First Circuit Adopts Defendant-Friendly 'But-For' Causation Standard for AKS-Based FCA Claims

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PRACTICES Government Contracts, Healthcare and Life Sciences, False Claims Act and Qui Tam Defense

On Feb. 18, 2025, in *United States v. Regeneron Pharm., Inc.*, the First Circuit joined two other appellate circuits by requiring plaintiffs to prove "but-for" causation when bringing claims under the False Claims Act (FCA) based on violations of the federal Anti-Kickback Statute (AKS). The decision will be well received by defendants as it creates a high pleading and evidentiary bar for plaintiffs.

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] Violations of the statute can also lead to civil liability 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] A circuit split has emerged over the years regarding what the phrase "resulting from" means or requires.

As detailed in an earlier alert, the Sixth and Eighth Circuits adopted an exacting "but-for" causation standard, under which a plaintiff must show "that the defendants would not have included particular 'items or services' [in claims for payment] absent the illegal kickbacks."[3] In contrast, the Third Circuit ruled that "resulting from" did not require "but-for" causation and instead only a "link" is needed—meaning only the demonstration of "some connection between a kickback and a subsequent reimbursement claim is required."[4]

Confusingly for litigants, judges in the U.S. District Court for the District of Massachusetts, located within the First Circuit's appellate jurisdiction, had issued multiple contradictory decisions on the issue—with two adopting the "but-for" standard and two rejecting it.[5] But the recent First Circuit opinion resolves the disagreement by joining the Sixth and Eighth Circuits in requiring a heightened showing by a plaintiff.

In *United States v. Regeneron Pharm., Inc.*, the First Circuit relied on Supreme Court precedent to conclude that the phrase "resulting from" presumptively imposes a requirement of "actual causality."[6] This would ordinarily require proof "that the harm would not have occurred . . . but for . . . the defendant's conduct."[7] The court found that nothing in the language of the AKS contradicted this presumption. The government made three contextual arguments to the contrary, focusing on the AKS's statutory scheme, statutory history and legislative history.[8] But the court rejected all three arguments and concluded it could "find no convincing 'textual or contextual' reason to deviate from the default presumption that the phrase 'resulting from' as used in the 2010 amendment imposes a but-for causation standard."[9] So, plaintiffs bringing FCA claims based on violations of the AKS in the First Circuit now face a high bar: They must establish that the submission of the allegedly false or fraudulent claim would not have occurred but for the kickback or kickback scheme at issue.

Stay tuned to Haynes Boone's News page for the latest news on other court opinions interpreting the elements of and defenses to an FCA claim as well as important legislation and enforcement actions. And if you have questions or need 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. Please also refer to the firm's annual False Claims Act – 2024 Year in Review publication.

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[1] 42 U.S.C. §1320a-7b(b).

[2] 42 U.S.C. § 1320a-7b(g) (emphasis added).

[3] See *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052–55 (6th Cir. 2023); *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 835 (8th Cir. 2022).

[4] See *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96–100 (3d Cir. 2018).

[5] Compare *United States v. Regeneron Pharm., Inc.*, No. 20-cv-11217, 2023 WL 6296393, at *10 (D. Mass. Sept. 27, 2023) (rejecting the Third Circuit standard for being "divorced from the actual language of the statute and from basic principles of statutory interpretation" and agreeing with the Sixth and Eighth Circuit's analysis to find "that the appropriate standard is but-for causation") *and Omni Healthcare, Inc. v. MD Spine Sols. LLC*, No. 18-cv-12558, 2025 WL 32676, at *8–9 (D. Mass. Jan. 6, 2025) (concluding "construing 'resulting from' to mandate a showing of but-for causation is consistent with basic principles of statutory interpretation") *with United States v. Teva Pharm. USA, Inc.*, 682 F. Supp. 3d 142, 146, 148 (D. Mass. 2023) (requiring only a "sufficient causal connection between an AKS violation and a claim submitted to the federal government," and rejecting the "but-for" causation standard) *and United States ex rel. Witkin v. Medtronic, Inc.*, No. 11-cv-10790, 2024 WL 1892405, at *19 (D. Mass. Mar. 31, 2024) (same).

[6] See *United States v. Regeneron Pharm., Inc.*, No. 23-2086, 2025 WL 520466, at *3 (1st Cir. Feb. 18, 2025) (citing *Burrage v. United States*, 571 U.S. 204, 211 (2014)).

[7] *Id.* (quoting *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346–47 (2013)).

[8] *See id.* at *5–*9.

[9] *Id.* at *10.