

Publications

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A Deepened Divide: Appellate Court Joins False Claims Act Circuit Split in Favor of Health Care Defendants

On February 18, 2025, the United States Court of Appeals for the First Circuit issued its opinion in *United States v. Regeneron Pharmaceuticals Inc.*, finding that, in Anti-Kickback Statute (AKS) cases, the government must show a claim would not have been submitted “but for” the AKS violation to establish False Claims Act (FCA) liability.¹

This appeal stemmed from allegations that Regeneron Pharmaceuticals induced prescriptions of Eylea, an ophthalmological drug, by covering copayments for certain recipients of the drug. The government contended that the funding of copayments constituted kickbacks and therefore resulted in false claims made to Medicare in violation of the FCA. At issue for the First Circuit was the interpretation of “resulting from” in the 2010 amendment to the AKS, which provides that 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 The Court ultimately decided that “statutory history provides no reason to deviate from the ordinary course, in which we treat ‘resulting from’ as requiring but-for causation” and that this interpretation would not render it difficult for the government to establish liability.³

The First Circuit’s ruling is favorable for health care providers, as it sets a higher bar for the government to prove causation in FCA cases involving AKS violations. Nevertheless, the decision deepens a circuit split regarding the causation requirements of FCA claims arising from AKS violations. While this decision aligns the First Circuit with the Sixth and Eighth Circuits, the decision contrasts with the Third Circuit, which requires only a demonstration of a link “between the alleged kickbacks and the medical care received . . .”⁴ This circuit split will continue to persist until the Supreme Court addresses the issue. However, the timing of such a decision is uncertain, especially after the Supreme Court declined to hear a related appeal from the Sixth Circuit in 2023.⁵

As courts continue to take on this issue, health care providers and FCA litigants should closely monitor developments in this area, particularly if they operate in jurisdictions without controlling case law. Understanding the applicable causation standard is crucial for navigating FCA litigation effectively and staying informed will be key to managing

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potential risks and liabilities as the legal landscape evolves.

Polsinelli's government investigations attorneys have extensive experience with the False Claims Act and Anti-kickback Statute and are prepared to assist with compliance or any potential enforcement action.

[1] *United States v. Regeneron Pharmaceuticals Inc.*, No. 23-2086, 2025 WL 520466 (1st Cir. Feb. 18, 2025).

[2] See 42 U.S.C. § 1320a-7b(g).

[3] *Regeneron Pharmaceuticals Inc.*, 2025 WL 520466, at *8-9.

[4] *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 93 (3d Cir. 2018).

[5] *United States, ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023), *cert. denied*, No. 23-139, 2023 WL 6378570 (Oct. 2, 2023).