FIRST CIRCUIT ADOPTS BUT-FOR CAUSATION STANDARD FOR KICKBACK-PREMISED FALSE CLAIMS ACT ACTIONS

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On 18 February 2025, the First Circuit Court of Appeals issued its decision in *United States v. Regeneron Pharmaceuticals, Inc.*, determining that "but-for" causation is the proper standard for False Claims Act (FCA) actions premised on kickback and referral schemes under the Anti-Kickback Statute (AKS). This issue has divided circuits in recent years, with the Third Circuit requiring merely some causal connection, and the Sixth Circuit and Eighth Circuit requiring the more defendant-friendly proof of but-for causation between an alleged kickback and a claim submitted to the government for payment.

This issue has major implications for healthcare providers, pharmaceutical manufacturers, and other entities operating in the healthcare environment. Both the government and qui tam relators have frequently brought FCA actions premised on alleged kickback schemes, and these actions pose significant potential liability. A higher but-for standard for proving causation represents a key tool for FCA defendants to defend against such actions. There is a good chance that the government petitions the US Supreme Court to review the First Circuit's decision, and, given the growing split, there is certainly a possibility that this becomes the next issue in FCA jurisprudence that finds itself before the high court.

BACKGROUND ON AKS-PREMISED FCA ACTIONS AND THE GROWING CIRCUIT SPLIT

To establish falsity in an AKS-premised FCA action, a plaintiff has historically needed to show that the defendant (1) knowingly and willfully, (2) offered or paid remuneration, (3) to induce the purchase or ordering of products or items for which payment may be made under a federal healthcare program. In 2010, Congress added the following language to the AKS at 42 U.S.C. § 1320a-7b(g): "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]." (Emphasis added). Courts have generally agreed that the AKS, therefore, imposes an additional causation requirement for FCA claims premised on AKS violations. However, courts have been divided on how to define "resulting from" and the applicable standard for proving causation.

In 2018, the Third Circuit was faced with this issue and explicitly declined to adopt a but-for causation standard. Relying on the legislative history, the Third Circuit determined that a defendant must demonstrate "some connection" between a kickback and a subsequent reimbursement claim to prove causation.

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Four years later, the Eighth Circuit declined to follow the Third Circuit and instead adopted a heightened but-for standard based on its interpretation of the statute. The court noted that the US Supreme Court had previously interpreted the nearly identical phrase “results from” in the Controlled Substances Act to require but-for causation. In April 2023, the Sixth Circuit joined the circuit split, siding with the Eighth Circuit and adopting a but-for causation standard.

EYES TURN TOWARD THE FIRST CIRCUIT

In mid-2023, two judges in the US District Court for the District of Massachusetts ruled on this causation issue as it related to two different co-pay arrangements, landing on opposite sides of the split. In the first decision, *United States v. Teva Pharmaceuticals USA, Inc.*, the district court adopted the Third Circuit's “some connection” standard. The court indicated it was following a prior First Circuit decision—*Guilfoile v. Shields*—though *Guilfoile* had only addressed the question of whether a plaintiff had adequately pled an FCA retaliation claim, as opposed to an FCA violation. In the second decision, Regeneron, the district court declined to follow *Guilfoile* (given *Guilfoile* dealt with the requirements for pleading an FCA retaliation claim); instead, the district court in Regeneron followed the Sixth Circuit and Eighth Circuit in applying a but-for standard. These dueling decisions set the stage for the First Circuit to weigh in on the circuit split.

FIRST CIRCUIT ADOPTS BUT-FOR STANDARD

On 18 February 2025, the First Circuit issued its opinion in Regeneron, affirming the district court's decision and following the Sixth Circuit and Eighth Circuit in adopting a but-for standard. The court first determined that *Guilfoile* neither guided nor controlled the meaning of the phrase “resulting from” under the AKS. Turning to an interpretation of the statute, the First Circuit noted that “resulting from” will generally require but-for causation, but the court may deviate from that general rule if the statute provides “textual or contextual indications” for doing so. After a thorough analysis of the textual language and its legislative history, the First Circuit concluded that nothing warranted deviation from interpreting “resulting from” to require but-for causation. The court also rejected the government's contention that requiring proof of but-for causation would be such a burden to FCA plaintiffs that the 2010 amendments to the AKS would have no practical effect.

Notably, the First Circuit made clear that its decision was limited to FCA actions premised on AKS violations under the 2010 amendments to the AKS. The court distinguished such actions from FCA actions premised on false certifications, where a plaintiff asserts that an FCA defendant has falsely represented its AKS compliance in certifications submitted to the government.

TAKEAWAYS

1. The growing confusion and disagreement among district and circuit courts over this issue, coupled with the issue's import to FCA jurisprudence, creates the potential that this could be the next FCA issue decided by the US Supreme Court.
2. Until this split is resolved, FCA practitioners must pay close attention to the choice of venue for AKS-premised FCA actions.

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3. But-for causation presents an important tool for FCA defendants in AKS-premised FCA actions. But-for causation may allow a defendant to argue that even if it had acted with an intent to induce referrals, no actual referrals resulted from the conduct, which would allow a defendant to avoid FCA liability altogether. Alternatively, but-for causation may allow a defendant to argue that FCA damages are lower than the total referrals made where the plaintiff is unable to prove all referrals "resulted from" the improper arrangement.
4. While this is a significant win for FCA defendants, its impact may be somewhat limited for FCA actions that are not premised on AKS violations. It also remains to be seen whether the government and relators will begin bringing FCA actions premised on alleged false certifications of compliance with the AKS (rather than solely relying on an alleged AKS violation itself).

The firm's Federal, State, and Local False Claims Act practice group practitioners will continue to closely monitor developments on this issue, and we are able to assist entities operating in the healthcare environment that are dealing with AKS-premised FCA actions.

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