"Resulting from" Unclear Language: Why Congress Must Amend the Anti-Kickback Statute to Clarify Its Intent to Hold Violators Accountable and Recover Fraud-Based Payments

Lauren Rutkowski*

I. INTRODUCTION

When patients trust a health care professional ("HCP") to provide medical care, they trust that the HCP will use their best medical judgment in determining a course of treatment that best serves the patient. This trust between HCPs and patients is greatly undermined by bribery within the health care industry. Bribery as such often exploits the United States’ federal health care programs, such as Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP): fraudsters request reimbursement from the federal government for services that were ultimately provided due to illegal bribes. In order to hold those engaged in bribery schemes accountable, the federal Anti-Kickback Statute (AKS) imposes criminal penalties upon those who initiate or accept remuneration in return for items or services that are payable in whole or in part by a federal health care program.1 The False Claims Act (FCA) also imposes civil penalties upon those who exploit the federal health care programs, and further seeks to recover government money and hold wrongdoers accountable.2

As Justice Holmes stated, “[c]itizens] must turn square corners when they deal with the [g]overnment.”3 The FCA imposes civil liability upon any person who knowingly presents a false or fraudulent

---

* J.D. Candidate, 2024, Seton Hall University School of Law; B.A., 2021, The Pennsylvania State University. I wish to extend many thanks to Professor Jacob Elberg for sharing his guidance and expertise throughout the writing process, and to my parents, James and Victoria Rutkowski, for their unwavering support in all of my endeavors.

1 See 42 U.S.C. § 1320a-7b(b)(1)–(2).


claim for payment or approval by the government,\(^4\) and allows the federal government “to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers,” by requiring those who bill the Treasury to be truthful.\(^5\) In the health care context, when HCPs treat patients who are insured by a federal program, the HCP bills the federal government for reimbursement for the provided treatment. The FCA can be implicated in this context when claims for over-reimbursement—or for reimbursement that results from wrongful conduct such as AKS or Physician Self-Referral (Stark) Law violations—are submitted to the government.\(^6\)

Enacted as a method of “strengthen[ing] the capability of the [g]overnment to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs,\(^7\) the AKS prevents bribery from influencing HCPs’ medical judgment when federal health care programs are involved, as these programs require providers to only seek reimbursement for items or services that are needed—and reasonable—to diagnose or treat injuries and illnesses.\(^8\) Those who violate the AKS could be fined, imprisoned, or excluded from participation in the federal health care programs by the Office of the Inspector General (OIG) of the US Department of Health and Human Services (HHS).\(^9\) The possibility of exclusion from federal health care programs is of particular concern, as “[t]he effect of an OIG exclusion is that no [f]ederal health care program payment may be made for any items or services furnished (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person”—this could be fatal to a provider’s career, because the prohibition broadly applies to all methods of payment from federal health care programs and would prevent the HCP from being paid for

---

\(^4\) § 3729(a)(1)(A).
\(^5\) United States v. Rogan, 517 F.3d 449, 452 (7th Cir. 2008).
\(^9\) See A ROADMAP FOR NEW PHYSICIANS, supra note 6, at 4.
treatment any patient who receives Medicare or Medicaid benefits in any form.\textsuperscript{10}

Because FCA violations commonly comprise overbilling to the federal health care programs, AKS enforcement is inherently connected to the FCA. The Patient Protection and Affordable Care Act (ACA) of 2010\textsuperscript{11} amended the AKS by adding a provision—42 U.S.C. § 1320a-7b(g)—to address situations as described above, where an AKS violation serves as the basis of claims submitted for reimbursement to a federal health care program.\textsuperscript{12} This provision formally codified what was already recognized by many courts: an AKS violation satisfies the “falsity” element of the FCA, which requires the claim for reimbursement to be false or fraudulent in order to impose FCA liability.\textsuperscript{13} Specifically, in order to satisfy the falsity prong of the FCA, the language of the 2010 AKS amendment (“2010 amendment”) requires that the false or fraudulent claim include items or services “resulting from” a violation of the AKS.\textsuperscript{14} Despite the fact that the 2010 amendment is directed at addressing the falsity element of the FCA, courts and litigants have struggled to determine what exactly “resulting from” means in terms of a causation standard since the provision’s enactment. Specifically, defendants argue for a stricter causal connection between an alleged kickback scheme and a subsequent claim for federal reimbursement, such as but-for causation, while plaintiffs argue that the connection can be more attenuated in order to establish an FCA violation.\textsuperscript{15} As the goal of the FCA is to preserve


\textsuperscript{12} See United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018); 42 U.S.C. § 1320a-7b(g).

\textsuperscript{13} See Greenfield, 880 F.3d at 95 (quoting Westmoreland, 812 F. Supp. 2d at 52); 31 U.S.C. § 3729(a)(1)(A). In Westmoreland, the District Court for the District of Massachusetts cited over fourteen opinions from various federal courts dating prior to the enactment of § 1320a-7b(g), which all agreed that compliance with the AKS is a precondition of receiving reimbursement from Medicare. 812 F. Supp. 2d at 54. At the time of the ACA’s enactment, however, some courts called into question the reach of the AKS. See infra note 73 and accompanying text.

\textsuperscript{14} See § 1320a-7b(g).

the public fisc, this goal would be undermined if providers who engaged in conduct that could warrant *exclusion* from participation in the federal health care programs\(^{16}\)—such as participating in kickback schemes—could still demand reimbursement for their services, due to the difficulty of proving but-for causation under the 2010 amendment.\(^{17}\)

In 2018, the Third Circuit established in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, a “middle of the road” definition of the words “resulting from” in the 2010 amendment,\(^{18}\) which the First Circuit follows,\(^{19}\) and district courts in the Second, Fourth, Fifth, Ninth, and Eleventh Circuits have also approved of.\(^{20}\) The Third Circuit’s *Greenfield* standard holds that in order to use an AKS violation as the basis of imposing FCA liability, the connection

\(^{16}\) See supra notes 9–10 and accompanying text.

\(^{17}\) Westmoreland, 812 F. Supp. 2d at 50.


\(^{19}\) See Guiffoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019) (declining to directly assess the impact of § 1320a-7b(g) but upholding the “sufficient causal connection” standard of *Greenfield* as the correct causation standard of the 2010 amendment). In late 2023, two diverging opinions within the District Court for the District of Massachusetts were certified for interlocutory appeal to the First Circuit so that the court of appeals may determine whether *Guiffoile* should be upheld in regards to what the causation standard of § 1320a-7b(g) is. Sheehan & Castañeda, supra note 15. In *United States v. Teva Pharmaceuticals USA, Inc.*, the district judge held that the *Greenfield* approach should apply and ruled in favor of the government. No. 20-11548, 2023 WL 4565105, at *4 (D. Mass. July 14, 2023). Conversely in *United States v. Regeneron Pharmaceuticals, Inc.*, the district judge ruled in favor of the defendant pharmaceutical manufacturer and applied a but-for causation standard. No. 20-11217, 2023 WL 6296393, at *11 (D. Mass. Sept. 27, 2023).

required between the alleged kickback scheme and subsequent claim for reimbursement is a “link.”^{21} Under this interpretation, the kickback does not have to be the actual cause of the later submitted false claim, yet cannot be a “merely attenuated” speculation that a false claim was submitted.^{22} In order to hold a defendant liable under the AKS and simultaneously establish the falsity element of the FCA under the Greenfield standard, the government is required to prove that the defendant submitted \textit{at least one} claim to a federal health care program that sought reimbursement for services or products provided in violation of the AKS.^{23}

In 2022, however, the Eighth Circuit held in \textit{United States ex rel. Cairns v. D.S. Medical, LLC}, that but-for causation is required in order to premise an FCA claim on an underlying AKS violation—meaning that the plaintiff must prove that false claims would have never been submitted \textit{but-for} the involvement of an illegal kickback scheme.^{24} The Sixth Circuit and the District Court for the District of Massachusetts reached the same conclusion in 2023.^{25} To satisfy this causal standard, plaintiffs will have the difficult task of demonstrating that the illegal kickback itself was the actual, direct cause of an item or service being reimbursed through billing to Medicare or Medicaid, in order to constitute a false claim.^{26}

This Comment explores why imposing a but-for causation standard leads to an incongruous result: a defendant could be criminally convicted for an AKS violation—and potentially excluded from participation in the federal health care programs—but escape civil FCA liability for the same conduct, if the plaintiff cannot prove but-for causation. In order to honor the intentions of all legislation involved, Congress must amend § 1320a-7b(g) to codify the “middle of the road” approach supported by the Third Circuit in Greenfield and remove the ambiguous “resulting from” language altogether, to read as follows:

^{21} \textit{See, e.g., United States ex rel. Greenfield v. Medco Health Sols., Inc.,} \textit{880 F.3d 89, 98 (3d Cir. 2018).}

^{22} \textit{See id.}

^{23} \textit{See id.}

^{24} \textit{See United States ex rel. Cairns v. D.S. Med., LLC,} \textit{42 F.4th 828, 836 (8th Cir. 2022).}


^{26} \textit{See Greenfield,} \textit{880 F.3d at 97–98.}
(g) Liability under subchapter III of chapter 37 of Title 31.

(1) In addition to the penalties provided for in this section, a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31, United States Code will be established if there exists at least one claim submitted seeking reimbursement for items or services that were distributed in violation of this section.

(2) Paragraph (1) does not require a relationship of actual causation between illegal remuneration and a subsequent reimbursement claim. Therefore, in the absence of a violation of this section, if a customer or patient would have purchased, or a health care provider would have sold or prescribed the items or services, the defendant is still subject to liability under subchapter III of chapter 37 of Title 31, United States Code.²⁷

Part II provides a general overview of the AKS and the FCA and describes how the AKS is commonly enforced through the FCA. Part III details the 2010 amendment to the AKS, 42 U.S.C. § 1320a-7b(g). Part IV analyzes the circuit split that has recently emerged regarding the proper causation standard of § 1320a-7b(g). Part V explores the policy implications of requiring but-for causation in order to establish an FCA action under § 1320a-7b(g). Finally, Part VI concludes by arguing that, because of the policy implications outlined, Congress should amend § 1320a-7b(g) in order to solve the “resulting from” mystery once and for all.

II. THE FEDERAL ANTI-KICKBACK STATUTE AND ITS ENFORCEMENT THROUGH THE FALSE CLAIMS ACT

The FCA contains a unique feature in that it allows for private individuals to initiate lawsuits on behalf of the United States as qui tam, or whistleblower, actions.²⁸ AKS enforcement occurs through qui tam actions under the FCA in many instances, because the AKS itself does not contain a private right of action but prohibits fraudulent conduct involving payment from the federal health care programs—payments which, under the FCA, require requestors to be truthful in the amounts that they seek reimbursement for. This Part details the AKS and how the FCA is commonly used to enforce it.

²⁷ See id. at 98; see also United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-cv-10601, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) ("It is sufficient to show that [the] [d]efendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.").
A. *The Federal Anti-Kickback Statute: Preventing the Corruption of Medical Decision-Making*

The AKS prohibits the knowing and willful solicitation, receipt, offer, or payment of remuneration in exchange for the purchase, prescription, or recommendation of items or services that are payable by federal health care programs, such as Medicare, Medicaid, or TRICARE.29 “Remuneration” can be anything of value, with common schemes including excessively expensive meals, free space rental, or sham speaker programs.30 The AKS imposes such criminal liability upon health care professionals for receiving or providing illegal remuneration because—despite being permissible in other professions—allowing transactions to be affected by bribes in the health care industry could lead to the corruption of medical decision-making, overutilization, and increased costs related to federal health care programs that are funded by taxpayers.31

AKS violations are classified as criminal felonies, and like all criminal charges, must be proven beyond a reasonable doubt.32 Violations could result in up to ten years imprisonment or up to $100,000 in criminal fines,33 Civil Monetary Penalties (“CMPs”),34 or mandatory or permissive exclusion from participation in federal health care programs.

---

29 See 42 U.S.C. § 1320a-7b(b)(1)–(2).
30 See Fraud and Abuse Laws, U.S. Dep’t of Health & Human Servs.: Off. of Inspector Gen., https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws (last visited Nov. 27, 2023). Drug and device manufacturers often sponsor speaker programs that are meant to educate health care professionals about the benefits, risks, and appropriate uses of their products. PHARM. R&H. MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS 11 (2022), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code—Final.pdf. Manufacturers often choose HCPs to speak at these events, and the presenting HCPs are typically paid an honorarium. Off. of Inspector Gen., U.S. Dep’t of Health & Human Servs., Special Fraud Alert: Speaker Programs 1 (2020), https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf. “Sham” speaker programs found to be in violation of the AKS may include instances where the drug or device company selected high-prescribing HCPs as presenters and rewarded them with excessive compensation (i.e., hundreds of thousands of dollars), held the program at a lavish restaurant or entertainment venue that was not conducive to informational presentations, or invited attendees who previously attended the same program. See id. at 1–2.
31 See A ROADMAP FOR NEW PHYSICIANS, supra note 6, at 4–5.
33 See § 1320a-7b(b)(1)–(2).
34 See § 1320a-7a(a)(7).
health care programs by the OIG. To convict a defendant under the AKS, the government must prove the following elements: "the defendant[] (1) knowingly and willfully[,] (2) solicited, received, paid, or offered to pay remuneration[,] (3) in return for, or to induce, referral or generation of [business that is payable in whole or in part by a federal health care program]." Notably missing is a causation requirement—the government need not prove that the remuneration resulted in the actual submission of claims to federal health care programs for a defendant to be criminally liable under the AKS on its own.

The “knowingly and willfully” element of the AKS requires the government to show that the defendant knew that their conduct was unlawful and that the defendant acted voluntarily. The defendant’s intent is a key aspect of determining AKS liability, as the government must prove that the defendant intended to engage in conduct that they knew was unlawful—the ACA, however, added a provision to the AKS in 2010, which clarified that specific intent to violate the AKS statute itself is not required for liability. The second element emphasizes how both the “briber,” who offers a bribe, and the “bribee,” who accepts it, are subject to liability under the AKS. “To induce,” as stated in the third element, is defined as acting “with the ‘intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.’” The “one purpose” standard, which is widely utilized by federal courts and endorsed by the OIG, holds that the AKS is violated as long as one purpose of an offer or payment was to induce referrals—even if this

35 See § 1320a-7(a)–(b); see also supra notes 9–10 and accompanying text.
36 Abby Rickeman et al., Health Care Fraud, 59 AM. CRIM. L. REV. 975, 985 (2022) (alteration in original) (citing § 1320a-7b(b)).
37 See infra note 77 and accompanying text.
38 See Rickeman et al., supra note 36, at 985 (citing § 1320a-7b(h)).
39 See id. at 985–86 (citing § 1320a-7b(b), (h)); see also Ropes & Gray, The Consequences of Obamacare for Healthcare Fraud Enforcement 4 (2014) (“In other words, pre-[ACA], the Ninth Circuit required the government to show that the defendant knew about the AKS’s requirements and had specific intent to violate those requirements, while other circuits did not require proof of the defendant’s actual knowledge of the AKS. Through [the ACA], Congress modified the AKS to explicitly state that a defendant does not need a specific intent to violate a particular provision of the AKS.” (emphasis omitted)).
40 See United States v. Vernon, 723 F.3d 1234, 1251–52 (11th Cir. 2013).
41 Rickeman et al., supra note 36, at 987 (quoting Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995)).
was not the primary motivation for the offer or payment.\textsuperscript{42} Importantly, the AKS does not serve to inquire into the subjective medical decisions of doctors or patients in imposing liability.\textsuperscript{43} It is irrelevant, for example, whether or not a physician who was paid a kickback to prescribe a drug would have prescribed the drug even in the absence of the kickback, because AKS liability can be imposed when services provided are genuinely of medical necessity and without a showing of causation—as long as the intent behind the remuneration was to induce the prescribing, the statute has been violated.\textsuperscript{44}

There are currently over twenty “safe harbors” that serve as exceptions to AKS liability.\textsuperscript{45} The implementation of safe harbors strives to achieve a balance between increasing access to quality care and holding those who engage in health care fraud accountable.\textsuperscript{46} Arrangements and actions that are covered by AKS safe harbors include practitioner recruitment to aid medically underserved areas, the transfer of medical supplies to an ambulance provider, and offering free or discounted local transportation to patients.\textsuperscript{47}

\textsuperscript{42} See Rickeman et al., \textit{supra} note 36, at 987–88 (citing United States v. Borrasi, 639 F.3d 774, 782 (7th Cir. 2011)); \textit{see also} United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985). Although the “one-purpose test” is currently the majority rule, some courts utilize a “primary purpose test,” which only imposes AKS liability if the primary purpose of an offer or payment is to induce referrals. \textit{See United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.}, 874 F.2d 20, 30 (1st Cir. 1989) (“[T]he issue of the sole versus primary reason for payments is irrelevant since any amount of inducement is illegal. . . . [T]he district court instructed that the defendants could only be found guilty if the payments were made primarily as inducements. At a minimum this comports with congressional intent.”).

\textsuperscript{43} See \textit{A ROADMAP FOR NEW PHYSICIANS, supra} note 6, at 5; \textit{see also} United States \textit{ex rel.} Greenfield v. Medco Health Sols., 880 F.3d 89, 97 (3d Cir. 2018) (“[T]he broad statutory context of the [FCA] and [AKS] supports the government’s reading, as neither requires a plaintiff to show that a kickback directly influenced a patient’s decision to use a particular medical provider.”).

\textsuperscript{44} See \textit{A ROADMAP FOR NEW PHYSICIANS, supra} note 6, at 5.

\textsuperscript{45} \textit{See} 42 C.F.R. § 1001.952(a)-(kk) (2022).


\textsuperscript{47} \textit{See} § 1001.952(n), (v), (bb).
B. Enforcement of the AKS Through the False Claims Act

Another tool used to fight fraud within federal health care programs is the FCA, which imposes civil liability upon any person who knowingly presents a false or fraudulent claim for payment or approval by the government. Because it is a civil statute, the elements of the FCA must be proven by a preponderance of the evidence to hold a defendant liable. The government must prove that (1) the claim was false or fraudulent; (2) the defendant presented, or caused to be presented, the false or fraudulent claim to a governmental department or agency; (3) the defendant possessed proper knowledge of the claim’s falsity; and (4) the falsity of the claim was material to the government’s payment decision. A “claim” includes reimbursement requests made by recipients of federal benefits. A false or fraudulent claim is “knowingly” presented or caused to be presented if the claimant “has actual knowledge of the information,” “acts in deliberate ignorance of the truth or falsity of the information,” or “acts in reckless disregard of the truth or falsity of the information”—but “no proof of specific intent to defraud” is required.

AKS enforcement occurs through FCA actions in many instances, because the AKS itself does not contain a private right of action, and a claim for reimbursement from a federal health care program that is based upon a violation of the AKS is likely to be “false.” A claim may be either factually or legally false to be actionable under the FCA. A factually false claim is made “when the claimant misrepresents what goods or services” were provided to the government. A legally false

49 See § 3729(a)(1)(A).
51 See Rickeman et al., supra note 36, at 1031 (citing § 3729(a)).
52 See § 3729(b)(2)(A); see also Universal Health Servs. v. United States ex rel. Escobar, 579 U.S. 176, 182 (2016).
53 § 3729(b)(1)(A)–(B); Escobar, 579 U.S. at 182. The Supreme Court’s recent opinion in United States ex rel. Schutte v. SuperValu Inc. clarified that the scienter element of the FCA refers to a defendant’s knowledge and subjective beliefs, as opposed to “what an objectively reasonable person may have known or believed.” 143 S. Ct. 1391, 1399 (2023).
54 See infra note 175 and accompanying text.
56 See id. at 94.
57 Id.
claim is made when the claimant knowingly misrepresents compliance with a regulation or statute, if compliance with the regulation or statute is a condition to receive reimbursement from the government. An example of this occurs when billing Medicare for reimbursement, as provider enrollment forms from Centers for Medicare and Medicaid Services (CMS) require certification that the underlying transaction complies with the AKS—therefore, any claim submitted to Medicare that is premised upon an AKS violation would satisfy the falsity element of the FCA. If a plaintiff alleges that a defendant has made a legally false claim, the plaintiff must prove that the defendant’s false representation of compliance with a statute or regulation was “material to the [g]overnment’s payment decision in order to be actionable under the FCA.” It has been a long standing view amongst courts that compliance with the AKS is absolutely material to the government’s decision to reimburse a claim.

The FCA contains a unique feature in that it provides private citizens with the right to bring an action against a defendant in the name of the US government. These actions are referred to as qui tam actions, in which the private citizen is referred to as a relator, or whistleblower. The US government may choose to intervene in the action, in which case the US government would undertake the primary

58 Id.
61 See Guilfoile v. Shields, 913 F.3d 178, 191 n.12 (1st Cir. 2019). The First Circuit stated the addition of 42 U.S.C. § 1320a-7b(g) to the AKS in 2010 obviated the requirement to plead the materiality element in AKS-based FCA actions because the 2010 amendment states that a claim submitted to a federal health care program resulting from an AKS violation constitutes a false or fraudulent claim—removing the need to engage in a materiality analysis of whether the claimant certified their compliance with the AKS upon submission. See Guilfoile, 913 F.3d at 190. By contrast, the Third Circuit stated in Greenfield that relators proving the falsity element of the FCA through an AKS violation “must also satisfy the [FCA]’s materiality requirement, as falsity and materiality are distinct requirements in this context.” 880 F.3d at 98 n.8.
63 See United States ex rel. Polansky v. Exec. Health Res., Inc., 143 S. Ct. 1720, 1726 (2023). Historically, some judges and scholars have called into question the constitutionality of qui tam lawsuits, as evidenced by Justice Thomas’s dissent in Polansky, but it remains to be determined whether these arguments will influence the majority of the Court. See id. at 1741–42 (Thomas, J., dissenting).
prosecution responsibilities, but the relator would continue as a party to the action. 64 If the US government declines to intervene, the relator retains the right to conduct the action, but the court may permit intervention at a later time. 65 Hundreds of millions of dollars could be at stake in individual FCA whistleblower actions that are based upon underlying AKS violations. In September 2022, biotechnology company Biogen Inc. finalized a $900 million settlement to resolve a qui tam action brought by a former employee, who himself received approximately 30 percent of the federal proceeds—the largest recovery to be secured by a whistleblower without government intervention in the history of the FCA. 66 In fiscal year 2022, the DOJ reported over $1.9 billion in settlements and judgments arising from qui tam actions initiated by private citizens under the FCA. 67 Health care fraud is the leading source of the DOJ’s FCA settlements; over $1.7 billion of the more than $2.2 billion total FCA settlements and judgments in 2022 arose from actions against perpetrators of health care fraud. 68

III. THE 2010 AMENDMENT TO THE AKS

Enacted in March 2010, the ACA aimed to reform health care in the United States with three primary goals: to increase the availability of affordable health insurance, to expand Medicaid, and to lower the costs of health care through innovative methods of care delivery. 69 The ACA also strengthened health care fraud enforcement by amending

---

64 See § 3730(c)(1).
65 See § 3730(c)(3).
68 See id.
both the FCA and AKS.70 As noted above, one way in which Congress amended the AKS was by removing the requirement of actual knowledge of 42 U.S.C. § 1320a-7b(b) itself, or specific intent to violate it, in order to constitute “willful conduct.”71

The ACA also added a new provision to the AKS that formally codified the longstanding practice of allowing AKS violations to qualify as “false or fraudulent” claims under the FCA.72 Around the time of the ACA’s enactment, however, the reach of the AKS was “called into question by recent litigation,” as when introducing the Health Care Fraud Enforcement Act of 2009 to the Senate, Senator Kaufman mentioned a recent district court decision that “defeat[ed] legitimate [FCA] enforcement efforts” as a reason behind amending the AKS to include § 1320a-7b(g).73 In the case mentioned, the court held that, despite a medical device company paying a kickback to a doctor for using a particular device, the bill to the government for the procedure to implant said device was not “false” in terms of FCA liability because the bill was ultimately submitted by the hospital where the patient obtained the procedure—with no involvement of the doctor in the submission of the claim.74 By enacting 42 U.S.C. § 1320a-7b(g), Congress sought to prevent this type of situation, where the root of a fraudulent claim for reimbursement is an illegal kickback, but the

70 See Joan H. Krause, Following the Money in Health Care Fraud: Reflections on a Modern-Day Yellow Brick Road, 36 Am. J.L. & Med. 343, 366 (2010).
72 See United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018) (quoting 42 U.S.C. § 1320a-7b(g)); see, e.g., McNutt ex rel. United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1260 (11th Cir. 2005) (holding that the government’s FCA claim was valid due to the defendants’ alleged violation of the AKS because compliance with the AKS is “necessary for reimbursement under the Medicare program; and the [defendants] submitted claims for reimbursement knowing that they were ineligible for the payments demanded in those claims”); United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009) (“Falsely certifying compliance with the . . . [AKS] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.”); United States ex rel. Madany v. Petre, No. 09-cv-13693, 2021 WL 1600041, at *4 (E.D. Mich. Apr. 23, 2021) (explaining that although the alleged kickbacks at issue occurred prior to the 2010 amendment, courts commonly permitted AKS violations to proceed under the FCA before 2010).
claim is later *cleansed* by an innocent third party actually submitting the claim to the government.\(^75\)

IV. **“RESULTING FROM” CREATES A CIRCUIT SPLIT OVER THE CAUSATION STANDARD OF § 1320A-7B(G)**

As § 1320a-7b(g) states, a claim including “items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]” requires a causal connection to exist between an AKS violation and a later reimbursement claim—which the written statute describes as “resulting from.”\(^76\) Nevertheless, the primary purpose of the amendment was to address the falsity element of the FCA, not the causation element. The 2010 amendment provides no further guidance as to what “resulting from” means in practice, leaving it to be deciphered by courts and parties to litigation. Section A describes how the respective elements of the AKS and FCA differ, given that they seek to accomplish different objectives: the AKS is punitive, while the FCA focuses on recouping wrongfully disbursed government funds. These objectives, however, are still interrelated as to how they punish those who exploit the federal health care programs. Section B describes how imposing a but-for causation requirement would impede upon the FCA’s specific focus of recouping losses. Section C summarizes how the Third Circuit in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.* reached its “middle ground” approach to causation in cases brought under the 2010 AKS amendment. Finally, Section D details recent decisions from the Eighth and Sixth Circuits, which rejected the *Greenfield* standard and held in favor of a but-for causation requirement, against a backdrop of many other courts expressly rejecting this stringent standard of causation under the 2010 amendment.

\(^{75}\) *Id.*

\(^{76}\) 42 U.S.C. § 1320a-7b(g).
A. Under Cairns and Martin, But-For Causation Would Become a Requirement for FCA Liability in Cases Brought Under § 1320a-7b(g), but Not AKS Liability

When analyzed separately as a criminal statute, the AKS notably lacks any actual or proximate causation requirement. Actual causation is often referred to as but-for causation, meaning that without the defendant’s conduct, the event would not have occurred. Proximate cause, or legal cause, is defined as “[a] cause that is legally sufficient to result in liability; an act or omission that is considered in law to result in a consequence, so that liability can be imposed on the actor.” On standard jury instructions, proximate cause is described as a cause that would have produced the injury or damage in a “natural and continuous sequence, unbroken by any new or independent cause.” Signifying its punitive nature, the text of the AKS contains no such causation requirement, as any remuneration offered or given with the intent of inducing action violates the criminal statute—regardless of whether the action would have occurred without the remuneration or even whether it ultimately occurred at all.

The FCA, however, includes a causation requirement. Civil claims in general, such as those brought under the FCA, are brought with the goal of making the injured party “whole”; the defendant is required to pay restitution to those faced with monetary loss caused by the defendant’s actions. Therefore, in order to properly repay the government for reimbursements it was fraudulently caused to make in

---

77 See § 1320a-7b(b).
78 See But-For Cause, BLACK’S LAW DICTIONARY (11th ed. 2019).
79 Proximate Cause, BLACK’S LAW DICTIONARY (11th ed. 2019).
81 § 1320a-7b(b); United States ex rel. Greenfield v. Medco Health Sols., 880 F.3d 89, 97 n.6 (3d Cir. 2018) (“[A]n offer alone may amount to a violation of the [AKS].”).
82 See, e.g., United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc., 34 F.4th 507, 518 (6th Cir. 2022) (“The FCA requires a relator to show ‘that the defendant submitted [the false statement] to the US government causing it to pay the claim.’” (alteration in original) (emphasis added)); Greenfield, 880 F.3d at 97 n.6 (explaining how the elements of the FCA and AKS differ).
FCA cases, the amount of improper claims must be measured. In 2023, the FCA imposes upon violators both (1) penalties of up to $13,508 per offense (up to a maximum total amount of $405,270), and (2) three times the amount of damages which the government sustains because of the act of that person.

At its core, the FCA is a civil fraud statute designed to protect taxpayer dollars by preventing the government from having to pay unnecessary amounts. The fact that the AKS on its own imposes liability upon pure offers or solicitations to participate in illegal kickback schemes—which may never actually result in items or services being obtained by patients or claims submitted to insurance programs—demonstrates why a causation requirement is unnecessary in that context, in contrast to the FCA.

When the AKS and FCA are simultaneously implicated, however, under the 2010 amendment—which intended to simplify FCA cases by clarifying that claims tainted by kickbacks are necessarily “false”—it may be impossible to demonstrate that a kickback was the actual cause of a claim being submitted for reimbursement, even if it is clear that the kickback had a causal effect on the provision of products or services that ultimately resulted in claims being submitted to federal health care programs. The specific language used in the 2010 amendment provides the unintended consequence of allowing defendants to argue just this—that but-for causation is required in the AKS-based FCA context even where it would not be in a criminal AKS action on its own. The Eighth and Sixth Circuits now accept this argument, establishing a substantial hurdle for plaintiffs initiating AKS-based FCA

83 See, e.g., United States ex rel. Marcus v. Hess, 317 U.S. 537, 551 (1943) (“The chief purpose of the [FCA] was to provide for restitution to the government of money taken from it by fraud . . . ”).
84 22 C.F.R. § 35.3 (2023); 31 U.S.C. § 3729(a)(1).
85 Nicole Henning et al., Keeping the False Claims Act Civil: Why FCA Damages Should Be Based on the Government’s Actual Losses, 22 W.L. J. HEALTH CARE FRAUD 3, 4 (2016) (“The [FCA] does not create liability merely for a health care provider’s disregard of governmental regulations . . . unless, as a result of such acts, the provider knowingly asks the government to pay amounts it does not owe.” (quoting United States ex rel. Clausen v. Lab’y Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002))).
86 See, e.g., Greenfield, 880 F.3d at 97 n.6 (“[A]n offer alone may amount to a violation of the [AKS].”).
87 See 155 Cong. Rec. 25,921 (2009) (statement of Sen. Edward E. Kaufman). As the AKS amendment attempted to remedy the issue of defendants in FCA cases “mount[ing] legal challenges that sometimes defeat legitimate enforcement efforts,” requiring plaintiffs to demonstrate but-for causation would not further the remedial goals of the amendment. Id.
claims. Until the Eighth Circuit’s 2022 decision, the words “resulting from” were interpreted by federal courts in a seemingly uniform manner since the enactment of the ACA—which never included a but-for causation standard. When the FCA is implicated in health care fraud cases involving the AKS by fraudsters requesting reimbursement for products or services provided due to kickbacks, it may be nearly impossible to prove that the kickback was the but-for cause of a claim being submitted to a federal health care program—making it far more difficult to impose civil FCA liability upon those who exploit the federal health care programs through bribery.

B. **Imposing a But-For Causation Requirement in Cases Brought Under § 1320a-7b(g) Impedes upon the FCA’s Goal of Providing Restitution to Federal Health Care Programs**

While the FCA focuses on ensuring that the government is repaid for losses through restitution, AKS violators are often required to pay forfeiture based upon the amount of wrongfully obtained proceeds from their illegal actions. While “an order of forfeiture may not feel much different [to a defendant] from an order of restitution,” the two types of orders serve differing purposes: “Restitution is loss based, while forfeiture is gain based.”

Forfeiture and restitution may be simultaneously imposed upon a defendant, but in such instances they both cannot be provided to the

---


89 See, e.g., United States ex rel. Booker v. Pfizer, Inc., 847 F.3d 52, 58 (1st Cir. 2017) (holding that “aggregate expenditure data by the government,” which fails to identify specific submissions of false claims, is insufficient to support an FCA claim (quoting United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 121 (1st Cir. 2013)); United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 313 (3d Cir. 2011) (holding that a relationship is not required to be alleged between AKS violations and claims submitted to the government, in order for an FCA “complaint to survive a Rule 12(b)(6) motion” to dismiss); United States ex rel. Kester v. Novartis Pharms. Corp., 41 F. Supp. 3d 323, 335 (S.D.N.Y. 2014) (“[A]ny claim connected in any way to an AKS violation was ineligible for reimbursement, even if the party that submitted the claim had no knowledge of the AKS violation.”).

90 United States v. Torres, 703 F.3d 194, 196, 201, 203 (2d Cir. 2012) (upholding the appropriateness of imposing both forfeiture and restitution penalties upon a defendant who underreported income to obtain subsidized housing, as the defendant profited from the fraud by saving “a discrete sum of money . . . exactly corresponding to the reduction she was granted on her rent, and available for her to use as a direct result of her fraud,” and caused a loss to the municipal housing agency by causing it to pay subsidies that it would not have paid if the income reports were truthful).

91 Id. at 203 (quoting United States v. Genova, 333 F.3d 750, 761 (7th Cir. 2003)).
same “victim,” or government agency, in order to avoid double recovery. In *United States v. Pikus*, the government accused the defendant of participating in a kickback scheme where they provided portions of Medicare and Medicaid reimbursements to program beneficiaries as a method of inducing business. While upholding an order for the defendant to pay forfeiture, the district court denied the government’s request for an additional order of restitution to the victim federal health care programs under the Mandatory Victims Restitution Act (MVRA), which the government argued should be in the full amount of reimbursements that were tainted by the defendant’s kickback scheme—as the agencies would not have provided reimbursements for any claims affected by kickbacks. In denying restitution under the MVRA specifically, the court distinguished against similar AKS cases involving FCA restitution because the FCA, unlike the MVRA, does not include a statutory mandate requiring restitution to be limited to losses that are the direct cause of conduct composing the offense of conviction. The court described one FCA case in particular, *United States v. Rogan*, in which the Seventh Circuit held that whenever the government offers a subsidy with conditions—such as reimbursement for treating Medicare or Medicaid patients, which is conditioned upon compliance with the AKS—and said conditions are not satisfied by an individual or entity who billed the government for reimbursement, the government owes nothing, and the FCA would require the noncompliant recipient to pay back the entire amount. As noted by the Seventh Circuit in

---

92 See *id.* at 204 (“[S]everal circuits have upheld orders of both forfeiture and restitution . . . [where] both awards were payable to the federal government, albeit to different federal entities.”); *United States v. Taylor*, 582 F.3d 558, 566 (5th Cir. 2009) (upholding orders of both forfeiture and restitution because the district court ordered the defendant to provide restitution to FEMA and to forfeit earnings to the DOJ, which are separate federal entities).


94 Id.

95 See *id.* at *2.

96 See 517 F.3d 449, 453 (7th Cir. 2008); see also *United States v. Novak*, No. 17 C 4887, 2018 WL 4205540, at *3–5 (N.D. Ill. Sept. 4, 2018) (holding that because the defendant’s AKS violations rendered them ineligible for Medicare reimbursements in the first place, the FCA damages should be equivalent to the entirety of what the government was caused to pay; further concluding that *Rogan*’s proposition that a defendant’s false claim renders the subsequent services “worthless” in certain circumstances is consistent with the Supreme Court’s *Escobar* decision regarding the FCA’s materiality element (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 187 (2016))).
Rutan, while the possibility may exist that patients obtained through illegal referral arrangements or who were provided with unnecessary medical services could have opted to pay for the services by themselves or through a private insurer, these possibilities still do not allow the defendant to keep wrongfully obtained federal health care subsidies because the conditions to obtaining said amounts were broken. The Eighth and Sixth Circuits failed to address this proposition in holding that AKS-based FCA actions require but-for causation.

C. The Third Circuit’s Analysis of Legislative History to Reach the “Middle Ground” Causation Standard

The “middle ground” causation standard, advocated for by the Third Circuit in its 2018 United States ex rel. Greenfield v. Medco Health Solutions, Inc. decision, became the uniform standard of causation for § 1320a-7b(g) relied upon by federal courts. In Greenfield, the plaintiff filed a qui tam action, alleging that Accredo Health Group, Inc. (“Accredo”), a specialty pharmacy that provides home care for patients with hemophilia, “violated the [FCA] by falsely certifying [that] it complied with the [AKS].” From 2007 to 2012, the pharmacy made annual donations ranging from approximately $200,000 to $550,000 to two charities that promoted Accredo: Hemophilia Services, Inc. (“HSI”) and Hemophilia Association of New Jersey (“HANJ”). In 2010, Accredo informed HSI and HANJ that it would be reducing its annual donation for the following year to $175,000. Based upon findings that Accredo’s business would be at a substantial risk if it reduced donations so drastically, Accredo

97 Rutan, 517 F.3d at 453 (“Nor do we think it important that most of the patients for which claims were submitted received some medical care.”); see also Yates v. Pinellas Hematology & Oncology, P.A., 21 F.4th 1288, 1304–05 (11th Cir. 2021) (holding that it did not matter that noncompliant laboratory tests billed to Medicare were actually conducted because the government still paid for something that it would not have paid for if the claims were truthful about the noncompliance). But see United States v. Vaghela, 169 F.3d 729, 736 (11th Cir. 1999) (holding that the defendant must only pay restitution for the amount received in illegal kickbacks and did not have to pay entire amount for which Medicare was billed, because medical services were performed).

98 880 F.3d 89, 98 (3d Cir. 2018).


100 Greenfield, 880 F.3d at 92.

101 Id. at 91.

102 Id. at 92.
increased its funding to $350,000 in 2012. 103 The relator, Greenfield, then commenced the *qui tam* action, accusing his former employer of violating the FCA by falsely asserting compliance with the AKS. 104

Greenfield argued that he did not need to identify any specific false claim that was directly related to the alleged kickback scheme. 105 Accredo countered that Greenfield could not prove a violation of the FCA because he could not provide evidence of any federally insured patient utilizing Accredo’s services as a result of its contributions to HSI and HANJ. 106 Accredo argued that the correct standard of causation was for the government or relator to be required to prove that beneficiaries of federal health care programs would not have used Accredo’s services *but-for* its charitable contributions to HSI and HANJ. 107 The Third Circuit rejected both arguments, and supported a “middle ground” approach by holding that the “resulting from” causation standard of § 1320a-7b(g) requires a “link” to exist between at least one of the kickbacks and subsequent false claims—but does not, however, require actual (or but-for) causation. 108 Specifically, the court reiterated that “[a] kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient.” 109 This meant that Greenfield would be required to prove that *at least one* of Accredo’s claims sought reimbursement from a federal health care provider for treatment that was provided in violation of the AKS, but would not be required to prove that the treatment was *only provided because of* the illegal remuneration. 110 The court reached this conclusion through interpretation of the legislative intent behind the enactment of the original AKS, the 2010 amendment, and various amendments of the FCA. 111

An aspect of Accredo’s argument included that defining “resulting from” as requiring actual causation would be consistent with the Supreme Court’s interpretation of “results from,” as written in the
Controlled Substances Act (CSA),\textsuperscript{112} pursuant to the \textit{Burrage v. United States} decision.\textsuperscript{113} In \textit{Burrage}, the provision of the CSA in question imposed a twenty-year sentence as a mandatory minimum upon any person who knowingly or intentionally manufactures, distributes, or possesses certain substances if “death or serious bodily injury \textit{results from} the use of such substance.”\textsuperscript{114} The Supreme Court held that a defendant cannot be held liable under the CSA unless the victim’s death or injury would not have occurred \textit{but-for} the use of the distributed drug.\textsuperscript{115} The Court reasoned that if Congress intended for a modified causation test, such as the contributing factor test, to govern the mandatory minimum provision of the CSA, the statute should have been written to indicate that the sentence would be imposed “when the underlying crime ‘contributes to’ death or serious bodily injury.”\textsuperscript{116}

By contrast, in \textit{Greenfield}, the Third Circuit rejected Accredo’s argument for \textit{but-for} causation by concluding that the intentions of the drafters of the original AKS in 1977 were to “strengthen the capability of the [g]overnment to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs,” which the court interpreted to support requiring a causation standard of “something \textit{less than} proof that the underlying medical care would not have been provided but for a kickback.”\textsuperscript{117} Turning to the legislative history of the FCA, which “is intended to reach \textit{all} fraudulent attempts to cause the [g]overnment to pay out sums of money or to deliver property or services,”\textsuperscript{118} the court concluded that Congress designed both the AKS and the FCA to “reach a broad swath of ‘fraud and abuse’ in the federal health care system.”\textsuperscript{119}

Next, the court considered the congressional intent behind the 2010 AKS amendment, which added § 1320a-7b(g).\textsuperscript{120} From

\begin{footnotes}
\footnote{112}{21 U.S.C. § 841(b)(1).}
\footnote{113}{\textit{See Greenfield}, 880 F.3d at 96 (citing \textit{Burrage v. United States}, 571 U.S. 204, 211 (2014)).}
\footnote{114}{\textit{Burrage}, 571 U.S. at 206 (emphasis added) (citing § 841(a) (1)–(2), (b)(1)).}
\footnote{115}{\textit{See id.} at 204.}
\footnote{116}{\textit{Id. at 216.}}
\footnote{118}{\textit{Id. at 96} (quoting S. REP. NO. 99-345, at 9 (1986), \textit{reprinted} in 1986 U.S.C.C.A.N. 5266, 5274).}
\footnote{119}{\textit{Id.}}
\footnote{120}{\textit{See id.}}
\end{footnotes}
congressional debate over the enactment of the Health Care Fraud Enforcement Act of 2009, which would “ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action[s] under the [FCA],” the court concluded that the purpose of the 2010 amendment was clear: it was to “strengthen[] whistleblower actions based on medical care kickbacks”—which did not support Accredo’s reading of § 1320a-7b(g). Therefore, Accredo inconsistently interpreted § 1320a-7b(g) with the intentions of the drafters of both the AKS and FCA.

The Third Circuit agreed with Greenfield that it would impede relators’ abilities to bring an FCA action if relators were required to prove that an alleged kickback—which in this case was charitable donations—actually influenced a patient’s choices or a doctor’s medical judgment in prescribing certain items or services. The court further described how imposing a but-for causation requirement in § 1320a-7b(g) would make direct causation to be a precondition for bringing an AKS-based FCA case, but not for bringing a claim under the AKS on its own.

The court also described its reasoning as consistent with CMS 855s, which requires certification that the care eligible for reimbursement is in compliance with the AKS. The form, however, fails to mention any guidance regarding a patient’s reasoning for selecting a certain provider, and does not require any type of intent-based inquiry in order to submit claims. The Third Circuit established that, although it would not require but-for causation, it would require some heightened form of a causal connection, because a “temporal connection” between an actual claim and a kickback scheme would not be enough to prove FCA liability under § 1320a-7b(g).

121 Id. (alteration in original) (second emphasis added) (quoting 155 CONG. REC. 25,921 (2009) (statement of Sen. Edward E. Kaufman)).

122 See id. at 97.

123 See Greenfield, 880 F.3d at 96–97.

124 See id. at 97.

125 See id.

126 See id.; see, e.g., MEDICARE ENROLLMENT APPLICATION, supra note 59.

127 A “temporal connection” could be demonstrated by showing that claims were “likely” or “should have been” submitted to the government. See Greenfield, 880 F.3d at 98 (quoting United States ex rel. Clausen v. Lab’y Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002)) (citing United States ex rel. Quinn v. Omnicare, Inc., 382 F.3d 432, 439 (3d Cir. 2004)).
D. The Eighth and Sixth Circuits Now Require But-For Causation, Departing from the Greenfield Standard

Many cases decided after Greenfield, analyzing § 1320a-7b(g), upheld and further refined the Third Circuit’s conclusion that a “link” between an AKS violation and a subsequent false claim is required, but the link does not require the strength of but-for causation. In 2022, however, the Eighth Circuit’s decision in United States ex rel. Cairns v. D.S. Medical, LLC created a circuit split. In Cairns, a Missouri neurosurgeon, Dr. Fonn, utilized spinal implants distributed by D.S. Medical LLC (“DS Medical”), a company wholly owned by his fiancée, Deborah Seeger. Ms. Seeger received $1.3 million in commissions from a single manufacturer, and due to Dr. Fonn being her only large customer, the manufacturer offered Dr. Fonn company stock. After Dr. Fonn purchased the stock, he ordered more spinal implants—causing other physicians to question his high use of the implants and subsequently file a qui tam complaint under the FCA against Dr. Fonn, his practice, Ms. Seeger, and DS Medical. The US government chose to intervene in the action and charged the defendants primarily under the 2010 AKS amendment. At trial in the District Court for the Eastern District of Missouri, the jury was instructed “that the government could establish falsity or fraud once it proved, by a preponderance of the evidence, ‘that the Medicare or Medicaid claim failed to disclose the [AKS] violation.’” The jury found in favor of the government on two of the three claims, and the defendants subsequently appealed to the Eighth Circuit, arguing that the district court should have instructed the jury on but-for causation.

---

128 See, e.g., Guilfoile v. Shields, 913 F.3d 178, 180 (1st Cir. 2019) (declining to directly assess the impact of 42 U.S.C. § 1320a-7b(g) but upholding the “sufficient causal connection” standard of Greenfield as the correct causation standard of the 2010 amendment); United States v. Teva Pharms. USA, Inc., No. 13 Civ. 3702, 2019 WL 1245656, at *23–24 (S.D.N.Y. Feb. 27, 2019) (holding that “the FCA does not require the kickback to be the ‘but for’ cause of the prescription;” also upholding the Greenfield “middle of the road” approach for causation under § 1320a-7b(g) in requiring that the relators only needed to show that referral of the defendant’s products “actually sat in the causal chain”).
129 42 F.4th 828 (8th Cir. 2022).
130 See id. at 831.
131 See id.
132 See id.
133 Id.
134 Id.
135 See Cairns, 42 F.4th at 832–33.
The Eighth Circuit agreed with the defendants and held that § 1320a-7b(g) requires a but-for causal connection between the kickback and the false claim, meaning that a party alleging a false claim must prove that the claims would not have included certain “items or services” without illegal kickbacks.\(^{136}\) The Eighth Circuit engaged in a detailed interpretation of the language of the 2010 amendment to reach this conclusion.\(^{137}\) Just as Accredo argued to, which the Third Circuit rejected in \textit{United States ex rel. Greenfield v. Medco Health Solutions},\(^{138}\) the Eighth Circuit analyzed the phrase “results from” as it is contained in the CSA.\(^{139}\) Relying upon \textit{Burrage v. United States},\(^{140}\) the Eighth Circuit agreed with the Supreme Court’s conclusion in that case that “results from,” as written in the CSA, requires actual causality, as evidenced by dictionary definitions and interpretations of the plain meaning of the statute.\(^{141}\)

The Eighth Circuit further concluded that no “contextual indications” supported requiring less than a but-for causation standard.\(^{142}\) Standing by its position that its job was to decipher “Congress’s actual words,” the court reasoned that if Congress aimed to do so, it would have worded the statute differently, by possibly using the words “provided in violation of” or “tainted by,” instead of “resulting from.”\(^{143}\) The legislative history behind § 1320a-7b(g) did not persuade the Eighth Circuit, reasoning that floor statements from Congressional debates were not the correct place to look.\(^{144}\) The Eighth Circuit expressly rejected the Third Circuit’s analytical framework in \textit{Greenfield}, which delved into the intentions motivating the drafters of § 1320a-7b(g).\(^{145}\)

\(^{136}\) \textit{Id.} at 831, 836.

\(^{137}\) \textit{See id.} at 836.

\(^{138}\) 880 F.3d 89, 96 (3d Cir. 2018).

\(^{139}\) \textit{See Cairns}, 42 F.4th at 834.

\(^{140}\) 571 U.S. 204, 210–11 (2014).

\(^{141}\) \textit{See Cairns}, 42 F.4th at 834.

\(^{142}\) \textit{See id.} at 835–36.

\(^{143}\) \textit{See id.} at 836 (citing \textit{Burrage v. United States}, 571 U.S. 204, 216 (2014)) (describing how Congress could have written a different causation standard for the CSA, if that was what it intended).

\(^{144}\) \textit{See id.} at 836 (citing \textit{United States v. Trans-Missouri Freight Ass’n}, 166 U.S. 290 (1987)).

\(^{145}\) \textit{See United States ex rel. Greenfield v. Medco Health Sols.}, 880 F.3d 89, 96 (3d Cir. 2018).
In March 2023, the Sixth Circuit became the only other court of appeals to adopt the Eighth Circuit’s but-for causation requirement under the 2010 amendment.\textsuperscript{146} In \textit{United States ex rel. Martin v. Hathaway}, Dr. Martin, a former employee of an ophthalmologist, Dr. Hathaway, brought a \textit{qui tam} action under § 1320a-7b(g) against Dr. Hathaway, alleging that, because Dr. Hathaway and a hospital agreed to continue referring patients to one another after Dr. Martin left Dr. Hathaway’s practice, the hospital refused to hire her as an internal ophthalmologist in order to avoid taking away business from Dr. Hathaway that would typically come from hospital referrals to his practice.\textsuperscript{147} The \textit{qui tam} action alleged that Dr. Hathaway and the hospital engaged in a kickback scheme by rejecting Dr. Martin’s employment, in exchange for Dr. Hathaway committing to continue sending his patients to the hospital for surgeries, and subsequently submitted false claims to Medicaid and Medicare as a result of the arrangement.\textsuperscript{148}

The Sixth Circuit’s opinion in \textit{Martin} first concluded that Dr. Martin’s complaint failed “to allege a cognizable kickback scheme,” because the hospital’s refusal to hire her did not involve any payment or transfer of value that would qualify as remuneration.\textsuperscript{149} The Sixth Circuit then turned to whether Dr. Martin alleged causation under § 1320a-7b(g), and held that because there was no “identifiable exchange of value,” no “connection” could exist between the alleged eight claims for reimbursement submitted to federal programs from Dr. Hathaway’s practice and the hospital’s decision to not hire Dr. Martin—these claims only demonstrated temporal proximity because the decisions of independent physicians at the hospital ultimately


\textsuperscript{147} See \textit{id.} at 1046–47 (“Dr. Hathaway [stated] . . . that, if the [b]oard approved [Dr. Martin’s] offer, it would be the ‘death knell’ of his practice because [the hospital]’s future patient referrals would go to Dr. Martin, the new, internal ophthalmologist.”).

\textsuperscript{148} See \textit{id.} at 1047–48.

\textsuperscript{149} \textit{id.} at 1051 (“[The hospital]’s decision not to hire someone does not entail a payment or transfer of value to Dr. Hathaway. While [the hospital]’s decision may have \textit{benefitted} Dr. Hathaway . . . [the hospital] never offered Dr. Hathaway anything at all.” (emphasis added)).
referred patients to Dr. Hathaway’s practice, therefore breaking “any plausible chain of causation.”

Directly following Cairns, the Sixth Circuit further held that the ordinary meaning of “resulting from” as written in the 2010 amendment is but-for causation,151 and cited the Supreme Court’s opinion in Burrage v. United States as dictating that but-for causation must apply unless textual or contextual indications to the contrary exist.152 In relying upon Burrage, the Martin opinion cited various cases from prior to 2010—with none involving either the AKS or any remote relation to fraud within the health care industry—that held that language similar to “resulting from” requires but-for causation, as evidence that no “textual” indications would point to a lower causation standard.153 Similar to Cairns, the Sixth Circuit rejected the Third Circuit’s analysis of the 2010 amendment’s legislative history in United States ex rel. Greenfield v. Medco Health Solutions, Inc.154 The Sixth Circuit also agreed with Cairns, however, that if Congress did intend to impose a lower standard than but-for causation, it could have utilized language other than “resulting from” in the 2010 amendment.155

Further, the government argued in Martin that, because the AKS lacks a causation requirement, no reason existed for Congress to impose a but-for causation requirement on a corresponding claim under the FCA.156 The Sixth Circuit rejected this, concluding that “resulting from” as written in the 2010 amendment “applies to all kinds of fraud claims without regard to whether the underlying claim has a causation component.”157

In interpreting § 1320a-7b(g) to require but-for causation, the Eighth Circuit, Sixth Circuit, and one opinion within the District Court

---

150 See id. at 1052–54. Despite rejecting the Third Circuit’s reliance on the legislative history of the 2010 amendment, see infra note 154, the Sixth Circuit agreed that a showing of only “temporal proximity” between an alleged kickback and subsequent reimbursement claim was not enough to allege that the claim resulted from an AKS violation. See id. at 1053 (citing United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 100 (3d Cir. 2018)).

151 See id. at 1053 (citing United States ex rel. Cairns v. D.S. Med., LLC, 42 F.4th 828, 834–36 (8th Cir. 2022)).

152 See Martin, 63 F.4th at 1052 (citing Burrage v. United States, 571 U.S. 204, 210–11 (2014)).

153 See id. at 1052.

154 Id. at 1054 (citing Greenfield, 880 F.3d at 96–97).

155 See id. at 1053 (citing Cairns, 42 F.4th at 836).

156 See id. at 1054; see also supra notes 77–81 and accompanying text.

157 Martin, 63 F.4th at 1054; see also infra notes 186–188 and accompanying text.
for the District of Massachusetts stand alone. The District Court for the District of Maryland expressly rejected the Cairns holding in a case involving two medical device companies that marketed the LAP-BAND gastric sleeve through a website, www.lapband.com. The relator who initiated the qui tam FCA action alleged that the defendants used the website to create a kickback scheme that gave the featured surgeons free advertising in exchange for meeting a requirement of performing at least forty LAP-BAND procedures per year. The court held that the relator’s allegations were “sufficient to allege that these surgeons’ LAP-BAND referrals ‘sat in the causal chain’ between the free marketing [d]efendants provided them [with] through the locator tool . . . and the allegedly false claims,” and declined to adopt the defendants’ proposed but-for causation standard:

This court declines to adopt the but-for cause standard endorsed by Cairns. . . . The [Eighth Circuit] cited the dictionary as support for its interpretation, and it relied upon several Supreme Court cases that have reached similar interpretations in different contexts [including Burrage]. . . . But the Burrage Court also indicated that . . . “[w]here there is no textual or contextual indication to the contrary, courts regularly read phrases like ‘results from’ to require but-for causality.” And here, there are contextual indications to the contrary. . . . [T]he legislative history of the 2010 amendments to the AKS indicates that Congress intended to make it

---

158 See United States v. Regeneron Pharms., Inc., No. 20-11217, 2023 WL 6296393, at *11 (D. Mass. Sept. 27, 2023). Despite the Regeneron case, district courts outside of the First, Sixth, and Eighth Circuits routinely adhere to Greenfield and do not require but-for causation in cases premised on § 1320a-7b(g). See, e.g., United States ex rel. Fitzer v. Allergan, No. 17-cv-00668, 2022 WL 3599139, at *10 (D. Md. Aug. 23, 2022); United States ex rel. Everest Principals, LLC v. Abbott Laboratories, Inc., 622 F. Supp. 3d 920, 921, 933 (S.D. Cal. 2022) (acknowledging Cairns but upholding the Greenfield standard of causation in an FCA case involving a kickback scheme of “patient referrals, lavish meals, [and] free marketing” to induce providers to perform procedures using a product manufactured by Abbott Laboratories in holding that the relator sufficiently established a “link” between the kickback and claim for reimbursement, as “the ‘broad statutory text’ of the FCA and AKS does not require ‘a plaintiff to show that a kickback directly influenced a patient’s decision to use a particular provider’”); United States ex rel. Hueseman v. Pro. Compounding Ctrs. of Am., Inc., No. 14-CV-00212, 2023 WL 2669879, at *10 n.4 (W.D. Tex. Mar. 27, 2023) (“This court is neither bound nor persuaded by the Eighth Circuit’s reasoning [in Cairns], which has been rejected by numerous courts.” (first citing Greenfield, 880 F.3d at 97; then citing Fitzer, 2022 WL 3599139, at *10; and then citing Everest Principles, 622 F. Supp. 3d at 933)).


160 See id. at *2.
easier, not harder, to bring (and ultimately prove) FCA claims predicated on violations of the AKS. This Court, therefore, finds the Third Circuit’s reasoning in Greenfield more persuasive than the Eighth Circuit’s analysis in Cairns and, accordingly, declines to adopt defendants’ preferred “but-for” cause standard.¹⁶¹

Within the Eighth Circuit, the District Court for the District of Minnesota addressed the impact of Cairns in a _qui tam_ action brought under the 2010 amendment in a January 2023 order pertaining to _United States ex rel. Fesenmaier v. Cameron-Ehlen Group, Inc._, where the plaintiffs alleged that a supplier of ophthalmic surgery equipment offered illegal remuneration to physicians in order to obtain business, and false claims for reimbursement were submitted to Medicare as a result of the kickbacks.¹⁶² Previously, in a 2021 order, the District Court for the District of Minnesota explicitly rejected the defendants’ argument for requiring the plaintiff to prove but-for causation, and the court cited in favor of the Greenfield “link” standard of causal connection under § 1320a-7b(g).¹⁶³ Because the District Court for the District of Minnesota is now required to follow Cairns in cases arising under the 2010 amendment, the parties in Fesenmaier disputed whether but-for causation must now apply to FCA cases brought under the “material falsity theory,” as after the Cairns decision the plaintiffs chose to solely prove their case under this theory—no longer utilizing the 2010 amendment.¹⁶⁴ The court held in favor of the plaintiffs, reasoning that the Cairns holding only applied to FCA cases in which the plaintiff seeks to establish falsity through the 2010 amendment—if the plaintiffs were able to establish all elements of their material falsity theory without relying upon § 1320a-7b(g), they could prevail by establishing that the kickbacks _proximately caused_ physicians to use the equipment without needing to prove but-for causation.¹⁶⁵


¹⁶⁴ _Id._ at *2. Some courts, however, conclude that the material falsity theory and the 2010 amendment are not exclusive: § 1320a-7b(g) codified pre-2010 holdings that AKS-premised FCA claims were false because kickbacks violate a material condition of reimbursement—conflating the falsity and materiality elements of the FCA. See cases cited _supra_ note 61 and accompanying text.

Circuit did not clarify in Martin whether its holding was applicable to only cases brought under § 1320a-7b(g) or whether it also applied to cases brought under the material-falsity theory.

V. POLICY IMPLICATIONS OF A BUT-FOR CAUSATION STANDARD

Requiring but-for causation will make it more difficult to impose FCA liability upon those who violate the AKS. Section A explains why the Greenfield standard best harmonizes the importance of avoiding too far an inquiry into subjective intent that would occur with a but-for cause analysis, while avoiding instances that would impose liability based upon speculation. Section B looks to the legislative history of the 2010 amendment, which points to clear congressional intent to simplify imposing FCA liability upon those who violate the AKS. Section C explains how the Eighth and Sixth Circuits failed to consider the specific policy goals of the AKS in reaching their respective decisions. Lastly, Section D posits that it was the vague language of the 2010 amendment that allowed for the Eighth and Sixth Circuits to reach these consequential holdings.

A. Why a “Middle of the Road” Approach Best Achieves the Goals of the AKS and FCA

Under the Greenfield “middle of the road” approach, a “temporal connection” between an illegal kickback and a subsequent false claim for reimbursement is not strong enough to establish a cause of action under § 1320a-7b(g). Plaintiffs must establish a “link” between at least one of the kickbacks and subsequent false claims. This standard, barring actions with too far attenuated of a relationship between a kickback and a fraudulent payment to the government, is sensible because it prevents FCA actions that are based upon mere

2669879, at *10 n.4 (W.D. Tex. Mar. 27, 2023) (“Cairns is inapplicable here because the government does not rely ‘exclusively’ on the AKS to demonstrate falsity.”).

166 See Greenfield, 880 F.3d at 100.

167 Id. at 99 (“Greenfield may not prevail on summary judgment simply by demonstrating that Accredo submitted federal claims while allegedly paying kickbacks. . . . Instead, he must point to at least one claim that covered a patient who was recommended or referred to Accredo by HSI/HANJ.”); see also Carrel v. AIDS Healthcare Found., Inc., 898 F.3d 1267, 1277 (11th Cir. 2018) (dismissing a complaint where relators alleged an AKS violation, but failed to establish that the defendant actually submitted a claim to the federal government for an unlawfully referred patient).
speculation. A causation standard requiring actual cause, however, would go too far. Because a but-for causal relationship is a strict standard, it will be more difficult—if not impossible—for plaintiffs to prove in many cases, allowing violators to escape liability. An actual causation analysis would require determining what a patient or customer subjectively considered when they chose to utilize a particular item or service—i.e., actual causation would be lacking if the patient still would have chosen to receive an item or service if no kickbacks were involved, and would require looking into the subjective decision-making processes of patients and health care providers in order to determine whether prescribing a certain item or service was directly caused by a kickback.

Inquiry into the “subjective medical decisions” of a physician or patient is not involved within the elements of the FCA or the AKS. A manual created by OIG, informing new physicians of relevant fraud and abuse laws, expressly reminds physicians that in terms of liability for kickback schemes, it does not matter that a drug or device would have been prescribed to a patient in the absence of illegal remuneration. Because AKS liability can be imposed upon pure intent to wrongfully induce purchases or referrals, any claim submitted to a federal health care program that results from an intention to induce patients to purchase a certain drug or device, for example, would be deemed “false” for purposes of FCA liability under the 2010 amendment.

168 See supra notes 82–86 and accompanying text. Although the Sixth Circuit ultimately held in favor of requiring but-for causation, the alleged kickback scheme in Martin likely would not have passed the Greenfield “link” standard that rejected mere temporal proximity. See supra note 150 and accompanying text.

169 See Greenfield, 880 F.3d at 95–97. In United States ex rel. Flanagan v. Fresenius Medical Care Holdings, Inc., the District Court for the District of Massachusetts posed a different potential approach to causation under § 1320a-7b(g) that would function as a burden-shifting framework: “[O]nce a relator has established the existence of a kickback scheme, arguably the burden should be shifted to the defendant to prove that certain referrals [or claims submitted to federal health care programs] were not caused by payment of kickbacks.” No. 21-11627, 2022 WL 17417577, at *18 (D. Mass. Dec. 5, 2022).

170 See Greenfield, 880 F.3d at 95.

171 A ROADMAP FOR NEW PHYSICIANS, supra note 6, at 5 (“Taking money or gifts from a drug or device company or a durable medical equipment (DME) supplier is not justified by the argument that you would have prescribed that drug [or device] . . . even without a kickback.”).

In *United States v. Teva Pharmaceuticals USA, Inc.*, Teva Pharmaceuticals ("Teva") was charged with submitting false claims as a result of donating over $328 million to two foundations to cover Medicare copayments for patients taking Copaxone, a drug manufactured by Teva—the government alleged that Teva did so "because it knew that the foundations would allocate [the donations] to cover Copaxone copayments, thus increasing Copaxone sales and enriching Teva." In denying Teva’s request for production of pharmacy and medical claims data, which it sought in order to prove that patients may have chosen Copaxone because they were not satisfied with other drugs, the court concluded that this data was irrelevant "because in an AKS-based FCA case, the government must prove only that Teva intended to induce patients to purchase Copaxone through its donations.”

In similar cases where an AKS violation is premised upon pharmaceutical manufacturer-run copayment assistance programs, in turn resulting in false claims being submitted for reimbursement, it would be incredibly difficult for the government to establish but-for causation under the 2010 amendment because that would require determining why patients chose to utilize the specific product or service as opposed to others. This evidence would only exist in the mind of the relevant provider or patient. Further, it would often be impossible for the government to prove, for example, that a physician would not have prescribed a drug in the absence of a kickback, because the physician would presumably argue that they would have prescribed it in the absence of a bribe, and it is unlikely independent evidence exists to the contrary. If the standard of actual causation for § 1320a-7b(g) is adopted, it will be easier for defendants to escape civil liability under the FCA because they would not be accountable if a patient still

---

173 *Id.* at *1.

174 *Id.* at *4*. The District Court for the District of Massachusetts later granted the government’s motion for summary judgment on causation under the AKS-based FCA claim, concluding that the government had "established evidence of a 'sufficient causal connection' between Teva’s payments to [charitable foundations] and the resulting Medicare Copaxone claims.” *United States v. Teva Pharms. USA, Inc.*, No. 20-11548, 2023 WL 4565105, at *3 (D. Mass. July 14, 2023); see also *Pfizer, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 42 F.4th 67, 69, 72 (2d Cir. 2022) (upholding an OIG advisory opinion regarding a copayment assistance program proposed by Pfizer, which concluded that the program would violate the AKS because “one purpose” of the program would induce Medicare beneficiaries to purchase a certain drug manufactured by Pfizer through the lowered copayment costs).
would have made a decision to obtain items or services if a kickback scheme were not involved.

B. Why the Legislative History of the AKS Does Not Support a But-For Causation Standard

Imposing the requirement of establishing but-for causation, in order for a private citizen to bring an action against a health care professional under both the AKS and FCA, goes against the clear intentions of the drafters of the 2010 amendment to the AKS and the original AKS. First, the 2010 amendment aimed to expand the power of whistleblowers to bring actions against medical care kickbacks under the FCA, because the AKS does not contain a private right of action. “The bill also strengthens whistleblower actions based on medical care kickbacks. . . . 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.” 175 Notably, the legislative history behind the 2010 amendment emphasizes the importance of preventing wrongdoers from escaping civil liability, because the government should be repaid for claims it was fraudulently caused to reimburse. Prior to the signing of the ACA into law, Senator Kaufman emphasized the importance of “recover[ing] money paid pursuant to these illegal practices.” 176 and Senator Leahy described how “[a]ll too often, health care providers secure business by paying illegal kickbacks, which needlessly increase health care risks and costs. [The 2010 amendment] will help ensure that the government is able to recoup from wrongdoers the losses caused by false health care fraud claims.” 177

Second, the legislative history of the original AKS further indicates that the drafters would not have hoped to make it easier for defendants to escape liability through a heightened causation standard: “[T]he activities of those who seek to defraud [the federal health care] programs unfairly call into question [the] honesty and integrity of the vast majority of practitioners and [health care]

176 Id. Statements made prior to the enactment of legislation can demonstrate the intent of Congress in passing said legislation. Consumer Prod. Safety Comm’n v. GTE Sylvania, Inc., 447 U.S. 102, 118 n.13 (1980) (“[S]ubsequent legislative history will rarely override a reasonable interpretation of a statute that can be gleaned from its language and legislative history prior to its enactment.” (emphasis added)).
institutions.” The legislative history also considers the difficulties involved in proving and correcting health care fraud, specifically among independent practitioners: “Since the medical needs of a particular patient can be highly judgmental, it is difficult to identify program abuse as a practical manner unless the overutilization is grossly unreasonable.” Propositions as such do not support the requirement of an actual causation standard in AKS-based FCA cases, which would require inquiry into the subjective decisions made by a patient or provider, as discussed above.

C. The Eighth and Sixth Circuits Misused Burrage and Failed to Recognize Policy Goals Specific to Preventing the Exploitation of the Federal Health Care Programs

In Cairns, when the Eighth Circuit brushed aside the legislative history of the relevant statutes, the court chose to disregard the reasons why Congress enacted § 1320a-7b(g). The court’s reliance upon Burrage v. United States, instead of analyzing the congressional intent behind the statutes at issue in Cairns, was misguided. Burrage centered on a provision of the CSA in which the determination of cause would result in a mandatory minimum prison sentence. In reaching its conclusion that but-for causation was required by the statute, the Supreme Court drew a connection between criminal law and employment discrimination law, which Leora F. Eisenstadt argues was misguided due to major differences between the nature of those areas of the law. Quite relevant to the Eighth Circuit’s reliance

179 Id. at 47.
181 See id. at 834–36.
183 See id. at 19 (“There are at least four major differences that suggest that the Court’s reliance on causation principles from employment discrimination cases to support its conclusions in a criminal case is inappropriate.”). In United States ex rel. Schulte v. SuperValu Inc., where the Court decided the scienter standard of the FCA, the Supreme Court refused to adopt the scienter standard used in Fair Credit Reporting Act (FCRA) cases as the Court previously held to be correct in Safeco Insurance Company of America v. Burr: While Safeco did reference the common law’s standards for “knowing” and “reckless” conduct, its interpretation was ultimately tied to the FCRA’s particular text. To take Safeco as establishing categorical rules
upon—and the Sixth Circuit’s acknowledgement of—Burrrage in Cairns is Eisenstadt’s description of the divergence of policy goals between mandatory minimum sentences under the CSA and the interests at stake in employment discrimination matters. The same divergence of interests rings true here: imposing a but-for causation standard upon a provision that determines the mandatory minimum sentence for causing death cannot be logically connected to imposing the same standard upon § 1320a-7b(g)—a provision that is meant to empower the government and whistleblowers to hold those exploiting the federal health care programs accountable, and to enable the government to recoup the losses caused by this exploitation.

The Sixth Circuit’s analysis of the 2010 amendment in Martin similarly lacked any consideration of how the AKS governs an area of the law containing specific policy goals. First, when the Sixth Circuit stated that no textual indications to the contrary of a but-for causation requirement existed when Congress added the 2010 amendment to the AKS, it pointed to a variety of pre-2010 Supreme Court and Sixth Circuit cases that interpreted language similar to “resulting from” as requiring but-for causation—but not a single cited case involved any relevance or connection to the prevention of conduct that exploits the federal health care programs. Further, the court stated that “the ‘resulting from’ language applies to all kinds of fraud claims without regard to whether the underlying claim has a causation component.” This proposition ignores the fact that § 1320a-7b(g) is a provision of the AKS itself, and exists to specifically address claims for reimbursement that are false under the FCA because they result from illegal kickback schemes within the health care industry—they are not just any “kind[] of fraud claims,” as characterized by the Sixth Circuit.

for those terms would accordingly “abandon the care we have traditionally taken to construe such words in their particular statutory context.” Schuette, 143 S. Ct. 1391, 1402 (2023) (citation omitted) (quoting Jerman v. Carlisle, McNellie, Rini, Kramer, & Ulrich, L.P.A., 559 U.S. 573, 585 (2010)).

See supra note 6, at 5 (explaining how kickbacks in health care can lead to overutilization, increased program costs, corruption of medical decision-making, patient steering, and unfair competition).


Id. at 1054.

Id.
D. The Consequences of Vague Statutory Language

Statutory definitions provide a threshold to the understanding and success of the legislation they accompany.189 Definitions “confer the authority [intended by the statute] and establish a structure that allows the . . . provisions to have effect; they inform and instruct as to how a particular outcome might be achieved or avoided.”190 Keeping this in consideration when reading § 1320a-7b(g), it becomes clear that the underlying reason the Eighth and Sixth Circuits were able to reach holdings requiring but-for causation is the fact that the provision itself does not define what the correct standard of causation should be—it simply states that claims including items or services resulting from an AKS violation constitute a false claim for purposes of the FCA.191 Because of this ambiguity, and the fact that the Supreme Court has not issued a decision on the matter, the Eighth Circuit, Sixth Circuit, and District Court for the District of Massachusetts had every right to reach this conclusion—even though it contradicts what the vast majority of other courts to consider the issue have determined. Therefore, the most effective way to ensure that this ambiguous provision is not interpreted in this manner again is to amend the statute to remove the phrase “resulting from” and replace it with the causation standard that Congress truly intended: a standard that avoids requiring parties and courts to “delve into . . . intent” in regard to medical decision-making.192

VI. Conclusion: Congress Must Amend § 1320a-7b(g) to Clarify the Correct Causation Standard

In order to inform and instruct as to how its intended outcome of recouping payments that stem from illegal kickbacks will occur, Congress must amend § 1320a-7b(g) to clarify that a “but-for” causation relationship is not required to exist between an alleged kickback and subsequent false claim. The statute should be amended to indicate that there must be at least one “link” between a kickback and false or fraudulent claim in order to impose civil FCA liability, as

190 Id. at 1002–03.
191 See 42 U.S.C. § 1320a-7b(g).
held by the Third Circuit in *Greenfield*.\(^{193}\) Section 1320a-7b(g) should now read as follows:

\begin{quote}
(g) Liability under subchapter III of chapter 37 of Title 31.

(1) In addition to the penalties provided for in this section, a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31, United States Code will be established if there exists at least one claim submitted seeking reimbursement for items or services that were distributed in violation of this section.

(2) Paragraph (1) does not require a relationship of actual causation between illegal remuneration and a subsequent reimbursement claim. Therefore, in the absence of a violation of this section, if a customer or patient would have purchased, or a health care provider would have sold or prescribed the items or services, the defendant is still subject to liability under subchapter III of chapter 37 of Title 31, United States Code.\(^{194}\)
\end{quote}

The Eighth and Sixth Circuits’ willingness to impede upon efforts to hold those exploiting federal health care programs accountable under the FCA is clearly at odds with the intentions of the drafters of the relevant statutes. Amending § 1320a-7b(g) will once and for all prevent other courts from reaching the same consequential conclusion and will preserve the purpose of the provision: to avert defendants from mounting “legal challenges that sometimes defeat legitimate enforcement efforts.”\(^{195}\) Therefore, Congress must follow its own advice and amend the provision in order to genuinely ensure that anti-fraud enforcement efforts remain empowered.

---

\(^{193}\) *See id.* at 100.


\(^{195}\) *Greenfield*, 880 F.3d at 96 (quoting 155 CONG. REC. 25,921 (2009) (statement of Sen. Edward E. Kaufman)).