

The False Claims Act and the Anti-Kickback Statute: Causation, Materiality, and the Connection Between the Two

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Violations of the federal Anti-Kickback Statute (the “AKS”)[1] have long served as a basis for liability under the federal False Claims Act (the “FCA”).[2] Recently, however, there has been increasing uncertainty regarding how far a violation of the AKS sweeps to render claims “false” under the FCA. Courts are currently at odds with each other regarding the appropriate causation standard—how directly an AKS violation must *cause* submission of a claim—in order for that claim to be false under the FCA. Because FCA defendants are liable for up to treble damages, plus substantial fines and penalties, for every false claim, this current state of flux has significant implications for the scope of damages in FCA cases predicated on violations of the AKS.

In its 2016 decision in *Universal Health Services v. United States ex rel. Escobar*, the U.S. Supreme Court confirmed that a defendant could be liable under the FCA for what are commonly referred to as “legally false” claims; or, claims that, despite being factually accurate, are rendered false due to an underlying non-compliance with law that is *material* to the government’s decision to pay a claim.[3] In the healthcare industry, non-compliance with the AKS became a quintessential predicate for FCA liability, with courts accepting that compliance with the AKS is material to the government’s decision to pay a claim.

Less settled, however, was the requisite nexus between the AKS violation and a given claim for the claim to be considered false. Some courts have accepted a broad “taint theory,” under which the entire relationship between two parties is considered tainted by a violation of the AKS. Under this theory, any claim for services referred between the parties would be grounds for liability under the FCA. Other courts have required that the AKS violation touch, with differing degrees of directness, the claims at issue. In such cases, an FCA defendant would be liable only for claims that had the requisite degree of connectedness to an AKS violation.

Then, in 2010, the Affordable Care Act codified in statute (the “ACA Amendment”) that a claim that includes items or services “resulting from” an AKS violation constitutes a false

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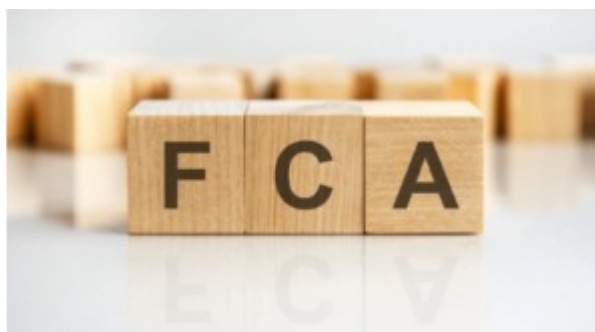
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or fraudulent claim under the FCA.[4] This “resulting from” language has proven to be a major point of disagreement among courts, creating significant confusion regarding whether and to what extent an AKS violation must cause submission of a claim in order for such submission to violate the FCA.

To further complicate matters, courts have far from settled the question of whether the same causation standard applies whether or not the government relies on the ACA Amendment’s *per se* falsity to plead that a defendant violated the FCA. This is to say that it remains largely unsettled whether the causation standard that applies to pleadings that invoke the ACA Amendment also apply where the government instead (or also) invokes *Escobar* and pleads that compliance with the AKS is material to the government’s decision to pay a claim.

So, what standard applies? Currently, it depends on the court.

- The Third Circuit has held that the ACA Amendment requires only some “link” or “connection” between the alleged kickback and the subsequent claims. In *S. ex rel. Greenfield v. Medco Health Sols., Inc.*[5], the court acknowledged that the Supreme Court had previously interpreted the plain meaning of the nearly identical phrase “results from” in the context of the Controlled Substances Act as requiring actual, or but-for causation.[6] However, without stating whether the plain meaning of “resulting from” was unclear, the court looked to legislative intent, finding that such a strict causation requirement would require proof that a kickback “actually influenced a patient’s or medical professional’s judgment,” which would be inconsistent with Congress’ apparent intentions to reach a “broad swath” of fraud and abuse.[7]
- The Sixth and Eighth Circuits have adopted a strict but-for causation standard, requiring that the government establish that the items or services would not have been submitted for payment if not for the AKS violation.[8] In *Cairns*, the court asserted that the “resulting from” language in the ACA Amendment is “unambiguously causal”, requiring but-for causation in accordance with the Supreme Court’s holding in *Burrage*. [9] Acknowledging that the Third Circuit came out differently on this issue in *Greenfield*, the court in *Cairns* rejected the Third Circuit’s approach, stressing that when the plain meaning of a term or phrase is unambiguous, review of legislative history is improper. The court further noted that it is not enough for the government to show that the defendant failed to disclose the AKS violation when submitting the claims at issue.[10]
 - In *S. ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, the U.S. District Court for the District of Minnesota clarified that, under *Cairns*, but-for causation only applies to claims that rely on the ACA Amendment to show falsity.[11] Conversely, where the government had pled that compliance with the AKS was material to a decision to pay the claim, the District Court required that the government show only proximate causation (established if the misconduct was a substantial factor in submission of the claims and such submission was reasonably foreseeable or anticipated as a natural consequence of the misconduct).[12]



- In a seemingly contradictory opinion, the U.S. District Court for the District of Minnesota in *S. ex rel. Louderback v. Sunovion Pharms., Inc.* held that a plaintiff may not establish FCA liability premised on a violation of the AKS by simply showing that compliance with the AKS was material to the government’s decision to pay the claim (which, under *Fesenmaier*, requires only proximate causation).^[13] In other words, a plaintiff *must* meet the ACA Amendment but-for causation standard. This holding is similar to the Sixth Circuit’s holding in *Cairns*, which also found that but-for causation is required to establish FCA liability on the basis of a violation of the AKS (although query whether the Sixth Circuit intended to limit this holding to pleadings that rely on the ACA Amendment).
- In the First Circuit, the U.S. District Court for the District of Massachusetts has created conflicting case law. In *S. v. Regeneron Pharms. Inc.* the court mixed concepts, creating an FCA causation standard that starts to merge with notions of intent under the AKS. While the court purportedly adopted the but-for causation standard from *Cairns*, it then stated that an AKS violation need only be a “substantial factor” in causing referrals, rather than the *sole* cause, in order for claims resulting from such referrals to be false.^[14] Conversely, in *U.S. v. Teva Pharms. USA, Inc.*, the court held that only a “sufficient causal connection” must exist between the AKS violation and a claim in order to render the claim false under the FCA.^[15] As a result of these conflicting holdings, the causation standard issue is now under interlocutory appeal with the First Circuit.^[16]

In addition to being determinative of whether a violation of the FCA occurred at all, a court’s view of the appropriate causation standard can have a significant effect on the scope of damages. If but-for causation is required, the number of affected claims will likely be limited to those claims for which there is evidence that the item or service would not have been referred absent the AKS violation. At the other end of the spectrum, where there is no requirement to show any sort of causal connection between the alleged violation of the AKS and the submission of a purportedly-false claim, damages can grow to include any claim for an item or service referred between parties whose relationship can be said to be “tainted” by a violation of the AKS.

In light of the FCA’s liability scheme—which includes treble damages and significant per-claim fines and penalties—the unsettled nature of this causation requirement can lead to significant uncertainty regarding a defendant’s potential exposure in FCA cases. Defendants facing allegations that they are liable under the FCA as a result of non-compliance with the AKS may see potential damages balloon if courts loosen causation requirements. If courts impose stricter causation requirements, on the other hand, the government may find it harder and harder to achieve the mammoth judgments and settlements that we have seen in the past.

^[1] 42 U.S.C. § 1320a-7b(b). The Anti-Kickback Statute imposes criminal liability upon any person who knowingly and willfully solicits or receives remuneration (i.e., anything of value) in return for, or offers or pays any remuneration to induce, the referrals of items or services for which payment may be made in whole or in part under a federal health care

program, including Medicare and Medicaid.

[2] 31 U.S.C. §§ 3729-3733. The civil False Claims Act imposes liability upon any person who knowingly submits, or causes to submit, false or fraudulent claims to the government.

[3] *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (noting that the FCA is not a “vehicle for punishing garden-variety breaches”, and emphasizing the importance of the government’s conduct in determining whether a particular AKS violation was material to the government’s decision to pay the claims).

[4] 42 U.S.C. § 1320a-7b(g).

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

[6] *See Burrage v. U.S.*, 134 S. Ct. 881, 887-88 (2014).

[7] *Id.* at 96-97.

[8] *See U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023), *cert. denied*, 144 S. Ct. 224 (2023); *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828 (8th Cir. 2022).

[9] *Cairns*, 42 F. 4th at 834-36.

[10] *Cairns*, 42 F.4th at 834.

[11] *U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-CV-3003, 2024 U.S. Dist. LEXIS 21897, at *8-9 (D. Minn. Feb. 8, 2024). This case is currently on appeal to the Eighth Circuit.

[12] *Id.* at *10, 29 (noting that it was insufficient, by itself, to establish that the claims were submitted within one year of the alleged kickback).

[13] No. 17-CV-1719, 2023 U.S. Dist. LEXIS 209990 (D. Minn. Nov. 27, 2023).

[14] *U.S. v. Regeneron Pharms., Inc.*, No. 20-11217-FDS, 2023 U.S. Dist. LEXIS 172618, at *31-34 (D. Mass. Sept. 27, 2023) (indicating that it would be sufficient to show that the defendant was giving copay assistance because it knew that patients would not fill prescriptions and/or physicians would not write prescriptions if such copay assistance were unavailable).

[15] *See U.S. v. Teva Pharms. USA, Inc.*, No. 20-11548-NMG, 2023 U.S. Dist. LEXIS 122272 (D. Mass. July 14, 2023).

[16] *See U.S. v. Regeneron Pharms., Inc.*, No. 20-11217-FDS, 2023 U.S. Dist. LEXIS 191418 (D. Mass. Oct. 25, 2023); *U.S. v. Regeneron Pharms., Inc.*, No. 23-8046, 2023 U.S. App. LEXIS 33107 (1st Cir. Dec. 11, 2023).

