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Fault Lines Expected to Deepen: Major False Claims Act Circuit Split

Health Care Law Brief on **October 11, 2024**

The health care industry is anxiously awaiting the First Circuit's ruling on the standard of causation for actions brought under the False Claims Act (FCA) predicated on a federal Anti-Kickback Statute (AKS) violation. The First Circuit will decide whether the FCA "result[s] from" a kickback if that claim would not have included the items or services payable by a federal health care program (FHCP) "but-for" such kickback.[1]

While the Sixth Circuit and the Eighth Circuit have concluded "yes,"[2] the Third Circuit concluded "no." As indicated in its briefs to the First Circuit, the government favored the Third Circuit approach, stating that the legislative history for the FCA's incorporation into the AKS[3] are relevant and that only a causal link or nexus between the AKS violation and the FCA claim is required.[4]

On July 22, 2024, the First Circuit heard oral argument. Based on the line of questioning, the panel judges seemed inclined to adopt the but-for causation standard.[5] For example, the panel judges used a hypothetical scenario involving changes to a physician's drug prescription pattern to compare outcomes under the different standards. Under such scenario, before receiving the alleged kickback, a physician prescribed 50 drugs from manufacturer A and 50 drugs from manufacturer B. After receiving the alleged kickback from manufacturer A, the physician's prescription patterns shifted to 75 drugs from manufacturer A and 25 drugs from manufacturer B.

For this scenario, the government contended it could view all 75 drugs from manufacturer A as actionable under the FCA because such drugs were prescribed after receipt of the kickback. The panel judges pressed the government on whether the mere existence of the kickback was enough, or whether the government must demonstrate whether and to what extent the kickback was the reason why any of the 75 drugs were prescribed in the first instance. The government reminded the panel judges that the AKS already criminalizes the offer, solicitation, provision, and/or receipt of a kickback, meaning that there need not be an actual claim submitted to any FHCP for there to be an AKS violation and, likewise, there need not be, under the hypothetical scenario, a prescription for any drug. The government's position was premised on its view that the "result[s] from" language was added by the Affordable Care Act (ACA) to the AKS as a codification of the link or nexus between an FCA claim premised on an AKS violation—not to require a more stringent, burdensome causation standard such as "but-for" causation.

By contrast, Regeneron explained that the Sixth and Eighth Circuits correctly concluded that but-for causation is appropriate and seemed to imply that the government should, and does, have the burden of proving each and every FCA claim premised on an AKS violation. For purposes of the hypothetical scenario, Regeneron would want, and expect, the government to prove a false claim resulting from each and every drug of the 75 drugs from manufacturer A that were prescribed post-kickback. Regeneron contextualized the "result[s] from" language in the ACA as analogous to the "result[s] in" language found in the Controlled Substances Act, citing United States Supreme Court precedent.[6]

Regardless of the First Circuit outcome, an obvious circuit split still exists that may be ripe for the Supreme Court to grant *certiorari*. If the First Circuit sides with Regeneron, then the government may have to balance the need for seeking clarity from the Supreme Court on whether three circuits are correct against the potential impact on its prosecutorial discretion at the district court level given the prevailing but-for causation. If the First Circuit restores balance to the circuit split and rules against Regeneron, then, as Regeneron noted in its appellate briefs, the defendants would remain exposed to damages, penalties, and other assessments of potentially hundreds of millions of dollars.[7]

The First Circuit decision will have a significant impact on FCA litigation and will affect the government's procedural posture when deciding to pursue FCA claims premised on AKS violations. It will also represent a major shift at the district court level in connection with dispositive motions seeking to dismiss FCA claims given the more stringent "but-for" standard. Moreover, it will affect the shape of the government's trial and jury instruction involving Regeneron. And FCA cases already in the pipeline will be affected if the government is evaluating whether to intervene. As is evident by the Third, Sixth, and Eighth Circuits' decisions, procedural posture is of utmost importance because it is integrally related with the potential, and likely, merits of the claims brought by the government.[8]

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[1] *U.S. v. Regeneron Pharmaceuticals, Inc.*, No. 23-2086 (1st Cir. 2024).

[2] *U.S. ex rel. Martin, et al. v. Hathaway, et al.*, 63 F.4th 1043 (6th Cir. 2023); *U.S. ex rel. Cairns, et al. v. D.S. Med LLC, et al.*, 42 F.4th 828 (8th Cir. 2022).

[3] The Patient Protection and Affordable Care Act of 2010 ("ACA") amended the AKS to add subsection (g): "In addition to the penalties provided for in [42 U.S.C. § 1320-7b] or [42 U.S.C. § 1320a-7a, the Civil Monetary Penalties Law], a claim that includes items or services resulting from a violation of [42 U.S.C. § 1320-7b] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320-7b(g).

[4] *U.S. ex rel. Greenfield v. Medco Health Sols. Inc.*, 880 F.3d 89 (3d Cir. 2018).

[5] A recording of the oral argument can be found here: ca1.uscourts.gov/sites/ca1/files/oralargs/23-2086_20240722.mp3.

[6] As interpreted by the Supreme Court, the phrase "results from" in the Controlled Substances Act requires but-for causation. *See Burrage v. United States*, 571 U.S. 204, 212 (2014).

[7] All of this obviously assumes the Supreme Court *grants* such *writ*.

[8] The Sixth Circuit affirmed the district court's dismissal of the *qui tam* complaint for the government's failure to establish a cognizable AKS violation. The Eighth Circuit reversed the district court's dismissal without prejudice the government's remaining claims after a jury verdict in favor of the government, and remanded for further proceedings. And the Third Circuit affirmed the district court's entry of summary judgment against the relator (the government chose not to intervene) and in favor of the defendants.

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