First Circuit Affirms Causation Defense for False Claims Act Based on AKS Violations

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On February 18, 2025, the United States Court of Appeals for the First Circuit issued a ruling in *United States v. Regeneron Pharms., Inc.*,[1] in which it held that when a lawsuit brought under the False Claims Act (the "FCA") is based on alleged violations of the Anti-Kickback Statute ("AKS"), the plaintiff (either the Department of Justice ("DOJ") or a relator acting on the government's behalf) must prove that the submission of a false claim would not have occurred "but-for" the AKS violation. This opinion is a significant win for defendants in the First Circuit (and the Sixth and Eighth Circuits, which have issued similar holdings) because the FCA plaintiff may have difficulty showing that the alleged kickback caused the submission of false claims for goods or services (e.g., a prescription drug or an implanted medical device). That said, the opinion should not be viewed as a license to dial back AKS compliance because the government has other routes, including criminal charges, to establishing liability based on AKS violations.

The Opinion. This matter arises from a lawsuit brought by DOJ against Regeneron related to Eylea, a prescription drug approved by the Food and Drug Administration to treat an eye condition called neovascular age-related macular degeneration (sometimes called "wet AMD"). For senior citizens, this drug is covered by the Medicare Part B program, under which Medicare pays 80 percent of the price of the drug and the beneficiary pays the remaining 20 percent as a copay. DOJ alleged that Regeneron's payment of more than $60 million to a foundation that provided copayment assistance to patients suffering from wet AMD violated the AKS because it functioned as a kickback to induce doctors to prescribe the drug. DOJ claimed that this alleged violation gave rise to FCA liability under a 2010 amendment to the FCA statute, which provides that "a claim [for reimbursement] that includes items or services resulting from a violation of [the AKS]" is a *per se* FCA violation.[2] DOJ argued that "resulting from" means that an AKS violation is necessarily an FCA violation. Regeneron, by contrast, argued for a "but-for" causation standard, meaning DOJ would have to prove that the government would not have paid for the drug absent the copay assistance. Put

[1] No. 23-2086, 2025 WL 520466 (1st Cir. Feb. 18, 2025).

[2] 42 U.S.C. § 1320a-7b(g).

differently, there would be no FCA liability if the doctor would have prescribed the drug even absent the copay assistance. The District Court agreed with Regeneron but granted an interlocutory appeal to the First Circuit to opine on this important issue.

The First Circuit affirmed that the words "resulting from" meant that there would be FCA liability only with respect to claims that would not have occurred **but-for** the AKS violation. Similar to the Sixth and Eighth Circuits, the First Circuit relied on prior Supreme Court precedent holding (in a different context) that the words "resulting from" create "a requirement of actual causality."[3] It therefore held that "to demonstrate falsity under the 2010 amendment, the government must show that an illicit kickback was the but-for cause of a submitted claim."[4] This holding deepens a split among circuits—with the First, Sixth and Eighth Circuits holding that proof of "but-for" causation is required and the Third Circuit holding that no such proof is required. It remains to be seen whether the United States Supreme Court will ultimately resolve this split.

While the First Circuit's discussion of the causation requirement under the 2010 amendment is decidedly helpful for FCA defendants, it also includes a less-than-helpful discussion about an entirely different pathway by which an FCA plaintiff can establish liability without proof of causation: false certification. The opinion discussed circumstances where the FCA plaintiff either proceeds under a theory of (i) express false certification (where the claimant specifically represents that it is complying with the AKS when it is violating the AKS) or (ii) implied false certification (where the claimant makes representations that do not directly address the AKS but are impliedly rendered false because of an AKS violation, e.g., certain types of representations about compliance). The court did note, however, that FCA plaintiffs who proceed under an implied false certification theory must meet the burden of showing that "AKS compliance was material to the government's payment decision"[5] (meaning that the government would not have provided reimbursement had it known of the AKS violations).

Lessons for Life Science and Healthcare Companies. DOJ (or relators acting on DOJ's behalf) are frequently on the lookout for cases where they believe a healthcare or life science company is providing some form of "kickback" that is leading providers to submit false claims to the government because these cases often lead to large recoveries. Such claims could mirror those brought against Regeneron (the alleged misuse of foundations to provide unlawful copay assistance); improper "speaker programs" that have the effect of compensating healthcare providers for prescribing certain drugs;

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3 *Burrage v. United States*, 571 U.S. 204, 211 (2014).

4 *Regeneron*, 2025 WL 520466, at *10.

5 *Id.* at *8.

incentives provided by a device manufacturer to surgeons to implant a specific device; or improper financial relationships between hospitals and local physicians. DOJ has several routes to establishing the liability of a company paying kickbacks: it can bring a civil or criminal action for an AKS violation or it can bring an FCA action if it can establish a viable linkage between the two statutes. In the case of relators, their only route to bringing an action (and potentially attaining a large recovery) is to bring an FCA action that is predicated on AKS violations. Therefore, where the rulings of the First, Sixth and Eighth Circuits are in force, defense counsel should seek to clarify whether the FCA plaintiff is proceeding under the 2010 amendment and, if so, seek to muster evidence (as appropriate) that prescribers' decisions were motivated by professional medical judgment and were not influenced by the alleged kickback. If the FCA plaintiff is proceeding under an implied false certification theory, defense counsel should seek (as appropriate) to (i) challenge the claim that the representations at issue impliedly certified compliance with the AKS and/or (ii) that the alleged violations were not material, i.e., the government would have provided reimbursement regardless of the alleged violation.

In any event, the best strategy is to develop rigorous compliance programs that seek to mitigate the risks of FCA suits arising in the first place (or lay the foundation for a robust defense if a suit is filed). Healthcare and life science companies should ensure that programs that potentially present elevated risk (including, for example, copay assistance and speaker programs) are developed and operated with the oversight of qualified compliance and legal personnel. In particular, if a pharmaceutical company is funding a patient assistance program that may be providing support to patients who are prescribed a drug that their company sells, the company should ensure that the program is appropriately vetted by skilled outside counsel. DOJ has brought a number of enforcement actions against companies that were funding patient assistance programs that it believed were improper, and the Department of Health and Human Services—Office of Inspector General has provided detailed guidance through, among other things, advisory opinions regarding the parameters of such programs. Additionally, companies should consider periodic audits and risk assessments by experienced counsel and outside vendors to ensure continuing compliance.

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Please do not hesitate to let us know if you have any questions.

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