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First Circuit Reins In Broad Theory of Liability Under Anti-Kickback Statute by Adopting "But-For Causation" Standard

The First Circuit joins the Sixth and Eighth Circuits in adopting a more exacting causation standard for False Claims Act liability premised on Anti-Kickback Statute violations.

In a victory for False Claims Act (FCA) defendants, on February 18, 2025, the First Circuit, in *United States v. Regeneron Pharmaceuticals, Inc.*, adopted a "but-for causation" standard for FCA liability resulting from Anti-Kickback Statute (AKS) violations.[1] In aligning with the Sixth and Eighth Circuits, the First Circuit joins the recent judicial shift toward a more stringent standard requiring plaintiffs to prove that a kickback was the determinative factor in the submission of a claim, and not merely a contributing factor.

The AKS, often in concert with the FCA, is the primary tool used by the Department of Justice (DOJ) when investigating life sciences companies. For example, in 2024, FCA recoveries exceeded $2.9 billion, with over $1.67 billion related to matters involving healthcare and life sciences companies.[2]

Speaker programs also remain in focus for DOJ, as do company interactions with patients, physicians, and insurance companies regarding coverage and reimbursement issues. DOJ's focus on reimbursement support programs reflects the reality that they are among the most commercially important programs for companies — and among those of greatest concern to DOJ, given DOJ's view that they drive patients and healthcare providers toward increasingly expensive therapies. We expect DOJ's scrutiny of the financial relationships between life sciences companies and those who purchase, prescribe, or pay for their products to continue as DOJ targets the activities it believes contribute to high drug and device prices.

This Client Alert summarizes the *Regeneron* decision and its implications and provides an overview of the current judicial landscape regarding but-for causation requirements.

Background

Regeneron Pharmaceuticals (Regeneron) manufactures Eylea, a drug for treating eye disease, which is classified under Medicare Part B as a "buy and bill" drug.[3] Physicians purchase, prescribe, and administer the drug, while patients pay a co-pay, and providers file a reimbursement claim with Medicare.[4] The government alleged Regeneron violated the AKS by knowingly inducing prescriptions for Eylea by paying approximately $60 million to the Chronic Disease Fund, which provided co-pay assistance to patients to

cover the cost of Eylea.[5] Regeneron argued that for a claim to "result from" an AKS violation, the AKS violation must be a "but-for" cause of the challenged claim.[6] The district court agreed with Regeneron's interpretation that "but-for" causation was required, relying on cases from the Sixth and Eighth Circuits that held the same.[7] The First Circuit affirmed the district court's ruling that "to treat an AKS violation as a false or fraudulent claim under the FCA, the government must prove that the AKS violation was a but-for cause of the false claim."[8]

First Circuit's Reasoning

In *Regeneron*, the First Circuit first relied on Supreme Court precedent in holding that the phrase "resulting from" in the 2010 amendment to the AKS imposes a requirement of actual causality, which in ordinary course takes the form of but-for causation.[9] The court recognized that it could deviate from this ordinary course "if the statute in question provides 'textual or contextual indications' for doing so."[10]

The First Circuit found no textual or contextual indications in the 2010 amendment that would have warranted deviating from the standard but-for causation requirement.[11]

The court acknowledged alternative pathways to FCA liability for AKS violations, such as false representations of compliance with the AKS.[12] The court noted that, under this theory, "it is not the AKS violation itself that renders the claim false[,]" but rather the false representation that no violation of the AKS has occurred.[13]

Key Takeaways

The First Circuit's holding has significant practical implications for companies facing FCA allegations for claims resulting from AKS violations, including the following:

- The First Circuit's narrow interpretation of "resulting from" may benefit parties facing investigations under broad kickback theories. Since the government bears significant litigation risk unless it can establish a direct but-for causation link for FCA violations, defendants may have an avenue to seek more favorable settlements that factor in such risk.

- Defendants may argue at the motion-to-dismiss stage that relators have failed to plead fraud with particularity under Federal Rule of Civil Procedure 9(b), unless they have alleged that the claims at issue resulted from an AKS violation and would not have occurred but for such a kickback being offered or paid.

- Defendants facing litigation in circuits that have not yet ruled on the causation issue (see chart below) should consider raising early arguments that the First, Sixth, and Eighth Circuits' rulings use the appropriate interpretation of "resulting from" and that the government or the relator must plead but-for causation to survive a motion to dismiss.

- Nevertheless, contracting entities and those in the healthcare and life sciences industry should remain vigilant that their financial relationships with counter-parties clearly articulate the nature of the bargained for exchange and ensure that related communications are clear about the purpose of the relationship. Given the First Circuit's acknowledgement that another pathway besides but-for causation may exist to establish a violation of the FCA premised on AKS violations, companies should expect that the government and relators will continue to bring such cases and may also see a rise in false certification-related theories.

Survey of Current Judicial Landscape

The First Circuit's opinion strengthens the recent trend toward a stricter causation requirement and intensifies the circuit split over the causation standard, increasing the possibility of Supreme Court review. Until then, FCA defendants must account for the current judicial landscape in framing causation arguments. The chart below provides a summary of the case law interpreting "resulting from."

Court	But-For Causation Requirement?	Holding
First Circuit Court of Appeals	**Yes**	In *United States v. Regeneron Pharmaceuticals, Inc.*, the First Circuit adopted a "but-for causation" standard for establishing FCA liability resulting from AKS violations. The court stated: "Simply put, there is no language in the 2010 amendment that by itself runs counter to the presumption that 'resulting from' calls for proof of but-for causation."[14]
Second Circuit District Courts	**No**	In *United States v. Teva Pharmaceuticals USA, Inc.,* the Southern District of New York observed that "the FCA does not require the kickback to be the 'but for' cause," and that relators need only show that the [defendants'] referral … actually sat in the causal chain."[15] In *United States ex rel. Kester v. Novartis Pharms. Corp.*, the Southern District of New York rejected the argument that FCA claims based on AKS violations require "strict 'but for' causation [] on a transaction-by-transaction, claim-by-claim basis."[16]
Third Circuit Court of Appeals	**No**	In *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, the Third Circuit held that the phrase "resulting from" does not impose a but-for causation requirement and that neither the AKS or FCA require a plaintiff to show that a kickback "directly influenced a patient's decision to use a particular medical provider."[17]
Fourth Circuit District Courts	**No**	In *United States ex rel. Fitzer v. Allergan, Inc.*, the District of Maryland favored a "middle of the road" approach similar to *Greenfield*. Under that approach, "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." It held that while a link was required, it is less than showing that the bribe succeeded in producing the claim.[18]
Fifth Circuit District Courts	**Not yet addressed**	In *United States ex rel. Hueseman v. Pro. Compounding Centers of Am., Inc.*, the Western District of Texas noted *in dicta* that it was neither bound nor persuaded by the Eighth Circuit's reasoning in *Cairns* requiring but-for causation. However, the question of whether to endorse the but-for causation standard was not properly raised before the Court.[19]
Sixth Circuit Court of Appeals	**Yes**	In *United States ex rel. Martin v. Hathaway*, the Sixth Circuit held that "only submitted claims 'resulting from' the violation are covered by the [FCA]" and "resulting from" requires "but-for causation"; effectively requiring a direct link between claims and alleged kickbacks. The court relied in large part on the ordinary meaning of "resulting from," established by the Supreme Court's decision in *Burrage v. United States* as requiring actual causality.[20] It also noted that Congress added the "resulting from" language to the statute in 2010 against the backdrop of cases[21] that had interpreted similar language to require but-for causation.[22]

Court	But-For Causation Requirement?	Holding
Seventh Circuit District Courts	**Not yet addressed**	As of the date of publication, district courts in the Seventh Circuit do not appear to have ruled on the causation standard required.
Eighth Circuit Court of Appeals	**Yes**	In *United States ex rel. Cairns v. D.S. Medical LLC*, the Eighth Circuit found that "resulting from" requires but-for causation relying on the common and ordinary usage of "resulting from."[23] It reasoned that Congress used "resulting from," an "unambiguously causal" standard, in the face of several pre-amendment cases that did not require a causal link between the kickback scheme and the claim presented when it could have used the terms "tainted by" or "provided in violation of."[24]
Ninth Circuit District Courts	**No**	In *Kuzma v. N. Arizona Healthcare Corp.*, the District of Arizona considered *Greenfield* and the existing weight of authority ultimately explicitly rejecting but-for causation and instead requiring "more than a mere temporal relationship."[25] In *United States ex rel. Everest Principals, LLC v. Abbott Lab'ys, Inc.*, the Southern District of California acknowledged the circuit split created by *Greenfield* and *Cairns*, but ultimately appeared to side more with *Greenfield* (though not explicitly) by requiring only a "link" at the motion-to-dismiss stage between the kickback and the claim for reimbursement.[26]
Tenth Circuit District Courts	**No**	In *United States v. Medtronic, Inc.*, the District of Kansas, after considering *Greenfield*, declined to require but-for causation, particularly at the motion-to-dismiss stage. The court noted that while "the phrase 'resulting from' does suggest a connection between violating the AKS and submitting a false claim," the language "does not expressly summon a but for causation standard."[27]
Eleventh Circuit District Courts	**Not yet addressed**	In *United States ex rel. Wallace v. Exactech, Inc.*, the Northern District of Alabama pointed out the split among courts regarding the causation standard, but declined to determine the exact requirement for the "link" that relators must establish. Instead, the court found that the relators satisfied a more stringent standard by demonstrating that the provision of illegal remuneration "actually caused" the submission of false claims to the government.[28]

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Endnotes

[1] *United States v. Regeneron Pharmaceuticals, Inc.*, No. 23-2086 (1st Cir. Feb. 18, 2025).

[2] DOJ Fraud Statistics Overview, Oct. 1, 1986 – Sept. 30, 2024, https://www.justice.gov/archives/opa/media/1384546/dl.

[3] *Regeneron,* No. 23-2086, at *4.

[4] *See id.*

[5] *See id.* at *6.

[6] *Id.*

[7] *See id.*

[8] *Id.*

[9] *Regeneron,* No. 23-2086, at *10-11, 13.

[10] *Id.* at *13.

[11] *Id.* at *14.

[12] *Id. at 20.*

[13] *Id.*

[14] *Id.* at *10-11, 13.

[15] *United States v. Teva Pharmaceuticals USA, Inc.,* No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *23 (S.D.N.Y. Feb. 27, 2019).

[16] *United States ex rel. Kester v. Novartis Pharms. Corp.,* 41 F. Supp. 3d 323, 332 (S.D.N.Y. 2014).

[17] *United States ex rel. Greenfield v. Medco Health Sols., Inc.,* 880 F.3d 89, 95–98 (3d Cir. 2018).

[18] *United States ex rel. Fitzer v. Allergan, Inc.,* No. 1:17-CV-00668-SAG, 2022 WL 846211, at 9 (D. Md. Mar. 22, 2022), amended on denial of reconsideration, No. 1:17-CV-00668-SAG, 2022 WL 1567645 (D. Md. May 18, 2022).

[19] *United States ex rel. Hueseman v. Pro. Compounding Centers of Am., Inc.,* No. SA-14-CV-00212-XR, 2023 WL 2669879, at *10 (W.D. Tex. Mar. 27, 2023). *See also U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013), aff'd sub nom. *U.S. ex rel. Parikh v. Brown*, 762 F.3d 461 (5th Cir. 2014), opinion withdrawn and superseded on reh'g, 587 F. App'x 123 (5th Cir. 2014), withdrawn from bound volume (Oct. 1, 2014), and aff'd sub nom. *U.S. ex rel. Parikh v. Brown*, 587 F. App'x 123 (5th Cir. 2014) (declining to require but-for causation at the pleadings stage; instead merely requiring that relator plead with particularity that kickbacks were made with the intent of inducing referrals).

[20] *Burrage v. United States,* 571 U.S. 204, 210–11, 134 S.Ct. 881, 187 L.Ed.2d 715 (2014).

[21] The Court cited cases such as *Gross v. FBL Fin. Servs., Inc.,* 557 U.S. 167, 176, 129 S.Ct. 2343, 174 L.Ed.2d 119 (2009) ("because of"); *Holmes v. Sec. Inv. Prot. Corp*., 503 U.S. 258, 265–68, 112 S.Ct. 1311, 117 L.Ed.2d 532 (1992) ("by reason of").

[22] *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052–55 (6th Cir. 2023).

[23] *United States ex rel. Cairns v. D.S. Medical LLC,* 42 F.4th 828, 834–36 (8th Cir. 2022).

[24] *Id.*

[25] *Kuzma v. N. Arizona Healthcare Corp.*, 607 F. Supp. 3d 942, 957 (D. Ariz. 2022).

[26] *United States ex rel. Everest Principals, LLC v. Abbott Lab'ys, Inc.,* No. 3:20-CV-286-W (AGS), 2022 WL 3567063, at *8 (S.D. Cal. Aug. 18, 2022) (finding that allegations that a company assisted a physician with "'practice building' meal events and free marketing and advertising assistance for the purpose of inducing" usage of a device sufficient).

[27] *United States v. Medtronic, Inc.,* No. 17-2060-DDC-KGG, 2021 WL 4168140, at *23 (D. Kan. Sept. 14, 2021).

[28] *United States ex rel. Wallace v. Exactech, Inc.,* No. 2:18-CV-01010-LSC, 2020 WL 4500493, at *19 (N.D. Ala. Aug. 5, 2020).