PLAUSIBLE CAUSE: CONNECTING THE FCA AND AKS IN THE CONTEXT OF HEALTH CARE FRAUD

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ABSTRACT

Healthcare fraud is a billion-dollar industry in the United States. Because healthcare fraud is varied in method and often subtle, it is difficult to catch. The federal government's main tool for fighting this fraud is the False Claims Act ("FCA"). One of the most important ways the government enforces the FCA is through its connection with the Anti-Kickback Statute ("AKS"). This connection provides that if a claim results from a violation of the AKS, it is false for FCA purposes. The difficulties of proof in this context have given rise to a circuit split about how to prove this causal connection. There are three main theories, each with its own problems. The taint theory, which holds that a claim is false if it is so much as tainted by a kickback scheme, has the potential to hold defendants liable for lawful conduct. The but-for cause theory holds plaintiffs to a standard of proof that is difficult to meet in healthcare fraud cases. Under the link theory, a plaintiff can prove a class of claims is false if plaintiff can prove that one of the claims is linked to a kickback scheme. The link theory seeks to ameliorate the plaintiff's difficulty in proving causation. However, it does not give the defendant a chance to contest the claims the theory allows plaintiff to skip. A new causation rule is required. It must be flexible but also fair to defendants. It should also be calibrated to account for healthcare fraud cases' factual variety and complexity. This Note proposes a new causation rule: if plaintiff can show that a kickback scheme is the kind of scheme that plausibly gives rise to the kinds of claims plaintiff alleges, the burden should shift to defendant to show that the kickback scheme was not the but-for cause of the claims.

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I. INTRODUCTION TO FEDERAL HEALTH CARE FRAUD

In 2022, healthcare fraud settlements, judgments, and administrative impositions paid to the federal government and private parties amounted to $1.7 billion.[1] In 2021, that number was just under $1.9 billion.[2] Although it is unclear exactly how much money is lost each year to healthcare fraud, it may be higher than $100 billion.[3] This

1. *See* U.S. DEP'T. OF HEALTH & HUM. SERVS., HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2022 1 (2022).

2. *Id.*

3. Scott Zamost & Contessa Brewer, *Inside the Mind of Criminals: How to Brazenly Steal $100 Billion from Medicare and Medicaid*, CNBC,

problem is not new.[4] Healthcare fraud is difficult to detect and penalize. One reason is that it occurs in a variety of ways.[5] It is not always

https://www.cnbc.com/2023/03/09/how-medicare-and-medicaid-fraud-became-a-100b-problem-for-the-us.html (Mar. 9, 2023, 11:11 AM).

4. *See* Pamela H. Bucy, *Fraud by Fright: White Collar Crime by Health Care Providers*, 67 N.C. L. REV. 855, 856 n.7 (1989).

5. *See, e.g.*, United States v. Krizek, 111 F.3d 934, 936–38 (D.C. Cir. 1997) (fraud consisting of doctors charging federal programs for forty-five to fifty minutes of treatment instead of twenty to thirty minutes); United States *ex rel.* Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497, 502 (S.D.N.Y. 2014) (pharmaceutical company hosting speaker events at which the company's drugs were barely or not discussed and which functioned as social events intended to induce doctors to prescribe company's drugs); United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 91–92 (3d Cir. 2018) (provider of hemophilia-related medical services reducing donation to hemophilia charities with approved provider list and then restoring the original donation after analyzing the dire effects alienating the charities would have on business); United States *ex rel.* Cairns v. D.S. Med. LLC, 42 F.4th 828, 831 (8th Cir. 2022) (neurosurgeon choosing to buy spinal implants from a distributor wholly owned by his fiancée); United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1046–47 (6th Cir. 2023) (hospital refusing to hire an internal ophthalmologist due to fears that external ophthalmologist that regularly referred to the hospital would pull his referrals); United States v. Teva Pharms. USA, Inc, 682 F. Supp. 3d 142, 144 (D. Mass. 2023) (defendant pharmaceutical company referring patients to a specialty pharmacy which then referred the same patients to two foundations which provided assistance paying co-pays for defendant's drug, defendant donating to those two foundations, and defendant raising its drug's wholesaler price all at the same time); United States *ex rel.* Flanagan v. Fresenius Med. Care Holdings, Inc., No. 21-11627, 2022 U.S. Dist. LEXIS 218302, at *6–8 (D. Mass. Dec. 2, 2022) (showing dialysis service provider improperly inducing referrals from hospitals by providing no or low cost services); United States v. Rogan, 517 F.3d 449, 452 (7th Cir. 2008) (medical center paying doctors for referrals and charging federal programs for unnecessary and unperformed services); United States *ex rel.* Johnson v. Golden Gate Nat'l Senior Care, LLC, 223 F. Supp. 3d 882, 889–890, 892, 894–95, 899, 902–03 (D. Minn. 2016) (skilled nursing facility submitting claims to Medicare while violating various statutory and regulatory requirements, including licensed professionals entering time for services they did not personally provide, licensed professionals failing to adequately supervise nonprofessionals, improper categorization of group therapy sessions as individual therapy sessions when billing Medicare, improper categorization of services as "skilled," billing Medicare for services not actually provided); United States *ex rel.* Brown v. Celgene Corp., 226 F. Supp. 3d 1032, 1035–36 (C.D. Cal. 2016) (pharmaceutical company engaging in a successful campaign to promote its drug to physicians to prescribe for off-label uses, resulting in federal programs being charged for non-reimbursable off-label prescriptions); United States *ex rel.* Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 16–17 (5th Cir. 2009) (a drug's distributor and promoter falsely inflating the "Average Wholesale Price," which Medicare uses for reimbursement purposes, marketing this inflation to medical providers, and providing kickbacks to providers for prescriptions in the forms of free samples, discounts, rebates, "'unrestricted education grants,' and 'phony drug studies'"); United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 184 (5th Cir. 2009) (doctors billing for face-to-face meetings that never occurred); United States *ex rel.* Schutte v. SuperValu, Inc., 598 U.S. 739, 745–46 (2023) (pharmacies regularly providing discounts to customers but charging federal programs undiscounted prices).

immediately clear when fraud has occurred.[6] Suspected fraud can be difficult to prove because doing so can require sifting through masses of complicated paperwork, shifting regulations, and innuendo.[7] In some schemes, each fraudulent transaction is small, and the fraud only becomes apparent after an examination of hundreds of seemingly insignificant transfers.[8] Investigating this type of fraud is expensive and can be hard to justify.[9] Another complicating factor is that fraud often occurs in large organizations.[10]

It can be difficult to draw the lines between fraud and lawful conduct—questions of materiality dog courts struggling to distinguish significant and insignificant violations of contractual, regulatory, and legal billing conditions.[11] Some commentators and judges argue that strong antifraud law makes socially beneficial conduct illegal.[12]

6. Bucy, *supra* note 4, at 875.

7. *See id*. at 877 ("It is often necessary to follow a lengthy paper trail simply to discover what occurred. This paper trail is especially arduous in the health care field because of complex and rapidly changing regulations. As one expert noted, 'The billing process itself, and the paperwork necessary to monitor numerous and complex third-party insurance contracts—with varying co–insurance, deductibles, and maximum benefit schedules and with widely varying coverage and criteria for major medical payments—boggle[s] the mind . . . . [I]t assuredly confuses both patients and their doctors.'") (citation omitted). For innuendo, see text accompanying notes 57–62.

8. Bucy, *supra* note 4, at 879–80 (some fraudulent transfers amounting to "only a few cents of fraud.").

9. *Id*. at 880 n.195.

10. *Id*. at 878. ("[Fraud] is often 'hidden within an organization.' This makes it difficult to find out what went on and particularly difficult to find evidence of a defendant's intent. In the health care field, fraud occurs when false bills are submitted for reimbursement by the provider to the third-party payer . . . To hold the provider responsible for the false statements in the bills requires . . . proof that the provider personally knew false information was included in the bills finally submitted.") (citations omitted).

11. *See generally* Universal Health Servs., Inc v. United States *ex rel.* Escobar, 579 U.S. 176 (2016); Jake Summerlin, Note*, Determining the Appropriate Reach of Escobar's Materiality Standard: Implied and Express Certification*, 38 GA. ST. U. L. REV. 571 (2022); 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 (2018). For further discussion on *Escobar*, see *infra* Section IV.A.

12. *See* United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1054 (6th Cir. 2023) ("Much of the workaday practice of medicine might fall within an expansive interpretation of the Anti-Kickback Statute."); James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, 15 HEALTH AFFS. 118, 121 (1996). Blumstein argues that strong antifraud measures make "practices that encourage cost-effective care, the formation of managed care organizations, innovation in the structure of health care delivery, and the development of efficient relationships among providers" illegal. *Id.* at 120. He further argues that some conduct deemed fraudulent is "often needed to reduce costs in managed care networks." *Id.* at 122; *see also* United States *ex rel.* Flanagan v. Fresenius Med. Care Holdings, Inc., No. 21-11627, 2022 U.S. Dist. LEXIS 218302 (D. Mass. Dec. 2, 2022).

Examples illustrate the variety of forms healthcare fraud takes as well as the difficulty of proving it. First, imagine that, whenever a doctor prescribes Pharmaceutical Company A's drug to a patient covered by Medicare, and A bills Medicare for the drug, A forwards a portion of the Medicare payment to the prescribing doctor. A pays the doctor with a check, and the check says "illegal kickback for drug prescription" on the memo line. Easy, right? That bill to Medicare is a false claim because it resulted from an illegal kickback scheme.[13] Now imagine Pharma Company A doesn't send doctors checks. Instead, A puts on speaker events where A pays doctors to speak to other doctors about A's drug.[14] The events contain very little substantive medical presentation and resemble social outings.[15] A plies the doctor attendees with food and drink and lets them bring friends.[16] The attending doctors are more likely to prescribe A's drug than doctors who are not invited.[17] But doctors who fall behind on prescriptions stop receiving invitations.[18] Is this fraud? Probably,[19] but how can plaintiff prove it? Does plaintiff have to show that doctors wrote prescriptions with the intent to keep receiving invitations? If so, how? Say doctor B, a regular at A's events, prescribes A's drug ten times in a given period. How many of the ten are false? Should B only face liability for that fraction directly caused by the kickback scheme, or for all ten? If the answer is the former, how can plaintiff show the difference?

Much of healthcare fraud is concentrated in a small number of large manufacturers—only six manufacturers paid over half of all pharma fraud settlement payments from 2006 to 2022.[20] These six repeat

13. *See infra* Section II.C.

14. See United States *ex rel.* Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497, 520 (S.D.N.Y. 2014) for this scenario.

15. *See id.* at 519.

16. *See id.* at 502. In *Bilotta*, the same doctors would go to multiple events on the same topic in a short period and take turns as speakers and attendees. *Id.* One doctor attended the same presentation ten times in a row and three others were consistently present at nine. *Id.* Many of the events took place at sports bars and high-end restaurants. *Id.* Many venues did not have private rooms, so it was difficult to hear the speaker. *Id.* Often, no educational slides were shown. *Id.* Some events took place in "inappropriate" settings—the *Bilotta* court singled out "'round table' programs at Hooters restaurants and fishing trips." *Id.* (quoting Amended Complaint at ¶¶ 122–24, United States *ex rel.* Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497 (S.D.N.Y. 2014) (No. 11 Civ. 0071PGG)).

17. *See id.* at 503.

18. *See id.*

19. *See id.* at 521–29 (declining to dismiss an FCA-AKS cause of action on similar facts).

20. Liam Bendicksen et al., *Federal Enforcement of Pharmaceutical Fraud Under the False Claims Act, 2006–2022*, 49 J. HEALTH POLS. POL'Y & L., 249, 253 (2024). They were GSK, Purdue, Pfizer, Johnson & Johnson, Novartis, and Merck. *Id.*

offenders paid over twenty-eight percent of all payments resulting from Department of Justice fraud actions.[21]

In summary, healthcare fraud is widespread, expensive, and difficult to stop. Some companies continue to violate antifraud laws despite repeatedly facing liability.[22] Healthcare fraud's existence as a continuing problem and some companies' flouting of the law suggest the current antifraud regime is insufficient.

This Note explores one facet of this quagmire: the connection between the False Claims Act and the Anti-Kickback Statute. This statutory connection's causation element is the subject of a growing circuit split.[23]

Part II of this Note will examine the policy, enforcement, connection, and recent history of the two statutes. Part III will outline the history of the circuit split. Part IV will look at other problems of antifraud law and argue for a two-step burden-shifting causation rule. The first step will consist of an analysis of whether a causal relationship is plausible. If the first step is met, the burden will shift to defendant to disprove the causal relationship.

II. THE FALSE CLAIMS ACT AND THE ANTI-KICKBACK STATUTE

A. The False Claims Act

Today, the False Claims Act ("FCA") is the federal government's main tool for fighting Medicare and Medicaid fraud.[24] The FCA imposes civil liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the United States government.[25] Civil liability under the FCA carries steep penalties: treble damages[26] and a civil penalty between $13,946 and $27,894 for each false claim.[27]

The FCA scienter requirement includes "actual knowledge . . . deliberate ignorance of the truth or falsity of the information . . . [or] reckless disregard of the truth or falsity of the information."[28] In practice, this means the scienter element is met when "submitted claims to the

21. *Id.*
22. *See id.*
23. *See infra* Part III.
24. Bendicksen et al., *supra* note 20, at 249–50.
25. False Claims Act, 31 U.S.C. §§ 3729(a)–(b).
26. 31 U.S.C. § 3729(a)(1).
27. Civil Monetary Penalties Inflation Adjustment, 28 C.F.R. § 85.5 (2024).
28. False Claims Act, 31 U.S.C. § 3729(b). This standard has been explained as "gross negligence–plus." United States v. Krizek, 111 F.3d 934, 943 (D.C. Cir. 1997).

Government are prepared in such a sloppy or unsupervised fashion that resulted in overcharges to the Government."[29]

The FCA contains a provision enabling private parties to bring civil FCA actions on behalf of the federal government.[30] A "*qui tam*"[31] plaintiff proceeding under this section has the right to part of the government's recovery.[32] The government chooses whether to intervene and take over the case—it even has the right to dismiss the case over the private plaintiff's objections, provided its actions are fair.[33] *Qui tam* makes private citizens into whistleblowers.[34]

B. The Anti-Kickback Statute

The Anti-Kickback Statute ("AKS") imposes civil[35] and criminal liability for knowingly and willfully soliciting, receiving, offering, or paying remuneration for referrals for the furnishing or purchase of goods or services for which a federal healthcare program may be charged.[36] A crime under the AKS is a felony carrying a fine of up to $100,000, up to ten years' imprisonment, or both.[37] The AKS bars all forms of remuneration, including in cash and in kind.[38] Some commentators argue the AKS threatens socially beneficial behaviors and relationships.[39]

Because of the AKS's breadth, the Department of Health and Human Services ("DHHS") has promulgated a number of regulatory exceptions

29. Krizek, 111 F.3d at 942 (quoting 132 CONG. REC. H9382-03 (daily ed. Oct. 7, 1986) (statement of Rep. Berman)).

30. False Claims Act, 31 U.S.C. § 3730(b)(1).

31. *Qui tam* is short for *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, Latin for "who pursues this action on our Lord the King's behalf as well as his own." Timson v. Sampson, 518 F.3d 870, 874 n.1 (11th Cir. 2008).

32. 31 U.S.C. § 3730(d).

33. *See* STEVEN W. FELDMAN, GOVERNMENT CONTRACT GUIDEBOOK § 12:10 (4th ed. 2023).

34. *See, e.g.*, United States *ex rel.* Greenfield v. Medco Health Sol., Inc., 880 F.3d 89, 92–93 (3d Cir. 2018) (*qui tam* plaintiff suing his own company after witnessing activity he thought fraudulent).

35. 42 U.S.C. § 1320a-7a(a)(7) (imposition of civil liability for acts described in the statute's criminal section).

36. 42 U.S.C. §§ 1320a-7b(b)(1)–(2).

37. *Id.*

38. *See id.*

39. *See, e.g.*, Blumstein, *supra* note 12, at 121–22 ("Thus, a motivation to develop business among Medicare or Medicaid patients or to assure a flow of such patients is illegal. Yet such types of arrangements are commonplace in the health care market, and they can be beneficial . . . . [T]he financial arrangements and inducements often needed to reduce costs in managed care networks—for example, the negotiated reduction of fees on the assurance of increased volume—may violate the fraud and abuse law.") (citation omitted)).

to AKS liability known as "safe harbors."[40] Each safe harbor can have multiple requirements.[41] The AKS also includes several statutory exceptions.[42] Even if a potentially illegal arrangement does not meet an exception or a safe harbor, it will not trigger AKS liability unless a defendant intended it to result in illegal referrals or sales.[43] The boundaries of this scienter are unclear.[44] DHHS's Office of the Inspector General ("OIG") propagates AKS advisory opinions.[45] If an arrangement does not fit into a safe harbor or exception, an advisory opinion will consider the facts of the arrangement to determine whether it has characteristics that "appear to be associated with an increased potential for program abuse."[46] While these opinions can be helpful, they have no precedential effect beyond the immediate parties.[47] The upshot is that interpreting the AKS requires wading through a mire of regulations, statutory exceptions, and OIG advisory opinions. It can be difficult to predict what violates the AKS, and violations can result in serious civil and criminal penalties.

C. Connecting the FCA and AKS

In 2010, as part of the Patient Protection and Affordable Care Act, Congress amended the AKS: "[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for [the] purposes of [the FCA]."[48] As a result of this change, *qui*

40. KAREN LOVITCH & ROBERT ROSSI, HEALTH L. PRAC. GUIDE § 41:2 (2023).

41. *Id.*

42. Andrew S. Feldman, *That Other Provision of the Anti-Kickback Statute: Should Plaintiffs and the Government Reconsider Its Potential Application and Benefits?*, 28 HEALTH L. 1, 3 (2016).

43. *See id.*

44. *See* United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985) (adopting a "one purpose" test); United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 29–30 (1st Cir. 1989) (approving, in dicta, a "primary purpose" test).

45. Feldman, *supra* note 42, at 5.

46. *Id.* at 5–6 (quoting OIG, Advisory Opinion No. 98-10 (1998)). The factors included:

> 1. [c]ompensation based on percentage of sales; 2. [d]irect billing of a federal healthcare program by the seller for the item or service sold by the sales agent; 3. [d]irect contact between the sales agent and physicians in a position to order items or services that are then paid for by a federal healthcare program, 4. [d]irect contact between the sales agent and federal healthcare program beneficiaries; 5. [u]se of sales agents who are healthcare professionals or persons in a similar position to exert undue influence on purchasers or patients; or 6. [m]arketing of items or services that are separately reimbursable by a federal healthcare program . . . whether on the basis of charge or costs.

Id.

47. *Id.* at 6.

48. 42 U.S.C. § 1320a–7b(g); United States *ex rel.* Greenfield v. Medco.

tam plaintiffs can now bring AKS claims through the FCA.[49] The specter of *qui tam* increases the risk of litigation under the difficult-to-predict AKS. The dangers of this combination make it essential that the connection between the AKS and FCA be well-understood.

It is equally important that the combination be strong enough to impose liability where appropriate. Healthcare fraud is a huge industry that has proven difficult to root out.[50] This is, in large part, because of how difficult it is to prove.[51] By connecting the FCA and AKS, Congress intended to strengthen the fraud-fighting potential of both statutes.[52]

These competing policy considerations reveal the need for an FCA–AKS connection that is (1) predictable, (2) flexible enough to catch fraudulent conduct, and (3) robust enough to allow innocent defendants to protect themselves from liability. However, the statutes' connection only indicates that the FCA imposes liability for claims including "items or services *resulting from* a violation" of the AKS.[53] The meaning of the words "resulting from" is the subject of a circuit split.[54]

III. HISTORY AND CURRENT STATE OF THE CIRCUIT SPLIT

A. History of Circuit Split

Federal circuits disagree about the meaning of the phrase "resulting from" in the amendment to the AKS connecting it to the FCA. What does a plaintiff have to prove to show a claim "result[s] from" a violation of the AKS?

1. *Greenfield*

The Third Circuit addressed this issue in *United States ex rel. Greenfield v. Medco Health Sols., Inc.*[55] Defendant Accredo was in the business of providing medication and nursing services to hemophilia

Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018); Feldman, *supra* note 42, at 8.

49. *See, e.g.*, *Greenfield*, 880 F.3d at 93–95 (allowing Greenfield to bring a *qui tam* action for an AKS violation).

50. *See supra* Part I.

51. *See Greenfield*, 880 F.3d at 94–95; *supra* text accompanying notes 5–10.

52. *Greenfield*, 880 F.3d at 96 ("It appears the drafters of the Anti-Kickback Statute 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.'") (quoting H.R. Rep No. 95-393, at 1, 47).

53. 42 U.S.C. § 1320a–7b(g) (emphasis added).

54. *See infra* Part III.

55. 880 F.3d 89 (3d Cir. 2018).

patients.[56] Accredo also regularly contributed to hemophilia charities, referred to here as HSI and HANJ.[57] HANJ advertised Accredo as an "HSI-approved provider" on its website and in communication with treatment centers.[58] HANJ's website claimed HSI-approved vendors "maintain the highest quality of care while providing [a] continuity of services and constantly supporting the community" and exhorted users to "[r]emember to work with our HSI [approved] providers."[59]

In 2010, Accredo gave about $363,000 to HSI/HANJ.[60] That year, Accredo notified the charities that it would reduce its donation to about $175,000 in 2011.[61] HSI sent its members a letter informing them of Accredo's decrease in donations and encouraging them to ask Accredo to restore the original donation amount.[62] HSI sent the same letter to treatment centers and condemned Accredo for "behav[ing] despicably, while enjoying the fruits of HANJ's labor."[63]

Accredo asked one of its area vice presidents, Greenfield, to analyze the effects of the lowered donation.[64] Greenfield predicted that, unless Accredo raised its donation back to $350,000, Accredo would face grave consequences: all its business would be at risk and it would likely "lose 100% of the margin" relating to patients who switched away from Accredo.[65] "Based on this analysis," Accredo restored its donations.[66]

Greenfield jumped ship. He filed an FCA *qui tam* suit against Accredo, arguing that Accredo's donations to HSI/HANJ were kickbacks in exchange for HSI/HANJ referring members to Accredo.[67] Accredo argued that plaintiff was required to show that, but for the donations, the federally insured patients would not have used Accredo's services.[68] Greenfield[69] argued that he was not required to prove patients' subjective

56. *Id.* at 91. While Accredo Health Group, Inc. and its affiliates were all defendants in this case, the Greenfield court referred to them collectively as "Accredo." *Id.* This section will do the same.

57. *Id.*

58. *Id.* at 91–92.

59. *Id.* The HANJ website also included hyperlinks leading to highlighted providers' websites. *Id.* at 92. Accredo was included in one list of four HSI-approved providers who "continually contribute to this community." *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.* After this letter, Accredo received about seventy-five letters from HSI members asking Accredo to restore its original donation. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.* The United States declined to intervene in the suit. *Id.*

68. *Id.* at 95.

69. And the United States Government, as amicus curiae. *Id.* at 93.

intent, but that it was enough to show the services were not provided in compliance with the AKS.[70]

The Third Circuit's opinion quoted the relevant AKS provision and then noted that the statute did not explain what it means for a claim to "result[] from" a violation of the AKS.[71] Noting that the object of statutory interpretation is to effect Congress's will, the court examined the Congressional record and observed that Congress intended to extend the AKS's reach to "avert 'legal challenges that sometimes defeat legitimate enforcement efforts.'"[72]

Since requiring proof of but-for causation for each allegedly false claim would make it more difficult for plaintiffs to bring and prove FCA claims, the *Greenfield* court considered the but-for construction inconsistent with Congressional intent.[73] Instead, the *Greenfield* court held that plaintiff had to provide actual evidence of at least one false claim to survive a motion for summary judgment.[74] The *Greenfield* plaintiff could have carried that burden by specifying one claim that covered a patient referred to Accredo by HSI/HANJ.[75]

Although the *Greenfield* court rejected defendant's strict but-for standard, it also rejected plaintiff's proposed taint standard, which would allow plaintiff to show causation at summary judgment by temporal

70. *Id.* at 95.

71. *Id.* ("[A] claim that includes items and services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act].") (emphasis added) (quoting 42 U.S.C. § 1320a-7b(g)).

72. *Id.* at 95–96. Congress

> 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"
>
> . . . .
>
> . . . . Congress intended both statutes to reach a broad swath of "fraud and abuse" in the federal healthcare system.

Id. at 96 (quoting H.R. Rep. No. 95-393, at 1, 47 (1977)).

73. *See id.* at 96–97.

74. *Id.* at 98. To prove but-for causation, Accredo argued that Greenfield had to show patients' reasons for choosing Accredo as a service provider, i.e., ask whether patients would have chosen Accredo in the absence of the referrals. *Id.* at 96–97. The Third Circuit rejected this argument, holding that it was sufficient, for purposes of establishing the "link" between the kickbacks and the claims, simply to point to one claim covering a patient referred to Accredo by HSI/HANJ. *Id.* at 98–99. This means, in effect, that the plaintiff does not need to show but-for cause even for the claim serving as a "link." *See id.* at 98 (explaining that such a claim is false "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") (citation omitted).

75. *Id.* at 98–99.

proximity alone.[76] Rather, the Third Circuit reiterated that plaintiff needed to point to at least one specific false claim.[77]

2. *Cairns*

Four years after *Greenfield*, the Eighth Circuit addressed the same issue in *United States ex rel. Cairns v. D.S. Med. LLC*.[78] In *Cairns*, a neurosurgeon, Sonjay Fonn, bought spinal implants from a company entirely owned by his fiancée, Deborah Seeger.[79] Seeger made $1.3 million in one year from one manufacturer's commissions, while Fonn received an offer to buy the manufacturer's stock.[80] Other physicians sued both Fonn and Seeger for FCA violations, and the government intervened.[81]

Unlike the Third Circuit, which emphasized legislative intent,[82] the Eighth Circuit employed a textual analysis.[83] Since the AKS does not define the phrase "resulting from," the Eighth Circuit turned to the phrase's plain meaning.[84] Citing two dictionaries and the Supreme Court's interpretation of a "nearly identical phrase" in the Controlled Substances Act, the Eighth Circuit decided that "in common and ordinary usage," the phrase connotes but-for cause.[85] Since the Eighth Circuit considered the phrase "resulting from" to be unambiguous, it declined to consider pre-amendment case law and the amendment's legislative history.[86]

The *Cairns* court held that when a plaintiff seeks to establish FCA liability through the AKS amendment, it must show a but-for causal relationship between the alleged kickbacks and the products/services allegedly received for them.[87] The Eighth Circuit acknowledged that it was creating a circuit split: "[w]e recognize that the Third Circuit came

76. *See id.* at 98.
77. *Id.* at 99.
78. United States *ex rel.* Cairns v. D.S. Med. LLC, 42 F.4th 828 (8th Cir. 2022).
79. *Id.* at 831.
80. *Id.*
81. *Id.*
82. *Greenfield*, 880 F.3d at 96–97.
83. *See Cairns*, 42 F.4th at 834–35.
84. *Id.* at 834.
85. *Id.* at 834 (citing Burrage v. United States, 571 U.S. 204, 210–11 (2014); Comcast Corp. v. Nat'l Ass'n of Afr. Am.–Owned Media, 589 U.S. 327, 332 (2020); THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1497 (5th ed. 2016); WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1937 (2002)).
86. *Cairns*, 42 F.4th at 835–36 ("Starting with legislative history and purpose, however, is no way to read a statute . . . . [W]hen a statute is unambiguous, we start and end in the same place: with the words of the statute itself.") (citations omitted).
87. *Id.* at 836.

out differently in [*Greenfield*]. Although we understand its point of view, it adopted an approach that we have already rejected: relying on legislative history and 'the drafters' intentions' to interpret the statute."[88]

3. *Martin*

The next year, the Sixth Circuit joined the Eighth in requiring but-for causation.[89] In *United States ex rel Martin v. Hathaway*, a hospital board refused to hire an internal ophthalmologist (Martin) because it feared losing referrals from an external ophthalmologist (Hathaway).[90] The board also predicted that Hathaway would increase the number of referrals after a contemporaneous merger was completed.[91] Before the board's vote against hiring, Hathaway wrote a letter to the hospital's directors, informing them that the hospital's hiring of Martin would be a mistake because it would "'force' Dr. Hathaway 'against [his] will (because [he had] no desire to pull out whatsoever), to pull out [his] cases and take them elsewhere.'"[92] Several directors raised concerns about losing business as a result of Martin's employment.[93] After the vote, two board members informed Hathaway of the outcome, one telling him that she "was '[l]ooking forward to increased surgical volume.'"[94]

The *Martin* court employed a textual analysis. It decided that, because the phrase "resulting from" ordinarily signifies but-for causation, the rule requires but-for causation.[95] The *Martin* court touched on policy: interpreting causation too broadly could render providers liable for "[m]uch of the workaday practice of medicine."[96] Since the decision not to hire Martin did not change the number of claims to federal programs, Martin could not point to any claims that would not have occurred if Martin had been hired.[97] Additionally, since Martin did not allege the hospital could tell its physicians where to refer patients, it could not have decided whether to direct referrals to Hathaway even if

88. *Id.* (quoting United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96 (3d Cir. 2018)).
89. United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1052 (6th Cir. 2023).
90. *Id.* at 1046–47.
91. *Id.*
92. *Id.* at 1046–47.
93. *Id.* at 1047.
94. *Id.*
95. *Id.* at 1052 (quoting 42 U.S.C. § 1320a–7b(g)).
96. *Id.* at 1054.
97. *Id.* at 1053.

the hiring had occurred—this also broke the causal chain.[98] As a result, Martin did not plausibly allege but-for causation.[99]

4. First Circuit

Massachusetts district courts are also divided on this issue. The First Circuit may be the next to enter the split.

a. *Teva*

In *United States v. Teva Pharms. USA, Inc.*, defendant Teva Pharmaceuticals USA, Inc. donated to two foundations ("CDF" and "TAF") that helped Medicare-eligible patients pay co-pays for Teva's multiple sclerosis drug, Copaxone.[100] At the same time, Teva raised Copaxone prices and referred Medicare-eligible Copaxone patients to specialty pharmacy Advanced Care Scripts ("ACS") and AssistRx, which in turn referred these patients to CDF and TAF.[101] After a three-year investigation, the federal government sued Teva under the FCA and AKS, claiming Teva donated to CDF and TAF with the intention of inducing the foundations to pay Copaxone Medicare claims.[102]

Teva argued that the government had to prove a but-for causal relationship between CDF/TAF's Medicare claims and Teva's donations.[103] The district court disagreed, noting that in *Guilfoile v. Shields* the First Circuit previously held that an FCA-AKS plaintiff need prove only a "sufficient causal connection."[104]

Significantly, the *Teva* court noted that this First Circuit case cited *Greenfield* in its analysis.[105] The district court then rejected the but-for standard.[106] It highlighted two pieces of evidence. First, Teva's internal documents showed that Teva "understood it was profitable to provide co-pay assistance to generate sales."[107] Second, a government expert identified 345,970 Copaxone Medicare claims for patients (1) referred by Teva to ACS or AssistRx and (2) thereafter enrolled by ACS or AssistRx

98. *Id.* at 1053–54.
99. *Id.*
100. United States v. Teva Pharms. USA, Inc., 682 F. Supp. 3d 142, 144 (D. Mass. 2023). "CDF" is short for Chronic Disease Fund, and "TAF" refers to The Assistance Fund. *Id.*
101. *Id.* at 144.
102. *Id.* at 145–46. Medicare would reimburse Teva for these claims. *Id.* at 144–45.
103. *Id.* at 145–46.
104. *Id.* at 146. (quoting Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019)).
105. *Id.* (citing United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96–98 (3d Cir. 2018)).
106. *Id.* at 148.
107. *Id.* at 146.

in CDF or TAF after Teva donated to CDF/TAF.[108] The court considered this evidence sufficient to establish the "sufficient causal connection" required by the First and Third Circuits.[109] Although the district court did not couch its rule in the same terms as the Third Circuit, the identification of 345,970 specific claims covering patients that Teva indirectly referred to CDF/TAF would likely satisfy the *Greenfield* rule.[110]

b. *Regeneron*

Two months later, another Massachusetts district court confronted the same issue under similar facts. Regeneron Pharmaceuticals, Inc. manufactures Eylea, a neovascular age-related macular degeneration drug.[111] The CDF operated a fund that helped patients pay copays for Eylea, and Regeneron donated to the CDF.[112]

Addressing the issue of causation, the *Regeneron* court noted that the *Guilfoile* court did not elaborate on what a "sufficient causal connection" was, and that as a result its citation to *Greenfield* did not make the Third Circuit rule binding in the First.[113]

The *Regeneron* court then discussed and compared the rules. It agreed with the Eighth and Sixth Circuits that the *Greenfield* court did not come to its rule through traditional statutory interpretation or common-law causation principles.[114] The Regeneron court therefore felt that *Greenfield* was difficult to apply.[115] Categorizing the *Greenfield* rule as "unclear," the district court noted that it did not work in every factual context.[116] The court noted that the *Greenfield* rule prevents defendant

108. *Id.*

109. *See id.* at 146, 148.

110. *Id.* at 146. *See Greenfield*, 880 F.3d at 99 (holding plaintiff "must point to at least one claim that covered a patient who was recommended or referred to Accredo by HSI/HANJ.").

111. United States v. Regeneron Pharms., Inc., No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *3–4 (D. Mass. Sept. 27, 2023).

112. *Id.* at 2, 5. *See supra* text accompanying note 100 for an introduction to CDF.

113. *Regeneron*, No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *20 (citing Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019)). *See supra* text accompanying notes 38–39.

114. *Regeneron*, No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *27.

115. *See id.* at *28.

116. *Id.* at *28–29. To make its point, the *Regeneron* court posited a hypothetical without a referral element: a doctor who increases prescriptions for a drug after receiving illegal remuneration from the manufacturer. *Id.* The hypothetical goes as follows: a doctor can prescribe either A or B to treat a patient. *Id.* She usually writes fifty prescriptions for A and fifty for B. *Id.* She receives illegal kickbacks from A's manufacturer and increases her A prescriptions to seventy-five while dropping her B prescriptions to twenty-five. *Id.* In the absence of the kickbacks, she would have written sixty-five A prescriptions and thirty-five B prescriptions. *Id.* Assuming all the prescriptions result in claims to federal programs, how many of these claims resulted from the AKS violation? *Id.* Under a but-for test the

from rebutting plaintiff's causation evidence.[117] "Proof of a 'link' thus becomes akin to an irrebuttable presumption: it leads to liability even if facts show no actual causation of any kind."[118] Raising the possibility of a burden-shifting scheme, the Regeneron court ultimately opted for the but-for standard.[119]

Plaintiff's evidence in *Regeneron* was similar to that in *Teva*.[120] It included matched claims-analysis from *Teva*'s government analyst: 115,192 Medicare claims partially or entirely paid by the CDF fund and for which Regeneron received over $68 million in reimbursements.[121] The evidence also suggested that an alternative therapy was "dramatically" cheaper than Eylea and that the prescribing physician would have to eat the difference if the copays went unpaid.[122] Despite its use of the but-for standard, the *Regeneron* court found the evidence sufficient to raise a triable question of fact as to but-for causation.[123]

c. What's Next in the First Circuit?

On August 14, 2023, interlocutory appeal was certified with respect to the causation issue in *Teva*.[124] On October 25, the same occurred for *Regeneron*.[125] The First Circuit granted appeal on December 11.[126]

answer is ten. *Id.* Under *Greenfield*, the *Regeneron* court claims, the number of false claims is unclear. *Id.* at *29. If the number is seventy-five, the *Regeneron* court asks, what separates the *Greenfield* rule from the taint rule? *Id.* The answer to the hypothetical is probably seventy-five. *See* United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 99–100 (3d Cir. 2018) (requiring plaintiff, in order to survive summary judgment, to point to "at least one" claim to serve as a "link" between the kickbacks and the other claims). In this case, the *Regeneron* court's point is that the rule is overinclusive: *Greenfield* would render the hypothetical doctor liable for sixty-five legitimate claims just because they look like the ten false claims. *See Regeneron*, No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *27–28.

117. *Regeneron*, No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *29.

118. *Id.* at *31.

119. *Id.* at *33; *see also id.* at *34 n.14 (citing United States *ex rel.* Flanagan v. Fresenius Med. Care Holdings, Inc., No. 21-11627, 2022 U.S. Dist. LEXIS 218302, at *52 (D. Mass. Dec. 2, 2022)).

120. *See id.* at *37 (citing United States v. Teva, 682 F. Supp. 3d 142, 144 (D. Mass. July 14, 2023)) (citing *Teva* for the proposition that matched-claims analysis is relevant in establishing causation in an FCA case).

121. *Id.* at *33–34.

122. *Id.* at *33–35. This is because Eylea is a "buy-and-bill drug." *Id.*

123. *See id.* In fact, the *Regeneron* court highlights the matched-claims analysis, also present in *Teva*, as especially persuasive. *See id.*

124. United States v. Regeneron Pharms., Inc., No. 20-11217, 2023 U.S. Dist. LEXIS 191418, at *2 (D. Mass. Oct. 25, 2023).

125. *Id.* at *4.

126. United States v. Regeneron Pharms., Inc., No. 23-8036, 2023 U.S. App. LEXIS 33107, at *2 (1st Cir. Dec. 11, 2023).

B. Policy Implications of Each Rule

Though each proposed rule fixes a different problem, none is adequate on its own. Applying the rules to the hypothetical earlier in this Note[127] will illustrate the point.

Add the following facts to the hypothetical. First, for reasons known only to B, B would have written five prescriptions for A's drug in the absence of kickbacks. These five are legitimate prescriptions ("LPs"). The other five, unnecessarily written, are overutilization prescriptions ("OPs"). Claims based on OPs are false and those based on LPs are not. Second, A submits one claim to Medicare for each prescription. Third, because of facts specific to each claim, a plaintiff in a fraud case could only show that one of the OPs would not have been made in the absence of a kickback scheme.

1. Taint Rule

Under the taint theory, if plaintiff could prove that A's events were illegal kickbacks, defendant would automatically be liable for all ten prescriptions, including the LPs.[128] Plaintiff would not need to show that any of the OPs were caused by A's kickbacks, nor would defendant have a chance to show the LPs were not caused by the events.[129]

The taint rule, proposed by plaintiff in *Greenfield*, fixes an important problem. Kickback-claim causation is difficult to prove.[130] The taint rule fixes this problem by creating another. It allows plaintiffs to hold defendants accountable for illegal kickbacks and claims (OPs) but also has the effect of imposing liability for legitimate conduct (LPs).

2. Link Rule

Under *Greenfield*'s link rule, all plaintiff would have to show is that B attended A's events and Medicare reimbursed A for one of B's prescriptions.[131] Then defendant would be liable for all ten prescriptions, including the LPs.[132]

127. The hypothetical about Pharma Company ("A") putting on sham speaker events which Doctor ("B") attends. *See supra* text accompanying notes 14–18.

128. *See* United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 97–98 (3d Cir. 2018).

129. *See id.*

130. *See supra* Section III.A.; *supra* notes 5–11 and accompanying text. *See generally* United States *ex rel.* Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497 (S.D.N.Y. 2014).

131. *See Greenfield*, 880 F.3d at 99.

132. *See id.* The *Regeneron* court identified this issue in its hypothetical. *See supra* note 116.

Like the taint rule, the link rule ameliorates the difficulty of proving causation.[133] It is also fairer to defendants than the taint rule, since it requires plaintiffs to show more than the mere existence of a kickback scheme.[134] However, by considering causation for all claims established on the showing of one link, this rule could also render defendants liable for lawful conduct.

3. But-for Cause Rule

Under *Cairns*'s but-for rule, defendant would only be liable for the one claim plaintiffs could show would not have been made in the absence of a kickback scheme.[135] Recall that in the hypothetical, plaintiff can only show but-for cause for one OP.[136] Under the but-for rule, defendants face no liability for the other four OPs.[137] By forcing plaintiffs to establish but-for cause for each claim, this rule adequately protects defendants.[138] However, by solving defendants' problem, the rule creates the opposite one: it does nothing to address plaintiffs' proof issue.[139]

But-for causation may have another effect. By shielding defendants from all but the most obvious false claims, the rule could make it economically viable for repeat offenders to flout the law.[140]

C. New Rule Required Because of Other Rules' Deficiencies

The point of the above exercise is to show that no currently existing rule solves all the problems unique to healthcare fraud cases. Taint and link causation solve the proof issue by sweeping the suspicious but lawful up with the fraudulent. But-for causation protects defendants by ignoring plaintiffs' unique difficulties. In short, no rule holds defendants accountable for actual fraud *and* adequately protects them when they engage in lawful conduct.

133. *See supra* Section III.A.; *supra* notes 5–11 and accompanying text.

134. It requires plaintiff to point to one specific claim connected to the kickbacks. *See Greenfield*, 880 F.3d at 98.

135. *See* United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1053 (6th Cir. 2023).

136. *See supra* text accompanying note 127.

137. *See Martin*, 63 F.4th at 1052–53.

138. *Id.*

139. *See supra* notes 4–11 and accompanying text. *See generally supra* Section III.A.

140. *See* Bendicksen et al., *supra* note 20, at 262 (noting that some pharmaceutical companies continue to settle healthcare fraud cases and suggesting that this shows current antifraud measures are insufficient).

IV. IN SEARCH OF A NEW RULE

Causation is not the only difficult issue in healthcare fraud cases. Judicial wranglings with materiality and pleading standards implicate similar policy considerations and are instructive.

A. Escobar *and Materiality*

In *Universal Health Servs., Inc. v. United States ex rel. Escobar*, the United States Supreme Court dealt with materiality.[141] *Escobar* was an implied false certification case.[142] Implied false certification is a theory of fraud contending that, by submitting a claim, a defendant impliedly certifies that it complied with the government's payment conditions.[143] Under this theory, if a defendant submits a claim while not complying with a condition of payment, that claim is false.[144] The *Escobar* court accepted this theory as a basis for fraud liability under the FCA, but clarified that a misrepresentation under this theory only rises to the level of fraud if the unmet payment condition was material to the government's decision to pay the claim.[145]

Like causation,[146] materiality is fact-dependent. "'[M]aterial' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[147] Whether the government designates something as a condition of payment can be relevant to, but is not dispositive of, materiality.[148] In fact, no single event or fact can be dispositive in every case.[149] "[M]ateriality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation."[150] In this sense it is similar to causation: in causation terms, materiality concerns whether a condition of payment was so important that defendant's lie about complying with it *caused* the government to pay a claim.[151] Causation can likewise be translated into

141. Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 190–96 (2016).
142. *Id.* at 180.
143. *Id.*
144. *See id.*
145. *Id.* at 181.
146. *See supra* Part III.
147. Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 192–93 (quoting Neder v. United States, 527 U.S. 1, 16 (1999)).
148. *Id.* at 190.
149. *Id.* at 191 (citing Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 39 (2011)) ("[M]ateriality cannot rest on 'a single fact or occurrence as always determinative.'").
150. *Id.* at 193 (quoting RICHARD LORD, WILLISTON ON CONTRACTS 549 § 69:12 (4th ed. 2003)).
151. *See id.*

materiality terms: was the existence of a kickback scheme *material* to defendant's decision to submit a claim to the government? Materiality and causation are both difficult to prove because they both rely on counterfactuals: What would a party have done if facts had been different? Would the government have paid a claim? Would a defendant have submitted one?

These similarities allow the Court's handling of materiality to inform how the Court will, and should, solve the causation problem. The *Escobar* Court gives an example. If a contractor sells guns to the government, and the government does not specify that the guns must be able to shoot, a defendant could still know that the guns' ability to shoot is material for two reasons.[152] The first is if defendant knows the government regularly rescinds arms contracts if, when it receives guns, they cannot shoot.[153] The second is that a reasonable person would recognize that the government is only buying guns because it wants to use them.[154] While some commentators have found *Escobar's* guidelines wanting,[155] the above example provides something helpful for present purposes.

Escobar's firearms example requires defendant to look beyond the present situation to determine whether something is material. The Court instructs the would-be arms contractor to examine (1) the government's past conduct and (2) what a reasonable person would know.[156] That is, the Court tells defendants to look beyond the present situation and incorporate information about past conduct into their judgments.[157] The

152. *Id.* at 191.

153. *Id.*

154. *Id.*

155. *See, e.g.*, Farringer, *supra* note 11, at 1256 ("[T]he opinion itself does not provide examples for what might fall in between . . . extremes.").

156. Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 191 (1999).

157. *See id.* The Court's explanation of materiality includes its tort and contract definitions. *Id.* at 193.

> In tort law, for instance, a "matter is material" in only two circumstances: (1) "[if] a reasonable man would attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not.

Id. (quoting RESTATEMENT (SECOND) OF TORTS § 538 (1976)). *Escobar*'s materiality standard has created some confusion in the lower courts. *See* Farringer, *supra* note 11, at 1254–55. At least some courts and the Department of Justice have interpreted *Escobar* materiality to be a version of the "natural tendency to influence" standard. *Id.* at 1253–54. The Fourth Circuit held that the standard incorporates elements of "common sense." *Id.* at 1254–55 ("'In analyzing materiality, we noted that a material falsehood was one that was capable of influencing the Government's decision to pay. We explained that the standard was a high one intended to keep FCA liability from attaching to "noncompliance with any of potentially hundreds of legal requirements" in a contract. Applying the standard, we

Court also instructs contractors to examine the character of the thing itself, divorced from present or past conduct: arms contractors should know the government wants working guns *because it is buying guns*.[158]

This can inform the causation rule the judiciary eventually adopts: causation does not just have to be about what plaintiff can definitively show, but about the character of defendants' relationships. Like the contractor pondering whether the *character* of an arms contract *is of the type* to require working guns, a court considering the evidence of a kickback scheme and claims can ask itself: is this the *kind* of kickback scheme that would tend to give rise to *these kinds* of claims?

Escobar shows that courts should be flexible when examining context-bound elements like materiality and causation. Courts examining FCA-AKS causation should consider the plausibility of plaintiffs' allegations.

B. Duxbury *and 9(b)*

Duxbury involves pleading standards under Fed. R. Civ. P. 9(b) in the healthcare fraud context.[159] The Federal Rules of Civil Procedure provide heightened pleading standards for fraud.[160] When a *qui tam* plaintiff alleges that a defendant induced third parties to submit false claims to the government, however, a more flexible pleading standard applies.[161] In this situation, FCA claims survive if plaintiff gives "'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim."[162]

One of the *Duxbury* plaintiff's allegations was that defendant gave Western Washington Treatment Center more than $5,000 of free medicine so that the center could ask Medicare for reimbursement under

found Triple Canopy's omissions material for two reasons: common sense and Triple Canopy's own actions in covering up the noncompliance. That conclusion perfectly aligns with [*Escobar*].'") (quoting United States v. Triple Canopy, Inc., 857 F.3d 174, 178 (4th Cir. 2017)).

158. *Escobar*, 579 U.S. at 191.

159. United States *ex rel.* Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (1st Cir. 2009).

160. FED. R. CIV. P. 9(b).

161. *See Duxbury*, 579 F.3d at 29. This is the case in the First and Fifth Circuits. *Id.* ("FCA claims under Rule 9(b) 'may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'") (quoting United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)).

162. *Id.* (quoting United States *ex rel.* Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007)).

the false pretense that the center paid for the drugs.[163] The complaint further alleged that defendant intended to induce the center to purchase more of its drugs by this gift.[164] The complaint dated the alleged kickbacks to 1997-98 and placed them in Olympia, Washington, where the treatment center was located.[165] Although the complaint did not identify specific false claims, the *Duxbury* court allowed it to stand because it alleged "the who, what, where, and when of the allegedly false or fraudulent representation."[166]

Because the plaintiff alleged that defendant induced a third party to submit false claims, instead of the defendant submitting false claims itself, plaintiff faced a lower pleading standard.[167] It was sufficient for plaintiff to "allege[] facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide."[168]

Like the situation in *Duxbury*, FCA-AKS claims involve attenuated causal chains.[169] Like *Duxbury*, then, the difficulty of proof in FCA-AKS cases suggests plaintiffs should face lower burdens.[170]

Using these policy considerations to modify causation proof requirements is not unheard of. Part of the reason the *Greenfield* court chose the rule it did was to address these difficulties.[171] Unlike

163. *Id.* at 30.

164. *Id.*

165. *Id.*

166. *Id.* at 30 (citing Rodi v. S. New Eng. Sch. L., 389 F.3d 5, 15 (1st Cir. 2004)). Here, the "who" was Western Washington Treatment Center, the "what" was the gift of drugs, the "where" was Olympia, Washington, the "when" was 1997–98. *Id.* at 29–30. Finally, the complaint alleged false claims: that the treatment center was reimbursed for the drugs. *Id.*

167. *See id.* at 29–30.

168. *Id.* at 31.

169. *See supra* Section II.C.

170. *See generally Duxbury*, 579 F.3d 13. *Grubbs* is another case construing 9(b) to fit the healthcare fraud context. United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)). The *Grubbs* court noted that FCA liability is premised on the presentment of false claims to the federal government and that the actual circumstances surrounding presentment "are often harbored in the scheme." *Id.* Since the essence of the fraud is not in "raw bills" but in the underlying scheme that caused those bills to be submitted, a plaintiff does not need to "necessarily and always . . . state[] the contents of a bill." *Id.* Instead, the *Grubbs* court stated 9(b) is "context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act." *Id.* The *Grubbs* court explained that it would construe 9(b) to "effectuate[] Rule 9(b) without stymieing legitimate efforts to expose fraud." *Id.* The court then held that a relator's claim may survive dismissal even if it does not allege the details of actual false claims so long as it alleges particular facts surrounding a scheme violating the FCA and "reliable indicia that lead to a strong inference" that false claims were submitted. *Id.*

171. *See* United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96 (3d Cir. 2018). ("'[I]t is difficult to identify program abuse as a practical manner unless the overutilization is grossly unreasonable.' This counsels requiring something less than proof

Greenfield, however, which requires identification of at least one specific claim,[172] *Duxbury* did not require the identification of specific claims at all—it simply required facts supporting the existence of a kickback scheme and allegations of claims that arose from it.[173] Additionally, neither *Greenfield* nor *Duxbury* required plaintiff to address every claim—when the *Duxbury* plaintiff pled facts relating to some false claims, all the claims survived dismissal.[174] Likewise, under the *Greenfield* rule, all plaintiff has to do to prove causation for all its claims is point to one claim—a "link"—between the kickback scheme and the claims.[175]

Elements of plausibility and presumptive shift must be in the rule for plaintiffs to have a chance.[176] But that is not enough. An irrefutable presumption of claims' falsity would deny defendant a chance to contest causation.[177] It would allow plaintiff to hold defendant liable for claims so long as plaintiff can show that the claims look suspicious.[178] In order to keep the presumption mechanism, burden shifting is necessary.

C. Elements of a New Rule

1. Plausibility

Healthcare fraud is difficult to prove.[179] Cases are fact sensitive.[180] Allowing plaintiffs to show causation through plausibility would give the causation rule the flexibility it needs to allow plaintiffs to hold defendants liable in difficult-to-prove cases. It would also make the rule more sensitive to context.[181]

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that the underlying medical care would not have been provided but for a kickback.") (internal citation omitted).

172. *Id.* at 99.

173. *Duxbury*, 579 F.3d at 30.

174. *See Greenfield*, 880 F.3d at 99; *Duxbury*, 579 F.3d at 31–32.

175. *Greenfield*, 880 F.3d at 98.

176. *See supra* Section III.A.; *supra* notes 5–11 and accompanying text.

177. *See* United States v. Regeneron Pharms., Inc., No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *29–31 (D. Mass. Sept. 27, 2023).

178. *See id.* at *29–30.

179. *See supra* Section III.A.; notes 5–11 and accompanying text.

180. *See supra* note 5.

181. Plaintiff could argue that causation is plausible because of the claims' and kickback scheme's qualitative characteristics. *See infra* notes 184–85 and accompanying text. Plaintiff could also point to statistics suggesting a connection between the two. *See, e.g.*, United States *ex rel.* Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497, 518 (S.D.N.Y. 2014) (including allegations that doctors who attended defendant's "lavish dinners" "wrote more prescriptions for [defendant's] cardiovascular division drugs" in a discussion of why plaintiff adequately pled an AKS violation). Of course, a plaintiff establishing causation under this rule would have to show plausibility, not just plead it. The example is

One drawback of a flexible standard is that, initially, it may be hard to predict.[182] This issue would shrink over time as the standard develops through use.[183] Additionally, OIG guidance, like AKS Advisory Opinions and Special Fraud Alerts, help private parties navigate antifraud laws.[184] These resources could help judges decide plausibility, and private parties predict it.[185] Plaintiff's use of statistics would make the rule administrable even in cases with complicated facts or elongated causal chains.[186] Another drawback of plausibility is that it could hold defendants liable for claims that seem like they resulted from kickbacks

nonetheless helpful as a demonstration of the kind of evidence plaintiff could point to. *Id.* at 503, 517 (noting that the complaint included "the change in the number of prescriptions for [defendant's] drugs these doctors wrote compared to their earlier prescription[s]," that doctors who wrote high numbers of prescriptions were invited to be "speakers" at events, and that doctors previously invited as speakers "had to maintain or increase that level of prescription-writing in order to be invited to appear as a 'speaker' again.").

182. *See* Hannah Almlöf & Per–Olof Bjuggren, *A Regulation and Transaction Cost Perspective on the Design of Corporate Law*, 47 EUR. J.L. & ECON. 407, 417 (2019) (noting that the application of a legal standard can be difficult to predict because "the interpretation is made ex post by the adjudicator") (citation omitted). A related issue is the possibility that the adoption of a standard would increase the cost of compliance. *Id.* (explaining that a standard which is difficult to predict can make it necessary to hire legal guidance). The cost issue would largely dissipate as the standard develops. *See id.* at 418.

183. *Id.* at 417 ("Legal uncertainty is always associated with high costs but as the number of precedents accumulates, the content of a standard may become clearer as each precedent supplements the standard with a case-based rule.").

184. *See Compliance*, U.S. DEP'T HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., http://oig.hhs.gov/compliance/ (last visited Jan. 5, 2025). Many of these resources advise private parties on the legality of parties' business arrangements. *See, e.g.*, OIG, Advisory Opinion No. 08-08 (2008) (advising a hospital corporation and a group of surgeon investors on whether their investment in an ambulatory surgery center complies with the AKS).

185. Special Fraud Alerts could be especially helpful here. These OIG publications identify especially suspicious business arrangements and activities. *See, e.g.*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., SPECIAL FRAUD ALERT: OIG ALERTS PRACTITIONERS TO EXERCISE CAUTION WHEN ENTERING INTO ARRANGEMENTS WITH PURPORTED TELEMEDICINE COMPANIES 1 (2022) (describing a type of fraud where telemedicine companies recruit individuals to act as patients, pay kickbacks to practitioners for medically unnecessary durable medical equipment, sell the equipment, and bill federal healthcare programs). Special Fraud Alerts can also identify specific characteristics of arrangements which are especially suspect. *Id.* at 4 (identifying the following, *inter alia*, as especially suspicious characteristics: the telemedicine company's purported patients are all federal healthcare program beneficiaries, the telemedicine company does not give practitioners the information necessary to follow up with purported patients, the telemedicine company only furnishes one product or type of product). Such resources could be helpful for judges deciding whether a fraudulent business arrangement is of a type that tends to produce the kinds of claims plaintiff points to as false. *See id.*

186. *See* United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1054–55 (6th Cir. 2023); Blumstein, *supra* note 12, at 120–21.

even if they did not.[187] This could discourage legitimate and socially beneficial relationships.[188] A burden-shifting scheme would neutralize this significant problem.

2. Burden-Shifting

In *United States ex rel. Flanagan v. Fresenius Med. Care Holdings*, the District Court of Massachusetts raised the possibility of a burden-shifting scheme without adopting it.[189] Under this Note's proposed framework, once plaintiff shows that claims and kickbacks are plausibly connected, a presumption of causation arises and the burden shifts to defendant to show that there is no but-for causal connection between claims and kickbacks.

This would solve several problems. By enabling defendants to defend lawful conduct—even if that conduct seems fraudulent—burden-shifting would prevent plausibility from discouraging suspicious but nonfraudulent transactions.[190] It would put the burden of arguing the minutiae of but-for causation on the party better able to do so.[191] It could even incentivize potential defendants to keep better records.

187. *See* United States v. Regeneron Pharms., Inc., No. 20–11217, 2023 U.S. Dist. LEXIS 172618, *1, *25–27. (D. Mass. Sept. 27, 2023); *Martin*, 63 F.4th at 1054 (noting that "reading causation too loosely" could cause "[m]uch of the workaday practice of medicine [to] fall within an expansive interpretation of the Anti-Kickback Statute. Worse still, the statute does little to protect doctors of good intent.").

188. *Martin*, 63 F.4th at 1054–55. *See generally Blumstein*, *supra* note 12, at 120–21.

189. United States *ex rel.* Flanagan v. Fresenius Med. Care Holdings, Inc., No. 21-11627, 2022 U.S. Dist. LEXIS 218302, *1, *52 (D. Mass. Dec. 2, 2022) ("It might also be entirely rational to shift the burden to the defendant: that is, once a relator has established the existence of a kickback scheme, arguably the burden should be shifted to the defendant to prove that certain referrals were not caused by payment of kickbacks.").

190. *See supra* text accompanying notes 177–78. Burden-shifting would fix the problem outlined in the *Regeneron* hypothetical. *See Regeneron*, No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *27. The fact that prescriptions for A rose after the beginning of the kickback scheme would help plaintiff show that a connection between the scheme and the claims is plausible. The burden would then shift to defendant to show that the scheme only caused ten of the seventy-five false–seeming claims. *See id.* Since defendant maintains the relevant records, defendant would know where to look to show that sixty-five of the claims were legitimate. *See infra* note 191. If the ten remaining claims were in fact false, it would be difficult for defendant to show that they were legitimate.

191. Defendants are generally in a better position than plaintiffs to prove/disprove causation because defendants hold their own records and understand their own billing processes. *See* Bucy, *supra* note 4 at 878 (explaining that one "reason white collar crime is difficult to investigate and prove is that it is often 'hidden within an organization'") (citation omitted). In addition, defendants' own analyses can be the best evidence for the existence or not of causation. *See supra* text accompanying notes 63–65; United States *ex rel.* Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497, 502–03 (S.D.N.Y. 2014) (describing defendant Novartis's alleged use of social outings to encourage doctor invitees to prescribe

V. CONCLUSION: A NEW CAUSATION RULE

It is unrealistic to expect plaintiffs in FCA-AKS cases to prove but-for cause for every false claim. The *Greenfield* court was right to lower plaintiff's burden on the issue of causation. But *Greenfield*'s alternative would result in defendant liability for non-fraudulent conduct.

Combining plausibility with a burden-shifting scheme would give plaintiffs a fighting chance while giving defendants the ability to defend lawful conduct. Allowing plaintiffs to meet the causation burden by pointing to the character of and statistics behind defendants' activities allows for reasonable presumptions which are limited to what context justifies.[192] Putting the burden of making arguments about specific claims on defendant will result in more precise litigation because defendants, as the party holding and keeping the significant records, are

defendant's drugs and how defendant's "internal analysis" showed that doctors who attended these events "wrote an increased number of prescriptions for Novartis drugs," how "the more incentives doctors received in the form of meals, entertainment, and honoraria from these events, the more Novartis prescriptions the doctors would write," and that the "highest return on investment came from doctors who were paid to 'speak' at the events"); United States *ex rel.* Kester v. Novartis Pharms. Corp., 23 F. Supp. 3d 242, 250 (S.D.N.Y. 2014) (describing an "internal email" that showed one of defendant's employees "reported that 73% of [a doctor targeted by a kickback scheme]'s patients were covered by Medicare"); United States v. Teva, 682 F. Supp. 3d 142, 146 (D. Mass. 2023) (noting that the government "cites contemporaneous Teva employee emails and other documents that demonstrate that Teva knew it would have lost Copaxone sales" without the alleged kickback scheme, including an email to that effect and an internal slideshow stating the scheme "[d]emonstrated significant ROI; result of not funding directly impacts top line revenue"); *Fresenius*, No. 21-11627, 2022 U.S. Dist. LEXIS 218302, at *3, *10 (describing plaintiff's allegations that defendant sought contracts with hospitals "'at any cost' to secure the referrals of discharged patients" and defendant's internal spreadsheets showing losses "in excess of budgeted losses" from hospital contracts).

192. For example, the *Bilotta* allegations were sufficient to withstand a 9(b) challenge, but plaintiffs might have had more difficulty surviving a motion for summary judgment. *See supra* notes 14–18 and accompanying text. Plaintiff could likely prove the existence of the kickback scheme by producing evidence about the fraudulent nature of Novartis's events, and a judge may accept that sham educational events about specific drugs are the type of kickback scheme that tends to result in attendees prescribing those drugs more often. *See generally* United States *ex rel.* Kester v. Novartis Pharms. Corp., 23 F. Supp. 3d 242 (S.D.N.Y. 2014). But if the attending doctors prescribed smaller quantities of the same drug before the kickback scheme, how many of the post-kickback claims should be covered by the shifting presumption of causation? See *supra* note 116 for another expression of this problem. By producing statistics showing increases of prescriptions after the creation of the kickback scheme, a plaintiff would hope to show the plausibility of the connection between the scheme and false claims. If plaintiff succeeds, however, the court could use the statistics to limit the amount of claims presumed false. In the *Regeneron* court's hypothetical, the court could limit the presumption to the increase of prescriptions: twenty-five. *See id.* Defendant would then have the burden to show that fifteen of those claims were not in fact false or else face liability for the twenty-five. *See id.*

in a better position than plaintiff to make those specific arguments.[193] All of the above allow this Note's rule to take full account of all the factual complexities and varieties FCA-AKS cases present.

193. *See Regeneron*, No. 20-11217, 2023 U.S. Dist. LEXIS 172618, at *27.