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# Anti-Kickback Circuit Split Holds Implications For Defendants

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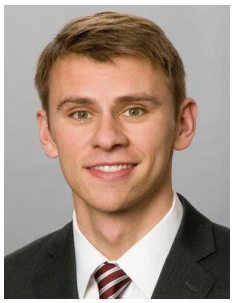

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A recent U.S. Court of Appeals for the Eighth Circuit decision, U.S. v. D.S. Medical LLC,[1] creates a circuit split on the proper causation standard for False Claims Act liability in cases involving purported Anti-Kickback Statute violations.

AKS-based FCA cases have resulted in billions of dollars in federal recoveries from entities in the health care industry, as both the government and qui tam relators aggressively pursue various AKS-based liability theories against drug and device manufacturers, diagnostic companies, providers of health care, and others in related industries, e.g., electronic health records entities.

In these cases, FCA plaintiffs invoke the specter of astronomical damages and penalties by asserting that improper remuneration taints — and thereby renders false or fraudulent — every subsequent claim for government program reimbursement.

But the Eighth Circuit's recent D.S. Medical decision, which is grounded in the plain language of the AKS and long-standing common-law principles, raises the bar to prove causation in AKS-based FCA cases.

In imposing a more rigorous standard, the Eighth Circuit also departed from precedent established by the U.S. Court of Appeals for the Third Circuit. This emerging circuit split could press the U.S. Supreme Court to interpret this important provision of the AKS in the near future.

**FCA and AKS Causation Elements**

The Eighth Circuit's decision arises from the interplay between the FCA and AKS. Under the FCA, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the government is liable for civil penalties, as well as up to three times the damages that the government sustains because of those claims.[2]

The AKS prohibits companies and individuals from offering, paying, soliciting or receiving remuneration to induce or reward referrals of business covered by Medicare, Medicaid or other federal health care

programs.[3]

The term "remuneration" generally has been defined to mean anything of value; thus, the AKS potentially reaches an extraordinary amount of conduct in the health care sphere. As amended by the Affordable Care Act in 2010, the AKS also provides 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]."[4]

Litigants in AKS-predicated FCA cases have pressed varying interpretations of the "resulting from" language in the amended AKS. The government and qui tam relators routinely argue that AKS violations taint subsequent claims submitted by or caused by those who received the remuneration at issue.

Defendants, however, contend that the statute's text imposes a more meaningful barrier and requires both but-for and proximate causation.

In recent years, several federal courts, including the Third Circuit in U.S. v. Medco Health Solutions Inc.,[5] have applied a purported middle-ground approach that requires an ill-defined link between the alleged kickbacks and subsequent reimbursement claims submitted by health care providers.

**The Third Circuit's Approach in Medco Health Solutions**

In Medco Health Solutions, a relator claimed that a pharmacy violated the AKS by donating to specific charities in return for patient referrals and then violated the FCA by falsely certifying that it complied with the AKS when seeking reimbursement for care provided to the referred patients.[6]

At the summary judgment stage, the U.S. District Court for the District of New Jersey concluded that the relator failed to offer evidence of any federal reimbursement claim linked to the alleged kickback scheme.[7]

The court reasoned that, even assuming the existence of an AKS violation, the relator could not establish an FCA violation without providing some evidence that the patients chose the pharmacy because of the donations at issue.[8] In other words, the court was unwilling to simply infer that false claims resulted from the alleged kickbacks without some evidence of that connection.

The Third Circuit affirmed the district court's ruling but departed from its causation analysis in significant part.

The court rejected the notion that the taint of alleged kickbacks automatically renders every reimbursement claim false and clarified that it is not enough at the summary judgment stage merely to show temporal proximity between the alleged kickback plot and the submission of claims for reimbursement.[9] But the Third Circuit stopped short of imposing a but-for causation standard based on the phrase "resulting from."

In light of potential incongruous results from doing so — namely, that but-for causation would be a requirement for bringing a civil FCA case but not an AKS case predicated on the same conduct — the Third Circuit looked to the legislative history of the FCA and AKS.[10]

The Third Circuit concluded that Congress intended both statutes to reach a broad swath of fraud and abuse in the federal health care system and that neither requires a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider.[11] Accordingly, the Third

Circuit asserted a relator need not provide proof that the underlying medical care would not have been provided but for a kickback.[12]

Instead, the Third Circuit required only that there is some record evidence that shows a link between the alleged kickbacks and the medical care received by at least one of the defendant's federally insured patients, or, in this case, that the relator point to at least one claim that covered a patient who was recommended or referred to the pharmacy by the charities in question.[13]

Since the Third Circuit's decision, federal courts have struggled to articulate this standard.[14]

**The Eighth Circuit's Decision in D.S. Medical**

The Eighth Circuit took a more textual, traditional approach in D.S. Medical, holding that the "resulting from" language in the AKS creates a but-for causal requirement between an anti-kickback violation and the items or services included in the claim to the government.[15]

In D.S. Medical, the relators brought an FCA suit against a neurosurgeon and his fiancée, the neurosurgeon's medical practice and a spinal implant distributor owned by the neurosurgeon's fiancée, on the grounds that commissions on the purchase of particular devices and stock offers from the manufacturer of devices used by the neurosurgeon were unlawful kickbacks.

The government intervened, alleging that the defendants submitted Medicare and Medicaid claims that were false under the FCA because of underlying AKS violations.

After trial, the jury returned a verdict in favor of the government on two of its three AKS-based FCA claims, awarding treble damages and statutory penalties totaling nearly $5.5 million. The defendants appealed, arguing that the court erred in failing to instruct the jury on but-for causation.[16]

Citing to a Supreme Court case interpreting the phrase "results from" in the Controlled Substances Act, the Eighth Circuit emphasized that it had little trouble concluding that, in common and ordinary usage, the participle phrase "resulting from" as used in the AKS also expresses a but-for causal relationship.[17]

Thus, according to the Eighth Circuit, it is necessary to prove that the defendants would not have included particular items or services absent the illegal kickbacks to demonstrate causation and falsity in AKS-premised FCA claims.[18]

The Eighth Circuit also rejected the government's contentions that AKS violations tainted claims submitted by those subject to the alleged kickback scheme and all that is required is that the anti-kickback violation itself may have been a contributing factor.[19]

The court explained that a taint could occur without the illegal kickbacks motivating the inclusion of any of the items or services; thus, showing that an AKS violation may have been a contributing factor does not establish anything more than a mere possibility.[20]

Although it acknowledged the Third Circuit's decision in Medco Health Solutions, the Eighth Circuit reiterated that its approach prioritized the statute's plain language over the legislative history and intuited intent of those who drafted the 2010 amendments to the AKS.[21]

In particular, the Eighth Circuit rejected the government's argument that the 2010 amendments codified

the pre-2010 cases, suggesting that a failure to disclose an AKS violation — regardless of the relationship between the illegal kickbacks and the items or services included — was sufficient.[22]

The court explained that "resulting from" is unambiguously causal, and that Congress could have selected different language had it wished to codify prior cases.[23]

**The Potential Impact of D.S. Medical**

This circuit split likely will have a significant impact on defendants' financial exposure in AKS-based FCA cases.

***Impact on the Taint Theory of Liability and Damages***

Despite significant questions regarding its continued viability after the 2010 AKS amendments, the taint theory has long driven the government's and relators' expansive liability and damages arguments in AKS-predicated FCA cases.

Some courts, including the Third Circuit in Medco Health Solutions, had started to push back on the most sweeping formulations of that theory. But even middle-ground approaches provided little solace to defendants because any dilution of the causation standard swells the scope of potential damages.

Under Medco Health Solutions and cases following it, the burden to allege or establish a link between purported kickbacks and claims submitted to the government has proven minimal in practice.

At least at the motion to dismiss stage, some courts have concluded that relators need only allege that the referral at issue actually sat in the causal chain to survive.[24]

As the U.S. District Court for the Southern District of New York put it in one such case, the link required is less than showing that the bribe succeeded in producing the prescription.[25]

Although defendants ultimately may succeed in defending against attenuated AKS-based FCA claims, permitting plaintiffs to proceed past the pleading stage in these circumstances can expose defendants to burdensome and costly discovery, as well as colossal damages estimates.

***Increased Importance of Expert Analysis***

Based on the taint theory, the government and relators historically have shrugged off questions about evidence tying kickbacks to particular claims.

D.S. Medical upends this approach. If the courts hold FCA plaintiffs to a higher causation standard, parties are likely to rely more heavily on econometric experts to untangle correlation from causation. FCA plaintiffs may assert that a drug or device manufacturers' speaker programs or consulting relationships with physicians increased prescriptions or orders.

But defendants may well be able to disprove a causal connection by leveraging data indicating that the recipients already were prescribing or ordering the products at issue or showing that the physicians received similar remuneration from defendants' competitors as well.

Because a strict but-for causation standard requires consideration of more granular potential factors,

the D.S. Medical approach may well decrease estimated damages in these cases.

***More Rigor in Analysis of the AKS and FCA***

As the Supreme Court has observed, the FCA should be construed in accordance with common-law fraud principles.[26] Similarly, even in statutes like the AKS, textual phrases that stem from common-law concepts should be interpreted in line with long-standing legal principles.

Yet, in Medco Health Solutions and other cases, the federal courts often allow perceived legislative intent to warp the interpretation of the statute's text and underlying common-law principles. If followed by other federal courts, D.S. Medical may spur increased attention to textual, traditional arguments about the proper contours of the AKS and FCA.

It remains to be seen whether other courts will follow D.S. Medical in applying but-for causation when evaluating AKS-based FCA suits at the motion to dismiss and summary judgment stages. Regardless, the Eighth Circuit's decision represents a significant step toward holding FCA plaintiffs to more exacting burdens of proof in AKS-related FCA suits.

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[1] United States ex rel. Cairns v. D.S. Medical LLC, No. 20-2445, --- F.4th ----, 2022 WL 2930946 (8th Cir. July 26, 2022).

[2] 31 U.S.C. § 3729(a)(1).

[3] 42 U.S.C. § 1320a-7b(b).

[4] 42. U.S.C. § 1320a-7b(g).

[5] United States ex rel. Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89, 100 (3d Cir. 2018).

[6] Id. at 91–92.

[7] Id. at 91.

[8] Id. at 93, 95.

[9] Id. at 100.

[10] Id. at 96–97.

[11] Id.

[12] Id. at 96

[13] Id. at 99, 100

[14] See, e.g., United States ex rel. Arnstein v. Teva Pharm. USA, Inc., No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *24 (S.D.N.Y. Feb. 27, 2019).

[15] 2022 WL 2930946, at *1.

[16] Id. at *1, 2.

[17] Id. at *4 (citing Burrage v. United States, 571 U.S. 204, 213 (2014)).

[18] Id.

[19] Id.

[20] Id.

[21] Id. at *5, 6.

[22] Id. at *5.

[23] Id.

[24] Arnstein, 2019 WL 1245656, at *24; see also United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-cv-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) ("[A] claim is false if it seeks reimbursement for a prescription that was not provided in compliance with the [AKS], regardless of whether the claim was the result of a quid-pro-quo exchange or would have been submitted even absent the kickback.").

[25] Arnstein, 2019 WL 1245656, at *24.

[26] See Universal Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176, 187 n.2 (2016) (in FCA cases, "we presume that Congress retained all other elements of common-law fraud that are consistent with the statutory text").