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Client Alert

White Collar Defense

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Circuit Split Deepens on Anti-Kickback Statute's Causation Standard

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Introduction: In its recent decision in *United States v. Regeneron Pharmaceuticals, Inc.*, the United States Court of Appeals for the First Circuit deepened an existing federal circuit court split regarding the causation standard to apply under the False Claims Act (FCA) for violations of the federal Anti-Kickback Statute (AKS).[1] The split is likely to invite the Supreme Court to weigh in on the issue sooner rather than later.

The FCA and AKS: The FCA is a powerful instrument in federal health care fraud enforcement. It imposes liability on individuals and companies that defraud the government by submitting "false or fraudulent" claims for payment by the government, such as reimbursement claims for medical goods and services covered, in whole or in part, by Medicare or Medicaid.[2] The AKS, in turn, prohibits, among other things, individuals and companies from knowingly and willfully inducing someone through incentives, such as cash payments or in-kind services, to buy or sell medical goods or services that are ultimately subsidized by the government.[3]

One way for the government to prove a claim is "false or fraudulent" under the FCA is by demonstrating that it included items and/or services "resulting from" a violation of the AKS. A 2010 amendment to the AKS expressly provided that FCA liability attaches where an individual or company bills the government for a medical item or service that "result[ed] from" a violation of the AKS.

The meaning of the phrase "resulting from" in the AKS, however, has become a focal point of disagreement among the federal circuits.

The *Regeneron* Case: *Regeneron* involved a drug manufacturer's contributions to a copayment assistance program. The drug manufacturer, Regeneron, funded an independent charitable organization, which in turn subsidized patient copayments for Eylea, Regeneron's blockbuster biologic drug for macular degeneration.[4] The government alleged that Regeneron's contributions to the charitable fund violated the AKS, thereby giving rise to FCA liability.[5] Regeneron contended that in order to impose FCA liability pursuant to an alleged violation of the AKS, the government needed to prove that the alleged kickback scheme was the "but for" cause of the submitted claims.[6] In other words, if the government could not prove that prescriptions written for Eylea, and the resulting Medicare reimbursement claim, would not have happened absent the copay assistance program, then the claim could not have "result[ed] from" a violation of the AKS.

The First Circuit agreed with Regeneron, interpreting "resulting from" in the AKS to require but-for causation. That means that the government had to allege and prove that the claims at issue would not have been submitted absent the alleged kickback scheme.[7] The court reasoned, in part, that the plain text of the statute compelled such a conclusion—indeed, it noted that the Supreme Court has interpreted language similar to "resulting from" as imposing "a requirement of actual causality."[8] Additionally, the court found no convincing textual or contextual reasons in the statute and legislative history to depart from the default presumption that the plain meaning of the text controls when it is not ambiguous.[9]

The Circuit Split: The First Circuit's decision in *Regeneron* aligns with decisions from the United States Courts of Appeals for the Sixth and Eighth Circuits, both of which have also adopted the but-for causation standard in similar cases, applying comparable statutory analyses.[10]

However, the *Regeneron* decision is at odds with the Third Circuit's decision in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*[11] In *Greenfield*, the Third Circuit adopted a more lenient standard, holding that it was sufficient to impose FCA liability where there was "a link"—rather than but-for causality—between the submitted claims and the kickback scheme.[12]

What's Next? Although the Supreme Court recently denied *certiorari* in the Sixth Circuit case, *United States ex rel. Martin v. Hathaway*, 144 S. Ct. 224 (Oct. 2, 2023), the now-growing circuit split may compel the court to take up the case to resolve the differing interpretations of the 2010 amendment to the AKS. Additionally, we anticipate that the Department of Justice will continue to advocate for the less stringent standard adopted by the Third Circuit in *Greenfield*. In the meantime, we also believe that litigants will begin to allege but-for causation in their complaints while, at the same time, protecting themselves if their proofs fail by also alleging false certification. Under that theory, each time an entity submits a claim for reimbursement, it must certify compliance with the AKS. If the entity violated the AKS, then it therefore would also have falsely certified its compliance with the statute when it submitted its claim for reimbursement—which then triggers liability under the FCA. This theory would amount to an end run around the circuit split because it does not depend on the causal link between the AKS violation and the submission of the false claim.

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[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).
[4] 2025 WL 520466, at *1–2.
[5] *Id.*
[6] *Id.*
[7] *Id.* at *4–9.
[8] *Id.* at *3 (citing *Burrage v. United States*, 571 U.S. 204, 211 (2014); *Paroline v. United States*, 572 U.S. 434, 445 (2014)).
[9] *Id.*
[10] *See United States ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023); *United States ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828 (8th Cir. 2022).
[11] 880 F.3d 89 (3d Cir. 2018).
[12] *Id.* at 90.

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