Patterson Belknap

Litigation Alert
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The First Circuit Requires But-For Causation in False Claims Act Cases Predicated on Violations of the Anti-Kickback Statute, Adding to Circuit Split

On February 18, 2025, in *United States v. Regeneron Pharmaceuticals*, the First Circuit held that to establish civil liability under the False Claims Act ("FCA") premised on violations of the Anti-Kickback Statute ("AKS"), the alleged kickback must have been the "but-for" cause of the reimbursement claim that triggers FCA liability. In other words, the government or whistleblowers proceeding on this theory must prove that a false claim for federal reimbursement would not have been submitted were it not for the alleged kickbacks.

In so holding, the First Circuit joined the Sixth and Eighth Circuits in adopting a stricter but-for causation standard for FCA claims based on AKS violations and eschewed the Third Circuit's more lenient standard, which requires only "some connection" between an illegal kickback and a reimbursement claim. *Regeneron* reflects a growing trend of courts applying a higher causation standard to many AKS-based FCA claims. Even so, the *Regeneron* court recognized that not all AKS-based FCA claims—most notably, FCA claims based on a false certification of AKS compliance—require proof of causation.

Key Points

- The First Circuit joined the Sixth and Eighth Circuits in ruling that the government or whistleblowers must prove but-for causation to establish FCA liability based on violations of the AKS. The decision deepened a circuit split with the Third Circuit, which adopted a more lenient standard requiring "some connection" between a kickback and a subsequent reimbursement claim.
- The decision raises the bar for FCA enforcement, making it harder for the government and whistleblowers to establish liability for reimbursement claims that are merely close in time to an alleged kickback.
- At the same time, the First Circuit recognized that the false-certification theory of liability does not require causation, and thus, no similar nexus must be drawn between the AKS violation and payment of federal funds in a false-certification FCA claim.

Background

In 2010, Congress amended the AKS to provide that a claim for federal healthcare payment "resulting from" an AKS violation is automatically a "false or fraudulent claim" for purposes of FCA liability.[1]

Regeneron Pharmaceuticals, Inc. manufactures Eylea, a prescription drug for treating a serious eye disease.[2] Because patients' annual co-pays for Eylea routinely exceed $2,000, Regeneron paid millions of dollars to a charitable foundation to subsidize co-pays for Medicare patients who purchased Eylea.[3] The government sued Regeneron in 2020, alleging that this co-pay assistance program violated the AKS.[4] According to the government, the subsidies constituted illegal kickbacks that violated the AKS because they were meant to induce physicians to increase prescriptions of Eylea at

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[1] *United States v. Regeneron Pharms., Inc.*, No. 23-2086, 2025 WL 520466, at *2 (1st Cir. Feb. 18, 2025).
[2] *Id.* at *1 (citing 42 U.S.C. § 1320a-7b(g)).
[3] *Id*.
[4] *United States v. Regeneron Pharms., Inc.*, No. 20-11217, 2023 WL 6296393, at *1 (D. Mass. Sept. 27, 2023).

the expense of the Medicare Part B program.[5] Further, the government contended that once it had proved that an AKS violation occurred, it need only prove that a patient was "*exposed* to an illegal recommendation or referral and a provider submitted a claim for reimbursement pertaining to that patient."[6] In other words, the government disputed that it needed to prove that physicians would not have submitted reimbursement claims for Eylea absent the co-pay assistance.

In September 2023, on the parties' cross motions for summary judgment, the district court rejected the government's argument that it could satisfy causation by merely showing that reimbursement claims were "linked" to AKS violations, or that patients had been "exposed" to an AKS violation.[7] Instead, the court held the "resulting from" standard requires a showing of but-for causation.[8]

Recognizing that its ruling regarding causation conflicted with that of another court in the Circuit, the district court then certified the ruling for interlocutory appeal to the First Circuit.[9]

The *Regeneron* Decision

As a matter of first impression, the First Circuit held that, to prove FCA liability premised on an AKS violation, "the government must show that an illicit kickback was the but-for cause" of a false claim submitted for federal reimbursement.[10] The court agreed with Regeneron that if a doctor would have prescribed Eylea anyway, then the subsequent Medicare claim could not have "resulted from" Regeneron's allegedly illegal co-pay subsidies.

The court began its analysis by noting that the Supreme Court has generally interpreted the statutory phrase "resulting from" to have the ordinary meaning of "but-for" causation.[11] To "deviate from this ordinary course" would require the statute in question to provide "textual or contextual indications" for doing so.[12]

Finding no "textual" basis in the 2010 amendment to overcome this presumption, the court considered, and rejected, the government's arguments that "contextual indications" signify "resulting from" means something other than but-for causation.[13]

First, the government argued that the AKS requires no but-for causation between the kickback and the subsequent reimbursement claim, illustrating that "financial conflicts in themselves corrupt medical decisionmaking."[14] The panel found this argument did not join issue. Using the RICO Act and wire fraud as examples, the panel reasoned that when Congress decides that violations of one statute create liability under another, it may require proof of additional elements that are not necessary to prove the predicate violation.[15] Moreover, the panel also emphasized that the government's logic implied that no proof of causation is required at all, which is contrary both to the statutory text and to the government's position that "some type of actual causality" is required.[16] The panel also rejected the government's reliance on the AKS's criminal provisions—which criminalize kickbacks regardless of whether they

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[5] *Id*.
[6] *Id*. at *10 (emphasis added).
[7] *Id*. at *15.
[8] *Id*. at *11, 15.
[9] *United States v. Regeneron Pharms., Inc.*, No. 20-11217, 2023 WL 7016900 (D. Mass. Oct. 25, 2023), at *1 (citing *United States v. Teva Pharms. USA, Inc.*, 682 F. Supp. 3d 142 (D. Mass. 2023)).
[10] *Regeneron Pharms., Inc.*, 2025 WL 520466, at *3, 10.
[11] *Id.* at *3 (citing *Burrage v. United States*, 571 U.S. 204, 211 (2014); *Paroline v. United States*, 572 U.S. 434, 445 (2014)).
[12] *Id.* at *4.
[13] *Id.* at *5–9.
[14] *Id.* at *5.
[15] *Id.* at *6.
[16] *Id.* at *5–6.

cause referrals or purchases—explaining that the AKS's civil and criminal provisions, respectively, serve different purposes and thus "impose different evidentiary burdens."[17]

Next, the government maintained that the 2010 amendment was passed against a backdrop of court decisions imposing FCA liability on a "false-certification" theory that does not require proof of but-for causation, and that Congress "did not clearly intend" to overrule those decisions with the amendment.[18] Under the false-certification theory, a defendant violates the FCA by presenting a claim that misrepresents compliance with a "statutory, regulatory, or contractual requirement" that "the defendant knows is material" to the government's payment decision.[19]

Again, the First Circuit was unconvinced. It agreed that the false-certification theory does not require any causation.[20] The court also noted other differences between false-certification cases and claims under the 2010 amendment. For example, under the false-certification theory, FCA liability arises when a defendant falsely represents AKS compliance on a form submitted to a federal agency, and such compliance is material to the government's payment decision. But the 2010 amendment does not require any representation of AKS compliance or similar showing of materiality.[21]

The court therefore concluded, based on the relevant statutory history, that "the 2010 amendment did not disturb alternative theories of FCA liability (e.g., false certification)" and that "claims under the 2010 amendment run on a separate track than do claims under a false-certification theory."[22]

Lastly, the court was unmoved by the government's stated concerns that it would be challenging to prove, under a but-for causation standard, "why a doctor prescribed a particular drug." The court observed that "the same could be said" about proving other FCA elements, such as scienter. Further, the panel noted that even applying a but-for causation standard, the district court still found the government had presented enough evidence to survive Regeneron's motion for summary judgment.[23]

Circuit Split

With this decision, the First Circuit joined the Sixth and Eighth Circuits in adopting a but-for causation standard for establishing FCA liability predicated on AKS violations. All three circuit courts relied on the Supreme Court's decision in *Burrage v. United States*,[24] which interpreted the phrase "resulting from" in the Controlled Substances Act[25] as requiring but-for causation.

The Third Circuit, in contrast, adopted a more lenient standard in *United States ex rel. Greenfield v. Medco Health Solutions Inc.*, requiring only "some connection" between a kickback and a subsequent reimbursement claim.[26] Under *Greenfield*'s holding, an AKS violation can give rise to FCA liability without proof that an alleged kickback actually caused the submission of a reimbursement claim, so long as a patient has been "exposed" to an illegal kickback or referral before such a claim is submitted. The Third Circuit found that the phrase "resulting from" requires the government or whistleblowers to prove only "a *link* between the alleged kickbacks and the medical care received."[27] In the Third Circuit's view, this lower causation standard furthered congressional intent animating the 2010 amendment "to ensure that *all* claims resulting from illegal kickbacks are considered false claims" under the FCA. But

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[17] *Id.* at *6.
[18] *Id.*
[19] *Id.* (citing *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 181 (2016) (alteration in original).
[20] *Id.* at *8.
[21] *Id.*
[22] *Id.*
[23] *Id.* at *9.
[24] 571 U.S. 204, 210–11 (2014).
[25] The statute specified an enhanced sentence whenever "death or serious bodily injury *results from* the use of [a distributed controlled] substance." 21 U.S.C. § 841(b)(1)(A)–(C) (emphasis added).
[26] *United States ex rel. Greenfield v. Medco Health Solutions Inc.*, 880 F .3d 89, 100 (6th Cir. 2023).
[27] *Greenfield*, 880 F .3d at 100 (emphasis added).

the Third Circuit still imposed some limiting principles: "[T]emporal proximity" between the kickbacks and the submission of claims, without more, is not enough, and "the taint of a kickback" does not render every reimbursement claim false.[28] No other federal Court of Appeals has agreed with the Third Circuit's reasoning.

Takeaways

The causation standard applicable to AKS-based FCA claims can have a significant impact on defendants' potential exposure. There is no civil liability for AKS violations; only by showing that an FCA violation "result[s] from" an AKS violation can the government or whistleblower unlock civil remedies, including damages. Thus, requiring proof that a reimbursement claim would not have been made without the kickback, as the First Circuit did, often imposes considerable evidentiary hurdles on plaintiffs. In turn, it offers defendants more ammunition and greater opportunities to undermine the plaintiff's ability to meet its burden of proof.

Although the First, Sixth, and Eighth Circuits have adopted a but-for causation standard that is friendlier to defendants, the *Regeneron* court made clear that false-certification FCA liability remains available and does not require proof of but-for causation. Indeed, the government and whistleblowers have prevailed in recent FCA actions brought under the false-certification theory. The *Regeneron* decision is another positive step for defendants who seek to hold the government and whistleblowers to their burden of proof on causation in AKS-related FCA claims, but it should not be construed as a blanket statement that all such claims require proof of causation.

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[28] *Greenfield,* 880 F.3d at 100.