 2009); *see also* *United States v. Lindsey*, 2017 U.S. App. LEXIS 3482, at *19 (9th Cir. Feb. 27, 2017) (“[M]ateriality measures natural capacity to influence, not whether the statement actually influenced any decision.”).

⁹ *Escobar*, 579 U.S. at 193; *Kungys v. United States*, 485 U.S. 759, 771 (1988) (“It has never been the test of materiality that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation.” (emphasis in original)).

by *Escobar* confirm that, “it is not necessary to materiality that a misrepresentation have even been the paramount or decisive inducement, so long as it was a substantial factor.”¹⁰

From that foundation, the Court went on to explain that the materiality inquiry was a holistic analysis that depends on a number of different factors. Among the non-exhaustive factors identified was “the Government’s decision to expressly identify a provision as a condition of payment,” which the Court viewed as “relevant, but not automatically dispositive.”¹¹ Additional factors include whether the violation goes to the “essence of the bargain,”¹² whether the violation is significant or “minor or insubstantial,”¹³ and what actions the government took in this or other cases where the government had “actual knowledge” of similar violations.¹⁴ Evidence in this last category supporting materiality “can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.”¹⁵ Conversely, “if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.”¹⁶ It is this last factor that has had the greatest impact.

III. The impact of government action (or inaction) in the wake of the *Escobar* decision

The *Escobar* decision specifically identified the government’s conduct in the face of the misrepresentation as one of the factors relevant to the materiality inquiry.¹⁷ In highlighting the actual behavior of the government in assessing materiality, the Court placed

¹⁰ Materiality, 26 Williston on Contracts § 69:12 (4th ed. 2003).

¹¹ *Escobar*, 579 U.S. at 194.

¹² *Id.* at 193 n.5 (quoting *Junius Constr. Co. v. Cohen*, 257 N.Y. 393, 400 (1931)).

¹³ *Id.* at 194.

¹⁴ *Id.* at 195.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

new emphasis on the government's decision to pay (or deny) a claim.¹⁸ This has created a challenge in the health-care context as defendants try to use the fact that the government "historically paid claims quickly without verifying the accuracy of the claims before payment,"¹⁹ as evidence a violation was not material. Taking this further, defendants have argued the government's decision to decline to intervene in a *qui tam* action also shows a lack of materiality; an argument that threatens the statutory ability of relators to litigate declined cases.²⁰

A. When the government continues to pay claims

Properly evaluating the significance of the government's decision to approve or deny claims tainted by misconduct is especially difficult in the health-care context. This is because the ultimate beneficiary is often an innocent third-party, who could suffer adverse collateral consequences from the denial of a claim, such as losing access to vital health care.²¹ As a result, the federal government uses a pay-and-chase system where it "automatically pays those claims represented as qualifying . . . [and] seek[s] reimbursement or recoupment if it later

¹⁸ *Cf.* *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) ("The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers.").

¹⁹ *Godecke ex rel. United States v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1206 (9th Cir. 2019).

²⁰ 31 U.S.C. § 3730(c)(3) ("If the Government elects not to proceed with the action, the person who initiated the action **shall** have the right to conduct the action.") (emphasis added).

²¹ *United States ex rel. Prose v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 744 (7th Cir. 2021) (The government "may have needed time to work out a way not to prejudice Medicaid recipients who had nothing to do with this problem."); *United States ex rel. Rahimi v. Rite Aid Corp.*, No. 2:11-CV-11940, 2019 WL 1426333, at *8 (E.D. Mich. Mar. 30, 2019) ("Even if the government decided to pay Rite Aid's prescription charges despite knowledge of violations, the payment decision would not necessarily reflect a lack of materiality. For example, the Government may have continued to pay to avoid 'adversely affecting[ing] the millions of Medicaid beneficiaries who rely on Rite Aid to meet their prescription needs.'"). *Cf.* *United States v. Pub. Warehousing Co. K.S.C.*, No. 1:05-CV-2968-TWT, 2017 WL 1021745, at *6 (N.D. Ga. Mar. 16, 2017) ("The more essential the continued execution of a contract is to an important government interest, the less the government's continued payment weighs in favor" of establishing that a particular violation is immaterial.).

determines that the claim should not have been paid.”²² Thus, the payment of a health-care claim should not, in most instances, demonstrate a lack of materiality.

The primary reason is that, when determining what weight to give to the government’s payment of claims, it matters whether the government had actual knowledge of the defendant’s misconduct. This is because, “[w]ithout actual knowledge of the alleged non-compliance, the government’s response to the claims submitted by the defendants—or claims of the same type—has no bearing on the materiality analysis.”²³ This focus on actual knowledge makes sense, because many, if not all, fraud schemes are deceptive. A defendant should not be permitted to “‘take advantage of [its] own wrong’ by making its liability hinge on the Government’s ability to detect something that is designed to be difficult to detect.”²⁴

Defendants have argued the *qui tam* complaint itself is evidence the government had knowledge of the alleged non-compliance, and any payments made during the pendency of an investigation therefore demonstrate a lack of materiality. A *qui tam* complaint, however, is only an unverified set of allegations and is not sufficient to give the government actual knowledge of a violation.²⁵ Continued payment

²² *Godecke*, 937 F.3d at 1206.

²³ *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 834 (6th Cir. 2018); *United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2017 WL 1344365, at *11 (E.D. Pa. Apr. 12, 2017) (“Absent evidence that the government had actual knowledge of Defendant’s fraud, we find the government’s continued payments of . . . claims insufficient to establish that Relators’ claims fail for lack of materiality.”). *But see* *United States ex rel. Cimino v. Int’l Bus. Machines Corp.*, 3 F.4th 412, 423 (D.C. Cir. 2021) (“[C]ontinued payment of claims the government knows might be fraudulent suggests the fraud was not material to the government.”) (citing *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017))(cleaned up).

²⁴ *Burciaga v. The Geo Group*, No. 3:12cv259-L-WVG, 2017 WL 10605270 at *6 (S.D. Cal. Feb. 28, 2017) (alteration in original) (citing *United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1216 (9th Cir. 1996)); *see also* *United States ex rel. Campie v. Gilead Sci., Inc.*, 862 F.3d 890, 905 (9th Cir. 2017).

²⁵ *United States ex rel. Escobar v. Universal Health Svcs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) (“[M]ere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance.”); *see also* *United States ex rel. Lutz v. Berkeley HeartLab*,

during the pendency of a qui tam investigation is thus not particularly relevant to the materiality inquiry.

The logic underlying such a conclusion was set out in detail in *United States ex rel. Lutz v. Berkeley HeartLab, Inc.* There, the court rejected the defendants' arguments that the kickbacks at issue were not material because the government continued to pay claims after it learned some facts about the case from the first relator's qui tam complaint.²⁶ The court reasoned that the qui tam complaint was not evidence the government knew "that any claims were *actually tainted* by an illegal kickback scheme."²⁷ Instead, "it took the Government years of investigation to determine whether any defendant had the requisite scienter to violate the [Anti-kickback Statute] and, in turn, the FCA."²⁸ The court observed that the government "does not enjoy the luxury of refusing to reimburse health-care claims the moment it suspects there may be wrongdoing."²⁹ The court further noted that the defendants vigorously argued throughout the course of the litigation that the elements of an FCA violation had not been established, undercutting their claims that the government had actual knowledge of the violations all along.³⁰ Other district courts have echoed this sentiment.³¹

In many instances, a relator's qui tam complaint alleges that an unidentified subset of claims submitted by a provider are fraudulent and should not be paid. Determining which specific claims were tainted by the fraud often takes years of investigation. In a case involving lack of medical necessity, for example, establishing the

Inc., No. 9:14-230-RMG, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017); *Public Warehousing Co.*, 2017 WL 1021745, at *6; *United States ex rel. Rose v. Stephens Institute*, No. 09-cv-05966-PJH, 2016 WL 5076214, at *6 (N.D. Cal. Sept. 20, 2016), *aff'd*, 909 F.3d 1012 (9th Cir. 2018).

²⁶ *Lutz*, 2017 WL 4803911, at *7.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* Cf. *Cimino*, 3 F.4th at 423 (Observing that the government "may have felt obligated to pay until it received a legal determination that it was relieved of the agreement's terms.").

³⁰ *Lutz*, 2017 WL 4803911, at *7.

³¹ See, e.g., *United States ex rel. Longo v. Wheeling Hosp., Inc.*, No. 5:19-CV-192, 2019 WL 4478843, at *7 (N.D.W. Va. Sept. 18, 2019) ("doubt[ing] that the hospital industry would warmly welcome a rule that required the Government to cut off hospital funding whenever a qui tam action is filed or forfeit its right to seek reimbursement.").

fraudulent nature of the claim often requires a detailed review of the underlying documentation supporting the claim. This can only be done well after payment, since the claim itself does not include that supporting documentation.³² In these circumstances, the government “would have no way of knowing” whether any particular claim submitted by that provider failed to comply with Medicare regulations.³³ As a result, “it does not follow” from the government’s general awareness of a scheme that it “had actual knowledge that particular claims were non-compliant and reimbursed them anyway.”³⁴

There are also various reasons why, even armed with actual knowledge of material violations, the government would have a good reason for continuing to pay claims. When the government “exercises its discretion to excuse non-compliance with a requirement,” that fact alone does not necessarily “establish that the requirement is immaterial as a matter of law.”³⁵ As the Seventh Circuit recently explained, “[m]any things could explain the government’s continued contracting with” a defendant accused of committing fraud.³⁶ For example, the government may have been under the impression that the defendant stopped committing the violations once it learned of an investigation.³⁷ The government may have also wanted to make sure

³² *Polansky v. Exec. Health Resources, Inc.*, No. 12-4239, 2018 WL 1403433, at *1 (E.D. Penn. Mar. 19, 2018).

³³ *Id.*

³⁴ *United States ex rel. Brown v. Celegene Corp.*, 226 F. Supp. 3d 1032, 1050 (C.D. Cal. 2016).

³⁵ *Id.*; see also *United States ex rel. Bonzani v. United Techs. Corp.*, No. 3:16-CV-1730 (JCH), 2019 WL 5394577, at *7 (D. Conn. Oct. 22, 2019).

³⁶ *Prose*, 17 F.4th at 777; see also *Campie*, 862 F.3d at 906 (“there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs”).

³⁷ *Prose*, 17 F.4th at 777; see also *Campie*, 862 F.3d at 906 (“Once the unapproved and contaminated drugs were no longer being used, the government’s decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance.”); *United States v. Coloplast Corp.*, 327 F. Supp. 3d 300, 308 (D. Mass. 2018) (concluding that a jury could find that the government did not have “actual knowledge” of the alleged violations because it reasonably assumed the defendant had ceased the conduct at issue after a prior settlement).

vulnerable populations continued to receive health-care services.³⁸ The Sixth Circuit recently echoed those observations in a non-health-care case.³⁹ In light of these considerations, the government’s continued payment of claims in the health-care context should not be fatal to establishing materiality.

B. When the government declines to intervene

Escobar has also spawned new debate over the import of the government’s election decision on the viability of a qui tam action. In its post-*Escobar* complaints-in-intervention, the government often highlights similar cases in which it has either intervened or settled as evidence the violation was material.⁴⁰ Numerous defendants have attempted to argue the converse and cite the government’s decision to decline to intervene in a qui tam action as evidence undercutting materiality.⁴¹ A handful of courts have agreed, concluding that the government’s declination decision is at least one factor weighing in favor of a conclusion that a violation is not material.⁴² The bulk of the

³⁸ See note 21.

³⁹ *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs.*, 34 F.4th 507, 517 (6th Cir. 2022) (“There are a variety of factors unrelated to the materiality of the allegations that could cause the Government to continue contracting with a party after the Government becomes aware of alleged fraud.”).

⁴⁰ See, e.g., *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017) (when examining materiality, observing that the government “immediately intervened in the litigation.”); *Longo*, 2019 WL 4478843, at *9 (noting that the government’s complaint-in-intervention “sets forth a number of instances in which the Government has settled and litigated violations of these statutes”); see also *United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 162 (5th Cir. 2019) (relator’s allegations that the government takes criminal and civil enforcement actions against other providers committing similar violations weighed in favor of finding the violations material). *But see* *United States v. Strock*, 982 F.3d 51, 63–64 (2d Cir. 2020) (holding the government’s prosecution decisions were “neutral” on the issue of materiality).

⁴¹ See, e.g., *Prather*, 892 F.3d at 836; see also *United States ex rel. Hanvey v. Sutter Health*, No. 14-cv-4100, ECF No. 131 at 33 (N.D. Cal., Mar. 17, 2021).

⁴² See, e.g., *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (holding that relator had not sufficiently plead materiality because, *inter alia*, in the six year since the qui tam was originally filed under seal, “the Department of Justice ha[d] taken no action against [the defendant] and declined to intervene in the suit.”); *United States v. Comstor*

decisions, however, have concluded that the government’s declination should be given little to no weight when assessing materiality.⁴³

Unlike the government’s decision to intervene—which clearly and unequivocally demonstrates its belief that a case has merit and that a particular violation is material—it may elect to decline for a myriad of reasons other than the substantive merits of the case. Before *Escobar*, courts recognized that the government’s declination decision was not a statement on the merits of a case,⁴⁴ and there is nothing in *Escobar* to suggest the reasoning of those cases no longer holds true. “[T]he government cannot intervene in every FCA action, nor can the government pursue every meritorious FCA claim.”⁴⁵ Thus, “[i]n any given case, the government may have a host of reasons for not pursuing a claim.”⁴⁶ The government may determine “that the costs of proceeding on [a relator’s] claims outweighed the anticipated

Corp., 308 F. Supp. 3d 56, 86 (D.D.C. 2018) (“The requirement of demonstrating materiality would seem especially crucial here where the government declined to intervene after almost five years of investigation, and has also declined to intervene in similar cases brought by this relator alleging similar fraudulent activity . . .”).

⁴³ See, e.g., *United States ex rel. IBEW Local Union No. 98 v. Fairfield Co.*, 5 F.4th 315, 346 (3d Cir. 2021) (“But intervention decisions are, at best, of minimal relevance.”).

⁴⁴ *United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005) (The FCA “does not require the government to proceed if its investigation yields a meritorious claim.”); *United States ex rel. Berge v. Bd. of Trustees of the Univ. of Alabama*, 104 F.3d 1453, 1458 (4th Cir. 1997) (“[T]he plain language of the Act clearly anticipates that even after the Attorney General has ‘diligently’ investigated a violation under [the FCA], the Government will not necessarily pursue all meritorious claims; otherwise there is little purpose to the qui tam provision permitting private attorneys general.”); see also 31 U.S.C. § 3730(a) (“[i]f the Attorney General finds that a person has violated” [the FCA], “the Attorney General *may* bring a civil action.”) (emphasis added).

⁴⁵ *United States ex rel. Ubl v. IIF Data Sols.*, 650 F.3d 445, 457 (4th Cir. 2011).

⁴⁶ *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006); *United States ex rel. Chandler v. Cook County*, 277 F.3d 969, 974 n.5 (7th Cir. 2002) (“The Justice Department may have myriad reasons for permitting the private suit to go forward . . .”).

benefits.”⁴⁷ This could be the case in a meritorious action where the defendant is (or nearly is) bankrupt and does not have the ability to satisfy any judgment. The government might also decline a case because of “limited prosecutorial resources and confidence in the relator’s attorney.”⁴⁸ Thus, the “government’s decision not to intervene in an FCA action does not mean that the government believes the claims are without merit, and the government’s decision not to intervene therefore is not relevant in an FCA action brought by a private party.”⁴⁹

Moreover, central provisions of the FCA expressly permit relators to proceed after declination.⁵⁰ As the Sixth Circuit recognized in a declined case, “if relators’ ability to plead sufficiently the element of materiality were stymied by the government’s choice not to intervene, this would undermine the purposes of the Act.”⁵¹ If materiality—a required element of an FCA cause of action—could not be established when the government declined to intervene in a case, then relators would never be able to proceed in a declined *qui tam*.⁵² Such an outcome would effectively eliminate the provisions permitting and encouraging relators to proceed in declined cases from the statutory text of the FCA and should be avoided.⁵³

⁴⁷ *Berge*, 104 F.3d at 1458; *see also* *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933–34 (2009) (recognizing that there are real costs and burdens attendant to intervening in an FCA action).

⁴⁸ *Chandler*, 277 F.3d at 974 n.5; *see also* *United States ex rel. Downy v. Corning, Inc.*, 118 F. Supp. 2d 1160, 1170 (D.N.M. 2000).

⁴⁹ *Ubl*, 650 F.3d at 457; *see also* *United States ex rel. Hunt v. Cochise Consultancy, Inc.*, 887 F.3d 1081, 1088 (11th Cir. 2018); *Atkins*, 470 F.3d at 1360 n.17 (“We do not assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrong doing insufficient or the *qui tam* relator’s allegations for fraud to be without merit.”).

⁵⁰ *See* *United States ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, 507 F. Supp. 3d 734, 766 (W.D. Tex. 2020), *reconsideration granted on other issue*, 2022 No. SA-17-CV-00317-XR, WL 80293 (W.D.Tex. Jan. 7, 2022).

⁵¹ *Prather*, 892 F.3d at 836.

⁵² *See* *United States ex rel. Rahimi v. Rite Aid Corp.*, No. 2:11-CV-11940, 2019 WL 1426333, at *8 (E.D. Mich. Mar. 30, 2019) (“[T]o infer a lack of materiality from the Government’s non-intervention would make the Government’s non-intervention dispositive of the materiality analysis.”).

⁵³ *See Eisenstein*, 556 U.S. at 933 (rejecting an interpretation of the FCA that “otherwise would render the intervention provisions of the FCA superfluous”

Finally, it is worth noting that *Escobar itself* was a declined case.⁵⁴ Despite the government’s decision to decline, the Supreme Court did not mention that fact as relevant to its materiality analysis.⁵⁵ Nor did the First Circuit on remand.⁵⁶ Although the government’s intervention in a case is evidence of materiality, the converse is not similarly probative.

IV. Establishing materiality after *Escobar*

More broadly, the *Escobar* decision elevated the importance of the materiality element in FCA cases. As the decision proclaimed, the “materiality standard is demanding,”⁵⁷ and many post-*Escobar* FCA cases now include multiple dispositive motions on materiality. In navigating this new landscape, three guide stars can be helpful.

First, there are cases where materiality can be established as a matter of law. Most significantly, courts applying the *Escobar* standard for materiality have held that violations of both the Anti-kickback Statute (AKS)⁵⁸ and the Stark Law⁵⁹ are *per se* material.⁶⁰ The court in *United States ex rel. Lutz v. Berkeley*

and “would contradict well-established principles of statutory interpretation that require statutes to be construed in a manner that gives effect to all of their provisions”); *see also* *United States v. Jicarilla Apache Nation*, 564 U.S. 162, 185 (2011). *Cf. Downy*, 118 F. Supp. 2d at 1170 (“[N]othing in the FCA indicates the government’s rights should be more at risk simply because the government has decided to refrain from intervention.”).

⁵⁴ *See Escobar*, 579 U.S. at 185.

⁵⁵ *Id.*; *see also Prather*, 892 F.3d at 836.

⁵⁶ *Escobar*, 842 F.3d at 112; *see also Prather*, 892 F.3d at 836.

⁵⁷ *Escobar*, 579 U.S. at 194.

⁵⁸ 42 U.S.C. § 1320a-7b.

⁵⁹ 42 U.S.C. §§ 1395nn *et seq.*

⁶⁰ *See, e.g.,* *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (“The statute’s use of the term ‘constitutes’ would be meaningless if courts had to engage in a materiality analysis . . . after establishing that a claim resulted from an AKS violation.”); *see also* *United States v. Reliance Med. Sys., LLC*, No. CV 14-06979, 2022 WL 524062, at *4 (C.D. Cal. Feb. 22, 2022) (“[C]ompliance with the Anti-[k]ickback Statute is necessarily material to the government’s decision to pay Medicare claims....”); *United States v. Marlin Med. Sols. LLC*, No. SA-21-CV-00160, 2022 WL 190308, at *8 (W.D. Tex. Jan. 12, 2022) (“And courts have found AKS violations to be inherently material to the government’s decision to pay claims presented. . . . The Court agrees: AKS violations are ‘serious, consequential, felony transgressions of law . . . precisely the kind of violation[s] the FCA is supposed to reach.’” (citations omitted)).

Heartlab, Inc., persuasively explained why.⁶¹ The court began by considering that Congress amended the AKS in 2010 to add the following provision: “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim [for purposes of the FCA].”⁶² The court observed that although the 2010 amendments to the AKS did “not explicitly state that [an] AKS violation is material to the Government’s payment decision, the only *reasonable* inference is that AKS violations are *per se* material.”⁶³

The court further concluded that even in the absence of that amendment, an evaluation of the *Escobar* factors demonstrated that a violation of the AKS remained material as a matter of law.⁶⁴ It started out by noting that other courts had consistently found compliance with the AKS to be a condition of payment.⁶⁵ It then observed that a “[v]iolation of the AKS is not a *de minimis* regulatory violation, nor is it a mere technical violation of adhesive fine print in Government contracts.”⁶⁶ Instead, a violation of the AKS is also a felony.⁶⁷ In fact, the government regularly brings both criminal and civil actions to punish AKS violations and recoup money it has paid to violators.⁶⁸ The court also pointed out that the Department of Health & Human Services has issued special fraud alerts concerning AKS violations.⁶⁹ As a result, the court concluded, “[t]here can be no question that the

⁶¹ United States *ex rel.* Lutz v. Berkeley Heartlab, Inc., No. CV 9:14-230-RMG, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017).

⁶² *Id.* at *2; *see also* 42 U.S.C. § 1320a-7b(g).

⁶³ *Lutz*, 2017 WL 6015574, at *2 (emphasis added).

⁶⁴ *Id.*; *see also* *Longo*, 2019 WL 4478843, at *9 (citing *Lutz* with approval).

But see United States *ex rel.* Gohil v. Sanofi U.S. Servs. Inc., 500 F. Supp. 3d 345, 361–62 (E.D. Pa. 2020) (noting that although some courts have found a violation of the AKS to be *per se* material, the “Third Circuit has stated otherwise”) (citing United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 98 n.8 (3d Cir. 2018)).

⁶⁵ *See* United States *ex rel.* Kester v. Novartis Pharmaceuticals, 41 F. Supp. 3d 323, 330 (S.D. N.Y. 2014) (collecting cases); *see also* United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 394 (1st Cir. 2011); United States *ex rel.* Wilkins v. United Health Group, Inc., 659 F.3d 295, 313 (3d Cir. 2011); United States *ex rel.* McNutt v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1260 (11th Cir. 2005).

⁶⁶ *Lutz*, 2017 WL 6015574, at *2.

⁶⁷ 42 U.S.C. § 1320a-7b; *Lutz*, 2017 WL 6015574, at *2..

⁶⁸ *Lutz*, 2017 WL 6015574, at *2 (collecting cases).

⁶⁹ *Id.*

Government would likely refuse to pay a claim that it actually knows is the result of an AKS violation.”⁷⁰ Consistent with this reasoning, the court instructed the jury that if found that a claim violated the AKS, then the claim was necessarily false or fraudulent.⁷¹ On appeal, the Fourth Circuit affirmed the judgment of the district court “in all respects,”⁷² and specifically affirmed the propriety of this instruction.⁷³ Another district court has used similar reasoning to find violations of the Stark Law to be material as a matter of law.⁷⁴ These decisions appropriately acknowledge the importance of compliance with certain health-care requirements.

Second, there are also cases where materiality can be proven by the same evidence necessary to establish another element of the case. For example, the fraud-in-the-inducement theory requires proof the falsity was the but-for cause of the government entering the contract, which also establishes the falsity was material. This was the case in the non-health-care matter of *United States ex rel. Cimino v. IBM*.⁷⁵

In that case, the relator alleged that the defendant created a false audit that showed the government owed millions in penalties under an existing contract in order to induce it to enter a new contract.⁷⁶ After finding the relator had to plead but-for causation to establish a claim for fraudulent inducement (that is, but for the false audit, the government would not have entered into the new contract), the D.C. Circuit logically concluded that the relator “plausibly pleaded materiality, with largely the same facts that supported his allegations of causation.”⁷⁷ Indeed, if an act actually influenced the government’s decision, then it certainly was capable of doing so.⁷⁸

⁷⁰ *Id.*

⁷¹ *United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021); *cert. denied sub nom. Dent v. United States*, No. 21-445, 2021 WL 5284633 (U.S. Nov. 15, 2021); *see also United States ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017) (“An AKS violation that results in a federal health care payment is a per se false claim under the FCA.” (citing 42 U.S.C. § 1320a-7b(g))).

⁷² *Lutz*, 988 F.3d at 735.

⁷³ *Id.* at 741.

⁷⁴ *Longo*, 2019 WL 4478843, at *10 (citing *United States ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 430–31 (W.D. Pa. 2017)).

⁷⁵ *Cimino*, 3 F.4th 412 (D.C. Cir. 2021).

⁷⁶ *Id.* at 416.

⁷⁷ *Id.* at 422–23.

⁷⁸ *Id.*

In the health-care-fraud context, such a theory of fraud in the inducement can manifest itself as a claim premised upon obtaining fraudulent regulatory clearance from the Food and Drug Administration (FDA). For example, in *Dan Abrams Co., LLC v. Medtronic, Inc.*, the relator alleged that the defendant fraudulently obtained clearance for several devices used in spinal fusion surgeries.⁷⁹ The relator specifically alleged two categories of fraudulently cleared devices which were (1) devices that could be used on-label but were intended to be used off-label; and (2) devices that could only be used off-label, that is, should not have been cleared for any use. The Ninth Circuit upheld the dismissal of claims arising from the first category of claims for lack of materiality because the “government allows reimbursement for off-label and even contraindicated uses.”⁸⁰ For the second category of devices, however, the court reversed because the relator alleged the defendant concealed safety concerns, which could have led the FDA to deny clearance to the devices at issue.⁸¹ This, in turn, would have been per se material to the Government’s payment decision, because the government will not pay for devices without FDA approval or clearance.⁸²

Other situations where this arises are cases that allege significant damages. Damages under the FCA are assessed using the proximate-causation standard.⁸³ Under that standard, a defendant is liable for damages that are the foreseeable result of his or her misconduct, that is, a reasonable person would consider the damages as a likely result.⁸⁴ Thus, to establish significant FCA damages requires evidence

⁷⁹ *Dan Abrams Co. LLC v. Medtronic Inc.*, 850 Fed. Appx. 508 (9th Cir. 2021). The relator also alleged that the defendant violated the FCA by marketing devices for uses not sanctioned by the FDA, which is often referred to as an “off-label” use. The Ninth Circuit affirmed the dismissal of such claims because whether a device is used on or off label is not material to the government’s decision to pay. Rather, what is important is whether the device is cleared by the FDA and the use is “medically reasonable and necessary.” *Id.* at 509–10.

⁸⁰ *Id.* at 511.

⁸¹ *Id.*

⁸² *Id.* at 509.

⁸³ *United States v. Luce*, 873 F.3d 999, 1014 (7th Cir. 2017); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995); *United States v. Miller*, 645 F.2d 473, 475–76 (5th Cir. 1981); *United States v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977).

⁸⁴ *Luce*, 873 F.3d at 1012.

that the defendant's misconduct caused significant harm, and that a reasonable person would understand that it was likely to do so. This evidence would almost certainly establish that the misconduct was capable of influencing the government's payment decision, as was the case in *United States ex re. Ruckh v. Salus Rehab., LLC*.⁸⁵

In that case, the relator alleged, among other things, that the defendant's Skilled Nursing Facility (SNF) exaggerated the duration and complexity of the services it provided by using false Resource Utilization Group (RUG) codes.⁸⁶ A jury found in favor of the relator, but the district court granted judgment as a matter of law to the defendant after concluding these errors were "a handful of paperwork defects."⁸⁷ In reversing and reinstating the jury verdict, the Eleventh Circuit explained that inflating the RUG codes resulted in the government paying the defendant "higher amounts than they were truly owed. This plain and obvious materiality went to the heart of the SNFs' ability to obtain reimbursement from Medicare."⁸⁸ Thus, where the violation resulted in significant damages, materiality should be plain and obvious.

Finally, there are differences between dealing with the fact that the government did not deny any of the claims at issue at the pleading stage versus the summary judgment or trial stage. At the pleading stage, courts do not look beyond the complaint.⁸⁹ Thus, where facts supporting actual knowledge and continued payment by the government of the violation are pleaded, courts have used those facts to find a lack of materiality.⁹⁰ Conversely, where those facts are not pleaded, courts have appropriately viewed the failure to deny any

⁸⁵ 963 F.3d 1089, 1097 n.3 (11th Cir. 2020).

⁸⁶ *Id.* at 1097.

⁸⁷ *Id.* at 1105.

⁸⁸ *Id.*

⁸⁹ See *Strock*. 982 F.3d at 63–64 (holding it inappropriate for a district court to use a government Accountability Office Report to conclude the government had a "spotty post-award enforcement record" of the requirement at issue); *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 113 (2d Cir. 2021) (holding it inappropriate for a district court to consider a Defense Contract Audit Agency report that was not referenced in the complaint).

⁹⁰ See, e.g., *id.* ("The allegations in the Complaint, coupled with the reports incorporated by reference, demonstrate that the government had actual knowledge of" the violations, which is "powerful evidence that any misrepresentations . . . were not material to the government's payment decision.").

claims as having “no bearing on the materiality analysis.”⁹¹ Of course, it would be helpful to plead additional facts where the government took other action against the defendant, such as excluding the provider from the Medicare program⁹² or instituting other administrative proceedings.⁹³ Also supporting materiality would be pleading other instances of government enforcement against similarly situated defendants for similar conduct, such as imposing fines and even orders to take corrective action.⁹⁴ And where the pleadings must include the fact of continued payment, it would be helpful to include facts “supporting [] possible alternative explanations” of why, other than a lack of materiality, the government acted as it did.⁹⁵ In any event, at the pleading stage, the fact that the government never denied any of the defendant’s claims need not be conclusively resolved.

⁹¹ *Prather*, 892 F.3d at 834.

⁹² *See, e.g., Triple Canopy, Inc.*, 857 F.3d at 179 (“Here, the Government did not renew its contract for base security with Triple Canopy and immediately intervened in the litigation. Both of these actions are evidence that Triple Canopy’s falsehood affected the Government’s decision to pay.”).

⁹³ *Luce*, 873 F.3d at 1007 (“HUD’s action upon learning of Mr. Luce’s indictment and false certifications confirms the centrality of this requirement: It instituted debarment proceedings to end Mr. Luce’s participation in the program. It did not simply refuse payment in one instance, but terminated its relationship with the loan originator so that no future payments could be made.”).

⁹⁴ *Rose*, 909 F.3d at 1022 (“There is evidence, then, that the Department did care about violations of the incentive compensation ban and did not allow schools simply to continue violating the ban while receiving Title IV funds. And in many cases, through one means or another, the Department recouped many millions of dollars from the violating schools, showing that it was not prepared to pay claims ‘in full’ despite knowing of violations of the incentive compensation ban. The Department can demonstrate that requirements, such as the incentive compensation ban, are material without directly limiting, suspending, or terminating schools’ access to federal student aid. A full examination of the Department’s past enforcement habits in similar cases, therefore, reveals that a reasonable trier of fact could find that Defendant’s violations of the incentive compensation ban were material.”). *But see Strock*. 982 F.3d at 63–64 (“Thus, while purely post hoc enforcement actions can carry some weight in a materiality analysis, they are less probative than allegations that the government actually refuses to make payments once it determines that the [SDVOSB] condition has been violated.”).

⁹⁵ *AECOM*, 19 F.4th at 115.

As the Seventh Circuit explained, arguments about the government's continued payment of claims is "better saved for a later stage, once both sides have conducted discovery."⁹⁶

At those later stages, possible explanations for the government's decision not to deny claims must be validated with evidence.⁹⁷ This distinction is illustrated by contrasting *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*⁹⁸ and *United States ex. rel. Bibby v. Mortgage Investors Corp.*⁹⁹ In *Janssen*, the relator alleged the defendant falsified patient arrival times, which resulted in inflated payments from the government under several qualify-of-care incentive programs.¹⁰⁰ In the complaint, the relator alleged that the allegations were being investigated by a third-party contractor but did not plead the results of that investigation.¹⁰¹ These details came to light during litigation, including an affidavit from the third-party contractor describing its investigation, and that the government did not take any action after being apprised of the investigation's results.¹⁰² The court found this evidence weighed "in favor of immateriality" and, partially on this basis, affirmed the district court's grant of summary judgment to the defendants.¹⁰³

Bibby, in contrast, is an example where the government's continued payment of claims was successfully addressed. That case involved allegations that certain lenders were charging borrowers' fees that were prohibited by regulation for loans guaranteed by the government.¹⁰⁴ The evidence showed the government obtained actual knowledge of the defendant's misconduct as a result of two audits, yet still honored all the loan guarantees.¹⁰⁵ In assessing the significance of

⁹⁶ *Molina*, 10 F.4th at 744.

⁹⁷ *AECOM*, 19 F.4th at 115 ("There may be circumstances where the government's payment of a claim or failure to terminate a contract despite knowledge of certain alleged contractual violations will not be particularly probative of lack of materiality. . . . But the plaintiff must plausibly plead facts to support such possible alternative explanations in the complaint (and at a later stage of litigation, must support these allegations with evidence).").

⁹⁸ 949 F.3d 533 (10th Cir. 2020).

⁹⁹ 987 F.3d 1340 (11th Cir. 2021).

¹⁰⁰ *Janssen*, 949 F.3d at 537.

¹⁰¹ Second Amended Complaint ¶ 132.

¹⁰² *Janssen*, 949 F.3d at 542.

¹⁰³ *Id.* at 545.

¹⁰⁴ *Bibby*, 987 F.3d at 1343.

¹⁰⁵ *Id.* at 1349.

this evidence, the court rightly observed “the significance of continued payment may vary depending on the circumstances.”¹⁰⁶ One key circumstance was that the government was statutorily obligated to honor its loan guarantees, regardless of any fraud by the lender.¹⁰⁷ The court also looked beyond a “strict focus on the government’s payment decision” and considered the numerous administrative actions the government took to address non-compliance with fee regulations, including issuing guidance, implementing more frequent and rigorous audits, and demanding the refund of any improperly charged fees.¹⁰⁸ Given these circumstances, the court concluded the government’s decision to not deny claims was not “very strong evidence” of immateriality, that there was sufficient evidence to support materiality, and that the ultimate determination should be left to the factfinder.¹⁰⁹

These cases demonstrate the importance of explaining the government’s decision not to deny claims at later stages of litigation. Was it because the government never received actual knowledge of the violations? If not, was the government statutorily obligated to pay? Was it concerned with potential collateral consequences of non-payment, such as loss of access to health care? Or was it even the result of administrative oversight?¹¹⁰ Absent some specific explanation, there is a significant risk a court or the jury will view the government’s continued payment as very strong evidence of immateriality, which, if unrebutted, can result in an adverse summary judgment ruling¹¹¹ or jury verdict.

¹⁰⁶ *Id.* at 1350.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 1351–52.

¹⁰⁹ *Id.* at 1352.

¹¹⁰ *Rogan*, 517 F.3d at 452 (“Another way to see this is to recognize that laws against fraud protect the gullible and the careless—perhaps especially the gullible and the careless—and could not serve that function if proof of materiality depended on establishing that the recipient of the statement would have protected his own interests.”).

¹¹¹ *Bibby*, 987 F.3d at 1352 (“To be sure, the materiality standard is ‘demanding’, and courts may dismiss FCA cases at summary judgment where relators fail to create a genuine issue of material fact on that element. That is particularly true where ‘very strong evidence’ . . . of . . . continued payment remains unrebutted.”) (internal citations omitted).

VI. Conclusion

Escobar has certainly caused much ink to be spilled on the issue of which violations are considered material under the FCA. However, there has not been a massive paradigm shift of what constitutes a meritorious FCA health-care-fraud case. Cases premised upon the violation of the AKS or Stark Law remain viable theories of FCA liability as courts have held such violations to be material as a matter of law. Declined cases have largely succeeded or failed not as a result of the government's decision to decline, but on their own merits. While the government sometimes has to explain why it did not deny claims, that hurdle can be cleared by showing it did not have actual knowledge of the violation, had compelling reasons to nonetheless pay claims, or that the alleged violation caused the government significant damages. Thus, with a little mindfulness of materiality, good health-care-fraud cases before *Escobar* remain good health-care-fraud cases.¹¹²

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¹¹² Indeed, as noted above, the *Escobar* court discussed materiality “under any understanding of the concept.” *Escobar*, 579 U.S. at 193.

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AKS-Predicated FCA Actions: The Link Needed Between Kickback And Claim

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I. Introduction

The False Claims Act (FCA)¹ “has long served as an important vehicle for ensuring compliance with the Anti-Kickback Statute [(AKS)²] Indeed, such cases have been at or near the top of the list of cases most frequently pursued by the Department [of Justice] over the last several years.”³

The Department of Justice’s (Department) commitment to eradicating kickback schemes that can corrupt medical decision making, at the expense of the government, has produced a wealth of court rulings that probe the legal parameters of FCA cases predicated on AKS violations. This article discusses decisions that address the question of whether an AKS violation must cause presentment of claims to the government for there to be FCA liability.

¹ 31 U.S.C. §§ 3729–33.

² 42 U.S.C. § 1320a-7b.

³ Michael D. Granston, Deputy Assistant Att’y Gen., Remarks at the ABA Civil False Claims Act and Qui Tam Enforcement Institute (Dec. 2, 2020) (internal statutory citations added).

The question is not entirely resolved.⁴ The better-reasoned cases have found that kickbacks need not have been the “cause” of the submission of claims.⁵ This conclusion is supported by the legislative history of the FCA and AKS, as Congress intended the FCA and AKS “to reach a broad swath of ‘fraud and abuse’ in the federal health care system.”⁶ It also recognizes that an incongruous result would manifest if a defendant convicted of inducing medical referrals in violation of the AKS nonetheless avoided liability under the FCA.⁷ At a minimum, however, these cases have required that there be at least some “link” between an AKS violation and presentation of claims.⁸

II. The FCA and AKS

A. The FCA

The FCA imposes liability when, among other things, a “person” “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval”⁹ or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.”¹⁰ The statute provides that a violator

is liable . . . for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person.¹¹

⁴ See *United States ex rel. Wallace v. Exactech, Inc.*, No. 18-CV-01010, 2020 WL 4500493, at *19 (N.D. Ala. Aug. 5, 2020) (comparing cases).

⁵ See *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95–98 (3d Cir. 2018); *United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702, 2019 WL 1245656, at *23 (S.D.N.Y. Feb. 27, 2019).

⁶ *Greenfield*, 880 F.3d at 96.

⁷ *Id.* at 96–97.

⁸ See *United States ex rel. Heller v. Guardian Pharm. LLC*, 521 F. Supp. 3d 1254, 1274–75 (N.D. Ga. 2021) (discussing cases).

⁹ 31 U.S.C. § 3729(a)(1)(A).

¹⁰ 31 U.S.C. § 3729(a)(1)(B).

¹¹ 31 U.S.C. § 3729(a)(1) (footnote omitted).

“Congress wrote expansively, meaning [for the FCA] ‘to reach all types of fraud, without qualification, that might result in financial loss to the Government.’”¹²

B. The AKS

The AKS prohibits “knowingly and willfully” offering or paying “any remuneration (including any kickback, bribe, or rebate)” to any person “to induce such person” to “(A) . . . refer an individual to a person for the furnishing . . . of any item or service for which payment may be made in whole or in part under a Federal health care program” or to “(B) . . . purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.”¹³ The AKS also prohibits knowingly and willfully soliciting or receiving any remuneration “in return” for the same conduct.¹⁴

In 2010, Congress amended the AKS to provide that, in addition to the “penalties” under the act, “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].”¹⁵

The legislative history of the AKS indicates that Congress intended for the AKS to “strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs.”¹⁶ “Similarly, Congress passed § 1320a-7b(g) in 2010 as part of an overall effort to ‘strengthen[] whistleblower actions based on medical kickbacks’ and ‘to ensure that *all* claims resulting from illegal kickbacks are considered false claims for the purpose of civil action[s] under the False Claims Act.’”¹⁷

¹² *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (citing *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

¹³ 42 U.S.C. § 1320a-7b(b)(2).

¹⁴ 42 U.S.C. § 1320a-7b(b)(1).

¹⁵ See 42 U.S.C. § 1320a-7b(g); see also *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018).

¹⁶ H.R. REP. No. 95-393, at *1 (1977).

¹⁷ *Greenfield*, 880 F.3d at 95 (citing 155 Cong. Rec. S10852, S10853-54 (daily ed. Oct. 28, 2009)) (alterations and emphasis in *Greenfield*).

III. Causation: Basic principles and the FCA

Basic principles of causation and precedent concerning causation under the FCA provide important context for this article.

In the simplest of terms, causation is a hybrid concept, consisting of two constituent parts: actual cause or cause-in-fact—sometimes referred to as “but-for” causation—and legal cause—sometimes referred to as proximate causation.¹⁸ An act is the actual cause of an injury where, in the absence of the act, the injury would not have occurred.¹⁹ An event may have many actual causes, only some of which may be proximate.²⁰ A proximate-causation requirement precludes liability where the link between a cause-in-fact and an injury is “so attenuated that the consequence is more aptly described as mere fortuity.”²¹ As a rule, Congress is presumed to have required “but-for” causation when legislating new causes of action.²²

A number of circuit courts have held, expressly or implicitly, that the FCA has a proximate-causation requirement.²³ Some decisions attach the requirement to the language of the FCA that provides for liability for a person who “causes” a false or fraudulent claim to be presented for payment.²⁴ At least one such case, *United States ex rel. Schmidt v. Zimmer, Inc.*, involved AKS violations, though it predated

¹⁸ See *Burrage v. United States*, 571 U.S. 204, 208–12 (2014).

¹⁹ See *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346–47 (2013).

²⁰ See *Paroline v. United States*, 572 U.S. 434, 444 (2014).

²¹ *Id.* at 445.

²² See *Comcast Corp. v. Nat’l Ass’n of African Am. Owned Media*, 140 S. Ct. 1009, 1014 (2020).

²³ See *United States v. Luce*, 873 F.3d 999, 1010–14 (7th Cir. 2017) (requiring proof of proximate causation in FHA fraud case); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714–15 (10th Cir. 2006) (requiring proof of proximate causation in Medicare fraud case); *United States v. Miller*, 645 F.2d 473, 475–76 (5th Cir. 1981) (ruling in FHA fraud case that not all false statements may have caused defaults on insured mortgage loans); *United States v. Hibbs*, 568 F.2d 347, 350–51 (3d Cir. 1977) (same).

²⁴ See *Sikkenga*, 472 F.3d at 714–15; *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244–45 (3d Cir. 2004).

42 U.S.C. § 1320a-7b(g).²⁵ Other decisions focus on the FCA’s damages provision,²⁶ which allows for recovery of “damages which the Government sustains *because of* the act” of the violator.²⁷ In some instances, the causation standard adopted by the court may be subject to debate, though proof of causation of some type or degree is certainly required.²⁸

As noted, the AKS provides that “a claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim for purposes of” the FCA.²⁹ Although the Supreme Court has not addressed the question of causation under section 1320a-7b(g), it has interpreted the similar phrase “results from” to require “but-for” causation.³⁰

Since the amendment of the AKS to add section 1320a-7b(g), courts have struggled with the question of whether the AKS requires that a

²⁵ See Schmidt, 386 F.3d at 244–45 (action alleging that an orthopedics manufacturer that paid kickbacks to hospitals had caused the hospitals to submit false claims to Medicare).

²⁶ See Luce, 873 F.3d at 1010–14; Miller, 645 F.2d at 475–76 (interpreting pre-1986 version of the FCA, which provided for recovery of “damages which the United States may have sustained by reason of” a violation); Hibbs, 568 F.2d at 350–51 (same). Notably, in *Miller*, the court observed that the “element of causation” applied only to the FCA’s damages provision, not the FCA’s penalty provision. 645 F.2d at 476 n.4.

²⁷ 31 U.S.C. § 3729(a)(1)(G) (emphasis added).

²⁸ For example, in *United States ex rel. Schwedt v. Planning Rsch. Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995), an action alleging fraud on the Pension and Welfare Benefits Administration, the United States Court of Appeals for the District of Columbia Circuit agreed with other circuit court decisions that the FCA “does not contemplate liability for all damages that would not have arisen ‘but for’ the false statement.” Although the decision has been interpreted as requiring proof of proximate causation, see *Luce*, 873 F.3d at 1013, the court itself has characterized the decision as applying a “but-for” causation test in assessing FCA damages. See *United States ex rel. Cimino v. Int’l Bus. Machs. Corp.*, 3 F.4th 412, 420 (D.C. Cir. 2021).

²⁹ 42 U.S.C. § 1320a-7b(g) (emphasis added).

³⁰ *Burrage v. United States*, 571 U.S. 204, 210–11 (2014) (holding in a Controlled Substance Act case that a “thing ‘results’ when it [a]rise[s] as an effect, issue, or outcome from some action, process or design.’ ‘Results from’ imposes, in other words, a requirement of actual causality. ‘In the usual course,’ this requires proof “‘that the harm would not have occurred’” in the absence of—that is, but for—the defendant’s conduct.”) (alteration in original) (citations omitted).

kickback violation cause the presentment of claims for payment to the government to establish FCA liability. As the Third Circuit remarked in *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, the issue “is what ‘link’ is sufficient to connect an alleged kickback scheme to a subsequent claim for reimbursement: a direct causal link, no link at all, or something in between.”³¹

IV. Discussion

A. *Greenfield*: Finding the right link

Greenfield is a watershed case because of the depth of its analysis of section 1320a-7b(g). It is also important because it reflects positions the Department took in its amicus briefing.³²

The case involved allegations that Accredo,³³ a specialty pharmacy which provided medication and home-nursing assistance to hemophilia patients, violated the FCA by submitting claims to Medicare that falsely certified compliance with the AKS.³⁴

The alleged kickbacks stemmed from donations made by Accredo to Hemophilia Services, Inc. (HSI), which in turn provided grants to Hemophilia Association of New Jersey (HANJ).³⁵ The grants funded an insurance program for patients who were not eligible for Medicare or Medicaid and supported outpatient hemophilia treatment centers.³⁶ HANJ recognized Accredo’s contributions by identifying it as an HSI-approved provider on its website.³⁷ Relator, a former Accredo vice

³¹ *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018).

³² The government had declined to intervene in the case, 880 F.3d at 90, but filed an amicus brief to “protect its broader interests” in the case. Brief of the United States as Amicus Curiae in Support of Neither Party at 8, *Greenfield*, 880 F.3d 89 (3d Cir. 2017) (No. 17-1152), 2017 WL 1509832, at *3.

³³ The action named Accredo Health Group and two affiliates, Medco Health Sols., Inc. and Hemophilia Health Services, Inc. as defendants. The court collectively referred to all three as “Accredo”. *Greenfield*, 880 F.3d at 91.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* The website “stated HSI-approved vendors ‘maintain the highest quality of care while providing [a] continuity of services and constantly supporting the community in numerous ways.’ It also directed users to ‘[r]emember to work with our HSI [approved] providers’ and included hyperlinks to the approved providers’ websites. HANJ also provided treatment centers with lists identifying specialty pharmacies that were

president, charged that the company made the charitable contributions to induce referrals of Medicare beneficiaries to Accredo.³⁸

The district court entered summary judgment against relator.³⁹ Essentially assuming that there was an AKS violation, the court focused on whether Accredo received payment from the federal government “as a result of” the AKS violation.⁴⁰ The court found that relator had “not shown the link between defendants’ 24 federally insured customers and defendants’ donations to HANJ/HSI.”⁴¹

The district court reasoned that each of Accredo’s patients was “free to make his or her own choices regarding providers.”⁴² Moreover, HANJ and HSI had not referred patients to the defendants for specific services. “Simply listing Accredo, among other providers, as ‘preferred’ and acknowledging their contributions to HANJ/HSI’s state-approved—even state-encouraged—charitable activities, [was] too attenuated a *causal* connection.”⁴³ Thus, the court concluded, “[a]bsent some evidence, any evidence, that those particular patients chose Accredo because of its donations to HANJ/HSI,” relator had failed to meet his burden on “an essential element of his claim.”⁴⁴

The Third Circuit affirmed the district court’s grant of summary judgment but did so using rationale that was consistent with the government’s amicus points rather than the district court’s reasoning.

The government argued that the case raised the question of “when a violation of the . . . AKS renders a claim for medical care false under the . . . FCA” and that “a claim for reimbursement for medical care that was not provided in compliance with the AKS is ‘false’ within the meaning of the FCA, regardless of whether the violation of the AKS caused the claim.”⁴⁵ It noted the district court had

designated as HSI-approved providers. Accredo was noted in one list as one of four HSI-approved vendors that ‘continually contribute to this community.’” *Id.* at 91–92 (alterations in original).

³⁸ *Id.* at 92–93.

³⁹ *Id.* at 93.

⁴⁰ *Id.*; United States *ex rel.* Greenfield v. Medco Health Sys., Inc., 223 F. Supp. 3d 222, 227 (D.N.J. 2016).

⁴¹ *Id.* at 230.

⁴² *Id.*

⁴³ *Id.* (emphasis added).

⁴⁴ *Id.*

⁴⁵ Brief of the United States, *supra* note 32, at *8 (citations and parenthesis omitted).

properly rejected relator’s argument that any AKS violation by Accredo rendered all claims by Accredo false, regardless of how the patients associated with those claims came to be customers of Accredo. Instead, to establish a false claim, relator had to show a connection between the alleged kickbacks paid by Accredo to the charities and the claims Accredo submitted for federal beneficiaries. The district court erred, however, to the extent that it required relator to prove a causal connection between the kickbacks and the claims.⁴⁶

In a decision that carefully considered the arguments of the parties and the government, the Third Circuit started its analysis with the statutory language at the core of the dispute: section 1320a-7b(g)’s provision that “a claim that includes items or services *resulting from* a violation of [that statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act].”⁴⁷

The court observed that the AKS does not define the key phrase “resulting from.”⁴⁸ It noted, however, that “*Black’s Law Dictionary* defines ‘result’ as ‘a . . . logical . . . or legal consequence; to proceed as an outcome or conclusion.’”⁴⁹ It also noted the Supreme Court has interpreted the words “results from,” as used in other statutes, to impose a requirement of actual, that is, “but-for” causation. In particular, the court considered *United States v. Burrage*, in which the Supreme Court held that use of similar language in the Controlled Substances Act required “proof the harm would not have occurred in the absence of—that is, but for—the defendant’s conduct.”⁵⁰

Continuing its analysis, the court addressed the government’s concern that a “but-for” causation requirement would lead to an incongruous result whereby a person could be liable for a criminal AKS violation but not be liable under the FCA.⁵¹

⁴⁶ *Id.* at *8–9.

⁴⁷ *Id.* (citing 42 U.S.C. § 1320a-7b(g)) (emphasis added).

⁴⁸ *Id.* at *5.

⁴⁹ *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018) (citing *Black’s Law Dictionary* (10th ed. 2014)).

⁵⁰ *Id.* at 96 (quoting *Burrage v. United States*, 571 U.S. 204, 210–12 (2014)).

⁵¹ *Id.* As the government put it, “Accredo’s argument would have the odd result that a defendant could be convicted of criminal conduct under the AKS for paying kickbacks to induce medical referrals, but would be insulated from civil FCA liability for the exact same conduct, absent additional proof that

To determine whether Accredo’s reading of the language would produce an incongruous result, the court looked to the legislative history of the AKS.⁵² This history indicated that the AKS was “intended ‘to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs’ . . . because ‘fraud and abuse among practitioners . . . is relatively difficult to prove and correct.’”⁵³ Moreover, the drafters of the AKS understood that, “[s]ince the medical needs of a particular patient can be highly judgmental, it is difficult to identify program abuse as a practical manner unless the overutilization is grossly unreasonable.”⁵⁴ From this, the court concluded that the statutory language required “something less than proof that the underlying medical care would not have been provided but for a kickback.”⁵⁵

The court added that, “[s]imilarly, Congress passed § 1320a-7b(g) in 2010 as part of an overall effort to ‘strengthen[] whistleblower actions based on medical care kickbacks’ and ‘to ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action[s] under the False Claims Act.’”⁵⁶ The court further noted that, although the legislative history of section 1320a-7b(g) did not define the phrase “resulting from,” the Congressional Record “indicates it was enacted to avert ‘legal challenges that sometimes defeat legitimate enforcement efforts.’”⁵⁷

The court also invoked the legislative history of the FCA, finding that it “echoe[d]” the intent of section 1320a-7b(g), and that the FCA “‘is intended to reach all fraudulent attempts to cause the Government to pay ou[t] sums of money or to deliver property or services,’ and ‘[a] false claim for reimbursement under Medicare, Medicaid, or similar program . . . may be false even though the services are provided as claimed.’”⁵⁸

each medical decision was in fact corrupted by the kickbacks.” Brief of the United States, *supra* note 32, at *22.

⁵² Greenfield, 880 F.3d at 96.

⁵³ *Id.* (quoting H.R. Rep. No. 95-393, at 1, 47 (1977)) (alterations in original).

⁵⁴ *Id.* (quoting H.R. Rep. No. 95-393, at 47).

⁵⁵ *Id.*

⁵⁶ *Id.* (quoting 155 CONG. REC. S10852, S10853–54 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman) (emphasis added)).

⁵⁷ *Id.* (quoting 155 CONG. REC. at S10853).

⁵⁸ *Id.* (emphasis omitted) (quoting S. Rep. No. 99-345, at 9, (1986)).

The court concluded that, as the government maintained, Accredo's reading of section 1320a-7b(g) was inconsistent with the intentions of the drafters of both statutes.⁵⁹ Accredo's reasoning that "a plaintiff would have to prove [that] a kickback actually influenced a patient's or a medical professional's judgment" "would hamper" FCA cases based on kickbacks.⁶⁰ "Moreover, it would dilute the [FCA's] requirements vis-à-vis the [AKS], as direct causation would be a precondition to bringing a [FCA] case but not an [AKS] case."⁶¹ Thus, the "broad statutory context" of the FCA and AKS establishes that there is no requirement for "a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider."⁶² The court further elaborated on its point by referring to a hypothetical the government posed in its amicus brief that "illustrate[d] this standard."⁶³

Under this standard, relator did not need to prove that the referrals in question actually caused members of HANJ or HSI to use particular health-care providers. All that was needed was some "link," that is, proof that "at least one of Accredo's claims sought

⁵⁹ *Id.* at 96–97.

⁶⁰ *Id.*

⁶¹ *Id.* at 97.

⁶² *Id.* The court added that its view was

also consistent with the language in CMS Form 855s, which requires providers to certify that 'the claim and the underlying transaction' (*i.e.*, the medical care being reimbursed) comply with the Anti-Kickback Statute. As is apparent from its language, the Form directs the provider's attention to the medical care that is the subject of a claim. It makes no mention of a patient's reason(s) for selecting a specific provider and does not require a provider to engage in an intent-based inquiry before submitting a claim for reimbursement.

Id.

⁶³ *Id.* at 97–98, referring to the following hypothetical in the government's amicus brief:

For example, if a medical service provider pays kickbacks to a doctor to induce referrals and then submits claims to Medicare for services it provided to patients who were referred by that doctor, the claims are false because the medical care was not provided in compliance with the AKS. That is so regardless of whether the doctor would have referred the patients absent the kickbacks, and regardless of whether the patients would have chosen the service provider absent the referral.

Brief of the United States, *supra* note 32, at *17.

reimbursement for medical care that was provided in violation of the [AKS].”⁶⁴

Although the court had rejected Accredo’s arguments and adopted a less stringent standard than the district court, it, nonetheless, affirmed the dismissal of relator’s complaint. The court rejected relator’s argument that he had met his burden because the patient referrals and submission of claims for the 24 federally insured patients took place “in close proximity” and Accredo had certified that it did not pay any illegal kickbacks.⁶⁵ This argument failed because “[a] plaintiff cannot ‘merely . . . describe a private scheme in detail but then . . . allege . . . that claims requesting illegal payments must have been submitted, were likely submitted[,] or should have been submitted to the Government.’”⁶⁶

The Third Circuit summed up its ruling saying that the AKS “prohibits kickbacks regardless of their effect on patients’ medical decisions” and “[b]ecause any kickback violation is not eligible for reimbursement, to certify otherwise violates the [FCA].”⁶⁷ Nonetheless, there “must be some connection between a kickback and a subsequent reimbursement claim” and mere “temporal proximity” is not enough.⁶⁸ Although it would be too “exacting” to require proof that “federal beneficiaries would not have used the relevant services absent the alleged kickback scheme,” proof that “at least one” patient “was exposed to a referral or recommendation” in violation of the AKS was necessary.⁶⁹

The Third Circuit’s assessment of the inadequacy of relator’s case may offer insight as to what evidence might have been sufficient to meet the court’s standard, that is, the “link” needed between the kickbacks and provision of medical care to federally insured patients. For example, the court noted that relator had failed “to demonstrate that any of Accredo’s 24 federally insured patients viewed HSI/HANJ’s approved provider list or that HSI/HANJ referred the federally insured patients to Accredo through some other means.”⁷⁰

⁶⁴ Greenfield, 880 F.3d at 98.

⁶⁵ *Id.*

⁶⁶ *Id.* (alterations in original, citing United States *ex rel.* Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002)).

⁶⁷ *Id.* at 100.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* at 99.

Moreover, relator had not established that “the 24 federally insured patients were members of HSI/HANJ and thus recipients of HSI/HANJ’s communications.”⁷¹ Whether any of these facts, if proved, would have established the required “link” is unclear. In the end, the absence of these facts led to the inexorable conclusion that it was possible that none of the 24 patients were HSI/HANJ members, and that none were “exposed to an illegal referral or recommendation.”⁷²

B. *Greenfield*’s wake: Causation, a continuing concern

A number of decisions interpreting 42 U.S.C. § 1320a-7b(g) have looked to *Greenfield* for guidance. While favorably citing *Greenfield*, however, not all of these decisions have based their rulings on *Greenfield*’s analysis. Some use language that arguably suggests a need to show that an AKS violation caused submission of claims. Others simply rule that there was causation without adopting a causation standard. Moreover, some cases address causation under the FCA’s liability provision. All of this indicates that the answer to the question of what “link” is needed between AKS violation and FCA claim is not settled.

Several cases stress one of *Greenfield*’s foundational premises: To state a predicate AKS violation, a complaint need not offer proof that medical care or services would not have been provided but for the kickback scheme.⁷³ They stand for the proposition that a kickback scheme need not have “actually corrupted clinical decision-making”⁷⁴ and that there need not be proof that there was quid pro quo exchange.⁷⁵

⁷¹ *Id.*

⁷² *Id.*

⁷³ See *United States v. Regeneron Pharms., Inc.*, No. 20-11217, 2020 WL 7130004, at *11 (D. Mass. Dec. 4, 2020) (citing, *inter alia*, *Greenfield*, 880 F.3d at 96); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) (citing *Greenfield*, 880 F.3d at 96); see also *United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, No. 13 CV 3702, 2019 WL 1245656, at *10 (S.D.N.Y. Feb. 27, 2019) (citing *United States ex rel. Kester Pharm. Corp.*, 23 F. Supp. 3d, 242, 263 (S.D.N.Y. 2014)).

⁷⁴ *Regeneron Pharms.*, No. 20-11217, 2020 WL 7130004, at *11.

⁷⁵ *Id.*; *Teva Pharms.*, No. 13 CV 3702, 2019 WL 1245656 at *10; *Bawduniak*, No. 12-cv-10601, 2018 WL 1996829, at *3.

Although these cases proceed from this premise, in some instances they nonetheless express their ultimate rulings in the language of causation. In *United States v. Regeneron Pharmaceuticals, Inc.*, the court ruled that the government’s complaint stated a claim against a pharmaceutical company that made donations to an alleged charitable copayment-assistance fund. Relators alleged that this scheme was meant to induce physicians to prescribe its drug for treating macular degeneration. The court reasoned that “but for” the donations, patients would not have received copayment subsidies from the fund, and those contributions thus resulted in claims being presented to Medicare.⁷⁶

The court in *United States v. Teva Pharmaceuticals USA, Inc.*, used similar reasoning in denying the defendant pharmaceutical companies’ (collectively Teva) motion for summary judgment. Relators’ complaint alleged that Teva’s “speaker program” induced health-care professionals to prescribe drugs that treated Parkinson’s disease and a form of multiple sclerosis.⁷⁷ After surveying the law interpreting 42 U.S.C. § 1320a-7b(g), including *Greenfield*, the court ruled that the relators only needed to show that the “referral of Teva drugs ‘actually sat in the causal chain.’”⁷⁸ The court expressly ruled that the relators had met their “burden of production to show causation” under the *Greenfield* standard.⁷⁹

Neither *Regeneron* nor *Teva* expressly requires proof of “but-for” causation. Indeed, *Teva* expressly rejects application of a “but-for” causation standard.⁸⁰ Still, they use language of causation the Third Circuit eschewed in deciding *Greenfield*⁸¹ and that was of particular concern for the government in *Greenfield*.⁸²

⁷⁶ *Regeneron Pharms.*, No. 20-11217, 2020 WL 7130004, at *14.

⁷⁷ *Teva Pharms.*, No. 13 CV 3702, 2019 WL 1245656 at *34.

⁷⁸ *Id.* at *24 (citing Richard Strassberg, William Harrington, & Annie E. Railton, *Two Recent Cases Illustrate Need to Rely on Causal Concepts in FCA Cases*, N.Y.L.J. (June 28, 2018)).

⁷⁹ *Id.* at *23.

⁸⁰ *Id.*

⁸¹ *United States ex rel. Greenfield v. Medco Health Sols.*, 880 F.3d 89, 100 (3d Cir. 2018).

⁸² See Brief of the United States, *supra* note 32, at *15 (“to the extent that certain aspects of the district court’s decision could be read to suggest that there is a need for proof of a causal effect between the kickbacks and the claims, the court erred . . . the district court incorrectly appeared to believe it was necessary for relator to show that the kickbacks *in fact* corrupted the

Other decisions have done the same. In *Guilfoile v. Shields*,⁸³ the First Circuit considered the AKS causation question in an appeal involving a whistleblower retaliation claim under 31 U.S.C. § 3730(h). Plaintiff alleged that he had been fired for disclosing a kickback scheme involving his employer, Integrated Entity (Integrated), a collection of companies that provided specialty pharmacy services to hospitals.⁸⁴ According to plaintiff, Integrated was making improper payments to a hospital consultant to use his influence with hospitals so they would use Integrated’s services.⁸⁵

The district court dismissed plaintiff’s complaint, ruling that it did not connect an AKS violation to a false claim within the meaning of the FCA.⁸⁶ On appeal, the First Circuit noted that the issue before it was the proper standard for pleading an FCA retaliation claim, not the standard for proving an FCA case based upon the AKS.⁸⁷ Nonetheless, the court noted that, “in light of § 1320a-7b(g) [a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA.”⁸⁸ Citing *Greenfield*, the court then ruled that, “drawing on the ‘resulting from’ language of [§ 1320a-7b(g)], if there is a sufficient *causal* connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA.”⁸⁹ Elaborating on this ruling, the court reasoned that, “if not for” the agreement with the consultant, Integrated would not have been able to “benefit from federal health care payments arising from its work with the hospitals.”⁹⁰ Applying this analysis to

charities’ decision to refer patients to Accredo and recommend Accredo’s services, and that those referrals and recommendations *in fact* corrupted the patients’ decisions to use Accredo’s services.” (emphasis in original)).

⁸³ *Guilfoile v. Shields*, 913 F.3d 178, 188–91 (1st Cir. 2019).

⁸⁴ *Id.* at 183.

⁸⁵ *Id.* at 183–84.

⁸⁶ *Id.* at 189.

⁸⁷ *Id.* at 190.

⁸⁸ *Id.* (alteration in original, citing *United States ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017)).

⁸⁹ *Id.* (citing *United States ex rel. Greenfield v. Medco Health Sols.*, 880 F.3d 89, 96–98 (3d Cir. 2018); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601, 2018 WL 1996829, at *5–6 (D. Mass. Apr. 27, 2018)) (emphasis added).

⁹⁰ *Id.* at 191.

the facts, the court found that plaintiff plausibly pleaded that the concerns he raised reasonably could have led to an FCA action.⁹¹

Like *Teva*, *Guilfoile* suggests that it is applying the *Greenfield* standard and does not expressly require “but-for,” despite couching the inquiry in the language of causation. Other cases do not claim to apply a causation standard, even though they refer to *Greenfield*. *United States ex rel. Wallace v. Exactech, Inc.*⁹² and *United States ex rel. Heller v. Guardian Pharmacy*⁹³ are two examples.

In *Wallace*, a relator alleged that a manufacturer of knee replacement systems paid kickbacks to physicians to use the systems.⁹⁴ Surveying the existing caselaw interpreting 42 U.S.C. § 1320a-7b(g), including *Greenfield* and *Guilfoile*, the court ruled that it need not decide “the extent of the ‘link’” between AKS violation and Medicare claims because relators had satisfied the “more stringent standard” of actual causation.⁹⁵

In *Heller*, a relator claimed that the defendant pharmacy sought to become a preferred provider to personal-care homes and assisted-living communities by performing services for free, below market value, or below cost.⁹⁶ The court noted that relator was obligated to identify “a claim . . . resulting from a violation of [the AKS]” to state a claim under the FCA.⁹⁷ As in *Wallace*, the court reviewed the range of cases interpreting 42 U.S.C. § 1320a-7b(g), including *Greenfield* and *Guilfoile*. Without deciding what link, causal or otherwise, was needed between an AKS scheme and claim, the court found that relator’s complaint stated an FCA claim because it alleged a quid pro quo scheme.⁹⁸

Consideration of what standard of causation, if any, applies in FCA actions predicated on AKS violations does not end with the *Greenfield* line of precedent. As noted, at least one circuit court decision, *United States ex rel. Schmidt v. Zimmer, Inc.*, applied a proximate-causation standard in an FCA case involving AKS violations where a defendant

⁹¹ *Id.* at 193.

⁹² No. 18-cv-01010, 2020 WL 4500493 (N.D. Ala. Aug. 5, 2020) (*Wallace*).

⁹³ 521 F. Supp. 3d 1254 (N.D. Ga. 2021) (*Heller*).

⁹⁴ *Wallace*, No. 18-cv-01010, 2020 WL 4500493, at *18–20.

⁹⁵ *Id.* at *19.

⁹⁶ *Heller*, 521 F. Supp. 3d at 1261.

⁹⁷ *Id.* at 1274 (citing 42 U.S.C. § 1320a-7b(g)) (emphasis and alteration in original).

⁹⁸ *Id.* at 1274–76.

had allegedly caused other defendants to present false claims to the government.⁹⁹ That case was decided before the enactment of 42 U.S.C. § 1320a-7b(g)¹⁰⁰ and before *Greenfield*.

United States ex rel. Lutz v. Laboratory Corp. of America Holdings,¹⁰¹ on the other hand, was decided after enactment of section 1320a-7b(g) and after *Greenfield*. The relator alleged that the defendant caused a lab testing company, which paid kickbacks to doctors using the testing company, to present false claims to the government.¹⁰² The court denied the defendant's motion for summary judgment without considering 42 U.S.C. § 1320a-7b(g) or the *Greenfield* line of precedent. Instead, the court looked to the "causes to be presented" language of the FCA, 31 U.S.C. § 3729(a)(1)(A). Working within that framework and citing *Schmidt*¹⁰³ and *United States ex rel. Sikkenga v. Regence Blue Cross Blue Shield of Utah*,¹⁰⁴ among other cases, the court found that relator needed to prove causation under a proximate-causation standard.¹⁰⁵

Exactly how *Lutz* squares with *Greenfield* is unclear. One answer is that *Lutz* is distinguishable because it implicated the FCA's "causes to be presented" liability provision. As the government observed, *Greenfield* was a case in which the defendants had submitted claims directly to the government and therefore did not turn on the "causes to be presented" provision.¹⁰⁶ Nonetheless, there is a persuasive argument that *Lutz* misses the mark, even though the court ultimately ruled that relator's case could go forward.

For example, although *United States ex rel. Bawduniak v. Biogen Idec, Inc. (Biogen)*¹⁰⁷ implicated the FCA's "causes to be presented" provision, the court applied the *Greenfield* standard. The complaint charged that Biogen paid illegal kickbacks to physicians through

⁹⁹ See *supra* notes 24–25 and corresponding text.

¹⁰⁰ *Id.*

¹⁰¹ *United States ex rel. Lutz v. Lab'y Corp. of Am. Holdings*, No. 14-3699, 2021 WL 2457693 (D.S.C. June 16, 2021).

¹⁰² *Id.*

¹⁰³ *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244–45 (3d Cir. 2004).

¹⁰⁴ *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714–15 (10th Cir. 2006).

¹⁰⁵ *Lutz*, No. 14-3699, 2021 WL 2457693, at *3–4.

¹⁰⁶ Brief of the United States, *supra* note 32, at *16 n.4.

¹⁰⁷ *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601, 2018 WL 1996829 (D. Mass Apr. 27, 2018).

sham consulting and speaking programs to increase prescriptions of certain drugs.¹⁰⁸ In accordance with *Greenfield*, the court held that relators sufficiently alleged that claims submitted to Medicare and Medicaid for the prescribed medications “resulted from” the kickbacks.¹⁰⁹ While the court said the prescriptions caused the submission of claims, it did so without suggesting that the FCA’s “causes to be presented” provision altered application of *Greenfield*, much less required proof of “but-for” or proximate causation.¹¹⁰

Teva is perhaps the most interesting of the cases to wrestle with this issue. In addition to arguing that the “resulting from” language in 42 U.S.C. § 1320a-7b(g) required proof of “but-for” causation, the defendants maintained that the FCA’s “causes to be presented” provision required proof of proximate causation.¹¹¹ Citing *Schmidt*, the court stated that, “[f]or a ‘cause to be presented’ claim, the unlawful behavior must be a ‘substantial factor in bringing about [the] filing’ of a false claim and the filing must be ‘a normal consequence of the situation created by that scheme.’”¹¹² The court, however, rejected *Teva*’s argument that this meant the relators had to show that *Teva*’s scheme actually caused an increase in prescriptions. Instead, the court ruled that, under *Greenfield*, the relators only needed to show that “a physician referred or recommended a patient to a provider after receiving an illegal payment from that provider.”¹¹³ Moreover, the court held that relators satisfied the “substantial factor” component of proximate causation “under largely the same circumstances that the ‘resulting from’ test is satisfied.”¹¹⁴ In other words, the court essentially determined that the *Greenfield* standard applied to an AKS-based FCA case brought under the FCA’s “causes to be presented” liability provision.¹¹⁵

¹⁰⁸ *Id.* at *1.

¹⁰⁹ *Id.* at *6.

¹¹⁰ *See id.*

¹¹¹ *United States v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702, 2019 WL 1245656, at *25 (S.D.N.Y. Feb. 27, 2019).

¹¹² *Id.* at *25 (citing *Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244–45 (3d Cir. 2004)).

¹¹³ *Id.* at 26.

¹¹⁴ *Id.*

¹¹⁵ Notably, the court added that *Teva*’s reading of the FCA would effectively result in the application of an actual causation standard in a “cause to be presented case” but not in cases where a defendant directly submitted false claims. *Id.* This, the court said, is “a distinction the case law does not

V. Conclusion

The proper reading of section 1320a-7b(g) focuses on whether a claim presented for reimbursement is “false.” The inquiry encompasses two principles. First, there is no need to show that the kickback scheme succeeded—that services, drugs, or devices would not have been provided but for the offer, payment, solicitation, or receipt of remuneration. Thus, there does not have to have been an actual quid pro quo. Second, there nonetheless must be evidence of some “link” between the kickback scheme and claim, though that link need not be “causal” and should not be characterized as such.

Greenfield exemplifies this analysis and sets a standard that subsequent decisions have recognized, though not necessarily adopted. These cases show a persistent resort to basic principles of causation, even in the absence of commitment to a particular standard. Thus, courts may continue to struggle with section 1320a-7b(g)’s “resulting from” language and whether it requires causality. Because the AKS violation serves as a predicate for an overall claim under the FCA, courts may apply causation precedent under the FCA’s provisions, particularly in “causes to presented” cases.¹¹⁶

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recognize, and one which would undermine Congress’ goal of increasing FCA enforcement with respect to the AKS.” *Id.*

¹¹⁶ As this edition of the DOJ Journal was being finalized, the United States Court of Appeals for the Eighth Circuit issued a significant decision on the topic of this article. In *United States ex rel. Cairns v. D.S. Med. LLC.*, 2022 WL 2930946 (8th Cir. July 26, 2022), the court held that a “but-for” causation standard applies to AKS-based FCA cases. In reaching this decision, the Eighth Circuit relied heavily on *Burrage v. United States*, 571 U.S. 204 (2014), and declined to follow the Third Circuit’s ruling in *Greenfield*. According to the Eighth Circuit panel, *Greenfield* was wrongly decided because it relied on “legislative history and ‘the drafters’ intentions’ to interpret” 42 U.S.C. § 1320a-7b(g). 2022 WL 2930946, at *6. Notably, the court stated that its ruling was “narrow” and not meant to suggest that that every case brought under the FCA required a showing of but-for causation. *Id.* *Cairns* now establishes a split among circuit courts on the question of what link is required between kickback and FCA claim.

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In Law and in Boxing: Lessons from the Sweet Science

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I. In law and in boxing

I am not a boxer. At least, not yet. As I settle into the routine of middle age, I find myself more concerned with improving my outside shot and maintaining a respectable mile time. As I grow older, there is something about the sport of boxing to which I find myself drawn. Boxing is a convergence of art and science. It demands discipline, months of preparation before each fight, and dedication to the craft. It is the chess match in the ring, where tactical moves must be made without hesitation—and often at great costs. There is something about the ring itself, roughly a 20-by-20-foot square, where disputes are finally settled in 12 three-minute rounds. Ultimately, there is a winner and a loser. One arm raised in victory, and one head bowed in defeat. At the end of the fight, it is over. Everything is left in the ring, and fighters return home to begin training for the next fight.

Maybe you are not a boxer either. Maybe you have little interest in the sport. But odds are that you are a trial lawyer, and it is likely that you prosecute criminal or civil health-care–fraud cases. In any case, the sport of boxing offers lessons in law and life for all of us.

Just before Christmas, we finished a three-defendant, Anti-kickback Statute conspiracy trial that ran over the course of six weeks.¹ We won one, lost one, and fought one to a draw. During the trial and in the preparation leading up to it, we learned several important lessons that warrant consideration.

II. Prepare for the fight

Late one evening midway through trial, our FBI case agent looked at the trial lawyers, who were feverishly researching and responding

¹ United States v. Lamb, et al., No. 19-CR-25 (E.D. Tex. Dec. 16, 2021).

to defense motions as we prepared for court the following day. He said, “That’s the difference. You never stop working.” He was right. That is a lesson in law and in boxing. Never stop working. Prepare yourself. Be ready for the fight.

For those who have practiced in health-care law enforcement, particularly in the Anti-Kickback Statute (AKS) space, you know that it is no easy task. The law is complicated and nuanced. Cases often turn on discrete facts, credibility determinations, and circumstantial evidence of notice and concealment. It is a given that you must know the law and the key cases from your circuit as well as the persuasive cases from other circuits. Remember that you are building a record for appeal, so you must build it correctly and support it with evidence.

It all starts with charging the case appropriately. Tracking the statutory language will ordinarily be sufficient. An indictment that tracks the statutory language will usually survive a motion to dismiss and moot a motion for bill of particulars.² Your charge, however, should fit the facts of your case. If you are charging an AKS conspiracy, consider whether it is a conspiracy to offer or pay illegal remunerations, a conspiracy to solicit or receive illegal remunerations, or a conspiracy to do both.³ You should also consider whether your case involves referrals or arranging for referrals, arranging for or recommending the ordering of items or services, or both.⁴

Like a boxer who simply goes through the motions in training before a fight, you are not adequately preparing yourself or your case if you merely go through the motions at the charging phase. You may not lose every fight that comes your way, but you will put yourself at a disadvantage from the onset. Unlike boxers, we are almost always able to frame the fight. Do not squander the opportunity to fight on your terms by failing to put in adequate work on the front end at the charging phase.

So put in the work. Manny Pacquiao said, “If you work hard in training, the fight is easy.”⁵ Preparation will pay dividends in trial.

² See *Hamling v. United States*, 418 U.S. 87, 117 (1974); *United States v. Beebe*, 792 F.2d 1363, 1366 (5th Cir. 1986).

³ 42 U.S.C. § 1320a-7b(b).

⁴ *Id.*

⁵ Manny Pacquiao is regarded by many boxing historians as one of the greatest professional boxers of all time. He is the only boxer in history to win 12 major world titles in 8 different weight divisions and the only boxer to hold world titles in 4 different decades. *Manny Pacquiao*, BIOGRAPHY (May 3,

Besides getting you to trial, the indictment frames the case for the court. Assuming that you present sufficient evidence to survive a directed verdict, you will find yourself at the charge conference. There, the court will look back to the indictment as it considers the jury charge. The indictment will inform the court and guide the advocacy of the parties. Do not find yourself in a position where you are unable to seek an instruction because you failed to charge the case appropriately. You live with the preparation you bring to the case. Prosecutors have found their cases reversed on appeal where late-breaking attempts to obtain an instruction resulted in the constructive amendment of the indictment to the prejudice of a defendant.⁶ Adequate preparation on the front end increases the likelihood that you will obtain the jury instructions you need in your particular case.

III. Choose your battles

If you grew up in the 1980s, you probably saw *Rocky IV*. If you saw *Rocky IV*, you probably remember Apollo Creed's classic warning to Ivan Drago before the fight: "It's time to go to school, son."⁷ What you may not remember is the admonishment the fighters received from the referee, Lou Filippo, just before that, "You boys know the rules . . . Shake hands, and let's have a good fight."⁸

2015), <https://www.biography.com/athlete/manny-pacquiao>; Kevin Iole, *This is a once in a lifetime guy: Manny Pacquiao's boxing records may never be broken*, YAHOO! SPORTS (Aug. 18, 2021), https://sports.yahoo.com/this-is-a-once-in-a-lifetime-guy-manny-pacquaios-boxing-records-may-never-be-broken-161642666.html?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2x1LmNvbS8&guce_referrer_sig=AQAAAGxhstrCRIsLUGdqotc6Sn6hgUQsLzt2cFXb4hqcvEHcUZhB7CaduuStPwKAZLpQieKO_ECyZ20LBGUJ_w665I1bbzKHLzaRuskWiULiT9jo0M4yCEktdCpnFCBxsHNIVISLAQx3XovM Md0OzhNIFXKrQnfFe0id-whFC3Bw2k3T. Pacquiao compiled a professional record of 62-8-2 with 39 knockouts (KOs). *Boxing world reacts to Manny Pacquiao's retirement*, ESPN (Sept. 29, 2021), https://www.espn.com/boxing/story/_/id/32304210/boxing-world-reacts-manny-pacquiao-retirement.

⁶ See, e.g., *United States v. Phea*, 953 F.3d 838, 842 (5th Cir. 2020).

⁷ *ROCKY IV* (Metro-Goldwyn-Mayer/United Artist Entertainment Company 1985).

⁸ *Id.* "Before becoming a ring official and refereeing and judging dozens of world championship bouts, [Lou] Filippo boxed professionally as a lightweight from 1947 to 1957, . . . compil[ing] a professional record of 23-9-3 with 8 KOs." Dan Rafael, *Hall of Famer Filippo dies at 83*, ESPN (Nov. 3,

Filippo's admonishment is not unlike the instructions we receive from trial judges in pretrial conferences. Our judges expect us to fight fairly and follow the rules. Trial lawyers should do just that, but they should also choose their battles carefully. Trial, like boxing, is a chess match—not a street fight. There are times to dodge, block, and parry. There are also times to throw hard and clean punches. Get your mind right and land the punches that matter.

IV. Motion in limine

In an AKS conspiracy trial, one of the punches that needs to land is your motion in limine to exclude any mention before the jury of statutory exceptions and regulatory safe harbors. The AKS is a flexible and far-reaching statute that is meant to stand up to challenges from constantly evolving fraudulent schemes. To bring some balance, the AKS statutory framework contains two major controls. First, the AKS contains a scienter element, requiring knowing and willful conduct. Second, the AKS contains statutory exceptions, and the Secretary of Health and Human Services also has the authority to establish safe harbors or specific payment practices that are not treated as criminal violations of the AKS.⁹ Safe harbors have been developed to “limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.”¹⁰

Together, it is possible for a defendant to intend prohibited conduct under the AKS and be protected from criminal prosecution if the conduct is covered by a statutory exception or regulatory safe harbor. Conversely, it is possible that a defendant who engages in conduct that does not meet a statutory exception or regulatory safe harbor

2009), <https://www.espn.com/sports/boxing/news/story?id=4618812>. Filippo appeared in television and film, most notably “as a referee in the second, third, fourth, and fifth installments of the ‘Rocky’ films.” *Id.*

⁹ See 42 U.S.C. § 1320a-7d(a)(1). The AKS statutory exceptions are found in 42 U.S.C. § 1320a-7b(b)(3). The AKS regulatory safe harbors are found in 42 C.F.R. § 1001.952.

¹⁰ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991); see also, Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-kickback Statute, 64 Fed. Reg. 63518-01 (Nov. 19, 1999).

may avoid criminal prosecution if, for example, the conduct is not covered by the AKS. As the United States Department of Health and Human Services' Office of the Inspector General (HHS-OIG) explains: “[S]afe harbor[] regulation[s] d[o] not expand the scope of activities that the statute prohibits. The statute itself describes the scope of illegal activities. The legality of a particular business arrangement must be determined by comparing the particular facts to the proscriptions of the statute.”¹¹ You may, however, be presented with a third situation—the arrangement violates the AKS and does not qualify for protection under a statutory exception or regulatory safe harbor.

In this scenario, a defendant may forgo arguing that conduct meets a statutory exception or safe harbor protection. Faced with a discrete set of elements for the jury to consider, a defendant may conclude that raising this affirmative defense is a doomed proposition. Instead, a defendant may try to introduce the existence of exceptions or safe harbors during trial to confuse the jury or shift the intent inquiry to whether a defendant intended to meet an exception or safe harbor. For example, percentage-based commission compensation is a troublesome practice that is prevalent in the health-care industry . If a defendant engages in this type of compensation arrangement, and it implicates the AKS, a jury must determine whether the parties had the requisite intent necessary to violate the AKS. A jury should only consider the elements of an exception or safe harbor when a defendant raises it as an affirmative defense and should only apply the defense if all elements are met.

Incomplete satisfaction of the exception or safe harbor does not negate intent. By definition, an affirmative defense is a “defendant’s assertion of facts and arguments that, if true, will defeat the plaintiff’s or prosecution’s claim, even if all the allegations in the complaint are true.”¹² In other words, the “fundamental concept of an affirmative defense is that it does not negate an element of the adversary’s

¹¹ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991); *see also*, Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-kickback Statute, 64 Fed. Reg. 63518-01, 63521 (Nov. 19, 1999).

¹² *Defense*, BLACK’S LAW DICTIONARY (11th ed. 2019).

case.”¹³ An affirmative defense, therefore, does not negate an intent element, including willfulness.

The AKS requires the government to prove that a party acted knowingly and willfully.¹⁴ More precisely, the government must prove that the defendants had “knowledge that [their] conduct [was] unlawful.”¹⁵ This knowledge is “all that is required” to prove their mens rea.¹⁶ The safe harbors “d[o] not controvert any of the elements of the offense itself.”¹⁷ In *United States v. Sanjar*, the Fifth Circuit upheld the district court’s instruction about the safe harbor precisely because the instruction set forth the correct order of operations: “A jury logically working through the charge . . . would have considered the safe harbor defense only after determining that the government had proven a violation of the statute.”¹⁸

Beliefs about the safe harbor do not negate willfulness. If so, the government would presumably have to prove beyond a reasonable doubt in every AKS case that the defendant did not believe the safe harbor applied. Such a result cannot be correct, because the AKS itself provides that “a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”¹⁹ If a person need not have actual knowledge of the AKS writ large, he certainly need not have actual knowledge that his conduct does not fit within the AKS’s safe harbors. If the government had the burden to negate the safe harbor as part of the willfulness element, a defendant would have no need to invoke the safe harbor defense, no need to provide notice about it, and no need “to set it up and establish it.”²⁰ That result would contradict the settled rule governing federal statutory provisos that do not define the offense but instead provide an

¹³ *United States v. Allen*, 449 F.3d 1121, 1125 (10th Cir. 2006).

¹⁴ 42 U.S.C. § 1320a-7b(b)(1), (b)(2), (h). *See United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019).

¹⁵ *Ricard*, 922 F.3d at 648 (quoting *Bryan v. United States*, 524 U.S. 184, 196 (1998)).

¹⁶ *Id.* (emphasis added) (quoting *Bryan*, 524 U.S. at 196).

¹⁷ *Cf. Dixon v. United States*, 548 U.S. 1, 6 (2006).

¹⁸ *United States v. Sanjar*, 876 F.3d 725, 742 (5th Cir. 2017) (emphasis added); *and see United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 651 (N.D. Tex. 2020) (describing the AKS safe harbors as affirmative defenses).

¹⁹ 42 U.S.C. § 1320a-7b(h).

²⁰ *Dixon*, 548 U.S. at 13 (quotation omitted).

exception.²¹ Indeed, that result would violate the Fifth Circuit’s express holding that “a defendant who fails to present evidence supporting the [safe harbor] defense is not entitled to [a] jury charge” on it.²² And it would be poor policy to boot. A defendant is best positioned to know what, if anything, they thought about the safe harbor, so it should be incumbent on them to provide notice of the issue and to prove it if they can.

For these reasons, a prosecutor should seek exclusion of argument, evidence, and testimony concerning a defendant’s purported knowledge or beliefs regarding exceptions or safe harbors for failure to meet relevance under Rule 401 and for its prejudicial, confusing, and nullifying effect under Rule 403. *United States v. Trumbo* out of the Eastern District of Michigan is instructive.²³ In *Trumbo*, the court granted the government’s request to preclude the defendant from mentioning the safe harbor provisions at trial.²⁴ The court held:

Since both parties agree that the safe harbor provisions do not apply in this case, the Court finds that introducing the safe harbor provisions at trial would be improper because the provisions are not relevant. If the Court were to permit Defendant to mention such provisions, that have no bearing on his case, it may cause the jury to consider a defense that is not raised by Defendant. Due to the potential confusion the introduction of the safe harbor provisions would create, the Court will preclude any mention of the Anti-[k]ickback Statute’s safe harbor provisions. While Defendant will be able to litigate and argue that the elements of the Statute have not been met by the Government, he will not be able to refer to the safe harbor provisions as a defense to his case or as an “available” defense to anyone charged under the Statute.²⁵

²¹ *Id.* (quotation omitted).

²² *United States v. Turner*, 561 F. App’x 312, 319 (5th Cir. 2014) (not precedential).

²³ No. 18-20403, 2019 WL 3289848 (E.D. Mich. July 22, 2019).

²⁴ *Id.* at *2.

²⁵ *Id.*

V. Motion to exclude

Another punch that needs to land is your motion to exclude experts. A defendant may attempt to introduce expert testimony to counter the government's assertion that the defendant possessed the requisite intent to commit the offense. This can frequently take two forms. First, a defendant could argue that they had a different interpretation of the AKS. Second, a defendant could argue that they were merely acting in conformance with industry standards. While it may be appropriate for a defendant to testify regarding these two issues, it is improper for a defendant to seek to introduce such mental-state evidence through expert testimony.

In our trial, we successfully excluded this type of testimony. One defendant sought to have an expert testify regarding his interpretation of the AKS, safe harbors, and agency guidance. The expert was a health-care-law attorney with former government experience who planned to testify regarding his subjective interpretation of health-care laws and government enforcement efforts. While we considered filing a *Daubert* motion, we ultimately decided to object based on Rule 702 and Rule 403 in a motion to exclude.

The case law was favorable. It is well established in many circuits that, while an expert may assert opinions embracing ultimate issues to be decided by the jury, an expert witness may not offer opinions amounting to legal conclusions. The law is not a proper subject of expert opinion testimony.²⁶ An expert's opinions must still satisfy Rule 702, which requires that the opinions assist the jury in understanding evidence or determining a fact at issue. The opinions must also satisfy Rule 403, which allows the court to exclude testimony when its probative value is substantially outweighed by the danger of unfair prejudice and jury confusion. "An expert's legal opinions do not assist the trier of fact and invades the Court's authority to interpret the law."²⁷ The Fifth Circuit has explained:

[A]llowing attorneys to testify to matters of law would be harmful to the jury. First, the jury would be very susceptible to adopting the expert's conclusion rather

²⁶ See *Lassberg v. Barrett Daffin Frappier Turner & Engel, L.L.P.*, No. 13-CV-00577, 2014 WL 12659958, at *3 (E.D. Tex. Sept. 18, 2014) (quoting *C.P. Interests, Inc. v. Cal. Pools, Inc.*, 238 F.3d 690, 697 (5th Cir. 2001)).

²⁷ *Lassberg*, No. 13-CV-00577, 2014 WL 12659958, at *4.

making its own decision. There is a certain mystique about the word “expert” and once the jury hears of the attorney’s experience and expertise, it might think the witness even more reliable than the judge. Second, if an expert witness were allowed to testify to legal questions, each party would find an expert who would state the law in the light most favorable to its position. Such differing opinions as to what the law is would only confuse the jury.²⁸

“[I]t must be posited as an *a priori* assumption [that] there is one, but only one, legal answer for every cognizable dispute. There being only one applicable legal rule for each dispute or issue, it requires only one spokesman of the law, who of course is the judge.”²⁹ The Fifth Circuit and the Eastern District of Texas are not alone in excluding legal-opinion expert testimony. In *RLJCS Enterprises, Inc. v. Professional Benefits Trust*, the Seventh Circuit affirmed the exclusion of proposed testimony from lawyer experts opining on the meaning and effect of Internal Revenue Service (IRS) private letter rulings.³⁰ Chief Judge Easterbrook wrote:

Argument about the meaning of . . . contracts . . . belong[] in briefs, not in “experts’ reports.” Legal arguments are costly enough without being the subjects of “experts’” depositions and extensive debates in discovery, in addition to presentations made directly to the judge. If specialized knowledge about tax or demutualization would assist the judge, the holders of that knowledge can help counsel write the briefs and present oral argument. In this court each side is represented by two law firms, and a professor of law also has signed plaintiffs’ brief. Enough!³¹

²⁸ *Askanase v. Fatjo*, 130 F.3d 657, 673 (5th Cir. 1997) (citing *Specht v. Jensen*, 853 F.2d 805, 808–09 (10th Cir. 1988)).

²⁹ *Id.* (quoting *Specht*, 853 F.2d at 807) (second alteration in original).

³⁰ *RLJCS Enters., Inc. v. Pro. Benefit Tr. Multiple Emp. Welfare Benefit Plan & Tr.*, 487 F.3d 494, 498 (7th Cir. 2007).

³¹ *Id.* See also *United States v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021) (affirming district court’s exclusion of health-care attorney’s testimony on basis that testimony presented a legal conclusion informing the jury about how it should apply the law, which is prohibited); *Hygh v. Jacobs*, 961 F.2d

In our trial, a second defendant sought to have an expert testify regarding the interpretation of contractual arrangements and whether those contractual arrangements met industry standards. The expert was a health-care-law attorney who would base the opinion on their experience as a health-care lawyer, as well as research. We raised the same arguments referenced above, objecting on Rule 702 and Rule 403 grounds and adding that it would be improper for an expert to testify regarding the application of subjectively chosen standards based on interpretation of the law. We also argued that, while experts may testify generally about industry standards in regulated fields, such testimony should be limited to avoid unduly usurping the judge’s role regarding ultimate legal issues and unduly influencing the jury’s role of applying the facts to determine whether a defendant violated the law.³² This concern is heightened when the proposed expert has no prior relationship with the defendant and is being used to establish a defendant’s hypothetical knowledge and alleged adherence to the law.

It may not be reasonable to expect a court to exclude an expert completely. To be sure, an expert can provide some testimony that would not constitute impermissible legal conclusions or usurp the role of the judge or jury. For example, an expert may testify regarding the existence of agency guidance. By moving to exclude testimony that goes beyond those limits, however, you preemptively cabin their testimony and render the expert largely ineffective. As a result, a defendant may decline to call such a witness.

VI. Preparing for the final round

The final round, the closing argument, is about to begin. As we discussed above, fight to exclude any instructions related to statutory exceptions and regulatory safe harbors for failure to meet relevance under Rule 401 and, for their prejudicial, confusing, and nullifying

359, 364 (2d Cir. 1992) (“Even if a jury were not misled into adopting outright a legal conclusion proffered by an expert witness, the testimony would remain objectionable by communicating a legal standard—explicit or implicit—to the jury.”); *DeGregorio v. Metro–North R.R. Co.*, No. 05 cv 533, 2006 WL 3462554, at *3 (D. Conn. Nov. 1, 2006) (“[A]n expert should not be permitted to express an opinion that is merely an interpretation of federal statutes or regulations, as that is the sole province of the Court.”).

³² See *United States v. Holmes*, No. 18-CR-00258-EJD-1, 2021 WL 2035177, at *4 (N.D. Cal. May 21, 2021).

effect under Rule 403. Likewise, fight to exclude any instruction alluding to a defendant's good-faith efforts to bring conduct within an exception or safe harbor.³³ If the defendant has not availed himself of an affirmative defense, he is not entitled to an instruction.

As the charge conference concludes and before argument begins, you have another opportunity to implore the court to follow the rules and allow for a fair fight. Remind the court of your motion in limine to prevent defense counsel from mentioning exceptions or safe harbors during their closing argument for failure to meet relevance requirements under Rule 401 and Rule 403. If the court already entered an order in your favor, you have provided the court with an opportunity to remind the parties of its previous order. If the court denied your motion in limine at an earlier stage of the trial or granted a modified order, take the opportunity to re-urge your motion in limine.

In our trial, we reminded the court of our motion, which had previously been denied. By that point in the trial, it was clear that any reference to statutory exceptions or regulatory safe harbors were irrelevant, confusing, and misleading. The court confirmed its view with all counsel that none of the defendants had raised an affirmative defense and indicated that the parties would not be permitted to make arguments concerning exceptions or safe harbors. Our preparation paid off, and we were squared away for the final fight.

VII. Fight a good fight

For those of you who have had the opportunity to try AKS cases, you can attest that they are tough. The AKS lies at a complex and developing intersection of criminal and civil enforcement. The statute is not as intuitive and straightforward as other statutes. The investigations are challenging. The fact patterns are not as relatable to the average juror as traditional fraud cases. Opposing counsel are often sophisticated and experienced. Nevertheless, we know the arrangements that violate the AKS increase the risks of “[o]verutilization[,] [i]ncreased program costs[,] [c]orruption of medical

³³ *United States v. Turner*, 561 F. App'x 312, 319 (5th Cir. 2014) (not precedential) (explaining that “a defendant who fails to present evidence supporting the [safe harbor] defense is not entitled to [a] jury charge”).

decision making[,] [p]atient steering[, and u]nfair competition.”³⁴ So while the fight may be a hard one, it is one worth fighting. As “Sugar” Ray Leonard said, “If you never know failure, you will never know success.”³⁵

When all is said and done, fight a good fight and leave it all in the ring. You may be the fighter with an arm raised in victory, or you may be the fighter with your head bowed in defeat. Win, lose, or draw, commit yourself to justice and count yourself blessed. You are among the chosen few “who prosecute[] on behalf of justice.”³⁶

Maybe you are a boxer or a trial lawyer, or maybe, like me, you aspire to be better when it comes to both. In either case, there are lessons we can all learn in law and in life from the sweet science.

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³⁴ See *Fraud & Abuse Laws*, U.S. DEP’T OF HEALTH & HUMAN SERVS. OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/> (last visited Feb. 18, 2022).

³⁵ “Sugar” Ray Leonard won a gold medal in the 1976 Summer Olympics and was the first boxer to win world titles in five weight divisions. *Sugar Ray Leonard*, SUGAR RAY LEONARD, <http://www.sugarrayleonard.com/about/> (last visited Feb. 28, 2022). During his 20-year professional career, he compiled a record of 36-3-1 with 25 KOs. *Id.*; *Sugar Ray Leonard*, BIOGRAPHY.COM (Apr. 27, 2017), <https://www.biography.com/athlete/sugar-ray-leonard>.

³⁶ *DOJ Seal – History and Motto*, U.S. DEP’T OF JUST., <https://www.justice.gov/about/history/doj-seal-history-and-motto> (updated Jan 13, 2020). “*Cf.* H.R. DOC. NO. [70-]510, [at 78 (1929)] (quoting Attorney General Sargent’s famous dictum (now inscribed in modified form (“The United States wins *its* case. . . .) over the door to the Attorney General’s office in the Main Building in Washington, D.C.), see [LUTHER A.] HUSTON, [THE DEPARTMENT OF JUSTICE] . . . 32 [(1967)] that ‘[T]he United States wins a case whenever justice is done one of its citizens in the courts’).”

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Toward a Safety Valve for Sharing Documents Obtained by Grand Jury Subpoena in Parallel Investigations

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Rule 6 of the Federal Rules of Criminal Procedure can have a profound impact on parallel fraud investigations. The best way to address these issues is to avoid them entirely through considered, cooperative use of other mechanisms for obtaining information like agency Office of Inspector General (OIG) subpoenas, Health Insurance Portability and Accountability Act (HIPAA) subpoenas, or civil investigative demands. By holding off on grand jury processes as long as possible, investigators can proceed in parallel investigations without concern for grand jury secrecy. In some cases, using other tools is not possible. In others, the civil issues may emerge mid-investigation, after a grand jury subpoena has already been used to obtain documents.

The Supreme Court's decision in *United States v. Sells Engineering, Inc.*² significantly limits parallel investigations once grand jury testimony begins. *Sells Engineering*, however, does not preclude cooperation between the Department of Justice's (Department) Civil and Criminal Divisions (referred to as civil and criminal, respectively, going forward) in all cases where grand jury subpoenas have obtained documents. In some cases, the civil and criminal Assistant U.S. Attorneys (AUSAs)³ can effectively cooperate and exchange information, even if documents have already been obtained by grand jury subpoena. But to maximize the opportunities for cooperation in some cases, critical documents obtained by grand jury subpoena

¹ The author gratefully acknowledges the contributions to this article of former USAO extern Timothy Cordova, former colleagues Margaret L. Hutchinson and Michael Levy, incomparable current colleagues Veronica Finkelstein and Anthony Scicchitano, and supervisors Charlene Keller Fullmer and Gregory David.

² 463 U.S. 418, 427 (1983).

³ This article refers to AUSAs by their function in a particular case.

should be shared with the civil AUSA. In such cases, a safety valve is required so the investigators can share information as broadly as possible.

The safety valve is provided by what AUSAs in the Eastern District of Pennsylvania call the “Not 6(e)” motion, which calls upon the judge supervising the grand jury to recognize that certain discrete materials, categorically described materials, or both are not “matter[s] occurring before the grand jury.”⁴ Therefore, they are not subject to grand jury secrecy in the first place.⁵ The Not 6(e) motion allows the civil and criminal AUSAs to share the most relevant categories of documents, even when those documents were obtained using a grand jury (documentary) subpoena. In so doing, the Not 6(e) motion leaves the government in a position to pursue a fuller panoply display of remedies against a broader range of potential targets, without undue delay or duplication of effort.

I. Rule 6(e) generally

A. Grand jury secrecy in criminal cases generally

The grand jury performs a dual role in American criminal law: It investigates the possibility a crime was committed and protects citizens of the United States against accusations made without probable cause.⁶

Each of these facets of the grand jury is independently sacred. On the investigative side,

It is a grand inquest, a body with powers of investigation and inquisition, the scope of whose inquiries is not to be limited narrowly by questions of propriety or forecasts of the probable result of the investigation, or by doubts whether any particular individual will be found properly subject to an accusation of crime.⁷

So “[t]raditionally the grand jury has been accorded wide latitude . . . [and] may compel the production of evidence or the testimony of witnesses as it considers appropriate, and its operation

⁴ FED. R. CRIM. P. 6(e)(2)(B).

⁵ Several other districts have similar practices, but the term “Not 6(e)” motion is the Eastern District of Pennsylvania (E.D. Pa.)’s own.

⁶ *See generally* *Branzburg v. Hayes*, 408 U.S. 665, 686–87 (1972).

⁷ *Blair v. United States*, 250 U.S. 273, 282 (1919).

generally is unrestrained by the technical procedural and evidentiary rules governing the conduct of criminal trials.”⁸

Even as they have empowered the grand jury to search widely and deeply, however, courts “consistently have recognized that the proper functioning of our grand jury system depends upon the secrecy of grand jury proceedings.”⁹ “Grand jury secrecy is . . . ’as important for the protection of the innocent as for the pursuit of the guilty” and, thus, “[b]oth Congress and [the Supreme] Court have consistently stood ready to defend it against unwarranted intrusion. In the absence of a clear indication in a statute or Rule, [courts] must always be reluctant to conclude that a breach of this secrecy has been authorized.”¹⁰

These powers and limitations are codified in Federal Rule of Criminal Procedure 6. Most salient for purposes of this article is Rule 6(e), which provides that virtually anyone associated with a grand jury investigation, except a witness, is forbidden from revealing “a matter occurring before the grand jury” other than: (1) to an attorney for the government for use in that attorney’s duties; (2) to government personnel necessary to assist that attorney in enforcing federal criminal law; or (3) where there is particularized need.¹¹

As the Supreme Court suggested in *Sells*, courts take these restrictions very seriously.¹² Misconduct in this arena that impacts

⁸ *United States v. Calandra*, 414 U.S. 338, 343 (1974). *See generally* Andrea M. Nervi, *FRCPP 6(e) and the Disclosure of Documents Reviewed by A Grand Jury*, 57 U. CHI. L. REV. 221, 231, 231 n.40 (1990) (citing Candace Fabri and Rebecca Cochran, *Criminal Discovery for the Civil Litigator*, 15 LITIG., Fall 1988, 13, 14, for the proposition that “the grand jury is often permitted fishing expeditions unheard of in civil litigation” and, thus, it is “reasonable to protect the subject of the investigation from disclosure of the materials to civil litigants who would otherwise be unable to obtain them.”)

⁹ *Douglas Oil Co. of Cali. v. Petrol Stops Nw.*, 441 U.S. 211, 218–19 (1979).

¹⁰ *United States v. Sells Eng’g, Inc.*, 463 U.S. 418, 424–25 (1983) (quoting *United States v. Johnson*, 319 U.S. 503, 513 (1943)).

¹¹ Other exceptions exist, principally in the banking context, the national security context, and to permit disclosure of one grand jury’s work to another. *See generally* FED. R. CRIM. P. 6(e)(3)(A), (C), (D). *Cf.* 18 U.S.C. § 3322. The particularized need standard is discussed *infra*.

¹² *See generally* Fred A. Bernstein, *Behind the Gray Door: Williams, Secrecy, and the Federal Grand Jury*, 69 N.Y.U. L. REV. 563, 600 (1994) (“A special shibboleth of secrecy has traditionally surrounded grand jury proceedings and made courts reluctant to disclose grand jury records.”).

fundamental fairness can lead to the dismissal of indictments on direct appeal.¹³

B. Grand juries and avoiding grand juries in parallel investigations

Department policy strongly encourages parallel investigations in white collar cases.¹⁴ As Chapter 27 of the Organizations and Functions Manual of the Justice Manual makes clear:

Department policy is that criminal prosecutors and civil trial counsel should timely communicate, coordinate, and cooperate with one another and agency attorneys to the fullest extent appropriate to the case and permissible by law. . . . By working together in this way, the Department can better protect the government's interests (including deterrence of future misconduct and restoration of program integrity) and secure the full range of the government's remedies (including incarceration, fines, penalties, damages, restitution to victims, asset seizure, civil and criminal forfeiture, and exclusion and debarment). . . .

[I]t is important that criminal, civil, and agency attorneys coordinate in a timely fashion, discuss common issues that may impact each matter, and proceed in a manner that allows information to be shared to the fullest extent appropriate to the case and permissible by law.¹⁵

¹³ See *United States v. Johns*, 858 F.2d 154, 160 (3d Cir. 1988); *United States v. Taylor*, 798 F.2d 1337, 1340 (10th Cir. 1986).

¹⁴ Much of the reasoning of Department policy also applies to cases involving violations of the Controlled Substances Act through drug diversion.

¹⁵ JUSTICE MANUAL, ORG. & FUNCTIONS MANUAL ch. 27. "There is nothing improper about the government undertaking simultaneous criminal and civil investigations," provided that those proceedings and their investigative tools are used for their proper purposes and in appropriate ways. *United States v. Stringer*, 535 F.3d 929, 933 (9th Cir. 2008). See also *United States v. Kordel*, 397 U.S. 1, 11 (1970) ("It would stultify enforcement of federal law to require a governmental agency . . . invariably to choose either to forgo recommendation of a criminal prosecution once it seeks civil relief, or to defer civil proceedings pending the ultimate outcome of a criminal trial.").

In short, truly parallel investigations add value in several independent ways, such as bringing additional resources and diverse perspectives to bear on topics including how the misconduct may have been perpetrated, who the key witnesses may likely be, where the key data may be housed, and how to obtain it. Once the investigations conclude, having proceeded in parallel provides the government with a wider range of potential remedies, and—because of the different, often lower burdens of proof and *scienter* standards for civil or administrative actions—they typically provide mechanisms to reach individuals and conduct what a purely criminal investigation may not.

Of course, this cooperation is only possible when the civil and criminal functions of the United States are permitted to share information. Ordinarily, that is not a problem, because United States Attorneys' Offices that initiate investigations in parallel will use investigative methods that do not trigger Rule 6(e) at all. Agency OIG subpoenas can obtain many of the same documents as grand jury subpoenas, as can HIPAA subpoenas for documents.¹⁶ Responses to civil investigative demands may also be freely shared with criminal prosecutors examining related subject matter.¹⁷ None of these are grand jury methods, so none trigger grand jury secrecy.

The coordination of investigative efforts is the *sine qua non* of effective parallel investigations, and it remains the first and best mechanism for obtaining information that both civil and criminal can use. Ounces of prevention are worth pounds of cure; the best solution remains reserving any grand jury processes as long as possible in an investigation.

Nonetheless, that coordination may not always be possible. For example, a criminal investigation may be well underway before the prosecutors discover that the United States itself was a victim. Also, the investigation of one scheme may lead investigators to discover another, unrelated scheme in which the United States is a victim. In such cases, the prosecutors may have already utilized grand jury subpoenas for documents. Using those subpoenas, they may have already discovered facts or documents that are foundational to the

¹⁶ See generally 18 U.S.C. § 3486(a)(1)(A)(i)(I) (authorizing administrative subpoenas in any investigation of a federal health care offense).

¹⁷ See 31 U.S.C. § 3733(i)(3) (permitting disclosure of CID material for an “official use”) and 31 U.S.C. § 3733(l)(8) (defining “official use” to include communications within the Department or between the Department and other federal, state, and local agencies in furtherance of a Department prosecution of a case.)

civil investigation. In cases where the grand jury has begun its investigation, even in a limited way, cooperation between civil and criminal requires consideration of Rule 6(e)'s secrecy requirements.¹⁸

C. Who is an “attorney for the government”?

Criminal AUSAs serve many functions for the grand jury. They are its legal advisor, explaining the elements of the offense. They are its eyes and ears, identifying areas to which it could direct its investigative attention. They are its arms, subpoenaing documents and witnesses for it. They are its voice, questioning the witnesses it has summoned. Ultimately, they are its quill, drafting the charging documents for the grand jury's ultimate decision. Each such AUSA is also an “attorney for the government” within the meaning of Rule 6(e).

Although the civil AUSAs who represent the United States in the same courts as their criminal colleagues are literally attorneys for the government, a five-Justice majority in *Sells* held that the only “attorney for the government” to whom grand jury matters could be disclosed is one who was involved in the prosecution of the *crime* at issue.¹⁹ That holding has not been revisited, and both *Sells* and its predecessors reject any distinction between private parties and the government in its capacity as a civil litigant.²⁰ Criminal AUSAs can no more routinely share matters occurring before the grand jury with their civil colleagues than they can turn them over in civil discovery between third parties.²¹

D. When are documents obtained by grand jury subpoena a “matter occurring before the grand jury”?

This raises a fundamental and critical question: When does something become a matter occurring before the grand jury? At one pole, we understand that actual grand jury proceedings—the

¹⁸ See generally JUSTICE MANUAL ORG. & FUNCTIONS MANUAL ch. 27 n.1 (“[T]he Department's civil and criminal attorneys should work together, and with agency attorneys, to consider and plan for grand jury secrecy and discovery issues early in the process of conducting parallel proceedings.”)

¹⁹ United States v. *Sells Eng'g, Inc.*, 463 U.S. 418, 426–27 (1983).

²⁰ *Id.* at 444.

²¹ As discussed in greater detail *infra*, the Supreme Court later authorized criminal attorneys for the government to participate in civil proceedings, even with their knowledge of grand jury matters. See *United States v. John Doe, Inc. I*, 481 U.S. 102 (1987).

discussions between the grand jury and its counsel, testimony it hears, and any record that exists of its deliberations—are clearly matters occurring before it²² and are, therefore, secret. Courts have extended this rule to conclude that if a record was created exclusively for the grand jury—a document created by a target to fulfill a response to the grand jury’s subpoena—then it is likely a matter occurring before the grand jury.²³

These documents can rarely be shared with civil. But they are not the critical ones early in investigations. Medical records, claims data, business accounts, bank records, and electronic mail, text, or other communications are at the heart of many federal criminal healthcare fraud investigations. These documents are all pre-existing records, created by businesses as part of their daily operations—criminal or otherwise—or by third parties, such as banks, accountants, and auditors, to support the businesses. If and when these records can be shared may define whether investigations can meaningfully proceed in parallel.

The most cogent analysis of whether pre-existing business records obtained by grand jury subpoena are matters occurring before the grand jury is the Ninth Circuit’s decision in *United States v. Dynavac, Inc.*,²⁴ which collected the authorities and forged a doctrine that subsequent courts have relied upon or echoed.

²² See *Before*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/before> (last visited Feb. 28, 2022) (as a preposition, defined in order as “in front of,” “in the presence of,” and “under the jurisdiction or consideration of”).

²³ See, e.g. *In re Grand Jury Matter*, 697 F.2d 511, 513 (3d Cir. 1982) [hereinafter *Garden Court*] (where tax authorities sought records of auditors that were prepared to assist the grand jury, and where results of audits were presented to grand jury, even if records were not, “a reasonable person would conclude that the audits or their results were presented to the grand jury. Thus[,] disclosure of the auditors’ analyses is governed by Rule 6(e)(2).”). See also *id.* at 516 (Garth, J., concurring) (auditors’ documents were not “summaries of books and records generated in the ordinary course of business”; instead “the selection of particular items and their placement in particular categories was obviously undertaken so as to best comport with the thrust of the grand jury investigation . . . [and] the auditor’s conclusions and impressions . . . carry forward explanations of the various entries, and in effect, argue for a specific conclusion”).

²⁴ 6 F.3d 1407, 1411 (9th Cir. 1993). *Dynavac* has been widely, positively cited nationally. See, e.g. *Church of Scientology Int’l v. U.S. Dep’t of Just.*, 30 F.3d 224, 235 (1st Cir. 1994) (adopting *Dynavac* rule); *In re Grand Jury Subpoena*, 103 F.3d 234 (2d Cir. 1996) (citing *Dynavac* approvingly); *In re*

The Ninth Circuit's analysis started with the seminal decision in *United States v. Interstate Dress Carriers, Inc.*,²⁵ in which the Second Circuit permitted the Interstate Commerce Commission (ICC) access to documents that were then in the possession of a grand jury, reasoning that the ICC had the authority to obtain those kinds of documents on its own.²⁶

Returning to this issue in 1993, the Ninth Circuit found that *Interstate Dress Carriers* had become the keystone decision on this issue, but a circuit split had developed from it:²⁷

- In the Second Circuit, *Interstate Dress Carriers* had been interpreted, in essence, to establish a per se rule that pre-existing documents are not subject to Rule 6(e).²⁸

Blood Reagents Antitrust Litig., 756 F. Supp. 2d 623, 635 (E.D. Pa. 2010) (citing *Dynavac* approvingly); RF Micro Devices, Inc. v. Xiang, No. 12CV967, 2016 WL 3212481, at *2 (M.D.N.C. June 9, 2016) (adopting the “purpose” test from *Dynavac* and citing it generally). Even those circuits that do not expressly adopt *Dynavac* adopt one or both prongs of its test, making *Dynavac* a valuable rule of thumb nationwide. See, e.g. Senate of the Commonwealth of Puerto Rico on Behalf of Judiciary Comm. v. U.S. Dep’t of Just., 823 F.2d 574, 582 (D.C. Cir. 1987) (effectively adopting “effects” test); Alpert v. Riley, No. CIV.A. H-04-CV-3774, 2009 WL 1226767, at *5 (S.D. Tex. Apr. 30, 2009) (effectively adopting “purpose”); *In re Sulfuric Acid Antitrust Litig.*, No. 1536, 2004 WL 769376, at *2–3 (N.D. Ill. Apr. 9, 2004) (citing *In Re The Special Feb.*, 1975 Grand Jury, 662 F.2d 1232 (7th Cir. 1981) as establishing test akin to “effects” test and *In The Matter of Special March 1981 Grand Jury*, 753 F.2d 575 (7th Cir. 1985) as establishing test akin to “purpose” test); *McArthur v. Robinson*, 98 F.R.D. 672, 677 (E.D. Ark. 1983) (functionally adopting “purpose” test); *Anaya v. United States*, 815 F.2d 1373, 1379 (10th Cir. 1987) (articulating holding akin to “effects” test); *Fed. Election Comm’n v. Rivera*, 333 F.R.D. 282, 288 (S.D. Fla. 2019) (expressing test like the “purpose” test); *Ford v. Comm’r*, 86 T.C.M. 259 (T.C. 2003) (adopting *Dynavac* tests). Only the Sixth Circuit seems to adopt a holding more expressly stringent than *Dynavac*. See *Dassault Systemes, S.A. v. Childress*, No. 09-10534, 2009 WL 3602084 (E.D. Mich. Oct. 27, 2009), *aff’d sub nom. Dassault Systemes, SA v. Childress*, 663 F.3d 832 (6th Cir. 2011) (explaining Sixth Circuit’s approach and identifying its conflict with that of its sister courts).

²⁵ 280 F.2d 52, 54 (2d Cir. 1960).

²⁶ As discussed both *supra* and *infra*, the Civil Division would be able to obtain pre-existing business records using civil investigative demands or other process in civil False Claims Act (FCA) matters.

²⁷ See *Dynavac*, 6 F.3d at 1411–12; see also *Nervi*, *supra* note 7, at n.4 (cited in *Dynavac* as collecting cases and identifying a fifth approach).

²⁸ *United States v. Weinstein*, 511 F.2d 622, 627 n.5 (2d Cir. 1975).

- In the Fifth Circuit, there was an opposite, equally per se rule that any material obtained by the grand jury is secret.²⁹
- In the Sixth Circuit, there was a rebuttable presumption that materials obtained by the grand jury are secret.³⁰
- Most circuits, however, were somewhere in the middle, relying on case-by-case examination of the documents or document requests to determine whether they ought to be governed by Rule 6(e).³¹

Ultimately, *Dynavac* established a clear, two-prong rule of decision: (1) Is civil trying to find out what the grand jury is thinking or to get the documents for its own sake (the purpose test)?; and (2) Would civil obtaining the documents compromise the grand jury process by revealing its thinking or deliberation (the effects test)?³² According to *Dynavac* and its progeny, if civil wants the documents for themselves, and those documents would not reveal the grand jury’s thinking, they may be shared without violating Rule 6(e).³³

In practice, the application of the purpose and effects tests may be less clear. The Third Circuit’s struggle with this issue is illustrative. In 1980, the Third Circuit articulated a test very similar to that in *Dynavac*:

(W)hen testimony or data is sought for its own sake—for its intrinsic value in the furtherance of a lawful investigation—rather than to learn what took place before the grand jury,” then “access to the records

²⁹ See *Texas v. U.S. Steel Corp.*, 546 F.2d 626 (5th Cir. 1977).

³⁰ See *In re Grand Jury Proceedings*, 851 F.2d 860, 864 (6th Cir. 1988).

³¹ See *In re Grand Jury Matter*, 682 F.2d 61 (3d Cir. 1982); *In re Grand Jury Subpoena* (United States v. Under Seal), 920 F.2d 235, 241 (4th Cir. 1990); *In re Special Mar.* 1981 Grand Jury (Almond Pharmacy), 753 F.2d 575, 578 (7th Cir. 1985); *In re Grand Jury Proceedings Relative to Perl*, 838 F.2d 304, 306 (8th Cir. 1988); *Anaya v. United States*, 815 F.2d 1373, 1379 (10th Cir. 1987); *Senate of Puerto Rico v. U.S. Dep’t of Just.*, 823 F.2d 574, 582 (D.C. Cir. 1987).

³² *Dynavac*, 6 F.3d at 1411–12.

³³ *F.T.C. v. A.M.G. Servs., Inc.*, No. 12-cv-536, 2015 WL176417, at *7 (D. Nev. Jan. 14, 2015) analogizes this issue to the attorney–client privilege context: What is actually said (between attorney and client, in a grand jury) is protected, as are the impressions formed, but no privilege is conferred over the underlying facts or documents simply by their being discussed or communicated.

should be refused only if it would compromise the secrecy of the grand jury.³⁴

Two years later, the Third Circuit extended this principle to hold that the District Attorney for Delaware County, Pennsylvania, could obtain investigative records that were “perhaps” developed by the FBI “with an eye toward ultimate use in a grand jury proceeding” and “exist[ed] apart from and w[ere] developed independently of grand jury processes,” but the District Attorney could not obtain the transcripts of testimony in the grand jury.³⁵ In the same year, a different panel of the Third Circuit held that “[n]o meaningful distinction can be drawn between [grand jury] transcripts and witness interviews conducted outside the grand jury’s presence but presented to it.”³⁶ This conclusion was reached without citing any authority, and seems contrary to the conclusion of *Catania*.

At least one judge seemed to recognize this tension. According to Judge Garth’s concurrence in *Garden Court*:

[I]f the documents were independently produced in the regular course of business, the court need go no further and may order disclosure. If the documents were independently produced but actually examined by the grand jury, the district court must determine whether the party seeking disclosure has sought the documents pursuant to an independent lawful investigation within the purview of Rule 6(e). If so, the district court may order disclosure.³⁷

Perhaps unsurprisingly, it is Judge Garth’s concurrence upon which the Ninth Circuit more strongly relied in *Dynavac*. It also seems to have become something akin to a rule of decision in subsequent district cases, which have permitted fairly free sharing of pre-existing business records that do not reveal the inner workings of the grand jury.³⁸

³⁴ *In re Grand Jury Investigation*, 630 F.2d 996, 1001 (3d Cir. 1980) [hereinafter *SCI*].

³⁵ *In re Grand Jury Matter*, 682 F.2d 61, 64–66 (3d Cir. 1982) [hereinafter *Catania*].

³⁶ *Garden Court*, 697 F.2d at 512.

³⁷ *Id.* at 517 (Garth, J., concurring).

³⁸ *See, e.g.* *United States v. Johns*, 688 F. Supp. 1017, 1024 (E.D. Pa. 1988) (holding that vendor lists, checks, and summaries of payment were “legitimate business records that had many uses unrelated to the grand

In most jurisdictions, “information does not become a matter occurring before the grand jury simply by being presented to the grand jury, particularly where it was developed independent of the grand jury.”³⁹ Thus, almost none of the most important documents in the parallel prosecution of healthcare fraud—claims data, medical records, accounting and payment records, email and other communications, and banking records—are typically matters occurring before the grand jury subject to Rule 6(e), even if obtained by a grand jury subpoena.⁴⁰

This is not to say, however, that pre-existing business records can never become grand jury records within the meaning of Rule 6(e). As the foregoing cases clarify, some pre-existing records may be so central to the grand jury’s thought process that merely knowing that the grand jury has them could reveal its inner thoughts, particularly if they are shared with the grand jury during its deliberations.

For similar reasons, categorical requests from civil or third parties for documents shown to the grand jury or exhibits before the grand jury will rarely, if ever, succeed. Most of an attorney’s list of hot documents in a particular case is opinion work product even if the

jury”); *United States v. OMT Supermarkets, Inc.*, 995 F. Supp. 526 (E.D. Pa. 1997) (where grand jury never reviewed pre-existing business documents, they were not matters occurring before the grand jury); *In re Plastics Additives Antitrust Litig.*, No. 03-2038, 2004 WL 2743591, at *11 (E.D. Pa. Nov. 29, 2004) (distinguishing between “documents generated for purposes independent of the grand jury investigation, such as during the ordinary course of a defendant’s business,” which are not matters occurring before the grand jury, and those that are “created at a grand jury’s request, such as subpoenas, transcripts, and document lists,” which are); *In re Blood Reagents Antitrust Litig.*, 756 F. Supp. 2d 623, 634 (E.D. Pa. 2010) (“Rule 6(e) does not protect materials that are created independently of the grand jury process” and citing, *inter alia*, *Dynavac*). *But see* *In re Grand Jury Matter*, No. 98-225, 2002 WL 1496993 (E.D. Pa. July 12, 2002) (accepting as conceded that materials requested were matters before the grand jury and refusing to permit disclosure of unidentified documents based on a slip opinion by the same judge that does not appear on Westlaw or LEXIS).

³⁹ *United States v. Chang*, 47 Fed. App’x 119, 121–22 (3d Cir. 2002) (not precedential).

⁴⁰ Again, if the grand jury has asked for exhibit lists or documents to be created, these documents had no life before its request and will likely be considered matters occurring before it. The concerns with investigative audit or summary documents are an illustrative example: Because they are work product tailored to meet the grand jury’s request, they may disclose the grand jury’s thinking in a way that pre-existing business records do not.

documents themselves are routine business records. Knowing which business documents were considered by the grand jury reveals too much about its thought process.

Likewise, a court is unlikely to allow civil discovery (or sharing with civil) of all documents provided to the grand jury; a list of all documents obtained by the grand jury; or other, similarly far-ranging requests that reveal what the grand jury is considering and, thus, might disclose something of its thought processes.

II. Rule 6(e) and the civil practitioner—the current state of affairs

As noted above, consistent with the Department’s parallel-proceedings policy, most documents obtained in parallel investigations are collected using HIPAA subpoenas or other mechanisms that allow them to be shared with civil. Rule 6(e) poses no challenge to such an approach.

But there are occasions where the criminal AUSA issues grand jury subpoenas early in an investigation, before realizing there may be a basis for a civil investigation or for other reasons. In such cases, a civil AUSA is often walled off. The civil AUSA is thereby left with a much leaner body of information or, perhaps, no information at all. Because of the risk of interfering with the criminal investigation, the civil AUSA will often be foreclosed from using civil investigative demands to obtain the information they need.

Functionally, this approach means the civil investigation is put on an indefinite hold or never begins at all.⁴¹ Although it is reasonable that criminal investigations take precedence, this result is problematic in several independent ways. First, in almost every instance, both the civil and criminal investigators must obtain and review the same documents, interview the same witnesses, and perform much of the same analysis, without being able to use any of the information the other division developed. This is a tremendous waste of time and energy.

⁴¹ This problem is exacerbated by the numerous cases holding that the risk to grand jury secrecy is lessened if disclosure occurs after the grand jury has reached its decision. “Accordingly, where DOJ civil lawyers seek to obtain grand jury material for use in civil proceedings, they often wait until after the conclusion of the criminal proceedings” Robert K. Huffman, *The Perils of Parallel Civil and Criminal Proceedings: A Primer*, HEALTH LAW, March 1998, at 1, 5.

Second, the subsequent, duplicative civil investigation will face additional hurdles. During the months or years of the criminal investigation, witnesses may become unavailable, documents never sought for criminal purposes may be lost, and memories may fade.⁴²

Third, during the months or years of the criminal investigation, while criminal AUSAs keep the door open to using covert methods, the statute of limitations is running, and civil cannot seek a tolling agreement until the matter is overt. When a criminal declination follows a protracted investigation, civil faces a loudly ticking clock.

Finally, there is the practical problem of case fatigue. If a civil investigation begins after many months of investigative work, perhaps years after the conduct, an enthusiasm gap could develop within the U.S. Attorney's Office or investigative agency asked to commit a new agent (untainted by purported grand jury information) to support a case that already may be perceived as a failure.

All these costs are in addition to the significant loss to the investigation of assigning a criminal AUSA without a civil partner for several years.

In sum, while walling off individuals is a common, effective, and accepted legal practice,⁴³ walling off civil during a criminal investigation hampers the government's ability to secure the full range of remedies. Sharing information by using a Not 6(e) motion is consistent with the Department's parallel-proceedings policy and allows Department attorneys to avoid this outcome.

One solution to this issue is combining the civil and criminal functions into a single individual. This solution was sanctioned by the Supreme Court in *United States v. John Doe, Inc. I*, 481 U.S. 102, 109 (1987) ("*John Doe I*").⁴⁴

⁴² As discussed *infra*, avoiding duplicative investigations is rarely, if ever, a "particularized need" for purposes of a Rule 6(e)(3)(E)(i) motion. Perhaps some judges would weigh the loss of memories, but even if such a motion were granted and the civil investigators obtained prior statements from witnesses who have become unavailable or have forgotten the events, that may be of limited utility. If the prior statements are not admissions by a party opponent, civil investigators will face hearsay hurdles on summary judgment or at trial.

⁴³ A *Kastigar* hearing—at which the government must demonstrate that its case consists of evidence generated independent of statements provided by an immunized individual—is an illustrative example.

⁴⁴ Rather than moving on parallel tracks, these offices place the investigation on a single, typically sequential track, giving the investigation to one or more AUSAs who investigate it for both civil and criminal purposes until it

Another solution typically pursued by United States Attorney's Offices is found in Rule 6(e)(3)(E)(i), which allows disclosure to civil AUSAs "preliminarily to or in connection with a judicial proceeding."⁴⁵ Rule 6(e)(3)(E)(i) does not provide any legal standard on which such requests will be judged, but the Supreme Court established one in *Sells*:

We have consistently construed the Rule, however, to require a strong showing of particularized need for

matures into one, the other, or both. *John Doe I* holds that this attorney may use the information obtained in the grand jury, even if the investigation eventually becomes entirely civil, so long as no matter occurring before the grand jury is further disclosed in a way that violates Rule 6(e). There are benefits and costs to this approach, and both *John Doe I* and this practice it spawned have been subject to some criticism in academic circles. See, e.g. Mark Kadish, *Behind the Locked Door of an American Grand Jury: Its History, Its Secrecy, and Its Process*, 24 FLA. ST. U. L. REV. 1, 68 (1996). In addition, if Rule 6(e)(3)(A)(ii) limits what information occurring before a grand jury may be shared with agents pursuing a purely civil investigation, this could provide a reason—in addition to those discussed *supra* in this section—to prefer simultaneous parallel efforts to sequential ones.

A fuller examination of this debate is beyond the scope of this Article.

⁴⁵ Virtually every FCA investigation could be considered "preliminary to . . . a judicial proceeding," that is, the FCA complaint that will be filed if the investigation finds sufficient basis. Similarly, every qui tam case already has such a complaint, and investigations of those allegations are "in connection with a judicial proceeding," either the litigation itself or the United States' determination of whether to intervene.

USAO-EDPA has had considerable success in obtaining documentary and sometimes testimonial grand jury material for use in bringing anti-fraud injunctions under 18 U.S.C. § 1345 because judges appreciate both the need to lock down assets and the utility to the government and the court in having Civil AUSAs litigating under the Rules of Civil Procedure. Arguably, such a use would not require judicial permission, because disclosure can always be made to government personnel necessary to enforce federal criminal law under Rule 6(e)(3)(A)(ii). Section 1345 is itself in the criminal code, and it serves to ensure that funds are available for restitution a defendant will be required to make under 18 U.S.C. § 3663A. In light of the consequences of a court determining that these uses are insufficiently "criminal" to justify a Rule 6(e)(3)(A)(ii) disclosure, however, many criminal AUSAs prefer to seek permission rather than forgiveness.

grand jury materials before any disclosure will be permitted. . . .

Parties seeking grand jury transcripts under Rule 6(e) must show that the material they seek is needed to avoid a possible injustice in another judicial proceeding, that the need for disclosure is greater than the need for continued secrecy, and that their request is structured to cover only material so needed

[D]isclosure is appropriate only in those cases where the need for it outweighs the public interest in secrecy, and . . . the burden of demonstrating this balance rests upon the private party seeking disclosure.⁴⁶

The court made clear that the omnipresent desire of saving time and expense will not suffice.⁴⁷

When civil AUSAs make a Rule 6(e)(3)(E)(i) motion to obtain information for use in a False Claims Act investigation, they face this exceptionally high bar. Although Rule 6(e)(3)(E)(i) provides a reasonable, practical mechanism to obtain access to grand jury records for use in a Section 1345 injunction or other special cases, it does not provide a realistic mechanism for meaningfully sharing information between the civil and criminal functions of a U.S. Attorney's Office. Rule 6(e)(3)(E)(i), therefore, provides no solution to the core issue of conducting a parallel investigation on a case criminal started alone.

III. Rule 6(e), the “Not 6(e)” motion, and the civil practitioner—a modest proposal

As the foregoing demonstrates, pre-existing business records are not typically “matters occurring before the grand jury,” even if those records are obtained by grand jury subpoena. In that sense, they should be freely shareable. But of course, “[a]ny . . . use of grand jury proceedings to elicit evidence for use in a civil case is improper *per se*.”⁴⁸ The Supreme Court's decision in *John Doe I* could stand for three propositions: (1) documents obtained by a grand jury may be used to further a civil investigation because they were obtained for a

⁴⁶ *United States v. Sells Eng'g, Inc.*, 463 U.S. 418, 443 (1983) (quoting *Douglas Oil Co. of Cali. v. Petrol Stops Nw.*, 441 U.S. 211, 222–23 (1979)).

⁴⁷ *See id.* at 431.

⁴⁸ *Id.* at 432.

proper, criminal purpose; (2) such documents may be used to further a civil investigation only because doing so is not sharing them; or (3) both. No prosecutor wants to risk losing a successful case by sharing one document too many.

Again, this problem is ideally resolved by avoiding it through using mechanisms to obtain documents that do not trigger Rule 6(e) protection.

Another mechanism exists, however, to solve these problems when they arise: court pre-approval of the disclosure through granting a Not 6(e) motion that demonstrates that the pre-existing business records were not matters occurring before the grand jury in the first place.

To be clear, this mechanism is used sparingly, because cooperative discovery planning avoids the issue. But in proper circumstances, the Not 6(e) motion provides the necessary space to reset the investigation into a fully parallel mode. If all the materials subpoenaed by the grand jury are subject to the Not 6(e) motion, once permission is obtained to share that information, the Department can capture the value of having two heads working together on legal strategy, document review, and witness interviews for months or years, until grand jury testimony is required.⁴⁹ Once the reset is accomplished, AUSAs can use mechanisms other than grand jury subpoenas to obtain future documents, consistent with how the investigation would have proceeded from the outset had the government's civil claims been known.

⁴⁹ One issue that arises is whether and to what degree cooperation can continue if the criminal AUSA uses a grand jury subpoena to obtain *additional* pre-existing business records. The Justice Manual does not speak specifically to this issue, and offices' practices may differ. As a general rule, criminal AUSAs in the possession of information obtained using a grand jury subpoena may still discuss the investigation with their civil colleagues, but they must be extremely circumspect in so doing not to disclose any matter occurring before the grand jury.

Some offices may take the view that, even following a Not 6(e) order, any additional information obtained using a grand jury subpoena is presumptively a matter occurring before the grand jury, and thus that a temporary wall should again be erected between civil and criminal AUSAs pending additional Not 6(e) determinations from the court. Others may take the view that limited, similar pre-existing business records are not matters occurring before the grand jury even if obtained with a grand jury subpoena, and thus that once the court has so held, additional, successive judicial determination of the issue is not required.

Not 6(e) motions protect the balance struck by Congress in Rule 6(e). As courts have repeatedly recognized since *Interstate Dress Carriers* more than a half-century ago, just as records do not become attorney-client privileged when an attorney obtains them from a client, pre-existing documents are not rendered secret merely because they were produced in response to a grand jury subpoena. Through a civil investigative demand, Civil would have likely obtained these records during its own investigation but for the existence of the criminal investigation.

For that reason, a Not 6(e) motion also mitigates the risk of adverse judicial decision. Because the motion is made before disclosure, the grand jury judge considers it without any hindsight bias against unilateral prosecutorial action. Even if a trial judge later disagrees with the grand jury judge's decision, that trial judge is unlikely to sanction a prosecutor who sought and received judicial approval before acting.

By limiting the risk of sanction and involving a neutral third party whose sole interest is the grand jury's protection, a Not 6(e) order solves the Goldilocks problem a criminal AUSA faces in deciding how much sharing is too little and how much sharing is too much. The criminal AUSA can ask to disclose the maximum number of pre-existing business records that the AUSA believes do not reveal the grand jury's thought processes. If the judge supervising that grand jury disagrees with where that line is drawn, that judge can pare down the disclosure. The criminal AUSA need no longer be chilled by the reasonable risk aversion of someone taking a unilateral action.

This is not to say that Not 6(e) motions are frictionless. Some courts may not initially be entirely comfortable with them. An AUSA might have to explain that the Department is seeking a declaration that something is not grand jury material that is clearly not grand jury material, out of an abundance of caution and respect. Over time, this initial concern or confusion fades, as a body of decisions develops granting these requests.

In practice, these requests have been occasional and not a constant drumbeat. Well-considered requests have typically been granted,⁵⁰ especially when all the AUSAs seek to share are the basic records of any fraud investigation: claims, patient records, and financial transactions. Courts correctly recognize that these records fit the

⁵⁰ This has been the author's experience, and it appears to be shared by other districts that have their own version of the "Not 6(e)" motion.

heartland of the *Interstate Dress Carriers* and *Dynavac* analyses, and they reveal little of a particular grand jury's deliberation because they are common to almost every fraud investigation.⁵¹

Using the safety valve of a Not 6(e) motion places both investigations in a far stronger position. By sharing the documents that are not matters occurring before a grand jury, the criminal AUSA allows the criminal and civil investigations to move in parallel. As the Justice Manual recognizes, two heads are better than one: The civil AUSA may have valuable perspective to offer on their overlapping goals, and the civil AUSA's presence during voluntary proffer sessions provides benefit to both investigations.⁵² To be certain, once the grand jury convenes to hear testimony (and, perhaps, once additional documents are subpoenaed by the grand jury⁵³), the civil AUSA will need to be walled off and either proceed independently or stand down. If an indictment is issued, the civil AUSA will often stand down to allow the criminal case to play out. At those points, much has already been accomplished, and the civil AUSA will be in a strong position to

⁵¹ Ironically, the more an AUSA limits the request to core pre-existing banking, accounting, or claims records, the more likely a court is to question why there is any need for its decision at all. And as often as not, it is not necessary to go beyond these documents, because there are limits on the use of subpoenas to obtain the content of critical *scienter* documents like emails and text messages. Accordingly, criminal AUSAs often obtain these from a cooperator or through search warrants, the fruits of which can freely be shared with civil AUSAs. Even so, if specialized subpoenas or grand jury subpoenas are used obtain non-content information from emails or texts from service providers, prosecutors may wish to consult the decisional law governing sharing this information and any local or CCIPS experts on the sharing of non-content information obtained by that particular form of process. In some cases, criminal AUSAs may wish either to hold off on disclosing this information to civil AUSAs until both content and (duplicative) non-content information has been obtained via search warrant or to seek an order permitting disclosure of non-content information.

⁵² If the investigation becomes overt, of the civil and criminal AUSAs determine together that the risk of it becoming overt is worth the benefit, the civil AUSA could also serve a civil investigative demand for deposition testimony. Although the civil AUSA would be limited to those lines of questioning relevant to the government's civil claims and a Fifth Amendment colloquy might be well-advised, the overlap between the civil and criminal False Claims Acts means that such depositions would be likely to generate relevant information for both investigations and, as noted *supra*, the fruits of CID depositions may be freely shared with federal criminal investigators.

⁵³ *Sells Eng'g, Inc.*, 463 U.S. at 432.

hit the ground running as soon as an overt civil investigation is possible.

For example, once a principal receives a target letter or an arrest is made, the matter will be overt. The civil AUSA can then seek a tolling agreement or file a protective complaint and stay the civil action, eliminating the pressure from the statute of limitations. If criminal ultimately declines, the civil AUSA is still far better positioned, because they have claims and financial documents and have developed the case as far as possible before pressing pause.

The United States may have millions of dollars at stake in fraud investigations. The civil division's ability to recover these funds and the penalties Congress demands from fraudsters is an important federal interest. By ensuring documents that are not matters occurring before the grand jury are shared as freely as the law allows, the Not 6(e) motion permits truly parallel work by civil and criminal. That is intrinsically good and also good policy.

Of course, there are limits to cooperation, even in parallel matters. Consistent with *Sells Engineering*, Department policy, and simple fairness, a criminal AUSA may never issue a grand jury subpoena in an effort to gather evidence for an administrative or civil proceeding. They may also never start nor continue a grand jury inquiry where no criminal prosecution is likely.⁵⁴ Any such use of grand jury proceedings to elicit evidence for use in a civil case or administrative proceeding is improper per se.⁵⁵ Criminal AUSAs must only use the grand jury for investigation of criminal matters.

On the other hand, as the Supreme Court implicitly recognizes in *John Doe I* and expressly recognized in *United States v. Kordel*, "It would stultify enforcement of federal law to require a government agency . . . invariably to choose either to forgo recommendation of a criminal prosecution once it seeks civil relief, or to defer civil proceedings pending the ultimate outcome of a criminal trial."⁵⁶ In other words, there is nothing wrong with a grand jury subpoena that obtains information useful to both a criminal investigation and a

⁵⁴ See generally JUSTICE MANUAL, ORG. & FUNCTIONS MANUAL, ch. 27 n.1.

⁵⁵ Whether and when civil or administrative processes can be used to obtain information for a criminal prosecution is less well-established, but the Justice Manual recognizes that some courts may be concerned should the Department do so. See generally JUSTICE MANUAL, ORG. & FUNCTIONS MANUAL, ch. 27 n.1 (citing *United States v. Scrushy*, 366 F. Supp. 2d 1134 (N.D. Ala 2005)).

⁵⁶ *United States v. Kordel*, 397 U.S. 1, 10–11 (1970).

parallel civil investigation, as long as the information was only originally obtained for a proper criminal purpose. Indeed, almost every criminal investigation into a federal healthcare offense involving Medicare, Medicaid, or TRICARE will give rise to evidence of a parallel civil violation, given the near-complete overlap between 18 U.S.C. § 287 and 31 U.S.C. § 3729(a) and the relevance of proof in cases under 18 U.S.C. §§ 1001, 1035, and 1347 to civil violations.⁵⁷

In other words, both the Supreme Court and Department policy recognize that information properly obtained by a grand jury subpoena may be useful in both criminal and civil investigations, but such information may only ever be sought for a proper (that is, criminal) purpose. If that test is met, however, a grand jury subpoena does not become improper simply because the information it obtains is also useful in a civil investigation or because the AUSA who issued that subpoena on behalf of the grand jury was aware information returned from it could be used in a civil investigation (as in *John Doe I*, by the same prosecutor in a subsequent, civil capacity). As the Justice Manual describes, there is a fine line that all AUSAs must walk in coordinating overlapping civil and criminal investigations: Each AUSA must use the process available to them only for the purposes of their investigation, and AUSAs may share thoughts on the material that each needs to obtain before they act, so long as each ultimately acts based on the needs of their investigation and not the parallel one.

By wisely sequencing investigative tools, criminal and civil AUSAs can fully cooperate without worrying about Rule 6(e). Even where achieving that goal is no longer possible, however, using a Not 6(e) motion to expressly permit sharing pre-existing business information can bolster both investigations, returning the matter to the parallel

⁵⁷ The overlap between criminal fraud charges and the elements of the civil FCA has been repeatedly recognized by courts, including by precluding individuals convicted of federal fraud offenses from contesting their violation of the civil FCA. *See, e.g.* *United States v. Aleff*, 772 F.3d 508, 510–11 (8th Cir. 2014) (collateral estoppel in civil action based on conviction for violation of 18 U.S.C. § 286); *United States v. St. Luke's Subacute Hosp. & Nursing Ctr., Inc.*, No. C 00-1976, 2004 WL 2905237 (N.D. Cal. Dec. 16, 2004) (collateral estoppel in civil FCA action based on conviction for violation of 18 U.S.C. § 287); *United States v. Thomas*, 709 F.2d 968 (5th Cir. 1983) (collateral estoppel in civil action based on conviction for violation of 15 U.S.C. § 714m). *Cf.* *United States ex rel. Doe v. Heart Sol., PC*, 923 F.3d 308, 314–17 (3d Cir. 2019) (no collateral estoppel because conviction for violations of 18 U.S.C. § 1347 was of executive, not company).

track the Justice Manual contemplates and leaving both civil and criminal in a better position ultimately to succeed.

IV. Special issues for civil practice relating to grand-jury-acquired documents

A Not 6(e) motion is not necessarily intuitive, but an AUSA who understands and anticipates the handful of mechanical and legal issues they raise can navigate them without difficulty.

A. The mechanics of parallel motion practice

When contemplating filing a Not 6(e) motion, the first problem is a practical one: The civil AUSA knows what the civil investigation wants, but not what the criminal AUSA may have obtained using a grand jury subpoena. The criminal AUSA knows what has been obtained but cannot—until the motion has been granted—freely share that information.

There are likely several ways to solve this issue, but the easiest is communication. The civil AUSA can explain or prepare a motion describing the type or categories of pre-existing documents that the civil investigation seeks if those records exist and if they have been obtained through a grand jury process. The criminal AUSA can pare the actual request to those records that have been obtained in that matter. The criminal AUSA can either prepare a motion or take the draft motion from the civil AUSA, revise it, affix a caption, and direct its filing to the judge supervising the grand jury that issued the subpoenas.⁵⁸

For other, more conservative courts and U.S. Attorneys' Offices, another approach exists.⁵⁹ In this approach, the criminal AUSA lists the specific documents that will be disclosed in the motion itself, rather than providing a categorical list to the court. The criminal AUSA may also include a provision permitting disclosure of other documents in the same categories that are obtained in the future

⁵⁸ In practice, the E.D. Pa. has had the greatest success where the civil AUSA drafts the “wish list” version of the motion, citing the local decisional precedent and walking the court through the *Dynavac* analysis, and the criminal AUSA narrows the draft to those pre-existing documents that have been obtained and that would not collectively reveal the grand jury's thought process.

⁵⁹ This practice is the most common in the E.D. Pa., on account of the diversity of local judicial opinions over the last forty years here.

criminal investigation to avoid having to file numerous Not 6(e) motions on the same subject matter.

Regardless of the music playing, the basic dance steps are the same: The civil AUSA prepares a wish list, and the criminal AUSA narrows it or adds any details considered proper, files the motion, and, if necessary, conducts oral argument on it. Once the motion is granted, the civil AUSA can be given access to the covered materials.

B. How much is too much and when to stop

As noted above, there are no crystal-clear jurisprudential signposts regarding exactly how much information discloses the grand jury's thought process. It is a case-by-case determination. Accordingly, any attempt to answer the question of how much is too much is necessarily somewhat speculative. But the existing signposts are still helpful, and they should be followed.

As detailed in the cases cited above, basic transactional, accounting, and banking information will rarely disclose the thinking of the grand jury, but requests for all documents subpoenaed by the grand jury, a list of all documents obtained by the grand jury, or the like most often will. Likewise, criminal AUSAs should not ordinarily unilaterally share documents specially prepared for the grand jury, such as auditor responses to its request or summary charts created in response to a subpoena. These would be very useful for civil, of course, but most courts have suggested that these are matters occurring before the grand jury. To minimize the risk of subsequent adverse judicial action, these materials should only be disclosed, if at all, after a highly specific, targeted Not 6(e) motion.

Similarly, testimony taken in the grand jury should not be shared with civil absent judicially determined particularized need (such as when a section 1345 injunction is being sought). The local precedent affects whether this wall should be erected when a grand jury subpoena for testimony has issued but the prospective witness chose to participate in a voluntary interview instead. As the Third Circuit decisions in *Garden Court* and *Catania* show, there can be considerable difference of opinion on how Rule 6(e) applies to preparation for grand jury presentations. Sensitivity to local judicial sentiment is wise, and caution may be advised considering the judiciary's historical protection of grand jury secrecy.

C. Rule 6(e) and personal financial records

One final note concerns the Right to Financial Privacy Act (RFPA).⁶⁰ RFPA protects banking privacy by limiting the process that can obtain these records and setting requirements for notifying the individuals whose records were obtained. The concern with RFPA is reasonable, particularly as some courts appear to broadly share it.⁶¹

The stronger view is that RFPA does not impede parallel investigations for several independent reasons: (1) RFPA does not apply to corporate records at all;⁶² (2) sharing records does not

⁶⁰ Right to Financial Privacy Act, 12 U.S.C. §§ 3401–3420, 3422.

⁶¹ See, e.g. *United States v. Residence Located at 218 3rd St.*, 622 F. Supp. 908 (W.D. Wis. 1985) (holding that any ambiguity in interpretation of RFPA should be construed against the government in light of cited legislative history that says RFPA “requires that the records be actually presented to the grand jury and used only for the purposes of the grand jury investigation, i.e. indictment and prosecution,” notwithstanding the contrary text of the statute), *overruled on other grounds*, 805 F.2d 256 (7th Cir. 1986).

⁶² Because RFPA’s strictures only apply to records of individuals or partnerships of five or fewer individuals, RFPA does not apply to (or constrain the sharing of) bank records of corporations, large partnerships, limited liability corporations, and unincorporated associations. See 12 U.S.C. § 3401; *Chao v. Cmty. Trust Co.*, 474 F.3d 75, 81–83 (3d Cir. 2007); *Pittsburgh Nat’l Bank v. United States*, 771 F.2d 73 (3d Cir. 1985); *Spa Flying Serv. Inc. v. United States*, 724 F.2d 95, 96 (8th Cir. 1984) (per curiam); *Donovan v. Nat’l Bank of Alaska*, 696 F.2d 678, 683 (9th Cir. 1983).

constitute a “transfer” for RFPA purposes;⁶³ and (3) any transfer that occurs is permissible because it is for law-enforcement purposes.⁶⁴

In virtually every case, the notification of transfer—if it is required at all—will already be tolled by an order permitting delayed notification under 12 U.S.C. § 3409(a), which criminal can obtain to protect its investigative process.⁶⁵

⁶³ Section 3412(a) of Title 12 requires a written certification before any RFPA-protected records may be transferred between “agenc[ies]” or “department[s].” For many years, the Department expressly considered intradepartmental transfers of protected financial information excepted from section 3412. See JUSTICE MANUAL, Crim. Resource Manual Section 420 – Interagency Transfers of Financial Records (now defunct). There is no corresponding statement in the Justice Manual, but the Department’s position was and is almost certainly correct. See *Trump v. Deutsche Bank AG*, 943 F.3d 627, 640–45 (2d Cir. 2019) *rev’d on other grounds*, *Trump v. Mazars USA, LPP*, 140 S. Ct. 2019 (2020) (examining the definitions of “department” mean and concluding that a “department” must typically be headed by a cabinet official); *Sussman v U.S. Marshals Serv.*, 808 F. Supp. 2d 192, 203–04 (D.D.C. 2011) (holding under Privacy Act that transfers between DEA and USMS, the Executive Office for U.S. Attorneys and a USAO, the FBI and the Department Inspector General, the INS and Department prosecutors, and FBI and the Department were transfers between Department units, not between “agencies” of the United States); *Dick v. Holder*, 67 F. Supp. 3d 167, 177 (D.D.C. 2014) (same).

⁶⁴ Section 3420(a)(2) of Title 12 limits the use of any RFPA-protected information obtained by a grand jury to criminal prosecution or purposes permitted by Section 3412(a), which permits sharing where records are “relevant to a legitimate law enforcement inquiry.” Section 3401(8) defines “law enforcement inquiry” as “a lawful investigation or official proceeding inquiring into a violation of, or failure to comply with, any criminal or *civil* statute.” (emphasis added). There can be no question that FCA investigations conducted pursuant to the authority of the United States are lawful, official proceedings inquiring into the violations of a civil statute. Thus, RFPA allows criminal to transfer personal banking records to civil in pursuit of such an investigation, but in any case, one can remove any risk of violating Section 3412’s requirements by having a civil AUSA formally notify the criminal AUSA that the records are sought for use in a civil FCA investigation (and thus a “law enforcement inquiry”) before the disclosure.

⁶⁵ *Cf.* 12 U.S.C. § 3405 (requiring notice to the customer). A court may permit delayed notification if the investigation is being lawfully conducted, the records are relevant to the investigation, and notice would engender life or property, lead to flight from prosecution, destruction of or tampering with evidence, intimidation of potential witnesses, or would seriously jeopardize an ongoing investigation. See 12 U.S.C. § 3409(a).

Section 3412 contains its own notice requirements for any transfer of records. Even assuming contrary to the foregoing analysis that there is a

In short, a prepared prosecutor can manage whatever strictures RFPA imposes without difficulty.⁶⁶

V. Conclusion

Federal Rule of Criminal Procedure 6(e) poses a challenge to parallel investigations, but that challenge can be surmounted. In most cases, AUSAs can avoid issues by using tools other than the grand jury to accomplish the government's objectives. Even in the cases where grand jury subpoenas have been or must be employed, however, pre-existing business records are usually not matters occurring before the grand jury. By acting with proper deference to a district court's role, AUSAs can avoid sequential, duplicative investigations; capture the full value of cooperation in their investigations; and fulfill the Justice Manual's mandate to effectively deploy the full array of tools Congress has afforded prosecutors to combat fraud.

About the Author

Paul Kaufman has been an Assistant U.S. Attorney in the U.S. Attorney's Office for the Eastern District of Pennsylvania since 2007 and a member of its Affirmative Civil Enforcement Strike Force since its inception in 2018. He represents the United States in civil False Claims Act matters and a small number of criminal matters and teaches a law school class on the investigation and prosecution of healthcare fraud at both the University of Pennsylvania and Temple University. He gets unduly excited about things like figuring out what a matter occurring before the grand jury is, and he is blessed to have supervisors willing to support his legal nerdism. He earned his J.D. from Yale Law School and his undergraduate degree with honors from the University of Chicago.

"transfer" when criminal shares with civil, Section 3412(b) states that notice of transfer may be delayed if the government has obtained a section 3409(a) order permitting delayed notification.

⁶⁶ This section summarizes the works E.D. Pa. has done on the Rule 6(e) RFPA intersection. Any Department attorney or investigator with questions should feel free to reach out to the author or AUSAs Veronica Finkelstein or Tony Scicchitano to discuss these issues more fully.

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Web of Fraud: *United States v. Anwar* Offers Crucial Insight into Clinical Trials

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I. Introduction

During the ongoing COVID-19 pandemic, clinical trials have gained a new importance in everyday parlance and imagination. Even as we eagerly devour the media-reported results of the latest clinical study examining a vaccine or treatment, how many of us fully understand how clinical trials are conducted and regulated, how data is reported, and how the results are used? In a three-week jury trial in November 2019, a Richland, Washington, laboratory owner and his two companies were tried and convicted for 47 counts of fraud, conspiracy, and opioid diversion, stemming from his falsification of numerous clinical trials. This case provides a fascinating window into **just** how dependent on trust our public health systems are, and how our controls and safeguards can be subverted by an individual for his own financial gain, putting millions of Americans at risk in the process.

II. Overview of Clinical Trials

A. Historical use of clinical trials

The basic concept behind the clinical trial is ancient and has been used throughout history. In the Book of Daniel, King Nebuchadnezzar of Babylon conquered Jerusalem and took Daniel and three other young men captive to be assimilated into Babylonian society.¹ Daniel, refusing to be assimilated, resisted eating the rich food and wine offered to him. Daniel's Babylonian handler liked him but feared he would get in trouble because Daniel and his friends would look frail if they did not partake in the royal food and drink. Daniel instructed his handler to conduct a clinical trial: He told the handler to feed him and his friends only vegetables and water for 10 days, and then to compare their appearance with those of other young men who ate the royal food

¹ *Daniel* 1:1-15 (New International Version).

and drink. The handler had a reasonable hypothesis that the richest and most expensive food would lead to optimal and obvious physical health. But Daniel's clinical trial disproved it. After 10 days, he and his friends "looked healthier and better nourished" than those who had eaten and drank the best the realm had to offer.²

In 1025, the Persian clinician and polymath Avicenna (Ibn Sina) provided detailed advice regarding how to study medicines and medical interventions by comparing results with a control group in his groundbreaking medical text, *The Canon of Medicine*, that remained in use in the Ottoman Empire for hundreds of years. These principles were put to use, albeit unintentionally, in an early clinical trial conducted by the Ottoman Empire's then-ally, France, during the Italian Wars of the 16th Century. Decades of war and overextended supply lines had deprived French combat medics of the boiling oil used in the field to cauterize wounds to prevent infection.³ French military surgeon, Ambroise Paré, devised a replacement using what he had on hand—turpentine, egg yolk, and rose oil—but, as he described in his journal, he feared that this would prove a poor substitute for the boiling oil and lead to greater rates of infection.⁴ Again, a reasonable hypothesis; boiling oil to cauterize wounds was the standard of care to treat gunshot wounds and had been since firearms became widespread in military combat. But again, clinical data provided a counterintuitive finding. Paré documented that soldiers treated with his liniment, and the bandaging that he used to cover it, suffered much lower rates of infection, and had far better outcomes, than those that he had previously treated with the boiling oil.⁵ From that point forward, Paré, using his data, advocated for a new standard of care, liniment and bandaging, rather than boiling oil.

B. Modern clinical trials

Aided by enlightenment thinking and the advent of the scientific method, in the 17th Century medical professionals and scientists began intentionally devising controlled clinical trials, using placebos and, eventually, blinded and double-blinded trials to study medical

² *Id.* at 1:15.

³ See Emma M. Nellhaus & Todd H. Davies, *Evolution of Clinical Trials Throughout History*, 3 MARSHALL J. MED. (2017).

⁴ *Id.*

⁵ *Id.*; see also Lisa O'Sullivan, *Ambroise Pare on Gunshot Wounds*, N.Y. ACAD. OF MED. (Aug. 25, 2016), <https://nyamcenterforhistory.org/2016/08/25/ambroise-pare-on-gunshot-wounds-item-of-the-month/>.

interventions by isolating as many variables as possible. Those efforts, in turn, gave way to the modern clinical trial.

1. Phases of clinical trials

Clinical trials of drugs and vaccines are regulated in the United States by the Food and Drug Administration (FDA), which has divided them into several phases.⁶ During the pre-clinical phase, which does not involve FDA regulation or approval, researchers study conceptual possibilities of drugs without testing them on humans. For example, if you have seen articles explaining whether a particular experimental vaccine produced an immune response under laboratory conditions, that is, in a cell culture in a petri dish, those are the types of pre-clinical results that assist researchers in determining which drugs might be worthy of further study. During the pre-clinical phase, researchers also study experimental medications on model organisms such as rats. These experiments provide valuable information regarding possible side effects as well as what might be a safe dose for humans.

Phase I trials are dedicated to drug safety and test experimental medications on a very small number (often fewer than 100) of healthy volunteers to identify some of the most serious potential adverse-event vectors, as well as how experimental medications are metabolized by the body.⁷ The primary purpose of Phase I trials is to assess whether the investigational drug can be safely tested for efficacy.⁸ Approximately 70% of investigational drug products pass this threshold and proceed to Phase II.⁹ During Phase II, the efficacy of the drug on humans is first studied by testing it on between 100 and 300 adults with a specific disease to assess potential side effects and whether the drug works. It also identifies a specific therapeutic dose, or doses, of the investigational product.¹⁰ Only one-third of Phase II drugs show sufficient efficacy and safety to proceed to Phase III. During Phase III, thousands of participants with a specific medical condition or disease are tested with the specific therapeutic dose of the drug. Their medical conditions, including any adverse events, are

⁶ See 21 C.F.R. § 312.21.

⁷ 21 C.F.R. § 312.21(a).

⁸ See *id.*

⁹ *The Drug Development Process Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> (updated Jan. 4, 2018) [hereinafter FDA Clinical Research].

¹⁰ 21 C.F.R. § 312.21(b).

closely monitored by medical professionals as well as clinical researchers.¹¹ Phase III trials are conducted by comparing results from an experimental medication with results for patients with the same condition who received a placebo. Phase III trials are double-blind, meaning that neither the patient nor the researcher who is compiling the data are aware which patients are receiving the placebo and which are receiving the experimental medication. Phase III trials produce detailed clinical data concerning the efficacy and safety of the therapeutic dose of the drug in humans.

Drug sponsors compile and review Phase III trial data to determine whether to seek FDA approval for the drug and dose for sale and marketing in the United States through a process called a New Drug Application (NDA). FDA reviews the NDA and trial data to determine if the drug can be used safely and if the benefits of the drug outweigh the harm. If FDA determines that the drug is safe and effective, and that the benefits outweigh the harm, FDA will approve the specific dose for the specific indication and will provide the drug sponsor with the authority to market the drug for the specific indication.¹² *See* 21 C.F.R. § 312.125. This process, however, is highly regulated. The FDA not only approves the dose and the medication, but also the packaging, including the warning information provided to patients and providers regarding potential side effects and contraindications. These are medical or other conditions (for example, pregnancy) that make a drug more likely to cause harm and, therefore, create special populations for which the drug should be avoided or closely monitored. While individual physicians may use their medical judgment to prescribe drugs for a use outside its approved use, pharmaceutical companies and their officials may be subject to criminal and civil penalties and sanctions in certain circumstances where the off-label marketing of a drug renders it misbranded.¹³

2. Regulation of human clinical trials

Before testing the drug on humans, a pharmaceutical company or other interested party known as a sponsor must file and receive

¹¹ FDA Clinical Research, *supra* note 6; 21 C.F.R. § 312.21(c).

¹² *See* 21 C.F.R. §§ 314.105, 314.125.

¹³ *See* 21 U.S.C. §§ 331(a), 333(a)(1), 352(f)(1); 21 C.F.R. §§ 201.5, 201.128. Off-label marketing of drugs paid for by Medicare or Medicaid also may lead to liability where the marketing causes false claims to be submitted under the False Claims Act, which gives rise to treble damages and penalties. *See, e.g., U.S. ex rel. Polansky v. Pfizer*, 822 F.3d 613 (2d Cir. 2016).

approval for an Investigational New Drug (IND) application with FDA.¹⁴ The contents of an IND are set forth in 21 C.F.R. § 312.23.¹⁵ Most sponsors do not conduct their own clinical trials. Instead, they contract with pharmaceutical research companies known as Contract Research Organizations (CROs), which in turn contract with research sites all over the country to actually perform the trials.¹⁶ Individual research sites may be health-care providers; academic, quasi-governmental, or non-profit institutions; or for-profit research companies.

Each site at which patients are participating in the trial must have a Principal Investigator (PI), who is typically, but not always, a medical doctor.¹⁷ If the PI is not a medical doctor, the PI works closely with a medical director for the study to ensure patient safety and that patients who participate in the trial provide informed consent to the experimental medication. Informed consent has been called the cornerstone of modern medicine and is specifically required by FDA regulation.¹⁸ Each subject must provide informed consent to participate in the study; must have an opportunity to have questions answered and concerns addressed by the PI or medical director; and may withdraw consent at any time.¹⁹ CROs evaluate individual sites and PIs as well as each site's plan for carrying out the study. CROs collect data from each site for multiple reasons: (1) to ensure the personnel are adequately trained in carrying out the trial; (2) to ensure that patients provide informed consent to participate; (3) to oversee the administration of the experimental medication; and (4) to make sure the sites are correctly carrying out the study in accordance with what is known as the study protocol.²⁰

A study protocol is a detailed document that sets forth each step for conducting a trial, each piece of data that must be collected, and each parameter for inclusion as well as exclusion of a new prospective subject from the trial.²¹ Rigorous adherence to the protocol is critical to ensure the safety of the drug trial for the participants as well as for

¹⁴ 21 C.F.R. § 312.20.

¹⁵ 21 C.F.R. § 312.23.

¹⁶ *See* 21 C.F.R. § 312.52.

¹⁷ *See* 21 C.F.R. § 312.53.

¹⁸ 21 C.F.R. § 312.60.

¹⁹ *See* 21 C.F.R. § 50.25.

²⁰ 21 C.F.R. §§ 312.50, 312.52.

²¹ 21 C.F.R. §§ 312.22, 312.30.

the integrity and accuracy of the data to be relied upon by the FDA in making its drug-approval decisions.

By FDA regulation, in addition to monitoring and oversight of the PI, CRO, and sponsor, a clinical trial must be overseen by an Institutional Review Board (IRB) in accordance with 21 C.F.R. Part 56. Research sites and PIs are responsible for reporting material deviations from the protocol to the IRB and are similarly responsible for reporting serious adverse events (SAEs) to the IRB so that potential side effects and contraindications can be assessed.²² An IRB may cease a patient's participation in the study or halt the entire study, if it determines it is necessary to do so to protect patient health.²³

SAE reporting is critical, and the obligation to report SAEs extends far beyond events that are obviously connected to use of the experimental drug product. For example, if a study participant gets into a car collision and is injured, that is likely an SAE that requires reporting. While an individual car collision may have nothing to do with the experimental product, it is also possible that a medication could alter reaction time or cause more risky behavior, leading to an increased risk of car collisions. Such a relationship can only be understood with robust reporting of SAEs and analysis of the data.²⁴

For studies involving experimental drugs, drug accountability is critically important. The experimental drug is, by its very nature, untested and unapproved. Its use must be carefully monitored, and each dose must be accounted for to ensure that it is being safely used in accordance with the protocol and that drug-efficacy data can be relied upon.²⁵ Drug accountability is most commonly accomplished through an interactive response technology (IRT). Most IRTs are web-based systems through which research sites enter anonymized data in real time as each dose is dispensed. CROs and sponsors collect and monitor this data to ensure that each dose of experimental product is accounted for.

The end result of any clinical trial is a complex dataset tracking the efficacy and safety of the experimental medication over thousands of anonymized patients with different backgrounds and in different locations, often over weeks or months of study. Most trials use an

²² See 21 C.F.R. § 312.66.

²³ See 21 C.F.R. § 56.113.

²⁴ See 21 C.F.R. § 312.32.

²⁵ See 21 C.F.R. § 312.61.

electronic data capture (EDC) system by which individual research sites record and submit data to CROs for monitoring. This enables CROs and sponsors to identify data anomalies, trends, and concerns, and to ensure that data capture is uniform, and its accuracy and integrity can be relied upon by sponsors and FDA.

3. Privacy law and clinical trials

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”²⁶ Research involving human subjects is also subject to the Common Rule regarding privacy²⁷ and the FDA’s human subject protection regulations,²⁸ which also protect the privacy of health information for human clinical research subjects. In general, sponsors, an IRB, and the FDA only have access to anonymized information for which personally identifying information has been removed.²⁹ Clinical research in the United States places a tremendous amount of trust in the site actually conducting the research because sponsors, the IRB, and the FDA are not permitted to learn the identities of the individual subjects or discuss their participation in the trials with them. For the safeguards and controls discussed above to function properly, PIs and clinical research sites must commit to following them and adequately train personnel to carry out the research appropriately and in accordance with the study protocol.

III. *United States v. Sami Anwar*³⁰

Fraud and wrongdoing involving scientific research intended to benefit humanity is sadly nothing new. For example, in 2016, the owner of a Colorado energy company pled guilty to falsifying research data from carbon-sequestration wells. He received federal grant funding to design and dig to provide valuable information regarding

²⁶ 45 C.F.R. § 164.501.

²⁷ See 45 C.F.R. §§ 46.101–46.116.

²⁸ See 21 C.F.R. §§ 50.1–50.56, 56.101–56.124.

²⁹ See, e.g., 45 C.F.R. §§ 164.502(d), 164.514.

³⁰ *United States v. Sami Anwar*, 18-cr-6054 (E.D. Wash., Oct. 6, 2020).

potential climate-change-mitigation technology.³¹ Instead of digging the wells, he fabricated the data and used the money to purchase expensive jewelry and lavish international travel.³² He was ultimately sentenced to 18 months in prison and had to pay a \$14.4 million penalty pursuant to the False Claims Act.³³ As another example, in 2019, Duke University paid \$112.5 million to resolve allegations that it falsified research data from at least 30 federal grants regarding research on mice it was conducting in its Airway Physiology Laboratory, which studies respiratory and pulmonary disease.³⁴

Even beyond other types of scientific and research misconduct, however, clinical trial research fraud creates a unique and heightened danger to patient and public health and safety. Not only does clinical trial fraud endanger the public who will rely on the integrity of the data to ensure the safety and efficacy of the drug, but it also endangers thousands of research subjects who are voluntarily using an experimental and untested product with unknown and unstudied dangers and side effects. This is particularly true given the inherent trust placed in PIs and research sites, considering sponsors and regulators are prevented by privacy laws from directly interacting with research subjects. Against the backdrop of the ongoing COVID-19 pandemic, *United States v. Sami Anwar*³⁵ provides an instructive example into the vital importance of the integrity of clinical research and how the controls and safeguards that protect it are subject to abuse and circumvention by a motivated fraudster out for his own gain.

A. Principal investigator

To perform human clinical research, FDA regulations require a PI who personally carries out the study.³⁶ All aspects of the study, including research staff involved in carrying it out, must be under the

³¹ Press Release, Dep't of Just., Colorado Energy Company Executive Pleads Guilty to Filing a False Claim Against the U.S. (Oct. 21, 2016).

³² *Id.*

³³ Press Release, Dep't of Just., North American Power Group Ltd and its Owner Agree to Pay \$14.4 Million to Resolve Alleged False Claims for Department of Energy Cooperative Agreement Funds (July 6, 2018).

³⁴ Press Release, Dep't of Just., Duke University Agrees to Pay U.S. \$112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct (Mar. 25, 2019).

³⁵ *United States v. Sami Anwar*, 18-cr-6054 (E.D. Wash., Oct. 6, 2020).

³⁶ See 21 C.F.R. § 312.60.

immediate direction of the PI.³⁷ Pursuant to 21 C.F.R. § 312.60, “[a]n investigator is responsible for ensuring an investigation is conducted according to” the protocol and all applicable regulations; “protecting the rights, safety, and welfare of subjects under the investigator’s care”; and “control[ing] the drugs under investigation.” PIs are typically medical doctors. In other situations, PIs partner with a medical doctor who serves as medical director for the study. PIs who repeatedly or deliberately fail to comply with their obligations are subject to disqualification from conducting further research, which, coupled with the PI or medical director’s medical license, provides a regulatory safeguard that PIs ensure studies are properly and safely carried out.³⁸ PIs must personally certify to FDA on an FDA Form-1572 that they will comply with all applicable requirements, personally conduct or directly supervise all aspects of the study, and assume responsibility for the health and safety of the participants and the accuracy of the data.³⁹

In *Anwar*, however, according to the witnesses who testified at trial, the defendant, Sami Anwar, who was not a licensed medical doctor, used the names of medical doctors who were PIs in name only and routinely forged their signatures on the FDA Form-1572s and other documents.⁴⁰ The doctors he used as PIs frequently did not know about the studies at all. In other situations, they were vaguely aware studies were taking place, but thought they were still attempting to secure subjects. Anwar, however, had filled the study with subjects without regard to their eligibility or whether they even had the requisite medical condition being studied. Anwar also routinely posed as the PI on the phone and sent emails from the PIs’ email accounts. He required his staff to come to him with any research-related concerns and forbade them from contacting or speaking to his PIs unless he was present. By Anwar’s design, research subjects typically had no interaction with the PI that was purportedly treating them and supposedly personally conducting the research. When CRO monitors came to the site to speak to the PI, they were invariably told that he was unavailable that day because he was seeing patients.

³⁷ 21 C.F.R. §§ 50.3(d), 312.53.

³⁸ 21 C.F.R. § 312.70(a).

³⁹ 21 C.F.R. § 312.53(c).

⁴⁰ References to the *Anwar* trial are to the sworn testimony provided by witnesses who testified during the criminal trial. The complete transcript from the trial is publicly available on PACER at <http://pacer.uscourts.gov>.

When they insisted on meeting with the PI, Anwar was there and answered all questions about the study.

Anwar's efforts ultimately resulted in the CROs and sponsors expressing grave concerns regarding his site's efforts. Because FDA regulations place responsibility on the PI, these concerns were expressed as to the PI that was, on paper, responsible for the study. Some sponsors took action to block Anwar's PIs from any further study with that sponsor. At one point, the FDA placed Anwar's company and one of his supposed PIs on its public warning list. When this happened, Anwar found a new puppet PI whose license he could use by targeting a doctor whose family practice was financially underwater and who was in deep personal debt. Anwar enticed him with promises of financial bailout. He then created a new company name associated with the new puppet PI, and thus, the warning list was thwarted, allowing the fraud to continue.

B. Informed consent

As discussed above, obtaining the informed consent of each subject to participate in the study is a critical safeguard for clinical research and a legal requirement.⁴¹ Informed consent is more than a form that is signed by a PI and a research subject, but rather a continuing process that begins before any research is conducted and continues until the study ends or the subject withdraws consent, which can occur at any time. Informed consent requires that a prospective subject has a legal right to be fully informed regarding the benefits, risks, and harms of the study medication, both known and unknown.⁴² A prospective subject must have the opportunity to have questions or concerns regarding the study addressed by a medical professional who is knowledgeable about the patient and the study. Minors must have a parent participate in the informed consent process.⁴³ During the course of the study, a subject may withdraw consent at any time and cannot be coerced into continuing to participate.⁴⁴

Anwar never allowed his supposed PIs to participate in the informed-consent process. Nor did he or his staff take the time to sit down with prospective subjects and discuss the potential benefits and risks of the study to ensure they were fully informed. Rather, he had

⁴¹ See 21 C.F.R. § 50.20.

⁴² See 21 C.F.R. § 50.25.

⁴³ See 21 C.F.R. § 50.55.

⁴⁴ 21 C.F.R. § 50.25(a)(8).

study coordinators who were not knowledgeable about the study and had no research background ask subjects to simply sign the required forms as part of the paperwork. If prospective subjects had any questions or concerns and refused to sign the paperwork until they were addressed, the study coordinators would fetch “Dr.” Anwar, who was not actually a licensed medical doctor but would pose as one to negotiate their signatures. Sponsors, FDA, and the IRB could not meet directly with subjects due to privacy laws. They could compare signatures on informed consent forms with the subjects’ scanned driver’s licenses in the file, but they were not handwriting experts, and they had no other way to verify whether any meaningful informed-consent process actually took place.

C. Training of research staff

While PIs are required to personally conduct and supervise the studies, they are not expected to conduct the research alone. Rather, the rules contemplate that other individuals, often known as study coordinators, will be involved in the research. PIs are required to certify in the Form FDA-1572 that they will personally ensure that any “associates, colleagues, and employees assisting in the conduct of the study” are adequately trained and informed regarding the study.⁴⁵

As discussed above, Anwar’s PIs were in name only and were not sufficiently trained or informed regarding the study. They were only being used for their medical licenses. Anwar, rather than the PIs, taught study coordinators how to conduct the studies, made all decisions, and supervised them. By hiring study coordinators with no research or professional background, often from minimum-wage food-service or retail jobs, he both kept costs down and ensured that his word regarding the studies would go unquestioned. It often took months or longer for new study coordinators to learn enough about the studies to know that they were committing fraud.

D. Adverse-event reporting and protocol deviations

It is critical to the integrity of a study and the safety of its subjects that adverse events are documented and that SAEs are immediately reported to the sponsor and the IRB.⁴⁶ The FDA uses adverse-event reporting to make determinations regarding whether to approve the drug; if so, under what circumstances; and what side-effect and

⁴⁵ 21 C.F.R. § 312.53(c)(1)(vi).

⁴⁶ 21 C.F.R. § 312.64(b).

contraindication warnings must be included in the packaging. Sponsors and the IRB use adverse-event reporting to make decisions if a particular study needs to be suspended, or if a particular subject needs to be discontinued from the study for the protection of study participants. For example, in the midst of the coronavirus pandemic in fall 2020, vaccine trials were temporarily suspended worldwide due to a concern regarding an SAE that one of the study subjects experienced, until the event could be studied to determine if the vaccine was the cause.⁴⁷ Significant deviations from a study protocol, such as missed visits, must also be reported because such deviations may require that the data no longer be used or that the subject be removed from the study for the subject's own protection.

Anwar knew that reporting adverse events and protocol deviations could cause trials to be suspended or patients to be discontinued, both of which would result in lost revenue for him. He also knew that reporting adverse events would invite increased scrutiny and review of his research. Because he was the PI in all but name, he was functionally in control of all reporting. He typically directed his staff not to report adverse events and protocol deviations, even when they were significant. For example, when one of his subjects in a liver cirrhosis study experienced hives from the study medication and disruption in her menstrual cycle, he directed his employees not to report it. When a subject in an Alzheimer's trial experienced a violent episode in which he attacked his spouse, Anwar directed his employees not to report it. When that same subject passed away from kidney failure while enrolled in multiple simultaneous studies, he directed his employees not to report it. When a teenage participant attempted suicide during a study of a smoking-cessation drug known to cause suicidal ideations, Anwar directed his employees not to report it. In retrospect, study sponsors and CROs frequently identified the lack of adverse-event reporting as a red flag. But during the studies, by not reporting these events and keeping these subjects enrolled in the studies, Anwar avoided additional questions and kept the money coming in.

⁴⁷ E.g., Katherine J. Wu & Katie Thomas, *AstraZeneca Pauses Vaccine Trial for Safety Review*, N.Y. TIMES, <https://www.nytimes.com/2020/09/08/health/coronavirus-astrazeneca-vaccine-safety.html> (updated Dec. 17, 2020).

E. Inclusion and exclusion criteria

FDA regulations require that a study's protocol sets forth the inclusion criteria that must be met for a patient to be included in the trial, as well as the exclusion criteria that would disqualify a patient from participating.⁴⁸ Inclusion and exclusion criteria are critical in protecting the integrity and accuracy of the study data and the individual subjects in the study. Inclusion and exclusion criteria protect the integrity of the data by ensuring that study participants have the appropriate disease conditions and other factors being studied, and that they do not have other conditions or circumstances that could skew the data or jeopardize a patient's health. It is not sufficient to simply check a box that a subject meets inclusion and exclusion criteria. Research sites are expected to obtain medical records and other documentation to support inclusion in the study pursuant to the criteria in the protocol.

Anwar, of course, was neither concerned with the integrity of the study, nor with the safety of his subjects. He understood that following inclusion and exclusion criteria would result in far fewer, if any, subjects in his studies. Because sponsors pay on a per-subject basis, this would render his scheme ineffective. Anwar directed his staff to ignore inclusion and exclusion criteria and admit as many subjects as possible into the studies, without regard to whether they met the criteria. For example, one exclusion criteria, common to virtually all drug trials, is that the subject cannot be simultaneously enrolled in another clinical trial. This is necessary for both data integrity and subject protection because trial drugs are experimental. One cannot know how they might interact with each other, or which drug might be responsible for a beneficial result or an adverse reaction. For Anwar, however, subjects that were already enrolled in trials were primary and reliable revenue sources because they were known quantities and could be billed to multiple studies in one visit. Anwar, therefore, frequently directed a subject in one study to be enrolled in a different study at the same time, even if the subject did not have the requisite disease conditions or other inclusion criteria. Anwar also directed the creation and alteration of fraudulent medical documentation to support the patients' inclusion in the studies. When monitors visited the site and asked to review the documentation, it appeared to support their inclusion.

⁴⁸ 21 C.F.R. § 312.23(a)(6)(iii)(c).

F. Drug accountability

Drug accountability is critical to patient safety and reliability of the study data. Because the investigational product is untested and unapproved except for research purposes and could be extremely dangerous if used outside of a controlled and monitored study, PIs are required to maintain and document control of the investigational products and ensure they are given only to subjects under the PIs' direct supervision.⁴⁹ Sponsors and CROs typically use an IRT system to track and monitor the investigative product in real time, which ensures that each dose is tracked from the point of manufacture to the point of delivery to a research subject. CROs also routinely audit drug accountability by verifying onsite that the number of empty vials or blister packs match the exact number of doses reflected in the IRT system as having been dispensed.

Because the vast majority, if not all, of subjects in Anwar's studies either did not have the disease being studied or were otherwise not legitimately participating in the studies, they were frequently not taking the investigational drugs at all. Anwar attempted to thwart the IRT systems by throwing away the study medication or pouring it down the drain, falsely certifying in the IRT system that it had been dispensed and saving the empty container to show the CROs for drug accountability purposes. This became evident in one study involving the use of a slow-release buprenorphine shot to treat back pain in opioid-dependent patients. In addition to the weekly injection of the buprenorphine shot, which at Anwar's direction was simply deposited down the drain, study participants were given a daily regimen of hydrocodone rescue medication to take as needed when the study medication wore off. If the study drug was working as intended, those receiving the study medication would, over time, need less hydrocodone than those receiving the placebo.

We will likely never know if Anwar was concerned about the safety risk of throwing thousands of hydrocodone pills into the trash and into the community; if his concern was that this would get him caught; or if he intended to sell or use the pills in some other way. Whatever his reason, Anwar directed that the hydrocodone pills be removed from their bottles and hoarded in large resealable bags which were placed in an attic area. They then showed the resulting empty bottles to the CRO. When federal investigators executed a search warrant at

⁴⁹ See 21 C.F.R. §§ 312.61, 312.62.

Anwar's business, they located thousands of hydrocodone pills in large resealable bags in the attic and hundreds of hydrocodone pills in a bag in Anwar's desk.

G. Record retention, patient diaries, and data integrity

PIs and research sites are required to maintain documentation and records regarding the research they are conducting.⁵⁰ During site-monitoring visits, CROs frequently compare the onsite paper records to the data entered by the site into the EDC system to ensure the study data is accurate, supported, and can be relied upon by the sponsor and FDA. As part of the onsite documentation, some study protocols also required patients to complete their own diaries, journals, or other documentation in which they discuss their own subjective experience with the study. These datapoints are also entered into the EDC. This data can be very important, particularly in studies concerning pain, which there is no objective way to externally measure.

When subjects were not legitimately participating in the studies and missed visits, Anwar directed that his staff fabricate data and documentation to make it appear as though visits were taking place. He then forged the PIs' signatures on the documentation and directed that the same fabricated datapoints be entered into the EDC so they would match. When blood testing was required, he would pass off as subjects' blood the blood of unwitting patients and unwilling employees. With regard to patient diaries on the opioid back-pain study discussed above, patients were required to complete weekly journals. Because the patients were not actually participating in the study, Anwar directed that his staff forge these patient diaries, dictating that they hold the pen with their non-dominant hand or assume an awkward grip as they moved from diary to diary. He wanted to ensure that each journal entry's handwriting would have distinct handwriting when the CRO reviewed the journals. He compiled a cheat sheet that he disseminated to his staff telling them what datapoints to enter into the diaries, to ensure they matched the EDC and expected parameters.

⁵⁰ 21 C.F.R. § 312.62.

H. Employee reporting, whistleblowing, and retaliation

In addition to being able to report misconduct or fraud to a sponsor, CRO, or IRB, one critical safeguard in clinical research is that FDA maintains a reporting hotline through which concerns can be anonymously communicated by phone or email to the FDA's Office of Scientific Investigations.⁵¹ If an employee is concerned that a sponsor or CRO is reluctant to take action regarding misconduct, the employee can report concerns directly to the FDA or the IRB, which, in certain situations, is required to report directly to FDA.⁵² Anwar correctly surmised that his greatest risk of detection was one of his employees would turning him in. Indeed, courageous whistleblowers who could not stomach the thought that the fraudulent studies were hurting people and would hurt more people, were what ultimately brought him down, bringing all of the above, and much more, to light.

During the *Anwar* trial, dozens of Anwar's former employees, including PIs, expressed concerns that they were involved in research fraud at Anwar's direction. Many of these employees also testified that Anwar engaged in concerted harassment, intimidation, and retaliation to prevent them from reporting their concerns. First, Anwar electronically surveilled his employees by installing cameras and recorders everywhere in the facility and made sure that his employees knew they were being watched and listened to, discouraging them from openly communicating during the workday. He also regularly surveilled their work emails and, for some of his key employees, phone communications. Anwar regularly threatened his employees that he would use his connections to ensure that they never worked again in the clinical research field, and that he would ruin their lives if they spoke out. When CROs or FDA auditors showed up at his facility, he took steps to ensure that they did not have access to employees that he doubted were sufficiently loyal or that he considered to be bad liars. When employees left or Anwar was concerned that they would leave and report him, he took steps to preemptively discredit them by making false complaints that they harassed employees and patients or engaged in other types of

⁵¹ *Reporting Complaints Related to FDA-Regulated Clinical Trials*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/reporting-complaints-related-fda-regulated-clinical-trials> (updated July 31, 2018).

⁵² See 21 C.F.R. § 56.108(b).

misconduct. He also filed false reports with local police, state regulatory bodies, and the FDA. As he became concerned that he was under investigation, he ratcheted up his campaign of threats and retaliation. He stalked one former employee at her new job at a bank, passing her a note listing the names of employees he believed were cooperating with law enforcement and insinuating that if she were to cooperate, he would know. He threatened another employee whose spouse had a tenuous immigration status that he would ensure her husband would be deported and her family shattered if she cooperated. Another employee whom he believed to be disloyal found all four of her car tires mysteriously slashed on multiple occasions after she refused to assist Anwar in covering up his crimes. One employee, whom he correctly surmised to be a whistleblower, found herself framed for theft, reported to the local police, and the subject of a false complaint filed with the state licensing board over her Medical Assistant license.

IV. Conclusion

During the three-week jury trial in which this and other evidence came to light, Anwar, who did not testify, attempted to skirt responsibility by stating that he was merely a business owner; that PIs assume responsibility for conducting the studies; and that he could not, therefore, be held responsible. This strategy failed. He was convicted on all 47 counts and ultimately sentenced to 340 months of imprisonment, \$2 million in restitution, and over \$5 million in forfeitures.⁵³ While Anwar's efforts were ultimately unsuccessful, they enabled him to carry out his fraud for five years before he was ultimately arrested and prosecuted. During that time, he falsified dozens of studies, injecting corrupt data for thousands of patients in support of clinical studies for experimental medications designed to treat life-threatening diseases and conditions including diabetes, rheumatoid arthritis, bipolar disorder, cardiovascular disease, drug addiction, muscular dystrophy, and many others. He not only stole and diverted millions of dollars from legitimate and potentially life-saving research, but also endangered the lives of hundreds of his subjects and millions of Americans that rely on the results of the research every time they fill a prescription. Understanding the legal

⁵³ Press Release, Dep't of Just., Richland Business Owner Sentenced to More Than 28 Years in Federal Prison for Falsifying Human Clinical Research Trials (Oct. 2, 2020).

and regulatory safeguards that he circumvented, and the manner in which he circumvented them, is critical to holding others that engage in clinical-research fraud accountable and preventing it from occurring in the future.

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Fighting Health-care Fraud Through the Federal and State Partnership

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I. Introduction

Our first health-care-fraud trial in the Eastern District of Texas involved an ambulance-services provider who was fraudulently billing Medicare, Texas Medicaid, and Blue Cross and Blue Shield for transporting patients to dialysis treatment. The Department of Health and Human Services Office of Inspector General (HHS-OIG) was our lead investigative agency.¹ With HHS-OIG as the lead and the Medicare program bearing most of the fraud loss, Medicare was naturally the primary focus of the investigation and prosecution. As the investigation developed, however, the Texas Medicaid Fraud Control Unit became a key partner. Throughout the investigation and during trial preparation, coordination between the Medicare and Medicaid programs was increasingly important.

Medicare and Medicaid rules and regulations are often consistent with one another. Largely, this was the case in the ambulance context. During the investigation, we learned that, in some instances, when a fraudulent claim was submitted to the Medicare program, a fraudulent claim also was subsequently submitted to the Medicaid program. This phenomenon was the result of cross-over claims, which occur in cases when patients are dually eligible beneficiaries under both programs.

When the Medicare and Medicaid program rules are followed, the programs work together to provide health-care coverage to the beneficiaries who need them most. When the programs are defrauded and abused, both the government and the beneficiaries, who rely on these programs, lose.

¹ See generally *United States v. Read*, 710 F.3d 219 (5th Cir. 2012).

This article provides an overview of Medicaid, including the Medicaid Integrity Program (MIP). It also discusses the federal and state partnership with Medicaid, as well as the partnership and roles played by the State Program Integrity Units and Medicaid Fraud Control Units. It will conclude by offering considerations and practical tips to help prosecutors implement effective strategies for successful Medicaid-fraud prosecutions.

II. Medicaid and the Medicaid Integrity Program

A. Overview of the Medicaid program

Before Medicare and Medicaid, the Old-Age and Survivors Insurance (OASI) Trust Fund, commonly known as Social Security, was established in 1940. In 1957, the Federal Disability Insurance Fund was established. Together, these programs provided benefits to retired and disabled workers and their families, but they did not provide health insurance. In 1965, Congress amended the Social Security Act, creating the Medicare and Medicaid programs.

Medicaid is a federal and state entitlement program established to help pay necessary medical expenses for low-income adults, children, and families.² For enforcement purposes, Medicaid is a “health care benefit program,” as defined by 18 U.S.C. § 24(b), in that it is a public plan affecting commerce under which medical benefits, items, and services are provided to individuals and under which individuals and entities who provide medical benefits, items, or services may obtain payments. Medicaid is also a “Federal health care program,” as defined by 42 U.S.C. § 1320a-7b(f), in that it is a plan or program that provides health benefits, whether directly, through insurance, or otherwise, that is funded directly, in whole or in part, by the United States.

The Medicaid program is run by each state in partnership with the Centers for Medicare & Medicaid Services (CMS). States typically use a fee-for-service model where the state contracts with providers for services and then either processes claims and pays them directly or uses a Managed Care Organization (MCO) to process and pay claims while the state pays the MCO a capitated rate.³ The federal

² Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286.

³ *Provider payment under fee for service*, MACPAC, <https://www.macpac.gov/subtopic/provider-payment/> (last visited Mar. 1, 2022); *Managed Care*,

government funds the Medicaid program through the Federal Medical Assistance Percentages (FMAPs). Sections 1905(b) and 1101(a)(8)(B) of the Social Security Act set out the FMAP formula to calculate how much money the federal government will offer to states to help fund their Medicaid programs. Regardless of the calculation, the federal government's contribution is always at least 50% of the total program budget.⁴ Unfortunately, whether a federal or state program, there is at least one thing that they have in common: They are obligated to protect their respective program from fraud, waste, and abuse.

B. The Medicaid Integrity Program

The Deficit Reduction Act of 2005 (DRA) increased funding to combat fraud, waste, and abuse and protect the interests of Medicaid recipients.⁵ Following the passage of the DRA, CMS established the MIP to help secure the integrity of the Medicaid program.⁶ Under the MIP, various entities can enter into contracts to promote the integrity of the program by reviewing the “actions of individuals or entities furnishing items or services;” auditing “claims for payment for items or services furnished, or administrative services rendered;” receiving “overpayments to individuals or entities receiving Federal funds;” and providing “[e]ducation or training . . . with respect to payment integrity and quality of care.”⁷

Fighting health-care fraud is a priority for the Department of Justice (Department).⁸ As stated in the Justice Manual, “[t]hrough increased resources, focused investigative strategies and better coordination among law enforcement, the Department continues to upgrade its efforts in combatting the full array of fraud perpetrated by health care providers.”⁹ Protecting the integrity of federally funded health-care programs, such as Medicaid, protects individuals in need both now and in the future. Incorporating Medicaid into health-care-fraud cases reflects the priority recognized by the Department and honors the recipients of the program.

MEDICAID.GOV, <https://www.medicaid.gov/medicaid/managed-care/index.html> (last visited Mar. 1, 2022).

⁴ 42 U.S.C. 1301(a)(8)(A).

⁵ Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006).

⁶ 42 U.S.C. § 1396u-6.

⁷ 42 U.S.C. § 1396u-6(a), (b).

⁸ JM Section 9-44.100.

⁹ *Id.*

III. The federal and state partnership

Working with state agency partners is a vital part of the effort to combat health-care fraud. Knowing with whom to work in each state is key. An important partner in the fight against Medicaid fraud is with your state's Program Integrity Unit (PI Unit).

A. State program integrity units

State PI Units are not law enforcement agencies; however, they are charged with identifying, investigating, and referring suspected fraud and abuse cases to appropriate law enforcement authorities. Specifically, they are instructed to “(1) [r]eport fraud and abuse information to the Department; and (2) [h]ave a method to verify whether services reimbursed by Medicaid were actually furnished to beneficiaries.”¹⁰

PI Units are on the front lines receiving reports of Medicaid fraud. When a PI Unit “receives a complaint of Medicaid fraud or abuse from any source or identifies any questionable practices, it must conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation.”¹¹ If the preliminary investigation shows that fraud or abuse exists, PI Units will refer matters to their state Medicaid Fraud Control Unit (MFCU). If there is no MFCU referral, the PI Unit will conduct a full investigation into the matter.¹² It should be noted that once a PI Unit starts a full investigation, it must continue the investigation unless legal action is initiated, the case is dropped due to insufficient evidence, or the state agency resolves the matter between the beneficiary and the provider.¹³ In certain instances, the PI Unit is authorized to do the following in an effort to reach a resolution:

- (1) Send[] a warning letter to the provider or beneficiary, giving notice that continuation of the activity in question will result in further action;
- (2) Suspend[] or terminat[e] the provider from participation in the Medicaid program;
- (3) Seek[] recovery of payments made to the provider; or

¹⁰ 42 C.F.R. § 455.1.

¹¹ 42 C.F.R. § 455.14.

¹² 42 C.F.R. § 455.15.

¹³ 42 C.F.R. § 455.16.

(4) Impose[] other sanctions provided under the State plan.¹⁴

Therefore, the PI Unit is not only a source of referrals to the MFCUs but a stakeholder in the fight against fraud, waste, and abuse.

B. State Medicaid fraud control units

MFCUs are key partners in the fight against Medicaid fraud. MFCUs are charged with the investigation and prosecution of health-care providers that defraud state Medicaid programs.¹⁵ MFCUs work together with their respective state Medicaid agencies in this regard.¹⁶

MFCUs operate in each of the 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. MFCUs, usually part of the State Attorney's General office, employ teams of investigators, attorneys, and auditors.¹⁷

Federal prosecutors should be aware that MFCUs investigate not only health-care-fraud cases involving the state Medicaid program, but also state abuse cases. MFCUs are the only law enforcement agencies in the country that are specifically charged with investigating and prosecuting abuse and neglect in nursing homes, other Medicaid-funded health-care institutions, and board and care facilities. State abuse cases are a significant portion of each MFCU's case load. To maintain their annual certification with HHS, however, MFCUs must show that they "[cooperate] with OIG and other Federal agencies in the investigation and prosecution of Medicaid and other healthcare fraud" on a regular basis.¹⁸

MFCUs receive information from the PI Units about fraud in each state and are required to regularly communicate with federal agencies about health-care fraud. The MFCU can serve as an investigative resource as well as a bridge to the PI Unit. Enlisting the MFCU in

¹⁴ *Id.*

¹⁵ *Medicaid Fraud Control Units*, NAT'L ASS'N OF MEDICAID FRAUD CONTROL UNITS, <https://www.namfcu.net/medicaid-fraud-control-units1.php> (last visited Mar. 1, 2022).

¹⁶ 42 C.F.R. § 1007.9(d)–(e).

¹⁷ *Medicaid Fraud Control Units*, HHS OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/> (last visited Mar. 1, 2022).

¹⁸ Revision of Performance Standards for State Medicaid Fraud Control Units, 77 Fed. Reg. 32,645, 32,647 (June 1, 2012).

health-care-fraud enforcement efforts in your district can add great value to your investigations and prosecutions.

IV. Practical tips for working cases involving Medicaid fraud

A. Resources

There is strength in numbers. We recommend that, regardless of the breakdown of Medicare versus Medicaid dollars involved in your case, you should enlist HHS-OIG and MFCU as partners. The simple division of labor the partnership creates can be productive. Your MFCU agent will have easy access to Medicaid claims data and program witnesses, who will be able to explain and testify regarding your state Medicaid program. Your HHS-OIG agent will be able to do the same on the federal side, accessing Medicare claims data and provider-enrollment documents and identifying Medicare program witnesses for trial.

Criminals do not often discriminate when it comes to which federal benefits program they chose to defraud. In some regions, HHS-OIG offices and MFCUs may be working with limited resources and personnel. A partnership between HHS-OIG and MFCU can be a true force-multiplier in the fight against fraud. Together, HHS-OIG and MFCUs can work toward their common goal of fighting health-care fraud. The agencies can collaborate by serving on health-care-fraud task forces together and sharing case-specific investigative information, jointly monitoring health-care-fraud trends in their area.

MFCU auditors can also offer value to the investigative team. MFCU auditors provide helpful financial analysis in cases that often involve voluminous financial records. They can also help federal and state agents identify dually eligible beneficiaries for interviews, thereby allowing prosecutors to prove their cases with fewer witnesses. MFCU auditors and other MFCU personnel can also act as intermediaries with other state agencies such as state departments of health, departments of state, departments of vital statistics, and state workforce agencies. These relationships can prove helpful in obtaining state documents during an investigation and certified documents for trial.

MFCUs also have attorneys, some of whom are Assistant Attorneys General cross-designated as Special Assistant U.S. Attorneys (SAUSAs). MFCU SAUSAs are often experienced attorneys, many of

whom have backgrounds and specializations in civil or criminal health-care-fraud enforcement. Depending on the size of your district, the availability of prosecutorial resources in health care, and other considerations, SAUSAs may lead federal investigations or alternatively serve as co-counsel to an Assistant United States Attorney (AUSA). Depending on the experience of the SAUSAs, they can be enlisted to work closely with the agents during the development of the investigation and trial preparation, mastering the facts and details of the case and assisting AUSAs as cases proceed to charging and trial. Ultimately, SAUSAs can serve as force-multipliers for a United States Attorney's Office (USAO) and gain invaluable experience in the process. If your office does not have designated SAUSAs, reach out to your state MFCU and start a dialogue. Bringing in an Assistant Attorney General on a case-by-case basis could develop into a practice of enlisting their assistance more regularly.

B. Collaboration and communication

Preserving the integrity of federal and state health-care programs is a goal shared by all stakeholders. A prosecutor's decision to pursue criminal action or refer the matter for civil or administrative action should be thoughtful and informed. Federal health-care prosecutors should be familiar with their PI Unit and maintain regular communication with their MFCU. Collaboration and communication will help prevent issues that may negatively impact criminal, civil, or administrative enforcement actions. For example, if a PI Unit has elected to move forward with a full administrative investigation, efforts to conduct a covert criminal investigation may be undermined. Like working with the Office of Counsel to the Inspector General or Medicare Program Integrity contractors, communication is the key to productive working relationships and successful fraud investigations.

C. Relationships

Federal prosecutors should make efforts to establish and build relationships with state prosecutors' offices and local law enforcement. Individuals who report crimes often call or visit their local police department or contact their state or county prosecuting authority. As part of your office's outreach efforts, you and your Law Enforcement Coordinating Committee Coordinator should reach out to these partners. You could offer to host or speak at a "meet and greet" where you can explain the investigative role of HHS-OIG and the MFCU, as well as the USAO's role in prosecuting Medicare and Medicaid fraud.

Information on how to contact these agencies should be provided, if available. Developing and maintaining these relationships will go a long way to ensure that, when individuals contact their office to report crimes or other suspicious activity involving health care, your partners will know to call HHS-OIG, MFCU, and the USAO.

V. Conclusion

HHS has invested heavily in efforts to fight health-care fraud, including Medicaid fraud. As federal prosecutors, we should be familiar with the stakeholders and coordinate with the agencies that are charged with protecting the Medicaid program from fraud and abuse.¹⁹ Together, we can work to protect the integrity of federal health-care programs and ensure that resources are available to those who need them most.

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¹⁹ Pub. L. No. 115-123, § 50323, 132 Stat. 64, 202 (2018).

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All Bite but No Bark? Reassessing the Role of Civil Penalties in False Claims Act Cases

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There's no question that health-care fraud is big business. According to the National Health Care Anti-fraud Association, “[a] conservative estimate [of fraud] is 3% of total health-care expenditures, while some government and law enforcement agencies place the loss as high as 10% of our annual health outlay, which could mean more than \$300 billion.”¹ But the government is not without recourse. As reflected in the Annual Report of the Departments of Health and Human Services and Justice on the Health Care Fraud and Abuse Control Program, the United States obtained more than \$5.0 billion in health-care fraud judgments and settlements in Fiscal Year 2021.² And a significant portion of those recoveries were through the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733.

The FCA—which Congress and commentators agree is the Department of Justice (Department)’s primary enforcement mechanism against health-care fraud³—allows the government to seek treble damages and statutory civil penalties for each false or fraudulent claim for payment made to the government or to recipients

¹ *The Challenge of Health Care Fraud*, NAT’L HEALTH CARE ANTI-FRAUD ASS’N, <https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/> (last visited Feb. 11, 2022).

² U.S. DEP’T OF JUST. & U.S. DEP’T OF HEALTH & HUMAN SERVICES, ANN. REP. OF THE DEPARTMENTS OF HEALTH & HUMAN SERVICES & JUST., HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM FY 2021, at 1 (2022), <https://oig.hhs.gov/publications/docs/hcfac/FY2021-hcfac.pdf>.

³ S. REP. NO. 99-345, at 2, 4 (1986); Jacob T. Elberg, *Health Care Fraud Means Never Having to Say You’re Sorry*, 96 WASH. L. REV. 371, 377 (2021) [hereinafter Elberg, *Never Having to Say You’re Sorry*].

of federal funds under federal benefits programs.⁴ Commentators have described these “massive penalties [as] the key reason health-care providers often settle rather than defend against FCA allegations in court.”⁵

The focus of this article is on the role of civil penalties in FCA cases. Those penalties are “not discretionary, but [are] mandatory for each claim found to be false” under the FCA.⁶ Yet as Professor Elberg recently observed in his analysis of 118 FCA settlement agreements executed between early 2018 and May 31, 2019:

While treble damages plus penalties are available under the statute, the data makes clear that no one—neither the Commercial Litigation Branch nor any individual U.S. Attorney’s Office[]—is requiring even close to treble damages, never mind penalties, when resolving FCA cases through settlement.⁷

Which raises the question: why not? Although there has been substantial litigation surrounding the proper measure of damages in FCA cases,⁸ the civil penalties calculus is (or should be) facially

⁴ 31 U.S.C. § 3729(a)(1); *see also* *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 182 (2016).

⁵ Joan H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud that “Counts” Under the False Claims Act*, 2017 U. ILL. L. REV. 1811, 1816 (2017); *see also* Roderick Thomas, Mark Sweet & Michelle Bradshaw, *Grassley Amendments Are Not the Way to Reform the FCA*, LAW360 (Aug. 25, 2021), <http://www.law360.com/articles/1415004/> (discussing the “statutory sledgehammer of treble damages and penalties”).

⁶ *United States v. Killough*, 848 F.2d 1523, 1533 (11th Cir. 1988).

⁷ Jacob T. Elberg, *A Path to Data-Driven Health Care Enforcement*, 2020 UTAH L. REV. 1169, 1206 (2020) [hereinafter Elberg, *Data-Driven Health Care Enforcement*].

⁸ *See, e.g.*, *United States ex rel. Roby v. Boeing Co.*, 79 F. Supp. 2d 877, 884–85, 893 (S.D. Ohio 1999) (“Because each case under the FCA involves unique types of damage to the government, a formula for calculating damages must be created for each case that will provide the government with its damages directly caused by the filing of a false claim.”); *see also* *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1305 (11th Cir. 2021) (“As a result, we think that the proper measure of damages in this case is the difference between what the United States paid and what it would have paid had Pinellas’ claims been truthful.”); *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 652–53 (5th Cir. 2017) (“The proper measure of the government’s damages in an FCA action where the government received

straightforward: Count the number of false or fraudulent claims at issue in the case and multiply that number by the statutory range. If the penalties truly are mandatory, then the baseline for FCA settlement discussions could begin (or end) there, possibly with some discounting for litigation risk on the merits. Yet experience⁹ and data¹⁰ suggest that FCA defendants routinely devalue (or ignore) the FCA's civil penalties.

That's a problem for several reasons. First, it undermines the effectiveness of the Department's efforts to combat actual fraud, waste, or abuse under the FCA by contributing to the perception that a FCA penalty is no more than a cost of doing business.¹¹ Second, it's unclear whether the Department is achieving sufficient deterrence of fraud, particularly in the health-care industry. As noted by Professors Jost and Davies, “[b]ecause the level of auditing and enforcement in federal health care programs is very low, deterrence theory would seem to dictate that penalties imposed on providers who are found liable for fraud and abuse must be set very high before even optimal deterrence is achieved.”¹² And “if only a small fraction of fraudulent

something other than what was promised is the standard formulation for contract damages: the difference between what was promised and what was received.”).

⁹ See *False Claims Act Penalties: A Complete Guide*, WHISTLEBLOWER LAW COLLABORATIVE (Dec. 19, 2021), <https://www.whistleblowerllc.com/false-claims-act-penalties/> (“When the Government settles a False Claims Act case they generally do not rely on the potential False Claims Act penalties to arrive at a settlement number. Instead, the settlements are usually based on a multiple of the agreed-upon damages.”).

¹⁰ See Elberg, *Data-Driven Health Care Enforcement*, *supra* note 7, at 1207 (“[A] large number of FCA settlements recovered no more—and often less—than the amount of damages plus interest.”).

¹¹ See Elberg, *Never Having to Say You're Sorry*, *supra* note 3, at 400 (“There is thus ample reason for concern that DOJ's FCA settlements are too lenient to achieve deterrence, instead sending the message that, even as payment for wrongdoing, they are an acceptable cost of doing business.”); see also Elberg, *Data-Driven Health Care Enforcement*, *supra* note 7, at 1206 (“For all of DOJ's statements about the power of the FCA to recover government money and deter fraud, the data calls into question whether, in many cases, DOJ's FCA resolutions accomplish either goal given the substantial incentives apparently being offered to defendants for settling their cases.”).

¹² Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 279 (1999).

claims are discovered or pursued, and only a fraction of these result in liability, civil FCA sanctions may, in some cases, be too mild rather than too severe.”¹³ Finally, there is the structural consideration that Congress has instructed the Executive Branch, through unequivocal text in the FCA, to pursue these penalties in all instances where false or fraudulent claims for payment are presented to government programs.¹⁴

There’s also reason to believe that the FCA’s civil penalties will play an increasingly prominent role in FCA litigation, especially in the health-care context. In 2021, “more than four in ten (42%) Medicare beneficiaries—26.4 million people out of 62.7 million Medicare beneficiaries overall—are enrolled in Medicare Advantage plans; this share has steadily increased over time since the early 2000s.”¹⁵ And under Medicare Advantage (also known as Medicare Part C), the federal government makes capitated payments to plan providers based, in part, on the number of enrolled beneficiaries in those plans.¹⁶

Medicare Advantage capitation payments are risk-adjusted, meaning that “the per-person, per-month payment is adjusted to reflect various characteristics of the enrollee that are likely to determine how much care she needs over the course of the coverage period.”¹⁷ “For example, the government pays a higher premium for enrollees with chronic health conditions like diabetes or heart

¹³ *Id.* at 280.

¹⁴ *Cf. Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1319 (11th Cir. 2021) (“Congress is generally free to select punishments with an eye to retribution, deterrence, or rehabilitation, *etc.*, or various combinations thereof. . . . [T]he Eighth Amendment gives us no power to displace Congress’s choices simply because we’d have made different ones.”) (Newsom, J., concurring).

¹⁵ Meredith Freed et al., *Medicare Advantage in 2021: Enrollment Update and Key Trends*, KFF (June 21, 2021), <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends/>.

¹⁶ *See* 42 U.S.C. § 1395w-23.

¹⁷ Lindsay F. Wiley, *Privatized Public Health Insurance and the Goals of Progressive Health Care Reform*, 54 U.C. DAVIS L. REV. 2149, 2183 (2021) [hereafter Wiley, *Privatized Public Health Insurance*]. A similar system applies to prescription drug coverage under Medicare Part D. *Cf. Francis B. Palumbo & Lindsay P. Holmes, Pharmacy-Related Compliance Issues Facing Pharmacies and Pharmacists in 2021*, 23 J. HEALTH CARE COMPLIANCE 31, 37–38 (2021).

disease.”¹⁸ “But otherwise, the financial risk that enrollees will need more health care goods and services than anticipated is borne by the private health plan, not the government.”¹⁹ The same is true for several Medicaid plans; many states have implemented so-called managed-care models, “the vast majority of which are run by private insurance companies pursuant to government contracts.”²⁰

There’s no question²¹ that submitting a false or fraudulent claim for payment to a Medicare Advantage provider (or a Medicaid managed-care organization) can constitute a FCA violation. A “claim” under the FCA includes “any request or demand” for payment that “is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest”²² So a Medicare Advantage plan provider “is essentially ‘the government’ for purposes of a claim under the FCA”²³ As a result, although the government incurs damages from fraud in the Medicare Advantage and Medicaid managed-care contexts,²⁴ those damages may be more difficult to quantify. Which raises another question: If there is no easily discernable relationship between payments made on false or fraudulent claims and actual losses to the government, then does the FCA require the United States to offer proof of damages to establish a prima facie case? And if not, are the FCA’s civil penalties still available?

These questions are not mere hypotheticals. FCA defendants are already arguing for the dismissal of FCA suits based on a purported inability to prove the government’s damages.²⁵

¹⁸ Wiley, *Privatized Public Health Insurance*, *supra* note 17, at 2183–84.

¹⁹ *Id.* at 2184.

²⁰ *Id.* at 2182–83 (also stating that “more than 70% of all Medicaid beneficiaries are currently covered by Medicaid Managed Care plans”).

²¹ At least not to these authors.

²² 31 U.S.C. § 3729(b)(2)(A).

²³ *United States ex rel. White v. Mobile Care EMS & Transport, Inc.*, No. 15-cv-555, 2021 WL 6064363, at *14 (S.D. Ohio Dec. 21, 2021).

²⁴ *Cf. generally* Statement of Interest of the United States at 1–4, 7–9, *United States ex rel. SW Challenger LLC v. eviCore Healthcare MSI, LLC*, No. 19-cv-2501 (S.D.N.Y. Mar. 1, 2021), ECF No. 39.

²⁵ *See, e.g., White*, 2021 WL 6064363, at *6 (seeking the dismissal of an FCA suit based on the argument that “independent of how ma[n]y transports LogistiCare arranges, the amount of federal money Aetna receives will not change”); *United States ex rel. Zemplenyi v. Grp. Health Coop.*, No. C09-603,

This article re-evaluates the role of civil penalties in modern FCA litigation with a view toward restoring the “bark” to those penalties’ “bite.” After some background, we consider two legal issues that we believe have clouded the civil-penalties analysis. First, we examine whether the FCA requires proof of damages as a component of the United States’ prima facie case. And second, we explore the perceived constitutional limitations on civil penalties, focusing on the Eighth Amendment’s Excessive Fines Clause. We conclude with our thoughts on how aggressively pursuing civil penalties in FCA matters can combat fraud, waste, and abuse in the modern health-care system.

I. An overview of the False Claims Act’s civil penalties

First, some statutory background.²⁶ “We start, of course, with the statutory text.”²⁷ Each violation of the FCA entitles the United States to “a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person.”²⁸ Inflation-adjusted civil penalties are between \$12,537 and \$25,076 per violation for penalties assessed after May 9, 2022, based on violations occurring after November 2, 2015.²⁹ Violations occurring before November 2, 2015, are subject to somewhat lesser penalties between \$5,500 and \$11,000.³⁰

Next, some history. “Enacted in 1863, the False Claims Act ‘was originally aimed principally at stopping the massive frauds

2011 WL 814261, at *2 (W.D. Wash. Mar. 3, 2011) (“Under [a capitated payment] system, it cannot be said that false claims are being made, since payments remain the same regardless of whether a surgery is performed or not.”); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017) (stating that “it is the Government’s materiality decision that ultimately matters”).

²⁶ Our use of the word *some* throughout this section is deliberate. Our goal here is to lay out foundational principles to analyze the modern role of civil penalties in FCA litigation. We’ve admittedly made no effort to be exhaustive in our approach.

²⁷ *BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 91 (2006).

²⁸ 31 U.S.C. § 3729(a)(1).

²⁹ 28 C.F.R. § 85.5.

³⁰ *Id.* § 85.3.

perpetrated by large contractors during the Civil War.”³¹ Upon a finding of liability, the initial version of the FCA permitted the government to recover a forfeiture of \$2,000 “and, in addition, double the amount of damages which the United States may have sustained by reason of the doing or committing such act, together with the costs of suit”³² The FCA has since been amended several times by Congress, notably including the False Claims Amendments Act of 1986. The 1986 Act increased the civil penalty range to between \$5,000 and \$10,000 and, for the first time, allowed the government to recover treble damages in all cases.³³ The legislative history behind those amendments suggests that Congress sought to “reaffirm[] the apparent belief of the [FCA’s] initial drafters that defrauding the Government is serious enough to warrant an automatic forfeiture rather than leaving fine determinations with district courts, possibly resulting in discretionary nominal payments.”³⁴ That history also reflects Congress’s view that “[t]he imposition of [a] forfeiture is automatic and mandatory for each claim . . . found to be false” and that “[t]he United States is entitled to recover such forfeitures solely upon proof that false claims were made, without proof of any damages.”³⁵

Finally, some jurisprudence. In 1943, the U.S. Supreme Court considered whether the FCA’s civil penalties are remedial or punitive in *United States ex rel. Marcus v. Hess*.³⁶ The defendants in *Marcus* were charged in a qui tam action under the FCA (in its pre-1986 form)

³¹ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)).

³² Act of Mar. 2, 1868, ch. 67, § 3, 12 Stat. 696, 698.

³³ False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153. Congress further amended the FCA with the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617, and then again with the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 901 (2010) and the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376, 2079 (2010).

³⁴ S. REP. NO. 99-345, at 17 (1986); see also H.R. REP. NO. 99-660, at 20 (1986) (“The Committee recommends this change in order that the False Claims Act penalties will have a strong deterrent effect; will make the Government whole for its losses; and to update the penalty enacted in 1863 to reflect the passage of time and the effects of inflation.”).

³⁵ S. REP. NO. 99-345, at 8 (1986).

³⁶ 317 U.S. 537 (1943).

“with defrauding the United States through the device of collusive bidding” on Public Works Act projects in the area of Pittsburgh, Pennsylvania.³⁷ Judgment was entered against the defendants for \$315,000, consisting of \$203,000 in double damages and \$112,000 in civil penalties.³⁸ The defendants were also “indicted for defrauding the government and on a plea of nolo contendere were fined \$54,000.”³⁹

The defendants argued to the Supreme Court that the FCA action violated the double jeopardy provision of the Fifth Amendment based on the prior indictment and criminal fine. But the Court rejected that argument, holding that the remedies available under the FCA—including (at that time) double damages and the \$2,000 forfeiture per violation—are “remedial” and would not “do more than afford the government complete indemnity for the injuries done it.”⁴⁰ And with regard to the civil penalties provision, the Court noted that “[t]he words ‘forfeit and pay’ are wholly consistent with a civil action for damages.”⁴¹ Further, “the chief purpose of the statutes here was to provide for restitution to the government of money taken from it by fraud, and that the device of double damages plus a specific sum was chosen to make sure that the government would be made completely whole.”⁴² The Court’s decision therefore reflects, in part, its deference to Congress. Or, to quote the Court: “The inherent difficulty of choosing a proper specific sum which would give full restitution was a problem for Congress.”⁴³

Such was the law for nearly six decades⁴⁴ until the Supreme Court’s decision in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*.⁴⁵ The question in *Vermont Agency* was whether a relator could bring a suit under the False Claims Act against a state

³⁷ *Id.* at 539.

³⁸ *Id.* at 540.

³⁹ *Id.* at 545.

⁴⁰ *Id.* at 549.

⁴¹ *Id.* at 551.

⁴² *Id.* at 551–52.

⁴³ *Id.* at 552.

⁴⁴ See also *United States v. Bornstein*, 423 U.S. 303, 314 (1976) (noting the “clear understanding that Congress intended the double-damages provision to play an important role in compensating the United States in cases where it has been defrauded” and citing *Marcus*).

⁴⁵ 529 U.S. 765 (2000).

or state agency.⁴⁶ In answering that question “no,” the Court partly backtracked from *Marcus*:

Although this Court suggested that damages under an earlier version of the FCA were remedial rather than punitive, that version of the statute imposed only double damages and a civil penalty of \$2,000 per claim; the current version, by contrast, generally imposes treble damages and a civil penalty of up to \$10,000 per claim.⁴⁷

The Court also noted that “[t]he very idea of treble damages reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers.”⁴⁸ The Court therefore determined that the FCA’s current damages provisions are “essentially punitive.”⁴⁹ Although the Court in *Vermont Agency* did not discuss the FCA’s civil penalties provision in isolation, its current view appears to be that “Congress . . . has increased the Act’s civil penalties so that liability is ‘essentially punitive in nature.’”⁵⁰

Having discussed text, history, and jurisprudence, we return to our two central questions. First, are civil penalties under the FCA available without proof of damages to the government? And second, how stringent are the Eighth Amendment’s limitations on the FCA’s civil penalties?

II. Does the FCA require proof of damages?

The first question we pose is whether the United States needs to offer proof of damages to establish a prima facie case of liability under the FCA. If not, then it should be clear that the government is entitled to civil penalties in all FCA matters, even if the government cannot prove (or has not incurred) any damages.

Unfortunately, the answer to this question is not straightforward. The Supreme Court appeared to have answered it affirmatively more than six decades ago in *Rex Trailer Co. v. United States*.⁵¹ There, the

⁴⁶ *Id.* at 768.

⁴⁷ *Id.* at 785 (citations omitted).

⁴⁸ *Id.* at 786 (citation and internal quotation marks omitted).

⁴⁹ *Id.* at 784.

⁵⁰ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 182 (2016) (quoting *Vermont Agency*, 529 U.S. at 784).

⁵¹ 350 U.S. 148 (1956).

Court analyzed the pre-1986 version of the FCA and held that “there is no requirement, statutory or judicial, that specific damages be shown” and that “it is the function of liquidated damages to provide a measure of recovery” in cases where damages “may be difficult or impossible to ascertain”⁵² Yet the case law among the lower courts remains mixed, particularly in light of the post-1986 revisions to the FCA. Compiled below are (so far as the authors can discern) the current views in each federal circuit regarding whether damages are a required element of a FCA case:⁵³

Circuit Court	FCA Damages Requirement?
First Circuit	Not required, but without discussion ⁵⁴
Second Circuit	Undecided ⁵⁵

⁵² *Id.* at 152–54.

⁵³ The authors recognize that 31 U.S.C. § 3729(a)(1) specifies seven distinct means by which defendants can be liable under the False Claims Act. We focus primarily on § 3729(a)(1)(A) because that provision is the most utilized basis for FCA liability. *Cf.* *United States ex rel. Johnson v. Golden Gate Nat’l Senior Care, LLC*, No. 08-1194, 2020 WL 2750092, at *4 (D. Minn. May 27, 2020) (noting that the relators’ FCA “conspiracy count is likely superfluous”). Where feasible, we’ve cited circuit court cases; however, in circuits where the circuit law was unclear or unavailable, we’ve referred to district court decisions from that circuit.

⁵⁴ *See* *Tavares v. R.I. Superior Ct.*, C.A. No. 19-291, 2019 WL 3940909, at *2 (D.R.I. Aug. 21, 2019); *see also* *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 117–18 (D. Mass. 2021) (distilling the elements as “falsity,” “scienter,” “causation,” and “materiality”). The First Circuit does not appear to have directly addressed whether damages are an element of a FCA case but has stated that “[t]he elements of a ‘violation’ of the FCA are . . . that an individual ‘knowingly presents, or causes to be presented, to an officer or employee of the Government . . . a false or fraudulent claim for payment or approval.’” *United States v. Rivera*, 55 F.3d 703, 706 (1st Cir. 1995) (quoting 31 U.S.C. § 3729(a) (1982)). However, the FCA has been revised since the First Circuit issued its *Rivera* decision.

⁵⁵ *See* *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001) (“Because plaintiff’s claims fail on other grounds, we need not decide whether the Act contains another element of proof, namely a showing that the United States sustained damages.”). The Second Circuit noted that the portion of the *Mikes* opinion requiring a particularity element for express false certification claims was overruled. *Bishop v. Wells Fargo & Co.*, 870 F.3d 104, 106–07 (2d Cir. 2017).

Circuit Court	FCA Damages Requirement?
Third Circuit	Possibly not required, but with mixed caselaw ⁵⁶
Fourth Circuit	Likely not required ⁵⁷
Fifth Circuit	Possibly not required ⁵⁸
Sixth Circuit	Likely not required ⁵⁹

However, the issue of whether damages is a required element of a FCA case still appears to be unresolved in the Second Circuit. See *United States v. Spectrum Painting Corp.*, No. 19 Civ. 2096, 2020 WL 5026815, at *14 (S.D.N.Y. Aug. 25, 2020) (“It is an open question in the Second Circuit whether an FCA plaintiff must show that the Government suffered actual damages.”).

⁵⁶ Compare *United States ex rel. Doe v. Heart Sol., PC*, 923 F.3d 308, 317 (3d Cir. 2019) (“An FCA violation has four elements: falsity, causation, knowledge, and materiality.” (citation and internal quotation marks omitted)), and *United States ex rel. Sanders v. Am.-Amicable Life Ins. Co. of Tex.*, 545 F.3d 256, 259 (3d Cir. 2008) (stating that civil penalties are available “even where the government suffers no monetary injury”), with *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 184 (3d Cir. 2001) (“[W]e hold the submission of false claims to the United States government for approval which do not or would not cause financial loss to the government are not within the purview of the False Claims Act.”).

⁵⁷ See *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 403–04 (4th Cir. 2013) (recognizing that a relator has standing to sue for only civil penalties under the FCA and stating that “the FCA ‘provides for penalties even if (indeed, *especially* if) actual loss is hard to quantify’” (quoting *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 917 (7th Cir. 2005))). But see *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008) (noting that a FCA fraudulent-inducement claim requires proof that the claim “caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)” (cleaned up)).

⁵⁸ Compare *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009) (“The False Claims Act, in contrast, lacks the elements of reliance and damages. . . . Put plainly, the statute is remedial and exposes even unsuccessful false claims to liability.”), with *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467 (5th Cir. 2009) (adopting the Fourth Circuit’s test for a FCA violation from *Kellogg Brown & Root*, 525 F.3d at 376), and *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 653–54 (5th Cir. 2017) (same).

⁵⁹ See, e.g., *Varljen v. Cleveland Gear Co.*, 250 F.3d 426, 429 (6th Cir. 2001) (“[R]ecovery under the FCA is not dependent upon the government’s sustaining monetary damages.”); *Wilkins ex rel. United States v. State of*

Circuit Court	FCA Damages Requirement?
Seventh Circuit	Not required ⁶⁰
Eighth Circuit	Likely not required ⁶¹
Ninth Circuit	Possibly not required ⁶²
Tenth Circuit	Likely not required ⁶³
Eleventh Circuit	Possibly not required ⁶⁴

Ohio, 885 F. Supp. 1055, 1059–60 (S.D. Ohio 1995) (stating that proof “that the United States suffered damages” as a result of a false claim or state is required under the FCA but the clarifying that “no damages need be proved in order to recover the civil penalty of \$5,000”); *United States ex rel. Morris v. Crist*, No. C-2-97-1395, 2000 WL 432781, at *8 (S.D. Ohio Mar. 29, 2000) (“[A]ctual damages are not an essential element of a successful cause of action under the FCA . . .”).

⁶⁰ See *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 917 (7th Cir. 2005) (“The [FCA] provides for penalties even if (indeed, *especially* if) actual loss is hard to quantify . . .”).

⁶¹ See *United States v. Rainwater*, 244 F.2d 27, 28 (8th Cir. 1957) (“[W]e believe that even if no damages were shown at the time of trial the United States could still recover the statutorily fixed sum of \$2,000.00 for each of the proscribed acts.”); *United States v. James B. Nutter & Co.*, No. 20-cv-00874, 2021 WL 5280964, at *3 (W.D. Mo. Nov. 12, 2021) (noting that the parties conceded that the FCA does not require damages as an element); *United States ex rel. Cairns v. D.S. Med., L.L.C.*, No. 12CV00004, 2018 WL 4607839, at *3 n.2 (E.D. Mo. Sept. 25, 2018) (“In addition, damages is not an element of a FCA claim.”).

⁶² Compare *Kelly v. Denault*, 374 F. Supp. 3d 884, 889–90 (N.D. Cal. 2018) (stating that a FCA claim requires as an “essential element” that “the government . . . pay out money or forfeit moneys due” (internal quotation marks omitted) (quoting *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006))), with *United States ex rel. Berg v. Honeywell Int’l, Inc.*, 226 F. Supp. 3d 962, 967 n.32 (D. Alaska 2016) (“[D]amages are not an element of an FCA claim.” (citing *United States ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991))).

⁶³ See *United States ex rel. Janssen v. Lawrence Mem’l Hosp.*, 949 F.3d 533, 540 n.9 (10th Cir. 2020) (suggesting in dicta that liability under the FCA does not require actual payment of a false or fraudulent claim); *Fleming v. United States*, 336 F.2d 475, 480 (10th Cir. 1964) (“Proof of damage to the Government resulting from a false claim is not a necessary part of the Government’s case under the Act.”).

⁶⁴ See *United States v. Killough*, 848 F.2d 1523, 1533–34 (11th Cir. 1988) (“Even if no payment was made on a claim or the government cannot prove actual damages, a forfeiture shall be awarded on each false claim

Circuit Court	FCA Damages Requirement?
Federal Circuit	Likely not required ⁶⁵
D.C. Circuit	Not required ⁶⁶

The law in the Fifth Circuit exemplifies some of the difficulties with disentangling liability from damages under the FCA.⁶⁷ The Fifth Circuit first considered whether the FCA requires proof of damages in *United States ex rel. Grubbs v. Kanneganti*.⁶⁸ The defendants in *Grubbs* allegedly “billed Medicare and Medicaid for services not

submitted.”); *United States v. Halifax Hosp. Med. Ctr.*, No. 09-cv-1002-Orl-31, 2014 WL 68603, at *7 (M.D. Fla. Jan. 8, 2014) (omitting a damages element from the prima facie FCA claim but then stating that “[t]he Government must prove all essential elements of an FCA claim, including damages, by a preponderance of the evidence” (citing 31 U.S.C. § 3731(d))); *United States v. A J B*, No. CA 09-621, 2010 WL 3748249, at *4 (S.D. Ala. Sept. 1, 2010) (“Furthermore, the FCA punishes the mere submission of fraudulent claims for payment, regardless of whether the Government pays them.” (internal quotation marks omitted) (quoting *United States v. Govereh*, No. 07-CR-131, 2010 WL 28565, at *2 (N.D. Ga. Jan. 5, 2010))), *report and recommendation adopted*, 2010 WL 3768349 (S.D. Ala. Sept. 17, 2010). *But cf.* *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (suggesting that a violation of the False Claims Act requires “actionable damage to the public fisc”).

⁶⁵ See *Commercial Contractors, Inc. v. United States*, 154 F.3d 1357, 1371 (Fed. Cir. 1998) (suggesting that a government contractor may still be liable for civil penalties under the FCA “even if the goods it delivered are of the same quality as the goods specified in the contract”); *Daewoo Eng’g & Constr. Co. v. United States*, 557 F.3d 1332, 1341 (Fed. Cir. 2009) (holding that the Court of Federal Claims did not err by awarding a FCA civil penalty despite the absence of damages).

⁶⁶ See *United States ex rel. Schwedt v. Planning Rsch. Corp.*, 59 F.3d 196, 198–99 (D.C. Cir. 1995) (stating that the FCA “impos[es] a civil penalty for the mere submission of a false claim, whether or not that claim brings about any damages” and emphasizing that liability for the FCA’s civil penalties is distinct from liability for damages); see also *United States ex rel. Davis v. Dist. of Columbia*, 679 F.3d 832, 840 (D.C. Cir. 2012) (stating that a relator “may still be eligible to share in the statutory penalties” even without a showing of damages).

⁶⁷ For readers who believe the authors have some self-interest in the Fifth Circuit’s jurisprudence, we plead guilty.

⁶⁸ 565 F.3d 180 (5th Cir. 2009).

performed.”⁶⁹ In determining that the relator’s complaint met the pleading standards under Rule 9(b) of the Federal Rules of Civil Procedure, the Fifth Circuit held that the “False Claims Act . . . lacks the elements of reliance and damages.”⁷⁰ As a result, damages “need not be shown to state a claim but which if shown will be doubled and may be trebled.”⁷¹

Yet only three months later, a separate panel of the Fifth Circuit⁷² appeared to reimpose a damages element into the False Claims Act. In *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, the United States alleged that the defendants “engaged in an elaborate pattern of false statements to secure research grants from the federal government.”⁷³ While affirming the district court’s grant of summary judgment to the United States, the *Longhi* panel noted that the court “ha[d] not yet delineated a succinct test recognizing” the elements of a FCA claim.⁷⁴ Thus, it adopted the Fourth Circuit’s test, including the requirement that a false or fraudulent claim “caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim).”⁷⁵

Longhi appears to have caused confusion in the Fifth Circuit.⁷⁶ For example, the Western District of Texas in *United States ex rel.*

⁶⁹ *Id.* at 183.

⁷⁰ *Id.* at 189.

⁷¹ *Id.* at 183–84 (referring to a prior version of the FCA).

⁷² Judge Higginbotham, who wrote the panel opinion in *Grubbs*, was also on the panel in *Longhi* and joined the opinion in that case. Curiously, there’s no mention of *Grubbs* in *Longhi*.

⁷³ 575 F.3d 458, 461–62 (5th Cir. 2009).

⁷⁴ *Id.* at 467.

⁷⁵ *Id.* (internal quotation marks omitted) (quoting *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008)).

⁷⁶ The authors also admit to their own confusion. One explanation for the perceived disparity between *Grubbs* and *Longhi* is that *Longhi*, unlike *Grubbs*, is a fraudulent-inducement case. *Id.* at 468 (discussing fraudulent inducement). But it’s unclear why that fact matters. Fraudulent inducement is not (or should not be considered) a distinct cause of action under the FCA; it is a theory of liability by which claims for payment under a contract procured by fraud are deemed to be false even if the claims themselves are facially true. *Id.* *But cf.* *United States ex rel. Cimino v. Int’l Bus. Machs. Corp.*, 3 F.4th 412, 424–27 (D.C. Cir. 2021) (Rao, J., concurring) (questioning whether fraudulent inducement “is a separate cause of action under the FCA” and suggesting that the theory “may reflect a judicial expansion of a

Campbell v. KIC Development, LLC, after quoting the *Longhi* elements, remarked in a footnote (citing *Grubbs*) that “[w]hile the language of the fourth element could be read to suggest otherwise, the Government need not prove actual damages in order to recover under the FCA.”⁷⁷ Yet the court offered no justification for that conclusion other than saying (citing *Grubbs*) that “[t]he statute offers a civil penalty for proof of fraudulent claims whether or not paid.”⁷⁸ So it’s unclear whether *Longhi*, *Grubbs*, or some combination of the two governs in the Fifth Circuit.

This confusion is understandable because the statute is inconsistent on this point.⁷⁹ For example, 31 U.S.C. § 3729(a)(1)(A) conditions FCA liability⁸⁰ on “knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval” Such presentation renders the defendant “liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.”⁸¹ So far, so good. The structure of the text—which lists the penalties before specifying the availability of treble damages—not only suggests that penalties and damages are analytically distinct but that the *primary* relief accorded to the government upon a finding of FCA liability is an award of penalties. To the extent that the United States can prove that it has incurred actual damages, it is then *also* entitled to an award of treble damages.⁸²

statutory cause of action layered on top of congressional expansion of prosecution outside the executive branch”). Regardless, the Fifth Circuit has applied the *Longhi* test outside the fraudulent-inducement context. *See United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 159 (5th Cir. 2019) (citing the *Longhi* test in a case involving allegedly improper billing by a hospice care provider).

⁷⁷ *United States ex rel. Campbell v. KIC Dev., LLC*, No. EP-18-CV-193, 2019 WL 6884485, at *6 n.7 (W.D. Tex. Dec. 10, 2019).

⁷⁸ *Id.* (cleaned up).

⁷⁹ Justice Alito has described the False Claims Act as “a terribly-drafted statute.” Transcript of Oral Argument at 23:10–11, *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507 (2019) (No. 18-315). The authors express no view on this matter.

⁸⁰ *Cf. supra* note 53.

⁸¹ 31 U.S.C. § 3729(a)(1) (emphasis added).

⁸² *See, e.g., United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 403–04 (4th Cir. 2013).

But jump forward two sections. Section 3731(d) states that “[i]n any action brought under [the FCA], the United States shall be required to prove all essential elements of the cause of action, *including damages*, by a preponderance of the evidence.”⁸³ That provision suggests that damages are one of the “essential elements of the cause of action”⁸⁴ under the FCA, meaning that the government’s claims would potentially be subject to dismissal without proof of damages.⁸⁵

There are a couple of responses to this line of reasoning. First, because section 3729(a)(1) specifies seven distinct means of violating the FCA, perhaps some, but not all, of those causes of action require proof of damages.⁸⁶ Second, perhaps damages are only “essential” when the government chooses to pursue them, thereby leaving the United States with the option of foregoing damages in favor of penalties. In fact, that approach appears to be the one adopted by the numerous courts cited above.⁸⁷

But then there’s the Supreme Court’s decision in *Escobar*.⁸⁸ As has been recounted extensively elsewhere,⁸⁹ the primary issue in *Escobar* was whether the implied-false-certification theory could provide a basis for liability under the FCA.⁹⁰ After confirming that (at least in some circumstances) it can be, the Supreme Court proceeded to

⁸³ 31 U.S.C. § 3731(d) (emphasis added).

⁸⁴ *Id.*

⁸⁵ *Cf. Essential*, BLACK’S LAW DICTIONARY (11th ed. 2019) (“2. Of the utmost importance; basic and necessary.”).

⁸⁶ *See, e.g., Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (stating that a FCA conspiracy claim requires proof “that the United States suffered damages as a result of the false or fraudulent claim” (citation and internal quotation marks omitted)); *United States v. Genesis Glob. Healthcare*, No. 18-cv-128, 2021 WL 4268279, at *17 (S.D. Ga. Sept. 20, 2021) (same).

⁸⁷ *See supra* notes 54–66.

⁸⁸ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016).

⁸⁹ *See generally* Joan H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud That “Counts” Under the False Claims Act*, 2017 U. ILL. L. REV. 1811, 1828–30 (2017) (discussing *Escobar*); Deborah R. Farringer, *From Guns That Do Not Shoot to Foreign Staplers: Has the Supreme Court’s Materiality Standard Under Escobar Provided Clarity for the Health Care Industry About Fraud Under the False Claims Act?*, 83 BROOK. L. REV. 1227, 1245–49 (2018) (same).

⁹⁰ *Escobar*, 579 U.S. at 186–90.

“clarify how [the FCA’s] materiality requirement should be enforced.”⁹¹ The Court noted that “materiality ‘look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation,’”⁹² and it emphasized that “[t]he materiality standard is demanding.”⁹³ In particular, the Court stated that it is not sufficient for a finding of materiality “that the Government would have the option to decline to pay if it knew of the defendant’s noncompliance.”⁹⁴ And although the Court declined to adopt a bright-line test for assessing materiality under the FCA, it did opine:

[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.⁹⁵

Predictably, and despite its purported “holistic” approach to materiality, *Escobar* has increased the focus on the government’s payment decision with respect to purportedly false or fraudulent claims.⁹⁶ And that’s where *Escobar* also muddles the damages (and

⁹¹ *Id.* at 192.

⁹² *Id.* at 193 (quoting 26 R. LORD, WILLISTON ON CONTRACTS § 69:12 (4th ed. 2003)).

⁹³ *Id.* at 194.

⁹⁴ *Id.*

⁹⁵ *Id.* at 195.

⁹⁶ *See, e.g.*, *United States v. Vora*, No. 20-cv-66, 2022 WL 89177, at *4–5 (W.D. Ky. Jan. 7, 2022) (dismissing in part the United States’ amended complaint because “[i]t made no representation regarding the consistency of the government’s refusal or non-refusal to pay claims subject to such regulatory violations”); *United States v. Strock*, 982 F.3d 51, 62 (2d Cir. 2020) (holding that in fraudulent-inducement cases “the government’s ‘payment decision’ under *Escobar* encompasses both its decision to award a contract and its ultimate decision to pay under that contract”); *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 660–68 (5th Cir. 2017) (holding that the relator failed to establish materiality where the government continued to approve payments for allegedly defective guardrails despite knowledge of the relator’s allegations).

penalties) analysis. Consider yet another case from the Fifth Circuit:⁹⁷ *United States ex rel. Harman v. Trinity Industries Inc.*⁹⁸ The relator in *Harman* accused the defendants of causing the federal government to pay highway subsidies for purportedly defective guardrails that the relator alleged had not been approved by the Federal Highway Administration (FHWA).⁹⁹ After the relator secured a jury verdict for \$663,360,750,¹⁰⁰ the Fifth Circuit reversed under *Escobar*, based primarily on the fact that the government “ha[d] never retracted its explicit approval” of the defendants’ guardrails, “instead stating that an ‘unbroken chain of eligibility’ has existed since 2005.”¹⁰¹

The *Harman* opinion is challenging for its analysis of all the issues that the panel purportedly was *not* deciding before reaching materiality. But, as relevant here, one of those “non-issue issues”¹⁰² was how the relator’s “failure to rebut the strong presumption against materiality also manifests in its effect on damages.”¹⁰³ After stating that the proper measure of damages in a FCA case is “the difference between what was promised and what was received,”¹⁰⁴ the Fifth Circuit observed that “FHWA’s continued approval of reimbursement . . . at the same amount strongly suggests that the government, the supposedly aggrieved party, considers the value of the units with the 2005 changes to be identical to the value of previous . . . units.”¹⁰⁵ So in the court’s view, “the proper measure of actual damages should be zero.”¹⁰⁶

In all fairness to *Harman*, the panel acknowledged that the defendants “could still face civil penalty assessments . . . for each individual sale,”¹⁰⁷ which is consistent with the Fifth Circuit’s

⁹⁷ And another decision by Judge Higginbotham.

⁹⁸ 872 F.3d 645 (5th Cir. 2017).

⁹⁹ *Id.* at 647–52.

¹⁰⁰ *Id.* at 651.

¹⁰¹ *Id.* at 664, 670 (“When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all.”).

¹⁰² Usually called *dicta*, but the Fifth Circuit recognizes (and increasingly employs) an “alternative holdings” doctrine. *See, e.g., United States v. Wallace*, 964 F.3d 386, 390 (5th Cir. 2020). So, who knows?

¹⁰³ *Harman*, 872 F.3d at 652.

¹⁰⁴ *Id.* at 652–53.

¹⁰⁵ *Id.* at 653.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

precedent in *Grubbs*. But is that right? The *Harman* panel appears to view the absence of damages as a *necessary* consequence of a lack of materiality under the FCA, even if it's not quite prepared to classify it as a *sufficient* condition for lack of materiality.¹⁰⁸ We'll call this the Necessity Argument—that is, no materiality implies no damages. It's then fair to ask, if materiality under *Escobar* turns on the United States' payment decision, and if the government pays no additional funds for a false or fraudulent claim (and thereby suffers no damages), how could that false or fraudulent claim have been material to the government (and thereby subject to a civil penalty)? We'll call that the Sufficiency Argument—that is, no damages implies no materiality.

As expected, the defense bar has shown no hesitation to push the Sufficiency Argument. Consider the recent decision from the Southern District of Ohio in *United States ex rel. White v. Mobile Care EMS & Transport, Inc.*¹⁰⁹ The defendants in that suit are an ambulance-transportation supplier and a non-emergency medical-transportation broker who have purportedly upcoded for medical-transportation services and billed for medically unnecessary transport services.¹¹⁰ One of the defendants, LogistiCare (now ModivCare Solutions, LLC), sought to dismiss the relators' claims for failure "to adequately allege any misrepresentation that was material to any government payment decision."¹¹¹ Here's LogistiCare's argument, as summarized by the district court:

To get there, LogistiCare makes a two-step argument. First, LogistiCare says that the second amended complaint fails to sufficiently allege that LogistiCare is involved in billing any government healthcare plan other than MyCare Ohio, which is managed by Aetna. Thus, according to LogistiCare, only the terms of that program are relevant to the claims against LogistiCare.

LogistiCare then asks the Court to take judicial notice of the payment structure under that program. In particular, according to LogistiCare, publicly available materials show that Aetna receives a capitated rate

¹⁰⁸ Though, in these authors' opinions, the panel comes close.

¹⁰⁹ No. 15-cv-555, 2021 WL 6064363 (S.D. Ohio Dec. 21, 2021).

¹¹⁰ *Id.* at *3.

¹¹¹ *Id.* at *5.

from the federal government for plan participants in MyCare Ohio. That means that, independent of how many transports LogistiCare arranges, the amount of federal money Aetna receives will not change.

Therefore, according to LogistiCare, the alleged conduct as a matter of law is not “material” to any government payment decision, and thus cannot support an FCA claim.¹¹²

In other words, no effect on government payments (that is, no damages) means no materiality, which means no FCA claim (presumably, not even for civil penalties). That’s precisely the Sufficiency Argument.

The district court in *White* rejected LogistiCare’s argument. To get there, the court found that the defendants’ alleged conduct “did ‘tend to influence’ the payment of money,” irrespective of whether “the entity *paying* the money (i.e., apparently Aetna) will . . . receive any additional federal funds”¹¹³ So even if “the federal government may not *pay* more, . . . the Defendants may *receive* more of the federal funds that the administrator (Aetna) was already paid.”¹¹⁴ However, the district court agreed to certify its decision on this issue for interlocutory appeal pursuant to 28 U.S.C. § 1292(b).¹¹⁵

So where do we stand? First, absent further developments in the case law and despite some lingering uncertainty, the broad consensus among federal courts, even post-*Escobar*, is that there is no requirement to prove damages to establish a *prima facie* FCA claim.¹¹⁶ Therefore, civil penalties under the FCA remain available to combat

¹¹² *Id.* at *6 (citations removed). Merits aside, this argument could logically extend to any federal health-care program involving capitated funding arrangements, including Medicare Advantage. *See supra* notes 15–25.

¹¹³ *Id.* at *13.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at *17–18. On December 29, 2021, ModivCare Solutions, LLC filed its petition for leave to file an interlocutory appeal under 28 U.S.C. § 1292(b). In re: ModivCare Solutions, LLC, No. 21-0310 (6th Cir. Dec. 29, 2021). On August 23, 2022, the Sixth Circuit denied the petition.

¹¹⁶ *See, e.g., United States ex rel. Janssen v. Lawrence Mem’l Hosp.*, 949 F.3d 533, 540 n.9 (10th Cir. 2020) (“[A] false statement can be material even if the government’s decision to pay or not pay the claim does not hinge on that statement alone. To erect such a bar—one requiring a showing of actual reliance—would impermissibly go beyond the text of the statute.”).

false or fraudulent claims, even if there is no proof of actual loss to the government. Second, there may be some daylight between the absence of materiality and the absence of damages to the government, particularly in instances (as in *White*) where the defendant has gained an undue benefit from its actions. That observation in turn suggests that vigorous pursuit of civil penalties in managed care and other capitated-payment arrangements may be necessary to ensure appropriate deterrence of health-care fraud in those settings.

III. The Excessive Fines Clause: How “mandatory” is “mandatory”?

Case elements aside, there’s another limitation on civil penalties under the FCA: the Constitution. Specifically, the Eighth Amendment states that “[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.”¹¹⁷ Only the “excessive fines” component of that amendment (the Excessive Fines Clause) is relevant here.

As it has acknowledged, the Supreme Court “had little occasion to interpret, and ha[d] never actually applied, the Excessive Fines Clause” until 1998, when the Court decided *United States v. Bajakajian*.¹¹⁸ *Bajakajian* was not a FCA case. Rather, the government sought forfeiture of \$357,144 from Mr. Bajakajian for attempting to leave the United States without reporting that he was transporting more than \$10,000 in currency.¹¹⁹ The Court held that the forfeiture violated the Eighth Amendment “because full forfeiture of respondent’s currency would be grossly disproportional to the gravity of his offense.”¹²⁰

The Court observed that “[t]he Excessive Fines Clause . . . ‘limits the government’s power to extract payments, whether in cash or in kind, as punishment for some offense.’”¹²¹ Therefore, a violation of the Excessive Fines Clause (tautologically) requires (1) a fine that (2) is excessive. And a “fine” means “punishment” in a (largely) criminal sense, which is why civil damages, even punitive damages, are not

¹¹⁷ U.S. CONST. amend. VIII.

¹¹⁸ 524 U.S. 321, 327 (1998).

¹¹⁹ *Id.* at 324 (citing 18 U.S.C. § 982(a)(1)).

¹²⁰ *Id.*

¹²¹ *Id.* at 328 (quoting *Austin v. United States*, 509 U.S. 602, 609–10 (1993)).

subject to the Excessive Fines Clause.¹²² With regard to “excessiveness,” the Court in *Bajakajian* observed that “[t]he touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality,” meaning that “[t]he amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish.”¹²³ Therefore, a fine violates the Excessive Fines Clause “if it is grossly disproportional to the gravity of a defendant’s offense.”¹²⁴

The notion of proportionality—though, as discussed below, in a different sense than in *Bajakajian*—existed in the FCA jurisprudence before *Bajakajian*. Consider the Fifth Circuit’s¹²⁵ 1975 decision in *Peterson v. Weinberger*.¹²⁶ There, the defendants were found liable under the pre-1986 FCA for submitting 120 false claims for physical-therapy services to Medicare Part B, resulting in a judgment of \$31,606.72 in double damages and a \$100,000 forfeiture for 50 of the 120 false claims.¹²⁷ On appeal, the defendants argued that there had been no violation of the FCA “because the physical therapy services were performed by qualified people, the patients receiving these services were entitled to them under Medicare, there was no financial loss to the Government, and the monies paid by the Government were therefore a liability which the Government was statutorily obligated to pay.”¹²⁸

The Fifth Circuit rejected those arguments, noting that the FCA, as a “remedial statute,” “reaches beyond ‘claims’ which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.”¹²⁹ Because the claims would not have been paid

¹²² See *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 260, 264, 268, 275 (1989).

¹²³ *Bajakajian*, 524 U.S. at 334.

¹²⁴ *Id.*

¹²⁵ See *supra* note 67.

¹²⁶ 508 F.2d 45 (5th Cir. 1975).

¹²⁷ *Id.* at 47–49. We’ve skipped some of the colorful details of the fraud scheme. The short story is that James Peterson, the owner of a nursing home and a separate physical-therapy provider, was barred from submitting any claims directly to the Medicare intermediate. So he purportedly directed one of his employees to draft Medicare Part B claims falsely representing that Mr. Peterson’s brother, Dr. Donald Peterson, had personally provided the services.

¹²⁸ *Id.* at 52.

¹²⁹ *Id.* (citation omitted).

had the fraud been apparent to the government, the United States was entitled to recoup its losses under the FCA.¹³⁰

Ordinarily, that would have (or should have) ended the matter. But the United States also argued on appeal, without filing a cross-appeal, that the district court “should have assessed a \$2,000 forfeiture for each false claim, or a total of \$240,000 . . . , instead of limiting the forfeiture to 50 claims totaling \$100,000.”¹³¹ The Fifth Circuit correctly stated that the issue was not properly before the court based on the government’s failure to file a cross-appeal, yet the court nonetheless noted the United States’ admission “that the court may exercise discretion where the imposition of forfeitures might prove excessive and out of proportion to the damages sustained by the Government.”¹³² The Fifth Circuit then concluded that “[t]he forfeiture should reflect a *fair ratio to damages* to insure that the Government completely recoups its losses.”¹³³ We’ll call that the Fair Ratio Standard.

It’s difficult to determine whether the Fifth Circuit’s Fair Ratio Standard truly derives from the Excessive Fines Clause for multiple reasons: (1) the analysis is dicta based on the government’s unpreserved argument; (2) the conclusion appears to be drawn from a government concession; and (3) there’s no reference to the Excessive Fines Clause in the *Peterson* opinion.¹³⁴ For those reasons, *Peterson* has been rejected and criticized by other federal courts.¹³⁵ But at least one district court¹³⁶ has applied *Peterson* to reduce FCA civil penalties in a case where the defendant stood “to be cast in judgment for

¹³⁰ *Id.* (“In short, the services billed were plainly not ‘covered’ services, and the Government thus paid on the basis of the false claims presented.”).

¹³¹ *Id.* at 55.

¹³² *Id.*

¹³³ *Id.* (emphasis added).

¹³⁴ The Fifth Circuit did cite the Supreme Court’s decision in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943), but it’s unclear for what purpose. As discussed above, *supra* Part I, the *Marcus* decision assessed the constitutionality of the FCA under the Double Jeopardy Clause and held, because the FCA’s damages and civil penalties are remedial and not punitive, that clause did not apply.

¹³⁵ See, e.g., *United States v. Killough*, 848 F.2d 1523, 1533–34 (11th Cir. 1988).

¹³⁶ Namely, from the authors’ home district.

\$311,688.20 even though the government sustained a loss of only \$39,729.40”—a penalties-to-damages ratio of 6.85.¹³⁷

Regardless, whether viewed as a precursor to the modern Excessive Fines Clause jurisprudence or a judicially created exception to the otherwise mandatory nature of the FCA’s civil penalties, *Peterson*’s penalties-to-damages Fair Ratio Standard is problematic. First, if it is doctrinally correct (as we believe it is) that the government need not prove damages as an element of its FCA case,¹³⁸ then *Peterson* would apparently foreclose every “no damages” suit based on the mathematical observation that any award of penalties divided by zero damages is infinitely large.¹³⁹ We’ll call that the Vanishing Denominator Problem. Second, to the extent that *Peterson* is attempting to tie its proportionality analysis to the Eighth Amendment’s prohibition on excessive fines, it errs under *Bajakajian* by assuming (1) that the FCA’s civil penalties are “fines” subject to the Eighth Amendment and (2) that the “gravity of the offense” for the excessiveness analysis can be equated with the government’s “damages.”

Contrast *Peterson* with the Eleventh Circuit’s more recent opinion in *Yates v. Pinellas Hematology & Oncology, P.A.*¹⁴⁰ There, the defendants were found liable under the FCA for submitting 214 claims for laboratory tests performed at a facility lacking a valid Clinical Laboratory Improvement Amendments (CLIA) certificate.¹⁴¹ The resulting damages to Medicare were only \$755.54, which the district court trebled.¹⁴² But the district court also imposed statutory civil

¹³⁷ *United States v. Charlton*, No. 11-817, 2012 WL 1678952, at *3 (M.D. La. May 14, 2012) (assessing one civil penalty of \$11,000 despite the submission of 35 false claims). *Contra* *United States ex rel. Sorensen v. Outreach Diagnostic Clinic, LLP*, No. H-12-480, 2021 WL 5310987, at *2 (S.D. Tex. Nov. 15, 2021) (awarding a total statutory penalty of \$170,553,350 based on the submission of 14,450 false claims despite single damages of \$807,450 to Medicare—a penalties-to-damages ratio of 211.22).

¹³⁸ *See supra* Part II.

¹³⁹ For mathematically minded readers, the authors acknowledge that this statement is, at best, imprecise and, at worst, nonsensical. Rather than attempting to refine the proposition, we simply ask for those readers’ indulgence with the understanding that the broader point, as stated, is sufficiently clear.

¹⁴⁰ 21 F.4th 1288 (11th Cir. 2021).

¹⁴¹ *Id.* at 1295.

¹⁴² *Id.* at 1295.

penalties of \$1,177,000, or \$5,500 for each of the 214 FCA violations.¹⁴³ On appeal, the Eleventh Circuit determined, as a matter of first impression, that (1) the FCA’s treble damages and civil penalties provisions are “fines” subject to the Eighth Amendment’s Excessive Fines Clause, but (2) the total award in the case was not “excessive.”¹⁴⁴

First, relying on the Supreme Court’s characterization of the FCA as “essentially punitive in nature” from *Vermont Agency*,¹⁴⁵ the Eleventh Circuit held that “though FCA treble damages have a compensatory aspect, FCA monetary awards are, at least, partially punitive,” thereby rendering them “fines” under the Eighth Amendment.¹⁴⁶

Second, on the issue of excessiveness, the court referred to the following three, non-exhaustive factors governing the analysis: “(i) whether the defendant is in the class of persons at whom the statute was principally directed; (ii) how the imposed penalties compare to other penalties authorized by the legislature; and (iii) the harm caused by the defendant.”¹⁴⁷ It also emphasized the principle that “penalties falling below the maximum statutory fines for a given offense . . . receive a strong presumption of constitutionality.”¹⁴⁸

Importantly, and unlike *Peterson*, the Eleventh Circuit in *Yates* rejected equating the government’s \$755.54 in damages with the gravity of the defendants’ offense and noted that “if [the defendants] were correct, then the FCA would not require the imposition of statutory penalties even when the United States does not pay a false claim.”¹⁴⁹ Rather, the court observed that “[f]raud harms the United States in ways untethered to the value of any ultimate

¹⁴³ *Id.* For those readers keeping track, a penalties-to-damages ratio of 1,557.83.

¹⁴⁴ *Id.* at 1307–08, 1314.

¹⁴⁵ *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784–86 (2000).

¹⁴⁶ *Yates*, 21 F.4th at 1308 (citations omitted, citing *Vermont Agency*, 529 U.S. at 784–86). The Eleventh Circuit also noted that its position is consistent with the Ninth, Eighth, and Fourth Circuits. *Id.* (citing *United States v. Mackby*, 261 F.3d 821, 830–31 (9th Cir. 2001); *United States v. Aleff*, 772 F.3d 508, 512 (8th Cir. 2014); *Drakeford v. Tuomey*, 792 F.3d 364, 387–89 (4th Cir. 2015)).

¹⁴⁷ *Id.* at 1314 (citing *United States v. Chaplin’s, Inc.*, 646 F.3d 846, 851 (11th Cir. 2011)).

¹⁴⁸ *Id.* (cleaned up) (quoting *Chaplin’s*, 646 F.3d at 852).

¹⁴⁹ *Id.* at 1316.

payment,” including through “a diminution of the public’s confidence in the government” and by “impos[ing] costs on the United States in the form of the expense of the constant Treasury vigil it necessitates.”¹⁵⁰ It also emphasized “the deterrent effect of a monetary award,” particularly since “the size of the award is a direct reflection of [the defendants’] repeated and knowing submission of false claims to the United States.”¹⁵¹

So where (at least in the authors’ view) does *Yates* succeed where *Peterson* errs? From *Bajakajian*, we know that proportionality is central to the Excessive Fines analysis. The question is: proportional to what? Whereas *Peterson* focuses on actual damages to the government (and thereby overlooks the fact that the United States need not offer proof of damages), *Yates* emphasizes the important, but less quantifiable, interests in programmatic and institutional integrity that are undermined by FCA violations. In doing so, *Yates* avoids the Vanishing Denominator Problem created by *Peterson*. Further, reflecting the separation of powers concerns evident in the Supreme Court’s decision in *Marcus*,¹⁵² *Yates* acknowledges the likely constitutionality of penalties awarded within the statutory range set by Congress.

With these guideposts in mind, *Yates* suggests that the government need not retreat from enforcing the FCA through the effective assessment of civil penalties. Or, more directly, the FCA’s civil penalties truly are “mandatory,” the Eighth Amendment notwithstanding.

IV. Lessons learned

We conclude our review of the FCA’s civil penalties with the following observations:

- So far, courts have been hesitant to require proof of damages as an element of a prima facie FCA case. If the United States intends to seek treble damages under the FCA, it has the burden of proving those damages at trial. But damages need not be the start (or the end) of a FCA case, particularly when considering

¹⁵⁰ *Id.* (cleaned up) (quoting United States *ex rel.* Bunk v. Gosselin World Wide Moving, N.V., 741 F.3d 390, 409 (4th Cir. 2013)).

¹⁵¹ *Id.*

¹⁵² See *supra* notes 36–43.

government programs (such as with managed care or Medicare Parts C and D) for which damages may be difficult to assess.

- The most compelling cases for “no damages” civil penalties liability will likely involve situations where the defendants have obtained money or benefits to which they otherwise were not entitled, even if the loss to the government is speculative or non-determinable.
- “Mandatory” means “mandatory.” The government can push back against the narrative that Excessive Fines Clause violations are “clear” or “obvious” in every case. The Excessive Fines calculus is not as simple as comparing potential civil penalties to actual damages. Indeed, the United States need not even offer evidence of damages for the purpose of establishing a FCA violation or combatting an Excessive Fines defense. In cases involving a significant number of false or fraudulent claims, a large civil-penalties assessment—particularly if it is within the statutory range set by Congress¹⁵³—reflects nothing more than the extensiveness and severity of the alleged violations and does not raise a per se Excessive Fines Clause violation.

Based on these points, the authors believe that the FCA’s civil penalties have the potential to play an increasingly central role—with both “bark” and “bite”—in FCA litigation.

About the Authors

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¹⁵³ As recognized by the Fourth Circuit in *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, the United States and FCA relators also retain the discretion to request a voluntary remittitur of penalties to avoid constitutional challenges. 741 F.3d 390, 406 (4th Cir. 2013) (noting that a voluntary remittitur is “just the sort of arrow that a plaintiff is presumed to possess within his quiver”).

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“The More Things Change”: Successor Liability in False Claims Act Enforcement

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I. Introduction

Let’s consider the following scenario. A company called “AlphaTest” conducts fake COVID-19 tests on senior citizens and bills them to Medicare.¹ A whistleblower files a qui tam complaint under seal, and the government begins a covert investigation. Before the government issues a civil investigative demand (CID) to the company, AlphaTest sells all its assets to a new entity, BetaHealth. BetaHealth has some new shareholders, but one old shareholder—controlling a plurality of shares of the new company—remains the same. BetaHealth hires a new CEO, but the AlphaTest CFO continues with BetaHealth. BetaHealth operates out of the same office park, though it has moved into a different suite. It has an all-new logo and website. Two months after the asset sale, AlphaTest is dissolved. It is unclear if anyone now working at BetaHealth knew of the fraud, including the old shareholder. The government issues its CID to BetaHealth, obtains evidence of wrongdoing, and demands a settlement. BetaHealth argues that it cannot be held liable for its predecessor’s fraud. Is BetaHealth correct?

When is a company legally responsible for the wrongdoing of its predecessor? This article explores the law of successor liability, specifically in the context of the mere continuation doctrine. The mere continuation doctrine provides that a successor is liable for the wrongdoing of its predecessor if, after an asset sale, only one company survives, and the same directors or shareholders continue to control the new company.

In this article, I’ll first explore the general rules of successor liability. Then, I will look at factors relevant to the mere continuation doctrine. After that, I will briefly discuss a parallel doctrine known as substantial continuity, which may apply in some circuits. Finally, I’ll

¹ This hypothetical is fictional.

attempt to answer the question in the hypothetical posed above (Spoiler alert: BetaHealth will probably be liable, but you'll have to read to the end to learn the reasons).

The most important factor to whether mere continuation applies is if the same shareholders continue to control the new company after the transaction. Other factors may bolster the argument for successor liability, but if the shareholders are different, the new company will almost certainly not satisfy the mere continuation test.

II. The law of successor liability

A. The basics

“The successor liability doctrine serves the purpose of identifying transactions where the essential and relevant characteristics of the selling corporation survive the asset sale, and it is therefore equitable to charge the purchaser with the seller’s liabilities.”² All cases relating to successor liability involve two companies: an old company and a new company. A note on terminology: The cases interchange the terms “predecessor,” “seller,” and “old company”; and “successor,” “purchaser,” and “new company.” For simplicity, I will try to use “old company” and “new company” as much as possible, unless a direct quote contains a different term, or if I am making specific reference to the parties’ roles as seller and purchaser in an asset sale. Most of the examples involve the old company selling its assets—that is, equipment, inventory, goodwill, trademarks, etc.—to a new company.³

Most cases discussing successor liability start by stating the general rule that a purchaser in an asset purchase is not liable for the wrongdoing of the seller.⁴ But we wouldn’t be here if there weren’t exceptions. The cases discuss four: (1) when the parties explicitly contract for successor liability; (2) when there is a fraudulent transfer; (3) when there is a de facto merger; or, most important for this article,

² *N. Shore Gas Co. v. Salomon Inc.*, 152 F.3d 642, 651 (7th Cir. 1998).

³ *See, e.g., id.*

⁴ *See, e.g., id.*; *United States ex rel. Bunk v. Gov’t Logistics N.V.*, 842 F.3d 261, 273 (4th Cir. 2016); *New York v. Nat’l Servs. Indus., Inc.*, 352 F.3d 682, 685 (2d Cir. 2003); *United States ex rel. Fisher v. Network Software Assocs.*, 180 F. Supp. 2d 192, 195 (D.D.C. 2002) (“The purchaser of the assets, as distinct from the stock, of a corporation generally does not acquire the seller’s liabilities”); *United States ex rel. Pilecki-Simko v. Chubb Inst.*, No. 06-cv-3562, 2010 WL 1076228, at *15 (D.N.J. Mar. 22, 2010); *HRW Sys., Inc. v. Wash. Gas Light Co.*, 823 F. Supp. 318, 326–27 (D. Md. 1993).

(4) when the new company is deemed a mere continuation of the old company.⁵ The first is straightforward—parties write into the contract that the purchaser assumes some potential liabilities of the predecessor. But many contracts say the opposite—the new company excludes some or all liabilities of the old company from its purchase. The successor liability doctrine comes into play to make the purchaser liable even though the parties attempted to contract around it.

The second and third exceptions are beyond the scope of this article—though it is worth noting that many of the elements supporting the mere continuation doctrine also support fraudulent transfer and de facto merger,⁶ and courts occasionally analyze the exceptions together.⁷ Our focus will be the mere continuation doctrine.

B. The mere continuation doctrine

“The mere continuation theory authorize[s] the imposition of liability if, ‘after the transfer of assets, only one corporation remains, and there is an identity of stock, stockholders, and directors between the two corporations.’”⁸ The purpose of the mere continuation doctrine is to prevent owners from using a new corporate form holding

⁵ See, e.g., *Bunk*, 842 F.3d at 273; *Nat’l Servs. Indus.*, 352 F.3d at 685 (The “traditional common law rule states that a corporation acquiring the assets of another corporation only takes on its liabilities if any of the following apply: the successor expressly or impliedly agrees to assume them; the transaction may be viewed as a de facto merger or consolidation; the successor is the ‘mere continuation’ of the predecessor; or the transaction is fraudulent.” (quoting *B.F. Goodrich v. Betkoski*, 99 F.3d 505, 519 (2d Cir. 1996)); *Chubb Inst.*, No. 06-3562, 2010 WL 1076228, at *15.

⁶ See, e.g., *Chubb Inst.*, No. 06-3562, 2010 WL 1076228, at *16; *N. Shore Gas*, 152 F.3d at 652 (“Two of the requirements for a de facto merger are that ‘there is a continuation of the enterprise of the seller in terms of . . . management, personnel, physical location, assets and operations’ and that ‘the purchasing corporation assumes the obligations of the seller necessary for uninterrupted continuation of business operations.’” (quoting *La.-Pac. Corp. v. Asarco, Inc.*, 909 F.2d 1260, 652 (9th Cir. 1990)).

⁷ See, e.g., *Luxliner P.L. Export Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69, 73 (3d Cir. 1993) (“[C]ontinuity is the basis and test for both the *de facto* and continuity doctrines.”) (quoting *Atlas Tool Co., Inc. v. Comm’r*, 614 F.2d 860, 871 (3d Cir. 1980)); *Chubb Inst.*, No. 06-3562, 2010 WL 1076228, at *16 (analyzing mere continuation and de facto merger using the same factors).

⁸ *Bunk*, 842 F.3d at 273–74 (quoting *United States v. Carolina Transformer Co.*, 978 F.2d 832, 838 (4th Cir. 1992)). See *Nat’l Servs. Indus.*, 352 F.3d at 685 (same).

everything but the old company's liabilities.⁹ In addition to mere continuation, there is also, confusingly, a doctrine called substantial continuity which appears to apply, if at all, in the Seventh Circuit.¹⁰ Some district courts also applied it.¹¹ I discuss when, if ever, the substantial continuity doctrine applies in Section IV below.

C. A note on the False Claims Act (FCA)

Successor liability is not an FCA-specific doctrine, rather it is a common law doctrine applicable whenever a party seeks to hold a new company liable for the wrongdoing of a predecessor. Although the FCA is silent about successor liability, courts apply the doctrine to the FCA nationwide.¹² But it is worth noting that much of the caselaw (and many of the cases discussed in this article) arise in different statutory contexts, most notably the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)¹³ and labor law.¹⁴

III. “The more things stay the same”: the mere continuation factors

A court will probably find a new company liable for the wrongdoing of its predecessor if, after an asset purchase, only one company remains, and the new company has the same owners (that is, shareholders), directors, or both. In other words, a new company is a mere continuation if “the purchasing corporation maintains the same or similar management and ownership but wears a ‘new hat.’”¹⁵ The factors enumerated for mere continuation vary from court to court, but they tend to include some or all of the following:

- I. whether two separate entities still remain after the transaction;
- II. identity of ownership;

⁹ See *N. Shore Gas*, 152 F.3d 642 at 651.

¹⁰ See *E.E.O.C. v. G-K-G, Inc.*, 39 F.3d 740, 747–48 (7th Cir. 1994).

¹¹ See *United States ex rel. Fisher v. Network Software Assocs., Inc.*, 180 F. Supp. 2d 192, 195 (D.D.C. 2022).

¹² See, e.g., *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 709 (N.D. Ill. 2012) (“Successor liability applies to FCA cases.”); *United States ex rel. Klein v. Omeros Corp.*, 897 F. Supp. 2d 1058, 1067 (W.D. Wash. 2012) (“The four traditional [successor liability] exceptions apply here [in the FCA context].”).

¹³ 42 U.S.C. §§ 9601–9675.

¹⁴ *Golden State Bottling Co., Inc. v. N.L.R.B.*, 414 U.S. 168, 184 (1973).

¹⁵ *N. Shore Gas*, 152 F.3d at 654 (quoting *Fletcher Cyc. Corp.* § 7124.10 (Sept. 2021)).

- III. how the nature and scope of the two businesses compare; and
- IV. whether the new company continues in the same trappings as the old company, such as the same address, the same physical space, and the same phone numbers.¹⁶

Courts typically say that no one factor should be determinative. Instead, they take a practical approach,¹⁷ and that form should not be elevated over substance.¹⁸ That said, courts also emphasize that identity of ownership is the most important factor, and that “if there is ‘no overlap of stock ownership’ between the two companies, then the second company is not a mere continuation of the first.”¹⁹ Below, I discuss some of the nuances to the factors found in the caselaw.

¹⁶ These factors come from *Dixon Lumber Co. v. Austinville Limestone Co.*, 256 F. Supp. 3d 658, 674–75 (W.D. Va. 2017) (quoting *Charles Schwab & Co. v. WS Wealth Mgmt., LLC*, No. 16-cv-352, 2016 WL 7033699, at *5 (E.D. Va. Dec. 2, 2016)). *Dixon* also includes factors such as: “whether there has been an asset transfer for less than adequate consideration,” and “how the two companies’ assets compare,” which I discuss briefly within the sections below. *Id.* For another enumeration, see *United States ex rel. Pilecki-Simko v. Chubb Inst.*, No. 06-3562, 2010 WL 1076228, at *16 (Mar. 22, 2010 D.N.J.): (“(a) continuity of management, personnel, physical location, assets, and general business operations; (b) a cessation of ordinary business and dissolution of the predecessor as soon as practically and legally possible; (c) assumption by the successor of the liabilities ordinarily necessary for the uninterrupted continuation of the business of the predecessor; and (d) continuity of ownership/shareholders.”) (citing *Portfolio Fin. Servicing Co. ex rel. Jacom Computer Servs., Inc.*, 334 F. Supp. 2d 620, 625–26 (D.N.J. 2004)).

¹⁷ *N. Shore Gas*, 152 F.3d at 654 (“Under federal common law no single factor is supposed to be determinative; instead, courts take a common-sense approach when deciding whether the seller’s corporate entity has continued after the sale of assets. This warrants emphasis, since there is a tendency to proceed as if each factor is always as significant as the others, regardless of the unique circumstances of a particular case. But not all corporations are created equal. And depending on the character of the corporations involved in the asset purchase, a factor that appears on the mere continuation laundry list may be utterly unilluminating about the true effect of the asset purchase. The mere continuation exception requires close scrutiny of corporate realities, not mechanical application of a multi-factor test.”) (citation omitted)).

¹⁸ *Dixon Lumber*, 256 F. Supp. 3d at 675.

¹⁹ *Id.* at 674–75 (citing *United States v. Carolina Transformer Co.*, 978 F.2d 832, 838 (4th Cir. 1992)).

A. There must be one meaningful company after the transaction

It's important that there be only one company after the transaction.²⁰ If the old company still exists, someone harmed by the old company can simply sue the old company.²¹ But even where the old company continues to exist after the transaction, the new company may still be liable if the old company is “denuded of assets.”²² If the old company is left without “appreciable assets to satisfy the claims of their creditors,” the court is more likely to find the new company open to liability.²³ Relatedly, courts look to the consideration paid in the asset sale—if it's an arm's length transaction, the old company will receive adequate consideration for the assets, and anyone harmed by the old company can seek recovery against those assets.²⁴ Form is less important than substance for this factor.

In *Knapp v. North American Rockwell Corp.*, the old company continued to exist after the asset sale. The new company took on the old company's corporate seal, articles of incorporation, minute books, corporate records, and \$500,000 in cash intended to cover the costs of the transaction.²⁵ The old company continued after the transaction but was meant to dissolve shortly thereafter.²⁶ The Third Circuit found successor liability.²⁷

In *United States ex rel. Bunk v. Government Logistics N.V. (Bunk)*, by contrast, an FCA relator was “unable to rely on the mere continuation theory because the two corporations . . . were both viable after the transfer.”²⁸

²⁰ See *New York v. Nat'l Servs. Indus., Inc.*, 352 F.3d 682, 685 (2d Cir. 2003); *Luxliner P.L. Export, Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69, 74 (3d Cir. 1993).

²¹ See *Knapp v. N. Am. Rockwell Corp.*, 506 F.2d 361, 366 (3d Cir. 1974). See also *Chubb Inst.*, No. 06-3562, 2010 WL 1076228, at *16 (rejecting mere continuation theory because the predecessor never ceased operations, among other reasons).

²² *Knapp*, 506 F.2d at 366–67.

²³ *Id.* at 367.

²⁴ *Id.* at 366–67.

²⁵ *Id.* at 363.

²⁶ *Id.* at 368–70.

²⁷ *Id.*

²⁸ *United States ex rel. Bunk v. Gov't Logistics N.V.*, 842 F.3d 261, 274 (4th Cir. 2016). The Fourth Circuit nonetheless held that the relator adequately pleaded that the asset sale was a fraudulent transaction, one of the other successor liability exceptions. *Id.* at 276. It is worth noting that a number of the factors assessed in the “mere continuation” test may also apply to

In our initial hypothetical, the fact that AlphaTest was dissolved two months after the asset sale would likely weigh in favor of finding BetaHealth liable.

B. There must be identity of controlling ownership, but perfect identity is not required

Identity of ownership is probably the most important factor for finding successor liability.²⁹ This makes sense because the point of the doctrine is to prevent a single owner from creating a new entity holding everything but the old company's liabilities. Put another way, the mere continuation doctrine is designed to separate true asset sales from reorganizations, mergers, or consolidations.³⁰ For example, a company purchasing lab equipment should not be liable if the seller committed Medicare fraud using that lab equipment. But if the old company committed Medicare fraud with the lab equipment, and the old company's shareholders form a new company and sell the lab equipment to the new company, mere continuation may come into play.

The identity-of-ownership factor is likely the one factor whose absence will doom application of the mere continuation doctrine.³¹ Ownership must be essentially identical, not perfectly so.³² "Mathematical precision" is not required for there to be identity of shareholders—identity does not mean identical.³³ What matters most is that, as a practical matter, the new company is controlled by the

determining whether a transaction was a fraudulent transfer meant to evade creditors. *Id.* In *Bunk*, for example, the successor held itself out as a continuation, hired most of the predecessor's employees, and took over nearly all the business of the predecessor. *Id.* at 273–76.

²⁹ *Dixon Lumber Co., Inc. v. Austinville Limestone Co., Inc.*, 256 F. Supp. 3d 685, 674–75 (W.D. Va. 2017).

³⁰ *See* *N. Shore Gas Co. v. Salomon, Inc.*, 152 F.3d 642, 651 (7th Cir. 1998); *United States ex rel. Pilecki-Simko v. Chubb Inst.*, No. 06-3562, 2010 WL 1076228, at *16 (D.N.J. 2010) (“[t]he crucial inquiry is whether there was an intent on the part of the contracting parties to effectuate a merger or consolidation rather than a sale of assets.”) (citations omitted) (quoting *Luxliner P.L. Export, Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69, 73 (3d Cir. 1993)).

³¹ *See Chubb Inst.*, No. 06-3562, 2010 WL 1076228, at *16 (dismissing the complaint for failure to allege identity of ownership, among other reasons).

³² *Fiber-Lite Corp. v. Molded Acoustical Prods. of Easton, Inc.*, 186 B.R. 603, 609 (E.D. Pa. 1994); *HRW Sys., Inc. v. Washington Gas Light Co.*, 823 F. Supp. 318, 332 (D. Md. 1993).

³³ *HRW Sys.*, 823 F. Supp. at 331.

same person or people.³⁴ This is true for both stockholders and directors.³⁵ For example, in *Fiber-Lite*, the new company was meant to have the same sole shareholder as the old company until a bank instructed that the new company's owners must be the sole shareholder's children.³⁶ This supported mere continuation because, "[i]n essence, [the shareholder] received an undeserved windfall all to the detriment of" the old company's creditors.³⁷

In *Luxliner P.L. Export, Co. v. RDI/Luxliner, Inc.*, the asset purchase was made in promissory notes to the old company's two shareholders who continued to hold security interests in the new company's equipment, effectively guaranteeing them continued control over the new entity.³⁸ Again, this was enough to apply mere continuation.

North Shore Gas Co. v. Salomon Inc. is a good example of a case in which a shareholder's stake was substantially diluted, but mere continuation still applied.³⁹ The new company's asset purchase reduced the primary shareholder's stake from 99% to 35% in the new company, which was "for all practical purposes sufficient to insure control of the [new company]."⁴⁰ Illustrating how the factors influence one another, the Seventh Circuit explained that, because the same shareholder "remained in control after the [reorganization], the next factor that the case law identifies as important—an identity of officers and directors between the selling and purchasing corporations—declines in significance."⁴¹

Reinforcing that this factor is likely the only necessary factor, the court in *Dixon Lumber Co., Inc. v. Austinville Limestone Co., Inc.* rejected mere continuation, despite some similarities between two entities, because there was "no overlap whatsoever" between the owners of the predecessor and successor.⁴²

³⁴ *Id.* (the rationale for the test was to determine whether there was "control over first one organization and then the other by the same group of stockholders...").

³⁵ *Id.* at 332.

³⁶ *Fiber-Lite*, 186 B.R. at 609.

³⁷ *Id.* at 610.

³⁸ *Luxliner P.L. Export, Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69, 74 (3d Cir. 1993).

³⁹ *N. Shore Gas Co. v. Salomon Inc.*, 152 F.3d 642, 655 (7th Cir. 1998).

⁴⁰ *Id.* (alteration in original).

⁴¹ *Id.*

⁴² *Dixon Lumber Co., Inc. v. Austinville Limestone Co., Inc.*, 256 F. Supp. 3d 658, 675 (W.D. Va. 2017).

Thus, in our initial hypothetical, the presence of the old shareholder—controlling a plurality of shares of the new company—will likely weigh strongly in favor of a finding that BetaHealth is liable for AlphaTest’s fraud.

C. Continuity of business is helpful but not necessary or sufficient

What about the business itself? Courts differ, and this factor seems to carry less weight, but if the new company conducts the same business as the old, it may tip the balance in favor of mere continuation. In *HRW Systems, Inc. v. Washington Gas Light Co.* (*HRW*), for example, a District of Maryland district court included continuity of business in its mere continuation analysis, because “the question of whether there is continuation of business between a predecessor and successor corporate entity does have a common-sense flavor about it.”⁴³

What does it mean to be in the same business? In *HRW*, the new company, Washington Gas, argued that, although both it and the old company supplied, stored, and transported gas to Washington, D.C., the new company did not *manufacture* gas—as the old company had done. Therefore, it was in a different business and not a mere continuation.⁴⁴ The court rejected this argument as “disingenuous at best.”⁴⁵

Continuity of business name, location, and corporate imagery also help.⁴⁶ In all likelihood, if the key factor—identity of ownership—is found, a court will not parse business continuity too closely. If ownership remains the same, this factor can help tip in favor of successor liability, but without ownership identity, this factor is probably not enough.

⁴³ *HRW Sys. Inc. v. Washington Gas Light Co.*, 823 F. Supp. 318, 330 (D. Md. 1993).

⁴⁴ *See id.* at 330–31.

⁴⁵ *Id.* at 330. *See also* *Luxliner P.L. Export, Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69, 74 (3d Cir. 1993) (both companies were in the business of converting Ford vehicles for export).

⁴⁶ *Fiber-Lite Corp. v. Molded Acoustical Products of Easton, Inc.*, 186 B.R. 603, 610 (E.D. Pa. 1994) (choosing the same name “kept the continuity of the company and the image of the company intact”); *Luxliner*, 13 F.3d at 73–74 (successor and predecessor had the same business address, phone, fax, and logos).

Thus, in the hypothetical above, because of the identity of ownership, a court would not likely parse the business of BetaHealth too closely. The new office suite, logo, and website could weigh against a finding of continuity, but they would not likely overcome the identity-of-ownership factor.

D. Identity of management or employees is helpful but not necessary or sufficient

What about identity of management or employees? Like continuity of business, this factor alone is probably not enough to create successor liability without identity of shareholders.⁴⁷ But a number of courts credit continuity of management or employees as a factor supporting successor liability.⁴⁸ If there is already identity of shareholders, the question may be “whether the controlling entity has the power to install responsive and compliant officers and directors at the helm of the purchasing corporation—not whether the controlling interest has in fact installed the *same* adherents who steered the selling corporation.”⁴⁹ As with shareholders, perfect identity of officers is not required.⁵⁰

In our hypothetical, the presence of a new CEO would likely weigh against continuity, but this factor would not likely overcome identity-of-shareholders factor.

IV. What is the substantial continuity test?

Some cases do not analyze the fourth successor liability exception through the mere continuation doctrine but rather through the slightly different substantial continuity doctrine. “Rather than considering ownership, the substantial continuity test focuses on the continuity of the business: Whether the successor maintains the same business, with the same employees doing the same jobs, under the same supervisors, working conditions, and production processes, and

⁴⁷ See *Portfolio Fin. Servicing Co. ex rel. Jacom Comput. Servs., Inc. v. Sharemax.com*, 334 F. Supp. 2d 620, 629 (D.N.J. 2004) (the fact that the predecessor and successor shared officers, by itself, was not enough to cause the mere continuation doctrine to apply).

⁴⁸ See, e.g., *United States ex rel. United States ex rel. Bunk v. Gov’t Logistics N.V.*, 842 F.3d 261, 269 (4th Cir. 2016) (19 of 20 employees of the successor came from the predecessor); *Fiber-Lite*, 186 B.R. at 610 (new company hired all of predecessor’s employees).

⁴⁹ *N. Shore Gas Co. v. Salomon Inc.*, 152 F.3d 642, 655–56 (7th Cir. 1998).

⁵⁰ *Id.* at 656–57.

produces the same products for the same customers.”⁵¹ The Supreme Court developed the doctrine “in the labor law context.”⁵²

In *Bunk*, the Fourth Circuit described substantial continuity as “more lax” than mere continuation,⁵³ and, for that reason, rejected it in the FCA context, because it would expand the common law without statutory provision to do so.⁵⁴ In *Bunk*, the relator could not rely on the mere continuation test because both the old and new companies remained viable after the transaction.⁵⁵ So the relator argued that the court should apply the substantial continuity test, which “expands on the mere continuation theory, allowing a court to look at an ensemble of at least eight factors to determine whether successor corporation liability should be imposed.”⁵⁶

Bunk was an FCA case, and the Fourth Circuit explicitly rejected application of the substantial continuity test in the context of the FCA. The Fourth Circuit reasoned that the mere continuation test is the common law rule; that the FCA does not speak to successor liability; that a statute must explicitly call for a common law rule to be changed if a court is going to do so; and, therefore, that applying substantial continuity would improperly alter the common law rule.⁵⁷ Therefore, in the Fourth Circuit, *Bunk* holds that the substantial

⁵¹ *New York v. Nat’l Servs. Indus., Inc.*, 352 F.3d 682, 685 (2d Cir. 2003) (internal quotation marks omitted) (quoting *B.F. Goodrich v. Betkoski*, 99 F.3d 505, 519 (2d Cir. 1996)).

⁵² *Id.*

⁵³ *Bunk*, 842 F.3d at 274.

⁵⁴ *Id.* (“The FCA does not speak to successor corporation liability and thus has no impact on the traditional common law principles governing successor corporation liability.”). The Second Circuit rejected substantial continuity for the same reason in the CERCLA context. See *Nat’l Servs. Indus.*, 352 F.3d at 687–88 (Leval, J., concurring) (holding “in the absence of a statutory authorization, courts are not free to impose federal statutory liability under standards that depart from the well[-]established principles of common law”); *United States ex rel. Klein v. Omeros Corp.*, 897 F. Supp. 2d 1058, 1067 (W.D. Wash. 2012) (same).

⁵⁵ *Bunk*, 842 F.3d at 274.

⁵⁶ *Id.* (citing *United States v. Carolina Transformer Co.*, 978 F.2d 832, 838 (4th Cir. 1992)). The eight factors are: “(1) retention of the same employees; (2) retention of the same supervisory personnel; (3) retention of the same production facilities in the same location; (4) production of the same product; (5) retention of the same name; (6) continuity of assets; (7) continuity of general business operations; and (8) whether the successor holds itself out as the continuation of the previous enterprise.” *Id.*

⁵⁷ *Id.*

continuity test cannot be applied to determine successor liability under the FCA.⁵⁸

A Washington D.C. district court took a different approach in *United States ex rel. Fisher v. Network Software Associates (Fisher)*.⁵⁹ In this FCA case, the defendant argued that it should have no liability because it merely purchased the assets of the old company.⁶⁰ The court quoted the Seventh Circuit's two-condition successor liability formulation:

The first [condition] is that the successor had notice of the claim before the acquisition. . . . The second condition is that there be substantial continuity in the operation of the business before and after the sale, and is satisfied if no major changes are made in that operation.⁶¹

In *Fisher*, one person allegedly controlled both the predecessor and successor entity.⁶² The court explained that “[s]ubstantial continuity in ownership and staff between the predecessor corporation and the successor entity ‘may well satisfy the notice prong’ by suggesting that there was actual knowledge of a claim by the successor corporation or its principals.”⁶³ The court denied defendant’s motion to dismiss.⁶⁴ This analysis is in concert with the mere continuation doctrine’s emphasis on identity of shareholders—if one shareholder controls both the old and new company, it stands to reason that the shareholder

⁵⁸ *Id.*

⁵⁹ 180 F. Supp. 2d 192 (D.D.C. 2002).

⁶⁰ *Id.* at 195.

⁶¹ *Id.* (quoting *E.E.O.C. v. G-K-G, Inc.*, 39 F.3d 740, 747–48 (7th Cir. 1994)). In *G-K-G*, the Seventh Circuit explained further: “The purchaser of the assets, as distinct from the stock, of a corporation generally does not acquire the seller’s liabilities, even if all the assets are transferred by the sale so that in effect the entire business has been sold, and the purchaser intends to continue it as a going concern. . . . Only if the sale is merely a step in a corporate reorganization designed to shift the liabilities to an empty shell will the creditors be allowed to go against the ‘purchaser.’ . . . Nevertheless, when a claim arising from a violation of federal rights is involved, the courts allow the plaintiff to go against the purchaser of the violator’s business even if it is a true sale and not a reorganization, provided [the conditions quoted above] are satisfied.” *Id.*

⁶² *United States ex rel. Fisher v. Network Software Associates, Inc.*, 180 F. Supp. 2d 192, 196 (D.D.C. 2002).

⁶³ *Id.* (citing *Chi. Truck Drivers, Helpers & Warehouse Workers Union (Ind.) Pension Fund v. Tasemkin*, 59 F.3d 48, 49–50 (7th Cir. 1995)).

⁶⁴ *Id.*

would have had notice of whatever wrongdoing created the liability at issue against the new company.

In summary, applying substantial continuity in the FCA context is confusing. The Second and Fourth Circuits seem to have clearly rejected the test, citing the Supreme Court's holding that, when a statute is silent, courts may not expand common law rules. The Seventh Circuit appears to have coupled the substantial continuity test with an element of knowledge to find successor liability, and that formulation has been applied by district courts elsewhere. But even in a jurisdiction where substantial continuity is not the rule, if substantial continuity factors are present in addition to the all-important identity-of-shareholders factor, one ought to lay them out for the court. Likewise, the test used by *Fisher* and *E.E.O.C. v. G-K-G, Inc.*—coupling substantial continuity with notice to the purchaser—shows that courts care whether the purchaser had notice of the wrongdoing. If the same shareholders are controlling both the old and new companies, it is more likely that the new company knew of whatever wrongdoing the old company was involved in.

VI. Conclusion

So what is the result for BetaHealth? Most courts would likely hold BetaHealth to be a mere continuation of AlphaTest. The key factor is that, although BetaHealth has some new shareholders, the key shareholder continues to control the new company. The old company wound down shortly after the transaction, also supporting mere continuation. The new CEO, new branding, and new-ish office location weigh in favor of no successor liability. This author, however, has not found a reported case where a successor avoided liability when it was controlled by a shareholder of the old company. Finally, if the investigation uncovered that the employees of BetaHealth knew about the COVID-19 testing fraud during their due diligence, BetaHealth would also likely be liable under the Seventh Circuit's formulation requiring notice to the successor before the acquisition.⁶⁵ The point of

⁶⁵ Even if they didn't know, the acquirer still has due diligence obligations. The Department of Justice has published guidelines for evaluating corporate compliance programs, which includes guidelines for comprehensive due diligence in mergers and acquisitions. *See* U.S. DEP'T OF JUST., CRIM. DIV., EVALUATION OF CORPORATE COMPLIANCE PROGRAMS 9 (2020), <https://www.justice.gov/criminal-fraud/page/file/937501/download>. Among other things, the guidance highlights that: “[f]lawed or incomplete pre- or post-acquisition due diligence and integration can allow misconduct to

the mere continuation doctrine is that an asset purchase must be a true asset purchase if the purchasing company is to avoid liability. A corporate reorganization dressed up as an asset purchase will not allow a new company to evade liability for wrongdoing.

About the Author

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continue at the target company, causing resulting harm to a business's profitability and reputation and risking civil and criminal liability." *Id.*

Note from the Editor-in-Chief

As Susan Strawn noted in her introduction to this issue, spending on health care accounted for almost one-fifth of this country's gross domestic product in 2020. Think about that for a moment. One out of every five dollars is spent on health care. With that much money in play, there is little room to wonder why white-collar crime and civil violations infest the health-care industry. This issue details the investigation and prosecution of those schemes—in civil and criminal forums—from COVID fraud to kickback schemes to the falsification of data in clinical drug trials. Investigators and prosecutors have seen it all and work tirelessly every day to bring those who seek to cheat the system to justice.

As usual, this page affords us the opportunity to thank some people who made this issue possible. The DOJ Journal staff would like to acknowledge the work of Denise Simpson and Susan Strawn, who acted as points of contact, recruiting authors, and policy reviewers. Of course, we would be remiss in not mentioning the wonderful collection of subject-matter experts who wrote articles and shared their expertise with us.

Here at the Office of Legal Education—Publications, Attorney Advisor Melissa Atwood served as Managing Editor for this issue. And we welcomed University of South Carolina contractor Kari Risher as our new permanent Associate Editor. Both came up to speed quickly on the process of putting a journal issue together and did a terrific job.

To all our readers, we hope this issue has given you greater insight into the challenges faced by those on the front lines of fighting health-care fraud. Until next time, stay safe and healthy.

Chris Fisanick
Columbia, South Carolina
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