Skirting Anti-Kickback Causation Standard Amid Circuit Split

By **Matthew Modafferi and Terence Park** (February 8, 2024)

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An emerging split among the federal appellate courts on the proper causation standard that applies to False Claims Act suits based on Anti-Kickback Statute violations is set to expand to a fourth circuit.

On Dec. 22, 2023, the U.S. Court of Appeals for the First Circuit announced that it will hear an interlocutory appeal to address the AKS causation standard in U.S. v. Regeneron Pharmaceuticals Inc., and thus will likely join the U.S. Courts of Appeals for the Third, Sixth and Eighth Circuits, which have already weighed in on the issue.

Regardless of how the First Circuit rules, however, at present and until the U.S. Supreme Court resolves the circuit split, defense lawyers will continue to pursue but-for causation defenses to alleged AKS-based FCA claims.

This article discusses the Regeneron case, the current circuit split, and potential arguments and theories that the government and relators may have to avoid motions to dismiss based on the but-for causation standard.

The Regeneron Case

As stated in a September 2023 decision by the U.S. District Court for the District of Massachusetts, the government alleged that Regeneron Pharmaceuticals, which manufactures the retinal injection drug Eylea, "funneled millions of dollars to the Chronic Disease Fund ... — a purportedly independent charitable foundation — to subsidize patient co-pays for Eylea."

The routine coverage of patient co-pays made Eylea highly attractive to both physicians and patients alike. Further, it allowed Regeneron to charge a higher price for the drug — here, $1,850 per dose — because the company knew that patients would not be responsible for the drug's high cost.

Regeneron allegedly profited in the tens of millions of dollars from the resulting increase in Eylea sales, much of which was paid by Medicare.

Notably, however, there was no direct quid pro quo agreement or understanding between Regeneron and the prescribing doctors to prescribe Eylea in exchange for payments to the Chronic Disease Fund. Instead, the kickback scheme indirectly influenced doctors to prescribe more of Eylea due to the lower cost borne by the patient.

Which causation standard is applied to such an indirect kickback scheme is critical.

Before the district court, the government argued for a causation standard that requires only a logical connection between the illegal kickbacks and the claims submitted to Medicare.[1]

Regeneron argued that the proper causation standard is but-for causation, i.e., that the government must prove that the doctors would not have prescribed Eylea had Regeneron not made the payments to the Chronic Disease Fund. This is the issue now up for appeal before the First Circuit.

The Emerging Circuit Split on the AKS Causation Standard

Unfortunately for the government, the 2022 U.S. Court of Appeals for the Eighth Circuit decision in U.S. ex rel. Cairns v. D.S. Medical LLC and the 2023 U.S. Court of Appeals for the Sixth Circuit decision in U.S. ex rel. Martin v. Hathaway both held that FCA claims based on AKS violations must satisfy the more stringent but-for causation standard.[2]

Both courts reached this conclusion based on the text of the 2010 amendment to the AKS, which provides, in relevant part, that "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]."[3]

The phrase "resulting from," according to the Eighth Circuit's opinion, "imposes ... a requirement of actual causality" and thus "expresses a but-for causal relationship."[4] Under the Sixth and Eighth Circuit standard, an FCA violation does not exist if the prescribing doctor would have submitted a claim regardless of whether a kickback was made.

In contrast, the U.S. Court of Appeals for the Third Circuit's 2018 decision in U.S. ex rel. Greenfield v. Medco Health Solutions Inc., relying heavily on the legislative history and purpose of the AKS, held that but-for causation is not required.

Instead, the government must show that at least one patient is "exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient."[5]

In other words, if a patient is referred to a provider in exchange for a kickback, and the provider submits a claim for that patient, the causation requirement is satisfied, even if the provider would have submitted the same claim in the absence of the kickback.

It is unclear how the First Circuit will rule, but, in its 2019 opinion in Guilfoile v. Shields, the court appeared to cite the Third Circuit's Greenfield decision with approval, and specifically stated that the resulting-from language only requires a "sufficient causal connection between an AKS violation and a claim submitted to the federal government."[6]

If this dictum from Guilfoile offers any clue, the First Circuit will likely lean toward the Third Circuit's more relaxed standard — although this remains to be seen.

Using the Express False Certification Theory to Get Around the But-For Causation Standard

The Sixth and Eighth Circuits adopted the but-for causation standard based on the statutory language in Title 42 of the U.S. Code, Section 1320a-7b(g).

However, these decisions leave open whether it is possible to bring an AKS-based FCA claim without relying on that statutory provision. Instead, litigants may seek to avoid that provision altogether by relying on an "express false certification" theory of FCA liability.

Under the express false certification theory, FCA liability attaches where a person or entity seeking payment certifies that it has complied with a particular legal or contractual requirement that is a condition of payment.[7]

It is well settled that compliance with the AKS is a material condition of payment for government health programs, including Medicare and Medicaid.[8] Also, virtually all claims submitted to the government use a claims form containing a certification of compliance with the AKS.

Therefore, we may begin to see the government and relators take the position that they need not prove that any false claims resulted from the payment of kickbacks — which would trigger the strict but-for causation standard — because, regardless of causation, the provider certified compliance with the AKS and the certification is false.

At least one court has found this argument persuasive — the U.S. District Court for the District of Minnesota, in its Jan. 4 decision in U.S. v. Cameron-Ehlen Group Inc.[9] But it is not yet clear whether this theory will hold water, especially on appeal, since this alternate theory would effectively render the resulting-from language of Section 1320a-7b(g) superfluous or ineffective.[10]

Takeaways

The growing circuit split means that where an FCA suit is filed is more important than ever. In a jurisdiction that has adopted the but-for causation standard, the government will have a more difficult time overcoming motions to dismiss and meeting its burden of proof at trial.

Additionally, if more courts adopt the but-for causation standard, it may severely curtail the government's ability to bring FCA suits that are based on indirect kickback schemes like the one at issue in Regeneron.

While all this sounds positive for potential FCA defendants, the government is not without recourse.

Specifically, because the but-for causation standard only applies to FCA suits, and not to criminal prosecutions under the AKS itself — an incongruity courts have already noted — wider adoption of the but-for standard may provide the government incentive to opt for criminal enforcement when facing a provider that has participated in a kickback scheme.

Indeed, there may be instances where it is potentially easier for the government to obtain a criminal conviction than to pursue a civil remedy.

Attorneys handling FCA claims await the Regeneron decision and for the Supreme Court to grant certiorari in a case to determine the AKS causation standard in the not-too-distant future. This appears at least somewhat likely, given the court's recent decisions resolving other FCA circuit splits.

In the meantime, attorneys litigating AKS-based FCA claims in districts that have adopted the but-for causation standard should carefully evaluate whether the evidence could satisfy the but-for standard, and the availability of any legal theories that might be used to circumvent that heightened causation standard.

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[1] See U.S. v. Regeneron Pharms. Inc., Civil Action No. 20-11217-FDS, 2023 U.S. Dist. LEXIS 191418, at *28 (D. Mass. Oct. 25, 2023).

[2] See U.S. ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 834 (8th Cir. 2022); and U.S. ex rel. Martin v. Hathaway, 63 F.4th 1043, 1052 (6th Cir. 2023).

[3] 42 U.S.C. § 1320a-7b(g).

[4] U.S. ex rel. Cairns, 42 F.4th at 834.

[5] U.S. ex rel. Greenfield v. Medco Health Sols. Inc., 880 F.3d 89, 100 (3d Cir. 2018).

[6] Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019).

[7] See U.S. ex rel. Lemmon v. Envirocare of Utah Inc., 614 F.3d 1163, 1168 (10th Cir. 2010).

[8] U.S. ex rel. Wilkins v. United Health Grp. Inc., 659 F.3d 295, 313 (3d Cir. 2011).

[9] U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp. Inc., No. 13-cv-3003 (WMW/DTS), 2023 U.S. Dist. LEXIS 788, at *47 (D. Minn. Jan. 4, 2023).

[10] U.S. ex rel. Louderback v. Sunovion Pharms. Inc., No. 17-cv-1719 (ECT/LIB), 2023 U.S. Dist. LEXIS 209990, at *36 (D. Minn. Nov. 27, 2023) (criticizing the Fesenmaier decision as rendering 42 U.S.C. § 1320a-7b(g) with "little practical effect").