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Government Investigations & White-Collar Alert

February 26, 2025

First Circuit adopts "but-for" causation standard for FCA claims based on AKS violations

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The decision to adopt a stringent causation standard deepens an existing split with the Third Circuit, which applies a more lenient approach.

What's the impact?

- The First, Sixth, and Eighth Circuits require the government to demonstrate that the claims would not have occurred "but for" an illegal kickback, while the Third Circuit allows FCA liability if the kickback was merely a contributing factor, creating greater exposure.

- Given the split and the potential for the Supreme Court or Congress intervening to clarify, the government may choose in the meantime to pursue FCA cases based on AKS violations under the false certification theory.

The United States Court of Appeals for the First Circuit has issued a significant ruling in *United States v. Regeneron Pharmaceuticals, Inc.*, No. 23-2086, affirming that to establish liability under the False Claims Act (FCA) predicated on a violation of the Anti-Kickback Statute (AKS), the government must demonstrate that the alleged kickback was a "but-for" cause of the claim

submitted to a federal healthcare program. This decision aligns the First Circuit with the Sixth and Eighth Circuits, which have adopted a similar stringent causation standard. The First, Sixth, and Eighth Circuit decisions contrast with the Third Circuit's more lenient approach, thereby deepening an existing circuit split.

False claims "resulting from" anti-kickback statute violations

The FCA imposes civil liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" by the government.[1] A 2010 amendment to the AKS provides that a claim "resulting from" a violation of the AKS constitutes a false claim under the FCA.[2] The issue in *Regeneron* was the level of causation required to satisfy the "resulting from" language.

Regeneron background

In *Regeneron*, the government alleged that the pharmaceutical company violated the AKS by funding copayments for certain patients prescribed its drug Eylea, thereby inducing physicians to submit claims to Medicare for the drug. The government argued that Medicare claims for those patients who received copay assistance funded by Regeneron "resulted from" a violation of the AKS, resulting in "false or fraudulent" claims for purposes of the FCA.

Conversely, Regeneron argued that a claim "results from" an AKS violation only if it would not have been paid for by the government but for the AKS violation.

First Circuit's ruling

The First Circuit affirmed the district court's ruling, holding 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. The court reasoned that the phrase "resulting from" in the AKS necessitates a direct causal link between the kickback and the subsequent claim. Thus, if a physician would have prescribed and sought reimbursement for the drug irrespective of the alleged kickback, the claim does not meet the "but-for" causation standard required for FCA liability.

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[1] 31 U.S.C. § 3729(a)(1)(A).

[2] 42 U.S.C. § 1320a-7b(g)

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The emerging circuit split

The First Circuit joins the Sixth and Eighth Circuits in adopting the more stringent "but-for" causation standard for AKS-based FCA claims.[3] In these jurisdictions, the government must demonstrate that the claims would not have occurred but for an illegal kickback. The First, Sixth, and Eighth Circuit standard may limit the scope of FCA liability.

By contrast, the Third Circuit has adopted a more lenient approach, allowing for FCA liability if the kickback was merely a contributing factor to the submission of the claim.[4] This standard exposes entities to broader liability under the FCA.

The First Circuit ruling intensifies the existing circuit split regarding the causation standard in FCA cases predicated on AKS violations.

What does this mean for FCA enforcement?

Given the circuit split that has emerged and the government's emphasis on investigating and prosecuting FCA liability predicated on AKS violations, it is possible that the Supreme Court will ultimately resolve this issue. It is also possible that Congress will amend the FCA to clarify its intent and the appropriate causation standard.

In the meantime, the government may opt to pursue FCA cases based on AKS violations under the false certification theory. The false certification theory may be triggered where compliance with the AKS is a recognized precondition of payment under a federal healthcare program. Under this theory, a violation of the AKS can give rise to FCA liability where, in making a claim, a provider falsely certifies compliance with material conditions of payment (express false certification) or implies compliance with material conditions of payment by failing to disclose non-compliance (implied false certification). This theory predates the 2010 amendments.

In *Regeneron*, the First Circuit examined the false certification theory and opined that AKS cases based on the 2010 amendment and false certification cases are separate pathways to FCA liability. For instance, the Court said the 2010 amendment does not require any representation or certification of AKS compliance nor a showing of materiality. The Court's analysis makes clear that the false certification and 2010 amendment theories are distinct: the former is based on a false representation of AKS compliance, while the latter is based on an AKS violation regardless of whether a representation of compliance was made. As such, as the Court stated, "claims under the 2010 amendment run on a separate track than do claims under a false-certification theory."

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

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

AKS-predicated FCA cases continue to feature prominently in the government's recent overview of FCA settlements and judgments for fiscal year 2024 (ending September 30, 2024). The Department of Justice (DOJ) also reported the highest level of qui tam lawsuits in history in fiscal year 2024, many of which allege AKS violations and FCA liability under the 2010 amendment.

Only time will tell what impact the now-majority "but-for" causation standard will have on the government's intervention and enforcement decisions for cases that arise under the 2010 amendment. Still, entities should expect the government to continue to pursue and potentially prioritize FCA cases under the AKS false certification theory.

And as to that theory, courts will continue to grapple with it as an alternative to the statutory, "resulting from" approach. A key element of false certification cases is materiality—the certification must be material to the government's payment decision. [5] We expect litigants to argue that, in light of the majority "but-for" rule, AKS compliance can no longer be considered material per se.

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[5] *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016).

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