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Recent Circuit Litigation Continues to Highlight "But-For" Causation Requirement for the Government to Demonstrate an FCA Violation Predicated on an AKS Violation

Health Care Law Brief on **May 28, 2024**

In recent years, a circuit split among the United States Courts of Appeals has emerged over how courts have interpreted the False Claims Act's ("FCA") causation element in cases where a violation of the Anti-Kickback Statute ("AKS") is a predicate violation for the false claim. The spotlight is now on *U.S. v. Regeneron Pharmaceuticals, Inc.*, which is currently being briefed by the government and Regeneron before the United States Court of Appeals for the First Circuit ("First Circuit").

Circuit Split Context

Federal Circuits are generally divided into two groups on the causation standard. The United States Court of Appeals for the Sixth Circuit and Eighth Circuit have applied a restrictive "but-for" causation standard, which requires the government to prove that, but for the unlawful remuneration in violation of the AKS, the claims would not have been submitted. We previously wrote about how the Sixth Circuit decision in *Martin v. Hathaway, 63 F.4th 1043 (6th Cir. 2023)*, followed the Eighth Circuit's standard reflected in, among other cases, Cairns v. D.S. Med LLC, 42 F.4th 828 (8th Cir. 2022).

By contrast, the United States Court of Appeals for the Third Circuit, in *Greenfield v. Medco Health Sols. Inc.*, 880 F.3d 89 (3d Cir. 2018), used a "proximate" cause standard, concluding that, to prove causation, "some connection between a kickback and subsequent reimbursement claim" must be demonstrated. Thus, the Third Circuit applies a much more relaxed standard for demonstrating a violation of the FCA predicated on a violation of the AKS.

***Regeneron* District Court Decision**

In *Regeneron*, the core of the dispute focuses on whether Regeneron's donations to a patient assistance program ("PAP"), *viz.* a charitable foundation operating a fund for patients, to cover the costs of the expensive copayments for one of its drugs, violated the AKS. In sum, the government alleges that Regeneron made its donations with the purpose of inducing purchases of its drug.

The procedural history at the trial court level is intriguing. Regeneron filed a motion to dismiss, and the United States District Court for the District of Massachusetts ("District Court") denied it, applying the proximate cause standard used in Third Circuit Court of Appeal's decision from *Greenfield*. To prove causation, the District Court wrote, the government "need only prove that a particular patient was exposed to an illegal recommendation or referral and that a provider then submitted a claim for reimbursement pertaining to that patient."

However, the District Court changed course at the summary judgment stage when ruling on Regeneron and the government's cross-motions for summary judgment. There, the District Court opined using the Sixth and Eighth Circuits' standard—i.e., but-for causation. Although it found that the government had presented sufficient evidence to create a triable issue of fact under the but-for causation, the District Court found that the government had not established the requisite connection between Regeneron's AKS violation as a matter of law.

Regeneron then proposed that the District Court *sua sponte* certify its summary judgment ruling for interlocutory appeal. The District Court agreed, and the government filed its current petition for permission to appeal, which the First Circuit court granted.

Current Appeal

In its appellate brief to the First Circuit, the government urges the court to embrace the Third Circuit standard, reiterating that it need not prove that the claimed items or services would not have been provided but for a kickback. Rather, the government contends that the AKS "forbids kickbacks that are given to induce the purchase of particular items or services, regardless of whether the kickbacks can be shown to have altered medical decision making." Thus, according to the government, there is no need to prove that the kickback "altered medical decision making" because it is irrelevant for the proximate cause standard. If kickbacks are "given to induce the purchase of a particular drug, and the intended purchase then happens, a claim seeking reimbursement for the purchase includes *items or services resulting from*" a violation of the AKS for purposes of the FCA.

Regeneron contends that the Sixth and Eighth Circuits' standard is correct, requiring the government to prove a but-for causation. That standard is correct, according to Regeneron, because it "follows directly from the plain text of the statute Congress enacted and Supreme Court precedent." Specifically, the phrase "resulting from" in the AKS means but-for causation "absent some overriding textual or contextual indication to the contrary. … A demonstration of but-for cause reflects the ordinary meaning of that phrase and constitutes the minimum requirements for a finding of causation recognized by our law." Upon this basis, Regeneron concludes that, "[t]o show that Medicare-reimbursement claims submitted on behalf of patients who received co-pay assistance from a charity resulted from a violation of the AKS (on the government's theory, Regeneron's donations to the charity), the government must show that the claims would not have been submitted but for the donations."

The government has until next month to reply to Regeneron's brief.

Takeaways

A unique and noteworthy aspect of the *Regeneron* matter is that there have been favorable advisory opinions (e.g., 24-02) and guidance issued in 2005 by the Federal agency tasked with interpreting the AKS—the Office of Inspector General for the U.S. Department of Health and Human Services ("OIG")—regarding PAP donations. While both the government and Regeneron refer to OIG's 2005 guidance in their briefs, it is unclear whether the First Circuit will consider the rationale set forth in any of OIG's favorable advisory opinions since neither Regeneron nor the government refer to any such advisory opinion in their briefs.

Notwithstanding the regulatory requirement that an OIG advisory opinion is only issued to and binding upon the party requesting such an advisory opinion, the potential disconnect between OIG's seemingly favorable view of PAPs and the government's current prosecutorial agenda in *Regeneron* may result in an opportune moment for both Federal agencies to discuss and discern their enforcement priorities.

Proskauer is monitoring the developments of this case.

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