

Another Win for Defendants on the Issue of Causation in AKS-Based FCA Cases

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On Sept. 27, the federal district court for the District of Massachusetts joined the Sixth and Eighth Circuits in ruling that a False Claims Act (“FCA”) case premised on violations of the Anti-Kickback Statute (“AKS”) requires the plaintiff to show that the false or fraudulent claims would not have been submitted “but for” the alleged kickbacks. This decision deepens the circuit split that has emerged regarding the correct standard for causation in such cases. The “but for” causation standard is a high bar for FCA plaintiffs, as it requires them to establish that the alleged kickback scheme was the direct cause or at least a substantial factor in causing an allegedly false or fraudulent claim to be submitted to the government.

This client alert summarizes relevant case law from the Third, Sixth, and Eighth Circuits and the recent district court decision and discusses the significance of the recent decision in the greater FCA landscape.

I. Relevant Background

A. AKS violations can lead to FCA liability.

The AKS imposes criminal liability on anyone that “knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate)” to induce or reward referrals for items or services reimbursable under a federal healthcare program.¹ In 2010, Congress amended the AKS such that violations of the statute can also lead to liability under the FCA because 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].”² Three Circuit Courts of Appeal have directly addressed what the phrase “resulting from” means.

B. The Third Circuit only requires a “link” between a kickback and a specific submitted claim.

In 2018, the Third Circuit said the phrase “resulting from” requires only a “link,” such that plaintiffs may prevail if they simply demonstrate “some connection between a kickback and a subsequent reimbursement claim.”³ Mere “temporal proximity” between a kickback scheme and submitted claims would not be enough.⁴ But showing that a patient for whom reimbursement claims were submitted was “exposed” to a referral or recommendation that violated the AKS would be sufficient.⁵ Importantly, the Third Circuit rejected a “but for” causation standard as too stringent because it would “dilute” the FCA’s enforcement effect by imposing direct causation as a requirement for FCA liability but not for AKS liability.⁶

C. The Eighth Circuit imposed a stricter “but for” causation standard.

The Eighth Circuit created a circuit split in 2022 when it disagreed with the Third Circuit’s reasoning and adopted the more rigorous “but for” causation standard.⁷ The Eighth Circuit concluded that, as a matter of statutory construction, the phrase “resulting from” unambiguously requires that “when a plaintiff seeks to establish falsity or fraud . . . it must prove that a defendant would not have included particular ‘items or services’ but for the illegal kickbacks.”⁸ Note, however, that the Eighth Circuit limited the application of “but for” causation to FCA cases where FCA liability was specifically based on an AKS violation. This meant that plaintiffs proposing alternative theories of falsity would not be required to meet the higher causation standard.

D. The Sixth Circuit agreed with the Eighth Circuit.

[As we previously discussed](#), the Sixth Circuit joined the Eighth Circuit in March 2023 in interpreting the phrase “resulting from” as imposing a “but for” causation standard.⁹ The Sixth Circuit disagreed with the Third Circuit’s reasoning that a “but for” standard would curtail the government’s ability to prosecute and punish healthcare fraud, reasoning that “a faithful interpretation of the . . . ‘resulting from’ requirements still leaves plenty of room to target genuine corruption.”¹⁰ In contrast to the Eighth Circuit, the Sixth Circuit’s holding was not limited to FCA cases premised on AKS violations, imposing a broader application of the “but for” standard.

E. The First Circuit has not explicitly taken a side in the circuit split.

Decisions from courts of the District of Massachusetts are appealed to the First Circuit, which has cited—but not discussed—the Third Circuit’s decision in interpreting the phrase “resulting from” to mean there must be “sufficient causal connection between an AKS violation and a claim submitted to the federal government.”¹¹ But the First Circuit declined to discuss the “full implications” of the AKS provision containing the “resulting from” language.¹²

II. The Recent District Court Decision

A. The Massachusetts district court followed the Sixth and Eighth Circuits in applying the “but-for” causation standard.

On Sept. 27, the U.S. District Court for the District of Massachusetts agreed with the Sixth and Eighth Circuits’ interpretation of the statute and held that the government is required to show that any alleged kickback scheme was the “but for” cause of the alleged false claims.¹³

The alleged kickback scheme at issue concerned Regeneron, a manufacturer of a drug that treats age-related macular degeneration (an eye disease). The government alleged that Regeneron improperly funneled millions of dollars of “donations” into the Chronic Disease Fund (“CDF”), “a purportedly independent charitable foundation,” so that the CDF would subsidize patients’ copays for Regeneron’s drug and, in turn, physicians would be incentivized to prescribe that drug to more Medicare patients.

The government argued that the district court was effectively bound by the Third Circuit’s lower standard of causation, since the First Circuit had already cited to it. But the district court disagreed that the First Circuit had actually set forth a causation standard in that case. The court also believed the Third Circuit’s standard was “fraught with problems” because it “is divorced from the actual language of the statute and from basic principles of statutory interpretation.”¹⁴ Further, the court reiterated the Sixth Circuit’s concern that requiring merely a “link” between the alleged AKS

violation and the alleged false claim would be “akin to an irrebuttable presumption” of FCA liability, posing a risk that physicians with good intent would be at equal risk of liability to those without.¹⁵ Instead, the district court found the statutory construction analysis set forth by the Sixth and Eighth Circuits to be more persuasive and adopted the more rigorous “but for” causation standard.¹⁶ Applying this standard, the court held there were genuine issues of material fact regarding whether Regeneron violated the AKS and caused the submission of false claims for payment and therefore denied both sides’ motions for summary judgment.

B. The causation standard question has been certified for interlocutory appeal to the First Circuit.

Interestingly, the *Regeneron* decision comes less than three months after a different judge in the same district denied a defendant’s motion for summary judgment, concluding “[t]he government need not prove ‘but for’ causation” and instead adopting the First Circuit’s “sufficient causal connection” language.¹⁷ However, on Aug. 14, 2023, that judge granted the defendant’s motion to pursue an interlocutory appeal of the summary judgment ruling, agreeing that the question of which causation standard is correct is “a controlling question of law as to which there is substantial ground of difference of opinion.”¹⁸ The judge stayed trial in the case until the First Circuit resolves the issue.

III. Takeaways

The *Regeneron* decision adds another arrow in the quiver of FCA defendants, as the Sixth Circuit (which covers federal district courts in Kentucky, Michigan, Ohio, and Tennessee), the Eighth Circuit (which covers federal district courts in Arkansas, Iowa, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota), and now the District of Massachusetts will require FCA plaintiffs to meet a more rigorous “but for” standard of causation and establish that, at a minimum, the defendant’s actions were a substantial factor in causing the alleged harm. On the other hand, the Third Circuit (which covers federal district courts in Delaware, New Jersey, and Pennsylvania) remains unfriendly to defendants as FCA plaintiffs there need only demonstrate a “link” or “some connection” between the alleged kickback and the alleged false claim; no evidence of actual causation or intent is required.

The precedential value of the District of Massachusetts decision will not be finalized until the First Circuit rules on the aforementioned interlocutory appeal. Stay tuned to Haynes Boone’s [News page](#) for the latest news on that decision and other important legislation, enforcement actions, and court opinions interpreting the various elements of and defenses to an FCA claim. And for more information about the FCA, please contact a member of Haynes Boone’s [False Claims Act, Qui Tam and Litigation](#); [Government Contracts](#); or [Healthcare and Life Sciences](#) practice groups below. Please also refer to the firm’s annual [False Claims Act - Year in Review](#) publication.

¹ 42 U.S.C. §1320a-7b(b).

² 42 U.S.C. § 1320a-7b(g) (emphasis added); see also *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (“[A]n AKS violation that results in a federal health care payment is a per se false claim under the FCA.”) (internal quotations and citations omitted).

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

⁴ *Id.* at 100.

⁵ *Id.*

⁶ See *id.* at 97.

⁷ *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834 (8th Cir. 2022).

⁸ *Id.* at 836 (emphasis added).

⁹ *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1053 (6th Cir. 2023).

¹⁰ *Id.* at 1055.

¹¹ *Guilfoile*, 913 F.3d at 190.

¹² *Id.*

¹³ *United States v. Regeneron Pharma, Inc.*, No. 20-cv-11217, 2023 WL 6296393, at *11 (D. Mass. Sept. 27, 2023).

¹⁴ *Id.* at *10.

¹⁵ *Id.* at *11.

¹⁶ *Id.*

¹⁷ See *United States v. Teva Pharm. USA, Inc.*, No. 20-cv-11548, 2023 WL 4565105, at *5 (D. Mass. July 14, 2023)

¹⁸ Order, *United States v. Teva Pharm. USA, Inc.*, No. 20-cv-11548 (D. Mass. Aug. 14, 2023), Dkt. No. 235.