Circuit Split Leaves Anti-Kickback Statute Standard Ripe for Guidance from the Supreme Court

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The First Circuit in *United States v. Regeneron* has joined two of its sister Circuits in adopting the "but for" standard to find that a violation of the Anti-Kickback Statute ("AKS") triggers the False Claim Act ("FCA"). Accordingly, the Third Circuit (which has jurisdiction over New Jersey, Pennsylvania, Delaware and the U.S. Virgin Islands) is now the lone federal Circuit Court relying on the less burdensome "causal link" standard to prove that a violation of the AKS also violates the False Claims Act. This widening split among the federal Circuits may mean that the issue is finally ripe for guidance from the United States Supreme Court.

Legislative History

The AKS criminalizes, in relevant part, the "knowing" and "willful" offer or payment of "any remuneration (including any kickback, bribe, or rebate)" to induce a person to "recommend ... ordering any ... service ... for which payment may be made in whole or in part under a [f]ederal health care program."[1] In other words, the AKS targets any remunerative scheme through which a person receives or solicits payment in return for directing a patient to a program under which payments may be made from federal funds.

Notably, there are statutory and regulatory safe harbors that protect certain business arrangements that might otherwise violate the AKS.[2] Those common business arrangements include personal services and management contracts, warranties, discounts, employment, GPOs, and certain managed care and risk sharing arrangements.[3] However, "[t]hese safe harbors apply only in very specific instances, to exempt[ ] only a small subset of such transactions."[4] Furthermore, while not satisfying a safe harbor does not necessarily mean that an arrangement is illegal under the AKS, safe harbor protection requires strict compliance with each of safe harbor elements; substantial compliance is not enough.[5]

The FCA offers protection to whistleblowers who seek to expose or to prevent government fraud. To enhance enforcement of the law, under the FCA, a private person, known as a relator, can sue any person who has submitted false claims for payment to the United States Government.[6] The suit, known as a qui tam action, is one in which "[t]he suit is brought in the Government's name, and the Government has the exclusive opportunity to intervene."[7]

In 2010, Congress amended the AKS to create an express link to the False Claims Act. Consequently, the AKS now provides "a claim that includes items or services resulting from a violation of [that Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."[8] The FCA, in turn, imposes civil liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[9]

The Statute does not define the term "resulting from." Consequently, the Circuits have split in their interpretation of the AKS's meaning of the words "resulting from."

Split Among the Circuits

The Third Circuit in *United States ex rel. Greenfield v. Medco Health Sols., Inc.,* interpreted the meaning of "resulting from" in 42 U.S.C. § 1320a-7b(g) by evaluating what "link" is sufficient to connect an AKS violation to a subsequent submission of a reimbursement claim subject to the FCA: a direct causal link, no link at all, or something in between.[10] Relying on legislative history and the drafters' intentions to interpret the statute, the Third Circuit adopted a lenient standard and simply determined that there must be "some connection" between a kickback and a subsequent challenged claim.[11] Thus, "[a] kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to

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that patient."[12] This more lenient standard is often referred to as the causal link standard.

In contrast, the First Circuit joined the Sixth and Eighth Circuits in adopting the more stringent view that the phrase, "resulting from," as used in the 2010 AKS amendment, imposes a "but-for" causation standard. A "but-for" causation standard requires proof that the harm would not have occurred in the absence of, i.e., but-for, the defendant's conduct.[13] Pursuant to the "but-for" causal standard, the government must establish that the defendants would not have included particular "items or services" absent the illegal kickbacks.[14]

The First Circuit in United States v. Regeneron found that an ordinary interpretation of the phrase "resulting from" would impose a "but-for" causation standard.[15] The First Circuit rejected the government's contextual arguments for deviating from the default but-for causation standard.[16] In contrast to the Third Circuit, the First Circuit found arguments regarding statutory history and legislative intent unconvincing.[17]

In rejecting the argument that any alleged false claims caused the violation of the anti-kickback statute, the Sixth Circuit in United States ex rel. Martin v. Hathaway cautioned that "reading causation too loosely or remuneration too broadly appear as opposite sides of the same problem."[18] The court expressed concern that "the statute does little to protect doctors of good intent, sweeping in the vice-ridden and virtuous alike."[19] However, the court ultimately determined that a faithful interpretation of the phrase "resulting from" requires a "but-for" causation standard "leaves plenty of room to target genuine corruption."[20] The Sixth Circuit did not consider legislative history in its interpretation because the court found it generally does not rely on legislative history in construing a statute with criminal applications.[21]

Likewise, the Eighth Circuit in United States ex rel. Cairns v. D.S. Med. LLC stated that its "holding here should be no surprise."[22] The court determined that courts regularly read phrases like "results from" to require but-for causality and there is no textual or contextual indication to the contrary.[23] Thus, the Eighth Circuit also rejected the Third Circuit's approach.[24]

Key Takeaways

The Third Circuit has adopted a more lenient causation standard that is less favorable to defendants. Conversely, the First, Sixth, and Eighth Circuits have adopted a "but-for" causation standard that arguably makes it more difficult for the government, as well as qui tam relators to establish liability. These substantially different standards could lead to a pattern of different results for similar AKS claims based on jurisdiction. Notably, the Supreme Court denied certiorari following the Sixth Circuit's decision in Hathaway. However, the First Circuit's decision and the recent expansion of this circuit split may finally motivate the Supreme Court to clarify the appropriate applicable standard when evaluating the meaning of "resulting from" as set forth in 42 U.S.C. § 1320a-7b(g). In addition, the increasing adoption of the "but-for" causation standard among the Circuits may impact settlements and judgments under the FCA. Settlements and judgments under the False Claims Act exceeded $2.9 billion in fiscal year 2024.[25] Over $2.4 billion of that figure arose from lawsuits that were filed pursuant to the qui tam provisions of the FCA and pursued by either the government or whistleblowers.[26] Moreover, matters involving the health care industry represented a disproportionately large role in FCA recoveries.[27] Of the more than $2.9 billion in FCA recoveries, over $1.67 billion related to health care matters, including managed care providers, hospitals and other medical facilities, pharmacies, pharmaceutical companies, laboratories, and physicians.[28] Accordingly, FCA recoveries for AKS violations may decline as Circuits abandon the more lenient causal link standard and embrace the more stringent "but-for" causation standard.

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[1] 42 U.S.C. § 1320a-7b(b)(2)(B).

[2] 42 U.S.C. § 1320a–7b(b)(3)(A)–(J).

[3] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731-01.

[4] U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 47 (D. Mass. 2011) (internal citations omitted).

[5] See id.

[6] 31 U.S.C. §§ 3729(a), 3730(b)(1).

[7] United States ex rel. Johnson v. Kaner Med. Grp., P.A., 641 F. App'x 391, 393 (5th Cir. 2016) (per curiam) (citing 31 U.S.C. § 3730(b)(1), (4)–(5)).

[8] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 759 (2010) (codified at 42 U.S.C. § 1320a-7b(g)).

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policy changes aren't just numbers, they shape lives. We owe it to our communities to fight for sustainable, compassionate healthcare." – Rahmatu Danawudu

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[9] *31 U.S.C. § 3729(a)(1)(A), (a)(1)(B).*
[10] *United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018).*
[11] *Id. at 89.*
[12] *Id.*
[13] *Burrage v. United States, 571 U.S. 204, 211 (2014).*
[14] *United States ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 835 (8th Cir. 2022).*
[15] *United States v. Regeneron Pharms., Inc., 128 F.4th 324, 329 (1st Cir. 2025).*
[16] *Id.*
[17] *Id.*
[18] *United States ex rel. Martin v. Hathaway, 63 F.4th 1043, 1054 (6th Cir.), cert. denied, 144 S. Ct. 224 (2023).*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *United States ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 835 (8th Cir. 2022).*
[23] *Id.*
[24] *Id. at 837.*
[25] *https://www.justice.gov/archives/opa/pr/false-claims-act-settlements-and-judgments-exceed-29b-fiscal-year-2024.*
[26] *Id.*
[27] *Id.*
[28] *Id.*