BRIDGING THE FALSE CERTIFICATION GAP: WHY "RESULTING FROM" IN THE 2010 AKS AMENDMENT REQUIRES BUT-FOR CAUSATION

*By Alexandra Wildman**

Before 2010, violators of the Anti-Kickback Statute (AKS) could avoid False Claims Act (FCA) liability if claims for items or services borne of their kickback scheme were submitted to federal healthcare programs by a third party. In 2010, as part of the Affordable Care Act (ACA), Congress attempted to close this loophole in the FCA by amending the AKS. Under the amendment's terms, claims submitted to federal healthcare programs for items or services "resulting from" an AKS scheme are false for the purposes of establishing FCA liability, regardless of who submitted the claims.

Although the amendment widened the FCA liability net, its language also raised a new question as courts grappled with what "resulting from" requires plaintiffs to prove in AKS-based FCA claims. This Note examines how federal circuit courts have analyzed the amendment's "resulting from" causation standard. The U.S. Court of Appeals for the Third Circuit imposed a relaxed standard that requires plaintiffs to establish a connection that is less stringent than but-for causation, whereas the U.S. Courts of Appeals for the Sixth and Eighth Circuits concluded that a but-for standard is required by the amendment's language. This Note argues that a but-for causation standard, like the one adopted by the Sixth and Eighth Circuits, is the proper standard considering the amendment's plain language. Ultimately, this Note argues a but-for standard is likely to be adopted by the U.S. Supreme Court should the Court grant certiorari on the question of what "resulting from" in the 2010 AKS amendment requires.

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INTRODUCTION

Healthcare fraud, waste, and abuse, in their ever-mutating forms, currently cost U.S. taxpayers about sixty billion dollars every year.[1] Sometimes, healthcare fraud is blatant, such as when someone receives 2.8 million dollars in Medicare reimbursements for home healthcare services they did not provide[2] or when an entity bills almost half a million dollars to Medicare for providing medical equipment to fictional patients.[3] The Cigna Group, an insurance provider for the Medicare Advantage Program, recently paid the U.S. government over 172 million dollars to settle alleged False Claims Act[4] (FCA) violations between 2014 and 2021.[5] Over time, the federal government has enacted statutes imposing criminal and civil penalties on those who engage in certain fraudulent healthcare activities.[6] Unfortunately, distinguishing between fraudulent and permissible healthcare transactions is not always straightforward.[7]

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1. *See* Press Release, U.S. Dep't of Just., False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022 (Feb. 7, 2023), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022 [https://perma.cc/B4VB-2BMC]; Press Release, U.S. Senate Comm. on Fin., Health Care Reform: Saving Taxpayer Dollars by Cutting Fraud, Waste, Abuse (Apr. 1, 2010), https://www.finance.senate.gov/chairmans-news/health-care-reform-saving-taxpayer-dollars-by-cutting-fraud-waste-abuse [https://perma.cc/D27Y-P9SS]; *Medicare Fraud Prevention Week (MFPW)*, ADMIN. FOR CMTY. LIVING, https://acl.gov/MFPW2023# [https://perma.cc/4H7K-WHUA] (last modified June 8, 2023). Some estimates for the annual cost of healthcare fraud reach up to 100 billion dollars annually. *See 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/ [https://perma.cc/D6DN-G4V2] (last visited Aug. 31, 2024).

2. *See* Press Release, U.S. Dep't of Just., Owner of Home Health Co. Convicted of $2.8M Medicare Fraud Scheme (Sept. 27, 2023), https://www.justice.gov/opa/pr/owner-home-health-company-convicted-28m-medicare-fraud-scheme [https://perma.cc/NT33-6FWQ].

3. *See* Contessa Brewer & Scott Zamost, *Inside the Mind of Criminals: How to Brazenly Steal $100 Billion from Medicare and Medicaid*, CNBC (Mar. 9, 2023, 11:11 AM), https://www.cnbc.com/2023/03/09/how-medicare-and-medicaid-fraud-became-a-100b-problem-for-the-us.html [https://perma.cc/49QK-7NAM]; *see also* United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1395–96 (2023) (describing a straightforward False Claims Act (FCA) scenario).

4. 31 U.S.C. §§ 3729–3733.

5. *See* Press Release, U.S. Dep't of Just., Cigna Group to Pay $172 Million to Resolve False Claims Act Allegations (Sept. 30, 2023), https://www.justice.gov/opa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations [https://perma.cc/K8ZM-UCF9].

6. OFF. OF INSPECTOR GEN., U.S. DEP'T HEALTH & HUM. SERVS., A ROADMAP FOR NEW PHYSICIANS 4, https://oig.hhs.gov/documents/physicians-resources/947/roadmap_web_version.pdf [https://perma.cc/GNY4-MBZM] (last visited Aug. 31, 2024).

7. *See Schutte*, 143 S. Ct. at 1395–96 (explaining that application of the FCA to some situations is not as clear as it is in others); Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001) ("Since the [AKS] on its face is so broad, concern has arisen among a number of health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.").

Two potent statutes targeting healthcare fraud are the Anti-Kickback Statute[8] (AKS) and the FCA.[9] Although each statute addresses healthcare fraud in different ways,[10] plaintiffs sometimes use the statutes in tandem, through what has become known as the false certification theory, to maximize recoveries.[11] To bridge a gap in the false certification theory,[12] Congress amended the AKS in 2010 to allow plaintiffs to raise FCA actions for reimbursement claims "resulting from"[13] AKS violations, even when the defendant was not the party who submitted the claim to the government.[14] There is a growing divide between several federal circuit courts over what burden the phrase "resulting from" in the 2010 AKS amendment imposes on plaintiffs bringing an FCA action under this provision.[15] Some courts, taking a plain meaning approach to the language, adopted a but-for causation standard,[16] while another court embraced a more relaxed causation requirement based primarily on legislative history.[17]

Healthcare entities and their counsel are closely following the evolution of this issue, as the surviving causation standard will undoubtedly influence their business plans, transactions, and compliance programs going forward.[18] Due to its impact on the healthcare industry, the causation question may reach the U.S. Supreme Court for review if the split continues or widens.[19]

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8. 42 U.S.C. § 1320a-7b(g).

9. 31 U.S.C. § 3729.

10. *See* Jeffrey B. Hammond, *What Exactly is Healthcare Fraud After the Affordable Care Act?*, 42 STETSON L. REV. 35, 67–68 (2012); Michael J. Castiglione, Austin M. Hall, Richard K. Hayes & Bonni J. Perlin, *AKS-Predicated FCA Actions: The Link Needed Between Kickback and Claim*, 70 DEP'T JUST. J. FED. L. & PRAC. 71, 71 (2022).

11. *See* Castiglione et al., *supra* note 10, at 1; *infra* Part I.A.2.i.

12. *See infra* Part I.A.3.

13. 42 U.S.C. § 1320a-7b(g).

14. *See id.*; *see also* Guilfoile v. Shields, 913 F.3d 178, 189 (1st Cir. 2019) ("In 2010, the AKS was amended to create an express link to the FCA."); United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018).

15. *See* Castiglione et al., *supra* note 10, at 88; Manvin S. Mayell, *Eighth Circuit Puts the Teeth Back in the AKS's Causation Requirement, Creating Yet Another FCA Circuit Split*, ARNOLD & PORTER (Aug. 2, 2022), https://www.arnoldporter.com/en/perspectives/blogs/fca-qui-notes/posts/2022/08/eighth-circuit-puts-teeth-in-causation-requirement [https://perma.cc/GB4P-GV46]; Jeff Overley, *The Litigation Jolting Health & Life Sciences in 2023's 2nd Half*, LAW360 (July 21, 2023, 11:44 PM), https://www.law360.com/articles/1702184/the-litigation-jolting-health-life-sciences-in-2023-s-2nd-half [https://perma.cc/XZ3P-4D92].

16. *See* United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1052–53, 1055 (6th Cir.), *reh'g en banc denied*, 2023 U.S. App. LEXIS 11994 (6th Cir. May 16, 2023), *cert. denied*, 144 S. Ct. 224 (2023); United States *ex rel.* Cairns v. D.S. Med., LLC, 42 F.4th 828, 834 (8th Cir. 2022).

17. *See Greenfield*, 880 F.3d at 96–97, 100.

18. *See* Amy Kearbey, Kaitlin Marino & Christopher Parker, *8th Circ. Ruling Raises Bar for Anti-Kickback FCA Claims*, LAW360 (Aug. 10, 2022, 4:51 PM), https://www.law360.com/articles/1519737/8th-circ-ruling-raises-bar-for-anti-kickback-fca-claims [https://perma.cc/XJH4-5JCL]; Jeff Overley, *50 Years in, Industry Has Knives out for Potent Kickback Law*, LAW360 (Mar. 18, 2023, 12:01 AM), https://www.law360.com/articles/1570400/50-years-in-industry-has-knives-out-for-potent-kickback-law [https://perma.cc/HU8F-ZRKY].

19. *See* Mayell, *supra* note 15. The U.S. Supreme Court has addressed two circuit splits over interpretations of FCA-related language in the last decade. *See generally* United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391 (2023) (clarifying the FCA's knowledge

This Note examines the divergent conclusions that three federal circuit courts have reached regarding the degree of causation required to bring an FCA claim under the 2010 AKS amendment. On the one hand, the U.S. Court of Appeals for the Third Circuit held that the amendment requires less than but-for causation but something more than a temporal association.[20] On the other hand, the U.S. Courts of Appeals for the Sixth Circuit and Eighth Circuits held that but-for causation is necessary.[21] Ultimately, this Note will recommend adopting the Sixth and Eighth Circuits' but-for causation standard.[22]

Part I provides background on the AKS and the FCA, the 2010 amendment to the AKS, and the legal concepts of statutory interpretation and but-for causation.[23] Part II examines the circuit split and addresses the meaning and implications of "resulting from" in the 2010 AKS amendment.[24] Finally, Part III argues that fact finders should apply a but-for causation standard in a highly fact-specific inquiry when dealing with FCA claims brought solely under the 2010 AKS amendment.[25]

PART I: THE ANTI-KICKBACK STATUTE, FALSE CLAIMS ACT, AND JUDICIAL INTERPRETATIONS OF CAUSAL LANGUAGE

This part will first provide an overview of the AKS and FCA, including the false certification theory of FCA liability and the 2010 amendment to the AKS. It will then briefly review the legal principles of statutory interpretation and causation. Lastly, it will examine relevant Supreme Court precedent and highlight the Court's recent approach to interpreting causal language.

A. Federal Statutes Taking on Healthcare Fraud

The AKS and FCA are two of the government's most effective weapons against healthcare fraud.[26] Even though both statutes stand independently, providing redress for healthcare fraud in different ways, courts have historically allowed plaintiffs to bring FCA claims based on a defendant's alleged AKS violations through the false certification theory, described below.[27]

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requirement); Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016) (clarifying the FCA's materiality requirement).

20. *See Greenfield*, 880 F.3d at 98; *infra* Part II.A.
21. *See Martin*, 63 F.4th at 1052–53, 1055; *Cairns*, 42 F.4th at 835; *infra* Part II.B.
22. *See infra* Part III.
23. *See infra* Part I.
24. *See infra* Part II.
25. *See infra* Part III.
26. *See* A ROADMAP FOR NEW PHYSICIANS, *supra* note 6, at 4; CTRS. FOR MEDICARE & MEDICAID SERVS., ICN MLN4649244, MEDICARE FRAUD & ABUSE: PREVENT, DETECT, REPORT 8 (2021).
27. *See* Hammond, *supra* note 10, at 67–68; Castiglione et al., *supra* note 10, at 71, 76; *infra* Part I.A.2.i.

In 2010, Congress amended the AKS to fill a gap identified in the false certification theory, officially linking the AKS and the FCA.[28] The 2010 AKS amendment created a path for FCA claims against AKS violators where one had not previously existed.[29] Now, the murky and potentially dispositive issue of how closely connected the AKS violations and FCA claims must be, in these particular circumstances, has captured the attention of the courts and commentators alike.[30]

Part I.A.1 will survey the AKS, Part I.A.2 will overview the FCA and false certification theory, and Part I.A.3 will examine the 2010 AKS amendment that formally tied the two statutes to each other and bridged the gap in the false certification theory.

1. Criminal Liability for Healthcare Fraud: The AKS

The AKS[31] imposes criminal liability on healthcare actors who knowingly and willfully pay, offer, solicit, or receive remuneration[32] in exchange for patient referrals or orders for items or services funded by federal healthcare programs including Medicare and Medicaid.[33]

The scope of the AKS is vast, extending to every corner of the healthcare industry.[34] It prohibits obviously illegal exchanges, like bribes and kickbacks,[35] as well as other sophisticated economic arrangements that go beyond simple payments for items or services.[36] The legislative history 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."[37] Congress demonstrated its intention for a far-reaching AKS when it amended the statute to make AKS violations general intent crimes in 2010.[38] As a general intent crime, a

28. 42 U.S.C. § 1320a-7b(g); *see* Guilfoile v. Shields, 913 F.3d 178, 189 (1st Cir. 2019); United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018).

29. *See* Hammond, *supra* note 10, at 67; *infra* Part I.A.3.

30. *See infra* Part II; *see also* Castiglione et al., *supra* note 10, at 88; Mayell, *supra* note 15; Overley, *supra* note 15.

31. 42 U.S.C. § 1320a-7b.

32. Remuneration, for the purposes of the AKS, includes excessive compensation, kickbacks, bribes (such as free rent or lavish vacations), rebates, and other things of value. *See* William Grioux, Jennifer Maul, Andrew Delaplane, Forrest Hane, Dorothy Josephy, Nicholas Pfeiffer & Pamela Safirstein, *Health Care Fraud*, 55 AM. CRIM. L. REV. 1333, 1341 (2018); A ROADMAP FOR NEW PHYSICIANS, *supra* note 6, at 4.

33. *See* A ROADMAP FOR NEW PHYSICIANS, *supra* note 6, at 4.

34. *See* Grioux et al., *supra* note 32, at 1341. This vastness is relevant to the 2010 AKS amendment because any violation of the AKS may form the basis for an FCA action brought under the 2010 AKS amendment if the claim submitted to the government "includes items or services resulting from" the AKS violation. 42 U.S.C. § 1320a-7b(g).

35. 42 U.S.C. § 1320a-7b(b).

36. *See* Grioux et al., *supra* note 32, at 1341 ("As a result, the statute applies to previously common business practices, including discount arrangements, incentives to pharmacists, and manufacturers giving gifts and offering business courtesies.").

37. H.R. REP. NO. 95-393, at 1 (1977).

38. *See* JOEL M. ANDROPHY, 6 WHITE COLLAR CRIME § 37:11, Westlaw (database updated Feb. 2023); John Dube, Note, *The Anti-Kickback Statute and the False Claims Act: How Statutory Interpretation Affects Access to, and Protects Against Fraud in, the Public*

violation of the AKS does not require the government to prove that defendants had specific intent to violate, or actual knowledge of, the AKS to prevail on an AKS claim.[39]

There are quite a few safe harbors enumerated in the AKS,[40] which are essential considering the statute's sweeping purview and the significant penalties available for AKS crimes.[41] Those who violate the AKS face a felony conviction, punishable by up to 100 thousand dollars in fines, a maximum ten-year prison sentence, or a combination of the two.[42] Healthcare providers found guilty of violating the AKS may also be excluded from participating in federal healthcare programs in the future.[43]

2. Civil Liability for Healthcare Fraud: The FCA

Enacted in 1863, the FCA imposes civil liability on those who knowingly submit or induce the submission of false claims to the government.[44] Although the FCA is a general fraud statute, it is often used to prosecute healthcare fraud because its significant penalties provide a strong deterrent against illegal actions.[45] Statutory damages for an FCA violation are three times the government's actual damages from the fraudulent activity (treble damages), plus an additional 5,000–11,000 dollars for each false claim submitted.[46]

Healthcare Sector, 19 J. HEALTH & BIOMED. L. 360, 378–79 (2023) (describing how Congress amended the AKS to make violations general intent crimes after courts had held that violations of the AKS required specific intent).

39. 42 U.S.C. § 1320a-7b(h) ("With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.").

40. 42 U.S.C. § 1320a-7b(b)(3).

41. *See* 42 U.S.C. §§ 1320a-7b(b)(1)–1320a-7b(b)(2); Grioux et al., *supra* note 32, at 1341 ("Due to the broad range of activities barred by the statute, the OIG designates safe harbor provisions for certain types of conduct that would otherwise be prohibited."); A ROADMAP FOR NEW PHYSICIANS, *supra* note 6, at 4.

42. 42 U.S.C. §§ 1320a-7b(b)(1)–(2); *see* MEDICARE FRAUD & ABUSE: PREVENT, DETECT, REPORT, *supra* note 26, at 9; Tycko & Zavareei LLP, *What is the Anti-Kickback Statute?*, NAT'L L. REV. (Jan. 11, 2023), https://www.natlawreview.com/article/what-anti-kickback-statute [https://perma.cc/5VXA-YM4M].

43. Tycko & Zavareei LLP, *supra* note 42.

44. 31 U.S.C. § 3729(a)(1)(A); *see* United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1045 (6th Cir.) ("The False Claims Act imposes civil liability for 'knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim [to the government] for payment or approval.'" (alterations in original) (quoting 31 U.S.C. § 3729(a)(1)(A))), *reh'g en banc denied*, 2023 U.S. App. LEXIS 11994 (6th Cir. May 16, 2023), *cert. denied*, 144 S. Ct. 224 (2023); *The False Claims Act*, U.S. DEP'T OF JUST., https://www.justice.gov/civil/false-claims-act [https://perma.cc/2PB9-8T6L] (last updated Feb. 23, 2024); U.S. DEP'T OF JUST., THE FALSE CLAIMS ACT: A PRIMER (2011), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf [https://perma.cc/3G3F-7C5V].

45. *See* Grioux et al., *supra* note 32, at 1377.

46. *See* James W. Adams, *Proof of Violation Under the False Claims Act*, 78 AM. JUR. 3D *Proof of Facts* § 1 (2004); Lori L. Pines, *Understanding the False Claims Act*, PRAC. L. LITIG., https://us.practicallaw.thomsonreuters.com/7-561-1346 [https://perma.cc/L27F-8T2Q] (last visited Aug. 31, 2024). The upper limit for supplemental damages for FCA violations change over time, so although the maximum amount was ten thousand dollars, it has since increased to eleven thousand dollars. *See* THE FALSE CLAIMS ACT: A PRIMER, *supra* note 44, at 1.

The U.S. Attorney General has the authority to bring FCA actions for the government because the government is the injured party in FCA claims.[47] The FCA also contains a whistleblower, or qui tam, provision that allows private citizens to bring FCA claims on the government's behalf.[48] The whistleblower provision incentivizes private citizens to bolster the government's anti-fraud efforts with their personal knowledge and resources.[49] Private individuals who bring these actions are called relators or qui tam relators.[50] Once a relator commences an FCA action, the government can intervene and take over the case.[51] Whether or not the government intervenes, relators who bring successful FCA claims often receive a portion of the recovered monetary damages.[52]

To prevail on an FCA claim, the plaintiff must prove the necessary elements of the claim, including falsity,[53] knowledge,[54] and materiality.[55] The 2010 AKS amendment addresses the falsity element specifically,[56] so it is the only element described at length in this Note.

A claim must be factually or legally false to establish FCA liability.[57] A claim is factually false when the submission to the government "misrepresents what goods or services" were provided.[58] For example, a

47. 31 U.S.C. § 3730(a).

48. *Id.* § 3730(b); *see* Adams, *supra* note 46, § 1; Pines, *supra* note 46.

49. *See* Sean Elameto, *Guarding the Guardians: Accountability in Qui Tam Litigation Under the Civil False Claims Act*, 41 PUB. CONT. L.J. 813, 817 (2012). Over time, Congress has imposed a number of restrictions on qui tam actions and additional protections for relators. *See generally id.*

50. *See* Adams, *supra* note 46, § 1.

51. 31 U.S.C. § 3730(b)(2)–(3); *see* Alexandra S. Davidson & Tanisha Palvia, *SCOTUS Clarifies Intent Requirement for False Claims Act Cases*, REUTERS (July 6, 2023, 2:51 PM), https://www.reuters.com/legal/litigation/scotus-clarifies-intent-requirement-false-claims-act-cases-2023-07-06/ [https://perma.cc/MLD8-RK5U].

52. Typically, relators receive 15–25 percent of the resulting damages if the government intervenes and 25–30 percent if the government does not intervene. *See* Adams, *supra* note 46, § 5.

53. *See* United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1398 (2023); Adams, *supra* note 46, § 4.

54. *See* Adams, *supra* note 46, § 4 (explaining that the knowledge element requires that the defendant knew the claim was false or fraudulent); *see also Schutte*, 143 S. Ct. at 1404 (holding that the FCA knowledge requirement refers to the defendant's subjective beliefs and knowledge, rather than the objective beliefs of a reasonable person); VICTORIA L. KILLION, CONG. RSCH. SERV., LSB10978, SUPREME COURT ADDRESSES SCOPE OF FALSE CLAIMS ACT'S KNOWLEDGE REQUIREMENT 3 (2023) (explaining that *Schutte* clarified the FCA's knowledge requirement, "thereby settling a question that had started to divide the lower courts").

55. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1996 (2016) (holding that to satisfy the FCA materiality requirement, the defendant's misrepresentation must be material to the government's payment decision); *see also* United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 94 (3d Cir. 2018) (asserting that when a plaintiff alleges a defendant's claim is legally false, they "must also prove the defendant's misrepresentation about its compliance with a legal requirement is 'material to the Government's payment decision.'" (quoting *Escobar*, 136 S. Ct. at 1996)).

56. 42 U.S.C. § 1320a-7b(g).

57. *See Greenfield*, 880 F.3d at 94.

58. *Id.* (quoting United States *ex rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011)).

claim submitted for medical equipment or services on behalf of a nonexistent patient would be factually false.[59] Legal falsity is less intuitive: a claim is legally false, although factually accurate, when the claimant misrepresents the claim's compliance with statutory, regulatory, or contractual requirements that are preconditions to reimbursement by the government.[60] Take, for instance, a Medicaid patient who received psychiatric services and medication for their ailments.[61] Medicaid reimbursement claims for the services provided to this patient would not be factually false because the services and medication were actually provided.[62] Still, if the healthcare provider who performed the patient's services and prescribed the medication did not have the proper licenses or authorization to do so, and proper licensing or authorization were preconditions for Medicaid reimbursement, then the claims could be found legally false, satisfying the FCA falsity element.[63]

a. False Certification Theory

The understanding that FCA claims can be legally, rather than factually, false evolved into the false certification theory.[64] Under the false certification theory, legally false claims are further partitioned into two subcategories: express false certification and implied false certification.[65] Express false certification, as the name suggests, applies when a claimant submits a claim that includes an express, albeit false, statement of compliance with a particular statute, contract, or regulation.[66] The implied false certification theory applies when "a claimant makes no express statement about compliance with a statute or regulation, but by submitting a claim for payment [the claimant] implies that it has complied with any preconditions to payment."[67] The Supreme Court officially acknowledged the validity and

59. *See supra* notes 2–3 and accompanying text.

60. *See Greenfield*, 880 F.3d at 94; Jake Summerlin, Note, *Determining the Appropriate Reach of* Escobar*'s Materiality Standard: Implied and Express Certification*, 38 GA. STATE U. L. REV. 571, 583 (2022).

61. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1997 (2016) (describing a similar factual scenario).

62. *See id.*

63. *See id.*

64. *See* CLAIRE M. SYLVIA, THE FALSE CLAIMS ACT: FRAUD AGAINST THE GOVERNMENT § 4:40, Westlaw (database updated Aug. 2023); JOEL M. ANDROPHY & CARLA LASSABE, FEDERAL FALSE CLAIMS ACT AND QUI TAM LITIGATION § 4.02(1)(b), Lexis (database updated May 2024) ("When interpreting the words 'false or fraudulent claim,' many courts have found that FCA liability can further attach to 'legally false' claims . . . . This theory is referred to as 'false certification' theory." (footnote omitted)).

65. *See* ANDROPHY, *supra* note 64, § 4.02(1).

66. *See* Laura F. Laemmle-Weidenfeld, *Express and Implied False Certification*, *in* 2 HEALTH L. PRAC. GUIDE § 29:14, Westlaw (database updated Sept. 2023); ANDROPHY, *supra* note 64, § 4.02(1)(b)(i); SYLVIA, *supra* note 64; Michael Holt & Gregory Klass, *Implied Certification Under the False Claims Act*, 41 PUB. CONT. L.J. 1, 16 (2011).

67. Holt & Klass, *supra* note 66, at 32 (alteration in original) (quoting United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 694 F. Supp. 2d 48, 62 (D. Mass. 2010), *rev'd*, 647 F.3d 377 (1st Cir. 2011)). Although many courts adopted implied false certification as a basis for FCA liability, some initially (before the Supreme Court decision in *Escobar*) refused to do

defined the scope of implied false certification theory in *Universal Health Services v. United States ex rel. Escobar*.[68]

The false certification theory allows plaintiffs to bring FCA claims in various scenarios, but there is a particular set of circumstances in which the theory falls short.[69] *United States ex rel. Bennett v. Medtronic, Inc.*[70] illustrates this distinct scenario. In *Medtronic*, the relators alleged that Medtronic violated the AKS by paying remuneration to doctors and hospitals in exchange for using one of the company's products.[71] They then argued that, under the false certification theory, Medtronic was subject to FCA liability for Medicare claims submitted by the involved doctors and hospitals for services using Medtronic's product.[72] The relators reasoned that because compliance with the AKS is a prerequisite condition for Medicare reimbursement and the claims were the product of Medtronic's kickback scheme, the claims were legally false under the false certification theory.[73]

The U.S. District Court for the Southern District of Texas, however, refused to hold Medtronic liable for violating the FCA.[74] The court emphasized that, under the false certification theory, "the basis of liability is certification of compliance, not the payment or acceptance of remuneration."[75] The court found that because the relators failed to allege "that Medtronic caused any hospital or physician to certify compliance with the [AKS]," it could not impart FCA liability to Medtronic.[76]

Medtronic highlighted a gap in FCA liability under the false certification theory, which arises when the party responsible for an alleged AKS violation does not submit a reimbursement claim to the government.[77] In cases like *Medtronic*, relators cannot use the false certification theory to allege FCA liability against such a defendant because the defendant was not the party that falsely certified anything to the government.[78] As the *Medtronic* court stressed, the basis for liability under the false certification theory is the certification of compliance, which is only made by the party submitting the claim.[79] So, as *Medtronic* illustrates, there was a gap in the false certification

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so because implied certification is not expressly contemplated in the statute. *See* ANDROPHY, *supra* note 64, § 4.02(1); Laemmle-Weidenfeld, *supra* note 66, § 29:14.

68. 136 S. Ct. 1989 (2016); *see* ANDROPHY, *supra* note 64, § 4.02(1), nn.74–81; Laemmle-Weidenfeld, *supra* note 66, § 29:14.

69. *See* 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman).

70. 747 F. Supp. 2d 745 (S.D.T.X. 2010).

71. *See id.* at 784.

72. *See id.*

73. *See id.*

74. *See id.* at 784–85.

75. *See id.* at 784.

76. *Id.*

77. *See id.*

78. *See id.* at 785; 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman).

79. *See Medtronic*, 747 F. Supp. 2d at 785; *see also* ANDROPHY, *supra* note 64, § 4.02(1)(b) (explaining that liability under implied false certification theory requires more than a bare regulatory violation).

theory that provided some AKS violators—those involved in an alleged kickback scheme but who did not submit any claims to the government for reimbursement themselves—with a loophole to avoid FCA liability.[80]

3. Bridging the Gap in False Certification Theory: The 2010 Amendment to the AKS

In 2010, Congress acted to fix the loophole in the false certification theory's blanket of FCA liability.[81] Congress did this by amending the AKS to state that "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]."[82]

The legislative history confirms that closing this gap was Congress's intent.[83] Congress noticed cases in which plaintiffs alleged that defendants had violated the AKS, and that claims were submitted to the government because of the defendants' kickback schemes.[84] Yet, courts refused to hold those defendants liable for violating the FCA because an innocent third party submitted the claims.[85] Alarmed by the FCA enforcement gap, Congress amended the AKS to "ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves."[86]

The 2010 AKS amendment provides plaintiffs with a statutory mechanism for bringing FCA claims against AKS violators that the false certification theory could not reach.[87] But a new question has arisen as circuit courts have reached different conclusions about what the amendment's "resulting from" language requires plaintiffs to prove in this type of AKS-based FCA claims.[88]

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80. *See Medtronic*, 747 F. Supp. 2d at 784; 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman).

81. 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman); 155 CONG. REC. S10854 (daily ed. Oct. 28, 2009) (statement of Sen. Patrick Leahy).

82. 42 U.S.C. § 1320a-7b(g).

83. 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman) (explaining that the loophole in false certification theory particularly limited the government's ability "to recover from pharmaceutical and device manufacturers, because in such instances the claims arising from the illegal kickbacks typically are not submitted by the doctors who received the kickbacks, but by pharmacies and hospitals that had no knowledge of the underlying unlawful conduct").

84. *See id.*

85. *See id.* ("In other words, a claim that results from a kickback and that is fraudulent when submitted by a wrongdoer is laundered into a 'clean' claim when an innocent third party finally submits the claim to the government for payment.").

86. *Id.*

87. *See id.*; 155 CONG. REC. S10854 (daily ed. Oct. 28, 2009) (statement of Sen. Patrick Leahy).

88. *See* Mayell, *supra* note 15.

B. Legal Principles and Supreme Court Precedent

This section will overview statutory interpretation and causation before examining the Supreme Court's application of those legal principles in interpreting causal language in two recent cases.

1. Principles of Statutory Interpretation

Judges may employ various tools when deciding how a law or statute applies to the facts of the case before them.[89] Theories of statutory interpretation and precedent govern how judges use these tools.[90]

A primary tenet of statutory interpretation is that the court's analysis begins with the statute's language.[91] Accordingly, courts give undefined terms their ordinary or plain meaning.[92] Courts determine a word or phrase's plain meaning by considering its dictionary definition, its commonly understood meaning, and the statutory context in which the word or phrase appears.[93]

2. Theories of Causation

Causation consists of two parts: actual cause and proximate cause.[94] An actual cause is an act or omission necessary for a later event to occur.[95] Proximate cause, sometimes referred to as "legal cause," considers whether a defendant should be held legally responsible for causing an event.[96]

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89. *See* VALERIE C. BRANNON, CONG. RSCH. SERV., R45153, STATUTORY INTERPRETATION: THEORIES, TOOLS, AND TRENDS 1 (2023).

90. *See generally id.*; LARRY M. EIG, CONG. RSCH. SERV., 7-5700, STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS (2014).

91. *See* 73 AM. JUR. 2D *Statutes* § 98 (2023); EIG, *supra* note 90, at 3; BRANNON, *supra* note 89, at 1; *see also* Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2364 (2019) ("In statutory interpretation disputes, a court's proper starting point lies in a careful examination of the ordinary meaning and structure of the law itself.").

92. *See* Burrage v. United States, 571 U.S. 204, 210 (2014); Taniguchi v. Kan Pac. Saipan, Ltd., 566 U.S. 560, 566 (2012). Sometimes, undefined terms have an "accepted and specialized meaning at common law," in which case, courts will consider the word or phrase a term of art and will use the specialized meaning in its analysis. EIG, *supra* note 90, at 7.

93. *See Burrage*, 571 U.S. at 212 ("Where there is no textual or contextual indication to the contrary, courts regularly read phrases like 'results from' to require but-for causality."); BRANNON, *supra* note 89, at 23.

94. *See Burrage*, 571 U.S. at 210; Michael Moore, *Causation in the Law*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY 5–6 (Edward N. Zalta & Uri Nodelman eds., 2024), https://plato.stanford.edu/entries/causation-law/#LawsExplDefiCaus [https://perma.cc/QXN9-FRDL].

95. *See Cause*, BLACK'S LAW DICTIONARY (11th ed. 2019); *But-For Cause*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("The cause without which the event could not have occurred."); *Actual Cause*, CORNELL L. SCH. LEGAL INFO. INST. (last updated June 2022), https://www.law.cornell.edu/wex/actual_cause [https://perma.cc/T84N-BS99].

96. 65 C.J.S. *Negligence* § 188 (2024) (Proximate causation "asks whether an act for which a defendant is responsible is of such a nature that courts of law will recognize it as the cause of an injury.").

Courts are divided over the standard of actual causation needed to satisfy the causal phrase "resulting from" in the 2010 AKS amendment.[97] As such, this Note primarily considers actual causation.

In many modern cases, courts apply the but-for causation test to determine if the defendant's conduct was an actual cause of an injury.[98] Under the but-for test, a court asks if the ultimate harm would not have occurred but-for the defendant's conduct.[99] In other words, "a but-for test directs us to change one thing at a time and see if the outcome changes. If it does, we have found a but-for cause."[100] Although alternative causal theories exist in modern jurisprudence,[101] the Supreme Court has consistently adopted "but-for" as its default causal standard in recent years.[102]

3. Statutory Interpretation of Causal Language: *Bostock* & *Burrage*

Two recent Supreme Court cases illustrate the Court's approach to interpreting causal language in significant federal statutes.[103]

In *Burrage v. United States*,[104] the Court interpreted the phrase "results from" in the Controlled Substances Act[105] (CSA).[106] On April 15, 2010, Joshua Banka went on an IV drug binge that ended in an overdose and,

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97. *See* Kearbey et al., *supra* note 18; Overly, *supra* note 18; *see also infra* Part II.

98. DAN B. DOBBS, PAUL T. HAYDEN & ELLEN M. BUBLICK, DOBBS' LAW OF TORTS § 186, Westlaw (database updated May 2023); *see Burrage*, 571 U.S. at 211 ("This but-for requirement is part of the common understanding of cause."); *cf.* Sandra F. Sperino, *The Causation Canon*, 108 IOWA L. REV. 703, 711 (2023) (explaining that the current but-for test for factual cause has not always been the default presumption).

99. Bostock v. Clayton County, 140 S. Ct. 1731, 1739 (2020); DOBBS ET AL., *supra* note 98, § 186.

100. *Bostock*, 140 S. Ct. at 1739; *see also* H.L.A. HART & A.M. HONORÉ, CAUSATION IN THE LAW 110 (2d ed. 1985); 65 C.J.S. *Negligence* § 206 (2023).

101. *See* HART & HONORÉ, *supra* note 100, at 129 (acknowledging that but-for is the most common test for actual cause but other constructions exist); CORNELL L. SCH. LEGAL INFO. INST., *supra* note 95. Courts and scholars have expressed that the but-for test can be impractical in certain circumstances. *See Burrage*, 571 U.S. at 215; HART & HONORÉ, *supra* note 100, at 407; Wex S. Malone, *Ruminations on Cause-in-Fact*, 9 STAN. L. REV. 60, 67 (1956); Sperino, *supra* note 98, at 713. Alternate theories of actual cause include the substantial factor test, multiple sufficient causes, and necessary element of a sufficient set. *See Burrage*, 571 U.S. at 215–16 (recognizing state courts' adoption of the substantial factor test); Paroline v. United States, 572 U.S. 434, 451 (2014) ("[The] courts have departed from the but-for standard where circumstances warrant."); 65 C.J.S. *Negligence* § 207 (2023); HART & HONORÉ, *supra* note 100, at 123–24; Sara M. Peters, *Shifting the Burden of Proof on Causation: The One Who Creates Uncertainty Should Bear Its Burden*, 13 J. TORT L. 237, 241–42 (2020).

102. *See* Sperino, *supra* note 98, at 704; *infra* Part I.B.3.

103. *See generally* Bostock v. Clayton County, 140 S. Ct. 1731 (2020); *Burrage*, 571 U.S. at 204. One scholar has identified the Court's allegiance to the but-for construction of causation as a relatively new phenomenon arising over the last decade or so and criticize it for doing so. *See* Sperino, *supra* note 98, at 703.

104. 571 U.S. 204 (2014).

105. Pub. L. No. 91-513, 84 Stat. 1242 (codified as amended in scattered titles and sections of the U.S.C.).

106. *See id.* at 206.

ultimately, his death.[107] The cocktail of drugs that Banka injected himself with on the day of his death included heroin that Banka had purchased from Marcus Burrage earlier that day.[108] Medical experts agreed that the heroin was a contributing factor to Banka's death but that it was not possible to determine "whether Banka would have lived had he not taken the heroin" because of the other drugs in his system at the time of his death.[109]

Against the background of these facts, the Court considered "whether the mandatory-minimum provision [of the CSA[110]] applies when use of a covered drug supplied by the defendant contributes to, but is not a but-for cause of, the victim's death or injury."[111] Much like the 2010 AKS amendment's "resulting from" language, the CSA imposes criminal liability on a defendant "who unlawfully distributes a Schedule I or II drug, when 'death or serious bodily injury results from the use of such substance.'"[112]

The CSA does not define "results from."[113] In the absence of a statutory definition, the *Burrage* Court, in alignment with the methods of statutory interpretation described above,[114] gave the phrase its ordinary meaning.[115] The Court cited dictionary definitions of "results,"[116] previous Court interpretations of the phrase, and the Model Penal Code's explanation of causation to hold that the language "results from" in the CSA[117] requires that plaintiffs prove actual causation.[118] It clarified that for a defendant's conduct to be an actual cause of the event in question, like the death of a drug user, it must be a necessary cause of the event, in other words, a cause that the event would not have occurred without.[119]

The Court asserted that "it is one of the traditional background principles 'against which Congress legislates' that a phrase such as 'results from' requires but-for causation."[120] It also emphasized that Congress could have phrased the enhancement to the CSA differently, with a phrase like

107. *Id.*
108. *Id.*
109. *Id.* at 207.
110. 21 U.S.C. § 841.
111. *Burrage*, 571 U.S. at 206.
112. *Id.* (quoting 21 U.S.C. § 841(b)(1)(A)). The mandatory minimum sentence is twenty years for a violation of this provision of the CSA. 21 U.S.C. § 841(b)(1)(C).
113. *Burrage*, 571 U.S. at 210.
114. *See supra* Part I.B.1.
115. *Burrage*, 571 U.S. at 210–11.
116. *Id.* ("A thing 'results' when it 'arises 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." (first quoting 2 LESLEY BROWN, THE NEW SHORTER OXFORD ENGLISH DICTIONARY 2570 (4th ed. 1993); and then quoting Univ. of Tex. Sw. Med. Ctr. v. Nassar, 570 U.S. 338, 346–47 (2013)).
117. 21 U.S.C. § 841.
118. *Burrage*, 571 U.S. at 211.
119. *Id.* (explaining that the cause does not need to be the sole cause, so long as it is a necessary one).
120. *Id.* at 214 (citation omitted) (quoting *Nassar*, 570 U.S. at 347).

"contributes to" or something similar, if it intended to impose a lesser or modified causation standard.[121]

A few years later, in *Bostock v. Clayton County*,[122] the Court confirmed its propensity for a textualist, plain meaning approach to interpreting causal language in federal statutes.[123] A central issue in *Bostock* was the meaning and impact of the causal phrase "because of" in Title VII of the Civil Rights Act.[124] Title VII of the Civil Rights Act asserts that it is "unlawful . . . for an employer to fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual . . . because of such individual's . . . sex."[125] The *Bostock* Court turned to a previous case in which the Court identified the phrase's ordinary meaning as "by reason of" or "on account of" and held such language to impart a but-for causation standard.[126] After determining the phrase's plain meaning, the Court acknowledged the strength and implications of imposing a but-for standard in the statute's application.[127] As in *Burrage*, the Court emphasized that a defendant's conduct need not be the only cause of an event for the defendant to face liability, but it still must be a but-for cause.[128] Also similar to *Burrage*, the Court noted that Congress could have worded Title VII differently, as it had in other statutes, if it intended for the provision to engender some standard besides but-for causation.[129]

Both *Burrage* and *Bostock* exemplify the Court's approach to interpreting causal language, which begins with the language's plain meaning, informed by dictionary definitions and precedent, before turning to the impact of that meaning on the statute's application.[130] Additionally, in each case, the Court supported its plain meaning approach in part by recognizing Congress's ability to craft and amend statutory language to accomplish its legislative goals.[131]

PART II: CIRCUITS CLASH OVER THE CAUSATION STANDARD: INTERPRETING "RESULTING FROM" IN THE 2010 AKS AMENDMENT

Plaintiffs bringing FCA actions under the 2010 AKS amendment have argued that "resulting from" requires an association between the AKS violation and the false claim submitted to the government but no evidence of

121. *Id.* at 216.
122. 140 S. Ct. 1731 (2020).
123. *See id.* at 1738 ("This Court normally interprets a statute in accord with the ordinary public meaning of its terms at the time of its enactment.").
124. 42 U.S.C. § 2000e-2; *see Bostock*, 140 S. Ct. at 1739.
125. 42 U.S.C. § 2000e-2(a)(1); *Bostock*, 140 S. Ct. at 1738.
126. *See Bostock*, 140 S. Ct. at 1739 (citing the explanation of the plain meaning of the phrase "because of" in *University of Texas Southwestern Medical Center. v. Nassar*, 570 U.S. 338, 350 (2013)).
127. *See id.* at 1739.
128. *See id.*
129. *See id.*
130. *See id.*; Burrage v. United States, 571 U.S. 204, 211–14 (2014).
131. *See Bostock*, 140 S. Ct. at 1739; *Burrage*, 571 U.S. at 216.

actual or but-for causation.[132] Defendants point to Supreme Court precedent[133] and the plain meaning of the phrase "resulting from" to support their position that plaintiffs must prove but-for causation to prevail on these claims.[134] As cases with parties advocating these contrasting positions have percolated through the judicial system,[135] courts have come down on opposite sides of the following question: What degree of causation do the words "resulting from" in the 2010 AKS amendment demand?[136]

The debate has come to a head in three recent circuit court cases.[137] In 2018, the Third Circuit found that "resulting from" requires some "link" between the AKS violation and the false claims but does not require proof of but-for causation.[138] Then, in 2022 and 2023, respectively, the Eighth and Sixth Circuits held that "resulting from" in the 2010 AKS amendment mandates that plaintiffs prove but-for causation between the alleged AKS violation and the FCA claims.[139] Part II.A will examine the more relaxed causation standard, and Part II.B will survey the stricter "but-for" position.

A. A Court Holds That "Resulting from" Requires a "Link" Less Than But-For Causation

The diluted reading of "resulting from" is a plaintiff-friendly standard that relies heavily on legislative history and public policy arguments for support.[140] So far, the only federal circuit court to adopt this position is the Third Circuit in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*[141]

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132. *See, e.g.*, United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1054 (6th Cir.), *reh'g en banc denied*, 2023 U.S. App. LEXIS 11994 (6th Cir. May 16, 2023), *cert. denied*, 144 S. Ct. 224 (2023); United States *ex rel.* Cairns v. D.S. Med. LLC, 42 F.4th 828, 835 (8th Cir. 2022); United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96 (3d Cir. 2018).

133. *See Burrage*, 571 U.S. at 211–12 ("Where there is no textual or contextual indication to the contrary, courts regularly read phrases like 'results from' to require but-for causality.").

134. *See Greenfield*, 880 F.3d at 96.

135. This Note discusses the circuit court decisions from the Third, Sixth, and Eighth Circuits. At the time of this Note's publication, the U.S. Court of Appeals for the First Circuit has granted interlocutory appeal to decide this question of law in *United States v. Regeneron Pharmaceuticals, Inc.*, No. 23-8036, 2023 WL 8599986, at *1 (1st Cir. Dec. 11, 2023), after the U.S. District Court for the District of Massachusetts adopted the "but-for" standard in its decision. United States v. Regeneron Pharms., Inc., No. CV 20-11217-FDS, 2023 WL 6296393, at *11 (D. Mass. Sept. 27, 2023), *cert. granted*, No. 23-8036, 23 WL 8599986 (1st Cir. Dec. 11, 2023).

136. *See generally Martin*, 63 F.4th 1043; *Cairns*, 42 F.4th 828; *Greenfield*, 880 F.3d 89.

137. *See Martin*, 63 F.4th at 1045; *Cairns*, 42 F.4th at 831; *Greenfield*, 880 F.3d at 95; *see also* Adam L. Braverman, Nathaniel R. Mendell & Kate Driscoll, *The Sixth Circuit Narrows the Scope of AKS and FCA Liability*, MORRISON FOERSTER (Apr. 24, 2023), https://www.mofo.com/resources/insights/230424-the-sixth-circuit-narrows-the-scope [https://perma.cc/6WGW-7SXZ].

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

139. *See Martin*, 63 F.4th at 1053; *Cairns*, 42 F.4th at 831.

140. *See Greenfield*, 880 F.3d at 98; Castiglione et al., *supra* note 10, at 72; Dube, *supra* note 38.

141. 880 F.3d 89 (3d Cir. 2018).

1. The Third Circuit

The Third Circuit addressed "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."[142]

Greenfield arose from a qui tam action brought by Steve Greenfield against his former employer, Accredo Health Group ("Accredo"), for alleged violations of the AKS and the FCA.[143] The action was dismissed on Accredo's motion for summary judgment.[144] Greenfield appealed the dismissal.[145]

Accredo, a specialty pharmacy offering home care to hemophilia patients,[146] donated hundreds of thousands of dollars yearly to Hemophilia Services Incorporated (HSI).[147] HSI, a hemophilia-focused charity, provided grants to the Hemophilia Association of New Jersey (HANJ) to fund HANJ's private insurance program and treatment centers.[148] HANJ acknowledged Accredo's donations by listing it as an approved vendor and provider on its website and encouraging HANJ patients to work with its approved providers.[149]

When Accredo indicated that it would reduce its contributions to HSI, and therefore HANJ, HSI/HANJ sent a letter to its members notifying them of the potential impacts of Accredo's financial pullback and asking them to write to Accredo requesting additional funding.[150] HSI also forwarded the letter to treatment centers, describing Accredo's behavior as "despicabl[e]."[151]

At Accredo's request, Greenfield, then an area vice president for the business, analyzed the potential return on investment if Accredo restored its funding amount to previous levels and the likely business decline if it failed to fund HSI as it had in previous years.[152] Greenfield's analysis revealed that reducing HSI's funding would put Accredo's business at risk.[153] Accredo restored its funding to HSI the following year, donating 350 thousand dollars.[154] Greenfield then filed a qui tam suit against Accredo, alleging that

142. *Id.* at 95.
143. *Id.* at 91.
144. *Id.*
145. *Id.*
146. *Id.*
147. *Id.*
148. *Id.*
149. *Id.* at 92.
150. *Id.*
151. *Id.*
152. *Id.*
153. *Id.* ("Greenfield's analysis indicated that, absent a funding increase to $350,000, 'all new and existing business [could be] at risk,' and Accredo could expect to 'lose 100% of the margin' associated with patients who switched out of Accredo's services." (alteration in original)).
154. *Id.*

Accredo violated the FCA by falsely certifying that it complied with the AKS.[155]

The *Greenfield* court began its analysis by acknowledging that it should abide by a statute's plain meaning in its application of the law.[156] The court also recognized that it could verify or "cross-check" that plain meaning with legislative history to ensure that its interpretation aligns with discernable congressional intent.[157]

The court's analysis focused on the relator's contention that reading a but-for causation standard into the AKS amendment would produce inconsistent results in AKS and FCA claims brought under the same facts.[158] The relator and government argued that a defendant convicted of violating the AKS could escape FCA liability if the relator (or government) fails to prove that each claim would not have been submitted to the government without the defendant's AKS violation.[159] The court considered the legislative history to determine whether a but-for causation standard would lead to inconsistent results.[160]

After considering congressional reports, the court opined that a but-for causation standard could lead to inconsistent outcomes in AKS and FCA claims arising from the same transaction.[161] Accordingly, it held that "resulting from" requires something *less* than but-for causation.[162] To meet the Third Circuit's causal standard, the court held that the relator or government must prove that at least one reimbursement claim submitted to the government is somehow linked to the alleged AKS violation.[163]

In the instant case, the court held that the relator did not need to prove that referrals from HSI/HANJ "actually caused" federal beneficiaries to use Accredo as their provider.[164] Instead, the court required evidence that at least one submitted claim "covered a patient who was recommended or referred to Accredo by HSI/HANJ."[165] The relator argued that a mere temporal relationship between the alleged kickback scheme and allegedly false claims was sufficient to establish FCA liability, but the *Greenfield* court rejected this reasoning.[166] Ultimately, the *Greenfield* court concluded that granting

155. *Id.* The Third Circuit did not actually decide the question of whether Greenfield had established that an AKS violation took place, but assumed for the purpose of its analysis that there was an AKS violation. *Id.* at 93 n.4, 98.

156. *Id.* at 95.

157. *Id.*

158. *Id.* at 96; Brief for the United States at 16, *Greenfield*, 880 F.3d 89 (No. 17-1152).

159. *Greenfield*, 880 F.3d at 96; *see also* Brief for the United States, *supra* note 158, at 29 ("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 each medical decision was in fact corrupted by the kickbacks.").

160. *Greenfield*, 880 F.3d at 96.

161. *Id.* at 96.

162. *Id.* at 100.

163. *Id.*

164. *Id.* at 98.

165. *Id.* at 99–100.

166. *Id.* at 98.

summary judgment to Accredo was proper because the relator, even under the relaxed causal standard, failed to prove the requisite "link" between the alleged kickback scheme and any of the twenty-four reimbursement claims submitted to the government.[167]

B. Two Other Courts Hold That "Resulting from" Requires But-For Causation

The Eighth and Sixth Circuits, when faced with the task of interpreting the words "resulting from" in the 2010 AKS amendment,[168] expressly rejected the Third Circuit's approach[169] and reached a different conclusion: the phrase "resulting from" does impose a but-for causation requirement on AKS-based FCA claims brought under the amendment.[170]

1. The Eighth Circuit

Dr. Sonjay Fonn, a neurosurgeon, used spinal implants to treat some patients at his practice, Midwest Neurosurgeons.[171] Multiple companies manufacture the implants and sell them to distributors who make significant commissions when they sell the implants to doctors like Fonn.[172] Dr. Fonn chose to use implants distributed by DS Medical, an implant distributor wholly owned by his fiancée, Deborah Seeger.[173] Dr. Fonn was not only Seeger's largest customer but also received an offer to purchase stock from one of the manufacturers whose implants he often purchased through Seeger.[174] Dr. Fonn continued to purchase these implants after he purchased the manufacturer's stock.[175]

Dr. Fonn's fellow physicians became suspicious of his higher-than-usual implant use and his connection to Seeger.[176] Based on these suspicions, Dr. Fonn's colleagues filed complaints against him, Midwest Neurosurgeons, Seeger, and DS Medical.[177] Three of the claims alleged that Dr. Fonn, Seeger, and their respective businesses submitted false or fraudulent claims for government reimbursement after violating the AKS.[178] The government joined the plaintiffs in their claim,[179] and after hearing from both parties on

167. *Id.* at 100.
168. United States *ex rel.* Cairns v. D.S. Med. LLC, 42 F.4th 828, 831 (8th Cir. 2022) ("This case requires us to determine what the words 'resulting from' mean.").
169. *Id.* at 836.
170. *Id.* at 831.
171. *Id.*
172. *Id.*
173. *Id.*
174. *Id.*
175. *Id.*
176. *Id.*
177. *Id.*
178. *Id.*
179. *Id.* ("The United States then intervened and filed its own complaint."); *see* 31 U.S.C. § 3730(a), (b)(2), (b)(4) (providing that the government may intervene and conduct the litigation).

the AKS-based FCA claims, the jury returned a verdict for the government.[180]

The defendants raised two issues on appeal,[181] both relevant to this Note. First, they argued that the jury received improper instructions because the jury instructions required finding liability by a preponderance of the evidence rather than beyond a reasonable doubt.[182] Second, the defendants took issue with the absence of a jury instruction on but-for causation.[183]

The *Cairns* court began its analysis by addressing the first issue, finding that the district court's instruction prescribing preponderance of the evidence as the plaintiff's burden of proof was proper.[184] The court then moved on to the issue of causation.[185]

The court began by examining the U.S. District Court for the Eastern District of Missouri's jury instruction on causation, which only required the plaintiff to show that the allegedly false claim did not disclose the AKS violation.[186] The Eighth Circuit ultimately held that the district court had "misinterpreted the 2010 amendment,"[187] holding that "when a plaintiff seeks to establish falsity or fraud through the 2010 [AKS] amendment, it must prove that a defendant would not have included particular 'items or services' but for the illegal kickbacks."[188]

In reaching this conclusion, the Eighth Circuit emphasized the long-standing principle of statutory interpretation that "when a statute is unambiguous, interpretation both begins and ends with the text."[189] It noted that the lack of a statutory definition for the words "resulting from" required the court to determine the phrase's plain or ordinary meaning when the statute was enacted.[190] The court then looked to the Supreme Court's analysis of a "nearly identical" phrase ("results from") in *Burrage v. United States*.[191] Recall that in *Burrage*, the Court used the same principles of statutory interpretation applied by the Eighth Circuit in the instant case[192] to conclude that "results from" "imposes . . . a requirement of actual causality."[193] The Eighth Circuit acknowledged that the context and tense of

180. *Cairns*, 42 F.4th at 831–32. Following the jury's verdict, the "district court [] awarded treble damages and statutory penalties" totaling almost 5.5 million dollars. *Id.* at 832.

181. *Id.* at 833.

182. *Id.*

183. *Id.*

184. *Id.* at 833–34 (holding that the government's reliance on proving the defendants violated the AKS, a criminal act, to support its FCA claims made "no difference" in assigning a preponderance of the evidence as the appropriate burden of proof).

185. *Id.* at 834.

186. *Id.*

187. *Id.*

188. *Id.* at 836.

189. *Id.* at 834 (citing Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2364 (2019)).

190. *See id.* (citing Tanzin v. Tanvir, 141 S. Ct. 486, 491 (2020)).

191. *Id.* at 834; *see supra* Part I.B.3.

192. *See supra* Part I.B.3.

193. Burrage v. United States, 571 U.S. 204, 210–11 (2014); *see supra* Part I.B.3.

the phrase at issue were not identical to those in *Burrage*.[194] Still, the court concluded that the plain meaning of "resulting from" in the 2010 AKS amendment necessitates a but-for causation requirement.[195]

The *Cairns* court considered and then rejected the relator's arguments that (1) an alternative causal theory should displace but-for causation and (2) adopting a but-for causation standard would contravene pre-2010 amendment precedent and legislative intent.[196] The relator advocated an alternative causal theory, which would only require that the alleged AKS violation "tainted" the claims or that the illegal kickbacks may have contributed to the claims' submission.[197] The court found that because the relator's suggested standard imparted no causal requirement, it would not comport with the 2010 AKS amendment's plain meaning, and thus, the court could not adopt it.[198]

The court then moved on to address the relator's legislative history argument.[199] The relator pointed to select pre-2010 amendment cases that held a failure to disclose an AKS violation sufficient to "taint" a claim, making it false or fraudulent under the FCA, and argued that the 2010 amendment merely codified the holdings in these cases.[200] The relator also argued that comments from the amendment's sponsors indicated Congress's intention for the amendment to expand, rather than narrow, potential FCA liability for AKS violations.[201] The Eighth Circuit, however, echoed the Supreme Court's point in *Burrage* that inferences from the congressional record do not override the unambiguous words that Congress voted into law.[202] The court recognized that its holding applies to a narrow segment of AKS-based FCA cases, in which the relator's claim is specifically brought under the 2010 AKS amendment.[203] It also explicitly departed from the Third Circuit's holding in *Greenfield*.[204] In the end, after concluding that proving but-for causation was an essential element of the relator's claim,[205] the Eighth Circuit remanded the case because the lower court failed to instruct the jury that but-for causation was required.[206]

194. *Cairns*, 42 F.4th at 834 ("The context here may be different, but our conclusion is the same. 'Resulting,' which is the present-participle form of the verb, has the same meaning as its present-tense cousin, 'results.'").
195. *Id.*
196. *See id.* at 835–37; *see also* Brief for the Appellee at 26–30, *Cairns*, 42 F.4th 828 (Nos. 20-2445, 20-2448, 20-3009, 20-3010).
197. *Cairns*, 42 F.4th at 835 (quoting Brief for Appellee, *supra* note 196, at 29).
198. *Id.*
199. *Id.*
200. *Id.* at 835–36.
201. *Id.* at 836; Brief for Appellee, *supra* note 196, at 29–30.
202. *Cairns*, 42 F.4th at 836.
203. *Id.*
204. *Id.*; *see supra* Part II.A.1.
205. *Id.* at 835 ("Causation is an 'essential element[]' that must be proven, not presumed" (quoting 31 U.S.C. § 3731(d)) (alteration in original)).
206. *Id.* at 837.

2. The Sixth Circuit

One year after the Eighth Circuit's decision in *Cairns*, the Sixth Circuit addressed the same causation issue, and, for many of the same reasons as the Eighth Circuit,[207] also adopted a but-for causation standard for claims brought under the 2010 AKS amendment.[208]

Oaklawn Hospital ("Oaklawn"), a hospital in a small Michigan city, and South Michigan Ophthalmology (SMO), the only local ophthalmology clinic near the hospital, referred local patients to one another for many years.[209] When SMO's owner, Dr. Darren Hathaway, started pursuing a merger with a larger practice based in Lansing, Michigan, one of SMO's employees, Dr. Shannon Martin, began discussing the opportunity for an internal position at Oaklawn, where her husband, Douglas Martin, was the director of finance.[210]

When Dr. Hathaway learned of Dr. Martin's potential new role, he sought out Oaklawn's interim CEO and some board members to clarify that while his practice was merging, it was not moving.[211] Dr. Hathaway also suggested that Oaklawn hiring Dr. Martin would be detrimental to his business[212] and stated that if the hospital hired Dr. Martin, he would be forced to pull his patients from Oaklawn and direct them to other hospitals.[213] Ultimately, Oaklawn's board voted not to hire Dr. Martin, Dr. Hathaway's merger plans fell through, and Dr. Martin set up her own ophthalmology practice.[214]

The Martins brought suit against Dr. Hathaway and Oaklawn, alleging they engaged in "a fraudulent scheme under the [AKS], and that claims for Medicare and Medicaid reimbursement resulting from the kickbacks violated the [FCA]."[215] They amended their complaint to add twenty-two reimbursement claims that Oaklawn and SMO submitted based on referrals to each other.[216] The defendants then moved to dismiss and the district court granted the motion.[217] The Martins appealed the dismissal.[218]

After analyzing whether the relators had identified a cognizable kickback scheme,[219] the U.S. District Court for the Western District of Michigan

207. *See* United States *ex rel.* Martin v. Hathaway, 63 F.4th 1043, 1052–53 (6th Cir.), *reh'g en banc denied*, 2023 U.S. App. LEXIS 11994 (6th Cir. May 16, 2023), *cert. denied*, 144 S. Ct. 224 (2023).

208. *Id.*

209. *Id.* at 1046.

210. *Id.* Dr. Martin believed that Dr. Hathaway's proposed merger would move SMO's surgeries away from the existing practice. *Id.*

211. *Id.* at 1046–47.

212. *Id.* at 1047.

213. *Id.*

214. *Id.*

215. *Id.* The Sixth Circuit summarized the Martins' allegations as centering around the theme "that Oaklawn Hospital's rejection of Dr. Martin's employment in return for Dr. Hathaway's commitment to continue sending local surgery referrals violated" the AKS. *Id.*

216. *Id.*

217. *Id.*

218. *See id.*

219. *See id.* The court agreed with the district court and held that the relators' allegations did not "turn on a cognizable theory of remuneration." *Id.* at 1048.

turned to the causation element within the 2010 AKS amendment, which would allow the Martins to bring FCA claims resulting from the alleged AKS scheme.[220]

Like the Eighth Circuit, the Sixth Circuit looked to the ordinary understanding of the 2010 AKS amendment's language to determine its meaning and held that but-for was the appropriate causation standard.[221] Citing *Burrage*, the court asserted that the "ordinary meaning of 'resulting from' is but-for causation."[222] To support its conclusion, the Sixth Circuit cited Supreme Court precedent and Sixth Circuit case law interpreting similar phrases.[223] The court also cited the explanation and support for requiring a but-for causation standard that the Eighth Circuit set forth in *Cairns*.[224]

The Sixth Circuit augmented the above arguments with two key points that further support its holding that the 2010 AKS amendment requires a but-for standard.[225] First, the *Martin* court rejected the government's contention that interpreting the amendment as requiring but-for causation would contradict the amendment's legislative history.[226] The court rejected the government's argument both for the same reasons described by the Eighth Circuit in *Cairns* and because the amendment is part of the AKS, a criminal statute.[227] In dismissing the government's legislative history argument, the court adhered to the principle that courts "generally do not consider legislative history in construing a statute with criminal applications."[228] Second, the court held firm to the more rigorous but-for causation standard because it recognized the AKS's sweeping nature and lack of protection for well-meaning providers who could get caught up in a broad reading of the amendment.[229]

After prescribing a but-for causation standard like the Eighth Circuit, the Sixth Circuit held that, in the instant case, the relators failed to plausibly prove but-for causation between the alleged kickback scheme and any claims for reimbursement.[230] It addressed several theories the relators set out to demonstrate a causal connection between the alleged kickback scheme and reimbursement claims.[231] Although the court addressed each of the

220. *Id.* at 1047.
221. *Id.* at 1052.
222. *Id.*
223. *Id.* at 1052–53 (noting that Congress added the "resulting from" language to the AKS "against the backdrop of a handful of cases that observed similar language as requiring but-for causation.").
224. *Id.* at 1053 (emphasizing the Eighth Circuit's rejection of the government's argument that the 2010 AKS amendment merely codified the "taint" theory of AKS-based FCA liability and its point that Congress could have used alternative language to give the amendment its intended effect); *see supra* Part II.B.1.
225. *See Martin*, 63 F.4th at 1054–55.
226. *Id.* at 1054.
227. *Id.*; *see supra* Part I.A.1.
228. *Martin*, 63 F.4th at 1054.
229. *Id.* at 1054–55.
230. *Id.* at 1053.
231. *Id.* at 1053–54.

plaintiff's theories,[232] it concluded that "the alleged scheme did not change anything."[233] So, because the Martins failed to allege a tenable but-for connection between the purported kickback scheme and a single reimbursement claim submitted to the government, the court held that the FCA claims must fail.[234]

PART III: BUT-FOR IS THE BEST AND THE MOST APPROPRIATE CAUSATION STANDARD FOR THE 2010 AKS AMENDMENT

Part III.A of this Note will first clarify the distinction between FCA claims brought under the false certification theory and those brought under the 2010 AKS amendment. Then, Part III.B will argue that the but-for causation standard adopted by the Eighth and Sixth Circuits correctly interprets the amendment. Finally, Part III.C will describe a highly fact-specific methodology that fact finders should use when applying the but-for causation standard in these 2010 AKS amendment cases and will suggest different types of evidence that relators can provide to meet the standard.

A. False Certification Theory Is Still a Viable Basis for FCA Liability

The government's fear that reading a but-for standard into the 2010 AKS amendment will severely limit its ability to recoup lost dollars due to healthcare fraud[235] is misplaced. It is misplaced because the 2010 AKS amendment supplemented, rather than replaced, false certification theory as a basis for FCA liability.[236] So, false certification theory remains a viable theory of liability for AKS-based FCA claims, even post-2010 amendment.[237] The government and relators have repeatedly asserted that

232. *Id.* at 1053. The Martins identified claims for fourteen surgeries that Oaklawn submitted to federal health care programs for reimbursement, eleven of which Dr. Martin performed herself. *Id.* The remaining three surgeries were performed by Dr. Hathaway, but two of the patients were initially referred to Dr. Martin before later going to Hathaway. *Id.* The court asserted that Dr. Martin's decisions to perform surgeries at Oaklawn, or to pass her patients on to Dr. Hathaway, were her independent choices that broke "any plausible chain of causation." *Id.* The final surgery that Dr. Hathaway performed occurred seven months after the Board decision, which the court, citing *Greenfield* among other cases, deemed too temporally distant from the alleged scheme to sustain a causal connection. *Id.* Finally, the Martins highlighted eight claims that Dr. Hathaway submitted for reimbursement that allegedly resulted from the hospital's referrals. *Id.* at 1054. The court, however, found that these referrals came from Oaklawn's individual physicians and, because the Martins did not allege that the hospital had any control over who individual physicians referred patients to, the doctors' independent choices quashed any tenable causal chain. *Id.*

233. *Id.* at 1053 ("When Oaklawn decided not to establish an internal ophthalmology line at the hospital, the same relationship continued just as it always had. There's not one claim for reimbursement identified with particularity in this case that would not have occurred anyway, no matter whether the underlying business dispute occurred or not."); *see supra* note 100 and accompanying text.

234. *Martin*, 63 F.4th at 1053.

235. *See supra* Part II.

236. *See supra* Parts I.A.2–3.

237. *See supra* Part I.A.2.i.

the 2010 AKS amendment was Congress's way of codifying the false certification theory and that a relaxed causal standard is necessary to achieve the amendment's purpose.[238] This contention, however, is not based on fact. Since the amendment was passed in 2010, courts have continued to hear and enforce AKS-based FCA claims brought under the false certification theory.[239] *Escobar*, which the Supreme Court decided in 2016, solidified false certification as a viable theory of FCA liability and clarified requirements for bringing FCA claims under the implied false certification theory.[240]

The following hypotheticals exemplify the distinction that relators and the government seem to overlook. The first illustrates a factual situation in which a relator could bring an AKS-based FCA claim directly under the false certification theory. The second hypothetical presents a situation in which a relator should bring an AKS-based FCA claim under the 2010 AKS amendment because the defendant's conduct falls within the gap identified in the false certification theory's blanket of liability.[241]

1. Hypothetical: Establishing Falsity Under the False Certification Theory

When defendants violate the AKS and subsequently submit a claim or claims to the government for items or services resulting from their AKS violation, plaintiffs do not need to rely on the 2010 AKS amendment to establish that the claim is false or fraudulent under the FCA.[242] Under these conditions, a plaintiff can rely on the false certification theory to establish falsity.[243] A viable false certification claim would arise in a scenario such as the following.

A physician is paid kickbacks by a pharmaceutical company to use its name-brand injectable anesthetic[244] instead of competitors or generics. The physician administers the anesthetic to a Medicare patient. The physician subsequently submits a claim for reimbursement to the government for the anesthetic used on the Medicare patient. Unaware of any fraud, the government pays the physician for the claim.

Then, the physician's nurse, as the relator, brings a qui tam action alleging that the claims the physician submitted for the anesthetic they used on the Medicare patient violated the FCA under the false certification theory. The claim is legally false in this situation because the physician is lying about their compliance with a federal statute (the AKS) when submitting this claim.[245] In other words, because the physician submitted the claim for the

238. *See supra* Part II.B.1.
239. *See supra* Part I.A.2.i. *See generally* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016).
240. *See supra* note 68 and accompanying text; *see also Escobar*, 136 S. Ct. at 1998–99.
241. *See supra* Part I.A.3.
242. *See supra* Part I.A.2.i.
243. *See supra* Part I.A.2.
244. Or insert physician-administered drug, device, or service.
245. *See supra* Part I.A.2.i.

anesthetic, which was administered as part of the physician and pharmaceutical company's kickback scheme in violation of the AKS, the physician falsely certified to (promised) the government compliance with the AKS. The physician's false certification to the government, that the claim for the anesthetic complied with all federal laws, would make the claim legally false under the false certification doctrine.[246] With the falsity element established, if the plaintiff can prove the other elements of the FCA claim, then the physician could be held liable for violating the FCA without relying on the 2010 AKS amendment at all.[247]

2. Hypothetical: Establishing Falsity Under the 2010 AKS Amendment

Instead of supplanting the false certification theory altogether, the 2010 amendment closes a gap that the theory leaves open.[248] Specifically, the amendment targets scenarios in which the entity or individual submitting the claim is unaware of any kickback scheme.[249] In some prior cases, courts refused to find FCA liability because the entity or individual who submitted the claim was unaware of the AKS violation upon which the FCA claim was based.[250] Unlike in the "knowing submitter" situation described above,[251] a situation in which the 2010 AKS amendment might be applicable could be as follows.

A device company pays a physician kickbacks to use a particular medical device in the physician's surgeries.[252] The hospital, totally ignorant of the AKS violation by the physician and medical device company, submits a bill to Medicare for reimbursement for the materials used in the Medicare patient's procedure, including the company's device.

Here, the hospital that submitted the claim is innocent. Before the 2010 AKS amendment, FCA defendants, in this case, the medical device company or physician, could argue with a reasonable expectation of success that they were not liable because they did not certify compliance with anything.[253] Rather, it was the hospital that certified compliance to the government, and it did not do so falsely because it was unaware of the claim's falsity when it submitted the claim.[254] Congress enacted the 2010 AKS amendment because it wanted an avenue for the culpable physician and medical device company to be held accountable for the legally false claim even though they were not the ones who submitted the claim to the government.[255] This scenario is one where a plaintiff should bring their FCA action under the 2010 AKS

246. *See supra* Part I.A.2.i.
247. *See supra* Part I.A.2.
248. *See supra* Part I.A.3.
249. *See supra* Part I.A.3.
250. *See supra* Part I.A.2.i; *supra* note 83.
251. *See supra* Part III.A.1.
252. *See supra* Part I.A.1.
253. *See supra* Parts I.A.2.i., I.A.3.
254. *See supra* Part I.A.2.i.
255. *See supra* Part I.A.3.

amendment. To prevail, the plaintiff would need to prove that the claim for the medical device resulted from the AKS violation by the physician and medical device company, even though the hospital submitted the claim.[256]

B. "But-For" Is the Proper Causal Standard for the 2010 AKS Amendment

Reading a but-for causation standard into the 2010 AKS amendment comports with the statute's plain meaning, congressional intent, and Supreme Court precedent.

1. The Eighth and Sixth Circuits Correctly Interpreted the Plain Meaning of the Amendment's Language

The 2010 AKS amendment contains a but-for causation requirement because the plain meaning of "resulting from" is clear and so requires it. As noted in Part I.B.1, it is a well-established legal principle that courts should interpret unambiguous statutory text according to its plain meaning.[257] When a "careful examination of the ordinary meaning" of the law "yields a clear answer, judges must stop."[258] The Supreme Court has confirmed its commitment to the plain meaning canon of statutory interpretation time and time again.[259]

Causal language is not exempt from the Supreme Court's plain meaning approach.[260] In *Burrage*, the Court held that the plain meaning of "results from" imposes an actual causation requirement, which the Court interpreted as imposing but-for causation.[261] As the Eighth Circuit pointed out in *Cairns*, the variation in tense between the language in *Burrage* and the language in the 2010 AKS amendment ("results from" versus "resulting from") does not affect the shared, unambiguous plain meaning of the phrases, which in both cases is but-for causation.[262]

Since the AKS does not define "resulting from," the Eighth and Sixth Circuits each conducted a plain meaning analysis of the phrase.[263] As is customary in a plain meaning analysis, the circuit courts looked to dictionary definitions of the phrase, confirming their findings with Supreme Court precedent interpreting similar causal language, to properly hold that the plain

256. *See supra* Part I.A.3.
257. *See supra* Part I.B.1.
258. Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2364 (2019); *see also supra* Part I.B.3.
259. *See supra* Part I.B.3; *see also Food Mktg. Inst.*, 139 S. Ct. at 2364 ("Even those of us who sometimes consult legislative history will never allow it to be used to 'muddy' the meaning of 'clear statutory language.'" (quoting Milner v. Dep't of the Navy, 562 U.S. 562, 572 (2011))).
260. *See supra* Part I.B.3.
261. *See supra* Part I.B.3.
262. *Supra* Part II.B.1; *see* United States *ex rel.* Cairns v. D.S. Med. LLC, 42 F.4th 828, 834 (8th Cir. 2022).
263. *See supra* Parts II.B.1–2.

meaning of "resulting from" is but-for causation.[264] Even the Third Circuit seemed to concede that the plain meaning of "resulting from" is understood as but-for causation.[265]

The Eighth and Sixth Circuits correctly dismissed the government and relators' arguments, which emphasized congressional intent, alternative causal theories, and interpretations of legislative history over the statute's plain meaning, and correctly held that the 2010 AKS amendment has a but-for causation requirement.[266]

2. A But-For Standard Does Not Contravene Congressional Intent or the Amendment's Legislative History

Unlike the Eighth and Sixth Circuits, the Third Circuit decided to forego the 2010 AKS amendment's plain meaning because it misunderstood the congressional intent behind the amendment.[267]

The undisputed purpose of the FCA is to catch and punish fraud.[268] The 2010 AKS amendment's drafters intended for the amendment to close a loophole that they had identified in the existing false certification theory of FCA liability.[269] It is clear from the congressional record that the purpose of the amendment was to create a mechanism for attaching FCA liability to defendants who violate the AKS but who are not the actual submitters (and therefore not the certifiers) of reimbursement claims to the government for items or services that are the result of their kickback schemes.[270] The application of a but-for standard is not inconsistent with this purpose.

Although but-for causation may be more challenging to prove than the tenuous "link" the Third Circuit imposed, it does not undermine the amendment's purpose of permitting FCA relief against parties that did not themselves submit the false claims at issue. Requiring but-for causation to establish a claim's falsity under the 2010 AKS amendment requires the plaintiff to provide, by a preponderance of the evidence,[271] that there exists a causal chain between the defendant's kickback scheme and the claims submitted by a third party to the government.

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264. *See supra* Parts II.B.1–2, I.B.3.
265. *See supra* Part II.A.1.
266. *See supra* Parts II.B.1–2.
267. *See supra* Part II.A.1.
268. *See supra* Parts I.A.2–3; *see also* 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman) ("By making all payments that stem from an illegal kickback subject to the [FCA], this bill leverages the private sector to help detect and recover money paid pursuant to these illegal practices.").
269. *See supra* Part I.A.3.
270. *See* 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman) ("This bill remedies the problem by amending the [AKS] to ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves.").
271. *See supra* Part II.B.1.

3. The But-For Standard Aligns with Modern Supreme Court Precedent

Based on recent decisions, the Supreme Court, if presented with the question of what causation standard "resulting from" the 2010 AKS amendment requires, is likely to align with the Sixth and Eighth Circuits' perspective that the statutes' text imparts a but-for causation standard. The Supreme Court has interpreted similar statutory language as requiring but-for causation in other laws that address wrongdoing.[272] In *Burrage*, the Court interpreted "results from" to impose a but-for causation standard in the context of the Controlled Substances Act,[273] in which the evidentiary standard is beyond a reasonable doubt, a significantly higher standard than the preponderance of evidence standard needed to prevail on a civil FCA claim.[274]

Additionally, particularly as of late, the Court has been unmoved by congressional intent or public policy arguments.[275] At least on the surface, the Court maintains a textualist approach to statutory interpretation whenever possible.[276] It has reiterated its position that the judiciary's role is to interpret statutory text according to its plain meaning, as Congress passed it and the President signed it into law.[277] By interpreting statutes according to their plain meaning, the Court leaves Congress with the option to amend the statutory text to better reflect congressional intent.[278]

The Court's propensity for leaving Congress with the task of clarifying statutory language can, and has, proven to be a successful motivator for Congress, even in the AKS and FCA context.[279] Court holdings in AKS and FCA cases that conflict with congressional intent have spurred Congress to revisit and clarify the statutory language.[280] When Congress took note of the courts' refusals to attach FCA liability under the false certification theory to defendants who did not submit the claims themselves, it amended the AKS to attach FCA liability to those defendants.[281] Also, as part of another 2010 amendment to the AKS, Congress, in reaction to a series of holdings that had created a specific intent requirement for AKS violations, added a provision expressly stating that specific intent was not required to violate the statute.[282]

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272. *See supra* Part I.B.3.
273. *See supra* Part I.B.3.
274. *See supra* Part II.B.1.
275. *See supra* Part I.B.3.
276. *See supra* Part I.B.3.
277. *See supra* Part I.B.3.
278. *See supra* Part I.B.3.
279. *See* Neal Devins, *Congressional Responses to Judicial Decisions*, *in* 5 ENCYCLOPEDIA OF THE SUPREME COURT OF THE UNITED STATES 400, 402 (David S. Tanenhaus ed., 2008).
280. *See supra* note 38 and accompanying text; *supra* Part I.A.3.
281. *See supra* Part I.A.3.
282. *See* 155 CONG. REC. S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Edward Kaufman) ("The bill . . . addresses confusion in the case law over the appropriate meaning of 'willful' conduct in health care fraud."); Benjamin C. Joseph, *Defining 'Referral' in the Anti-Kickback Statute*, AM. BAR ASS'N (Apr. 22, 2022), https://www.americanbar.org/groups

So, in the event that the but-for standard contravenes congressional intent, it is within Congress's power to effect its preferred causal standard by amending the statute's language.

C. The But-For Inquiry Must Be Highly Particularized

The but-for inquiry in FCA claims brought under the 2010 AKS amendment should be fact-intensive and particularized. Fact finders must determine not simply whether some service or prescription similar to the one submitted would have been submitted but-for the AKS violation but, more specifically, whether a reimbursement claim for this *particular* device, medication, service, and or referral would have been made absent the AKS violation.

To answer such a question, the government or relator would conduct a fact heavy and situationally specific inquiry into factors like rates and patterns of prescription, use, or referrals. The government and relators could also call expert witnesses to testify to the standard of care relevant to the allegedly false claims.

If the 2010 AKS amendment hypothetical described in Part III.A.2[283] was subjected to a but-for analysis to establish the falsity element of the claim, the relator would have to prove that if the kickback scheme between the physician and medical device company had not existed, then the claim for the medical device company's product used in that physician's surgery would not have been submitted.

In this situation, to prove but-for causation, the relator may be able to use statistical evidence and expert testimony to demonstrate that the medical device company's product was outside the standard of care or that the price paid by the physician to the company was unreasonable. It could look at cost differences between that device and others, the efficacy of other devices, and the frequency of that device's use at that hospital by other providers versus the implicated physician. Once the relator has put forth evidence that the claim resulted from the kickback scheme, the burden of production shifts to the defendants to provide evidence of a legitimate reason why they used that device, prescribed those drugs, or performed those services. Once the parties fully argue their positions, the fact finder must weigh the evidence to determine whether the reimbursement claims resulted from the defendant's AKS violation under the but-for standard.

CONCLUSION

A highly specific but-for causation requirement is the best resolution to the circuit split over the causation standard imparted by the words "resulting from" in the 2010 AKS amendment. The Third Circuit's attenuated "link" is

/health_law/publications/aba_hhealt_esource/2021-2022/april-2022/def-ref/ [https://perma.cc/PY5T-TBWN].

283. *See supra* Part III.A.2.

based on a misunderstanding of the amendment's purpose and legislative history. The amendment's enaction allows FCA liability to attach to defendants who have participated in kickback schemes but who have not submitted claims for reimbursement to the government. Rather than undermining this purpose, requiring but-for causation ensures that the FCA can reach defendants who actually cause false claims to be submitted to the government and protects parties who do not. And, if Congress deems the but-for standard to be too high a burden for the government or relators to prove, then the courts' adoption of the standard could catalyze Congress to rephrase the amendment to fit its original intent more accurately.