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BLOG

First Circuit Joins Circuit Split in Favor of "But For" Causation Required To Show Falsity in AKS-Based False Claims Act Cases

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On February 18, 2025, the United States Court of Appeals for the First Circuit issued its decision in *United States v. Regeneron Pharmaceuticals, Inc.*[1] adopting the more stringent "but for" causation standard for alleged violations of the False Claims Act (FCA)[2] based on violations of the Anti-Kickback Statute (AKS).[3] The First Circuit now joins the Sixth[4] and Eighth[5] Circuits, widening an emerging split among the circuits that may open the door for Supreme Court review. In the meantime, the United States and whistleblowers will face a heightened standard for proving liability in FCA cases piggybacked on alleged kickbacks.

1. REGENERON'S ALLEGED VIOLATIONS OF THE AKS

The AKS imposes criminal liability on anyone who "knowingly and willfully offers or pays any renumeration. . . to any person to induce such person[] . . . to purchase . . . any good, facility, service, or item for which may be made in whole or in part under a Federal health care program."[6] Under a 2010 Amendment, "a claim [for payment by a federal health care program] that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."[7]

In *Regeneron*, the United States alleged that Regeneron Pharmaceuticals, Inc. ("Regeneron") engaged in a kickback scheme to induce physicians to prescribe a Regeneron-manufactured drug, which in turn led to the submission of false claims in violation of the FCA. Regeneron manufactures the drug Eylea, which is one of only a few drugs that treat neovascular age-related macular degeneration. Eylea is a "buy & bill" drug under Medicare Part B whereby: (i) physicians buy the drug and submit reimbursement claims after prescribing and administering the drug; and (ii) the drug is subject to Part B's cost-sharing requirement in which Medicare pays eighty percent, and the patient pays twenty percent. Even with this cost-sharing, Eylea is an expensive drug for patients. Accordingly, as argued by the Department of Justice (DOJ), Regeneron sought to offset the patients' copay to incentivize physicians to prescribe Eylea. To do so, Regeneron allegedly donated tens of millions of dollars to a charitable foundation, which in turn covered the copay for patients. Physicians, in turn, allegedly knew patients would receive this assistance and prescribed Eylea, and then submitted those claims to Medicare. The district court determined that Regeneron violated the FCA due to the alleged kickback. For the purposes of this appeal, the parties and the court assumed, without deciding, that at least some of the donations made by Regeneron to charitable foundations constituted unlawful kickbacks.

2. THE FIRST CIRCUIT'S OPINION

At issue on appeal to the First Circuit was the appropriate standard for causation under the 2010 Amendment to the AKS. Regeneron argued that the words "resulting from" in the 2010 Amendment compels a "but for" causation standard requiring the United States prove that the AKS violation actually caused the physician to provide different medical treatment. The United States countered that the First Circuit should adopt the more lenient standard embraced by the Third Circuit[8]—"all that is required to prove a causal link is that 'a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient.'"[9]

The First Circuit analyzed Supreme Court precedent interpreting "resulting from" in other statutory contexts, concluding that "the phrase 'resulting from' imposes a requirement of actual causality, which in ordinary course takes the form of but-for causation, but [the court] may deviate from this ordinary course if the statute in question provides 'textual or contextual indications' for doing so."[10] The Court then explained that all the United States' arguments failed to overcome this presumption in favor of "but for" causation.

First, the United States argued that the "animating principle" of the AKS is that "financial conflicts in themselves corrupt medical decisionmaking," and therefore it follows that "because the 2010 amendment was 'built on' such a statutory scheme, it too should require only that payments are meant to induce the provision of items or services and that those items or services are subsequently provided."[11] The Court rejected this argument, reasoning in part that Congress can easily "make a violation of one statute a per se violation of another" and chose instead to include a causation requirement.[12] Additionally, the United States' interpretation position would result in no causation requirement, which is contrary to Supreme Court precedent and the plain language of the statute. Consequently, the Court rejected this argument.

Next, the United States argued that the legislative history favors a rejection of the "but for" causation standard. The United States relied on a floor statement from Senator Ted Kaufman indicating that the "provision would 'ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves."[13] The First Circuit also rejected this argument, finding the Senator's statement consistent with a "but for" causation standard.

The First Circuit affirmed the district court's ruling and agreed with Regeneron that "to demonstrate falsity under the 2010 amendment, the government must show that an illicit kickback was the but-for cause of a submitted claim."

KEY TAKEAWAYS

- There is a growing consensus amongst the Circuits that the 2010 Amendment calls for a "but-for" causation standard. This more restrictive view of FCA liability based on AKS violations will inure to the benefit of defendants facing such allegations, regardless of the jurisdiction in which a case is brought.
- The First Circuit's decision to join the Sixth and Eighth Circuits may pave the way for Supreme Court review.
- The United States has brought several claims against healthcare companies for alleged use of charities to cover patients' drug costs, resulting in settlements valued in the hundreds of millions.[14] The First Circuit's adoption of "but for" causation may stymie DOJ's efforts to resolve such cases via settlements.
- In general, it will be harder for the United States to establish FCA violations based on alleged unlawful kickbacks.
- Defense and in-house counsel should caution clients on the careful use of charities that may later be characterized as a conduit for kickbacks in FCA litigation.

If you have any questions regarding this or related subjects or if you need assistance, please contact the authors of this article (Suzanne Jaffe Bloom, Reed Stephens, Amandeep Sidhu, Christopher Parker, Elayna Napoli), members of our Government Investigations, Enforcement, and Compliance Practice or your Winston & Strawn relationship attorney. You can also visit our Government Investigations, Enforcement, and Compliance Practice webpage and our Government Program Fraud, False Claims Act & Qui Tam Litigation Playbook for more information on this and related subjects.

[1] No. 23-2086, 2025 WL 520466 (1st Cir. Feb. 18 2025).

[2] 31 U.S.C. § 3729(a)(1)(A)

[3] 42 U.S.C. § 1320a-7b(b)(2)

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

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

[6] *Id.*

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

[8] *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F. 3d 89, 96–98 (3d Cir. 2018).

[9] *Medco Health Sols., Inc.*, 880 F.3d at 100.

[10] No. 23-2086, 2025 WL 520466, at *13 (1st Cir. Feb. 18 2025).

[11] *Id.* at 14.

[12] *Id.* at 16–17.

[13] *Id.* at 24.

[14] For example, in 2017, United Therapeutics paid $210 million to settle similar allegations, *Drug Maker United Therapuetics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks*, DOJ (Dec. 20, 2017) https://www.justice.gov/archives/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability, and in 2018, Johnson & Johnson agreed to pay $360 million to settle allegations that their subsidiary pharmaceutical company used a charity to funnel illegal kickbacks. Katie Thomas, *Drug Maker Pays $360 Million to Settle Investigation into Charity Kickbacks*, NY Times (Dec. 6. 2018) https://www.nytimes.com/2018/12/06/health/actelion-johnson-and-johnson-kickback-medicare.html.

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