

District courts wrestle with causation in kickback cases while circuit courts remain divided

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Two Massachusetts federal district courts recently addressed — and disagreed about — an important False Claims Act (FCA) issue that has also divided the federal circuit courts: when an alleged FCA violation is based on an underlying violation of the Anti-Kickback Statute (AKS), what kind of causal link must the government or a relator show between the alleged AKS violation and the allegedly false claim for payment?

According to the Sixth and Eighth Circuits — and one of the two Massachusetts courts — but-for causation is required. According to the Third Circuit — and the other Massachusetts court — something less will do. Because one of the two Massachusetts courts certified its order for interlocutory appeal, the First Circuit may soon weigh in as well. Regardless of the result, the First Circuit's decision will likely only add momentum to an issue that already appears ripe for Supreme Court review.

False claims 'resulting from' AKS violations: What kind of connection is required?

The issue addressed by the two Massachusetts courts arises from Congress's 2010 amendments to the AKS, which now provides that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."¹ In other words, a claim for payment is *per se* false under the FCA if it "result[ed] from" a violation of the AKS.

But federal circuit courts have parted ways on what it means for a claim to "result[] from" an AKS violation. In 2018, the Third Circuit held² in *U.S. ex rel. Greenfield v. Medco Health Solutions* that the statute's use of the phrase "resulting from" does *not* require strict but-for causation. Instead, the Third Circuit held that the government or a relator need show only some "link" between the claim for payment and a violation of the AKS — for example, that the defendant sought reimbursement for specific medical care provided in violation of the AKS or that a patient to whom the care was provided was "exposed" to an illegal referral or recommendation.

More recently, however, two other circuits have held the government and relators to a higher causation standard. Last year, the Eighth Circuit held³ in *U.S. ex rel. Cairns v. D.S. Medical LLC* that but-for causation is required. That is, the alleged AKS violation must be the but-for cause of the submission of the claim for payment. Under the

Eighth Circuit's holding, it would not be enough to show merely that an AKS violation somehow "tainted" the claim for payment or that it *may* have been "a contributing factor" to the claim's submission.

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The Sixth Circuit agrees.⁴ Earlier this year, in *U.S. ex rel. Martin v. Hathaway*, it likewise held that "the ordinary meaning of 'resulting from' is but-for causation," while cautioning that a looser standard — particularly when paired with a broad definition of "remuneration" — could turn "much of the workaday practice of medicine" into an AKS violation.

Teva Pharmaceuticals: 'sufficient causal connection'

In *United States v. Teva Pharmaceuticals USA*, currently pending in the District of Massachusetts, the government has alleged that Teva violated the FCA by paying kickbacks in the form of illegal co-pay subsidies in connection with the sale of one of its drugs. On July 14, Judge Nathaniel Gorton granted partial summary judgment to the government with respect to the legal requirements for proving causation.

Citing the Third Circuit's decision in *Greenfield*, as well as the First Circuit's more recent decision in *Guilfoile v. Shields*, the court held that the government could prove its FCA claims simply by establishing a "sufficient causal connection" between the claims for payment and an underlying violation of the AKS. Although the court provided little additional explanation about what kind of "connection" would be "sufficient," the court expressly rejected Teva's argument that but-for causation is required.

Following that decision, Teva asked the court to certify the order for interlocutory appeal. While citing the circuit split described above,

Teva also emphasized that the First Circuit's decision in *Guilfoile* had not specifically addressed whether but-for causation is required. On August 14, the district court granted Teva's motion over the government's objection, setting the stage for the First Circuit to resolve whether an FCA plaintiff must show that an underlying AKS violation was the but-for cause of the submission of a false claim.

Regeneron Pharmaceuticals: but-for causation

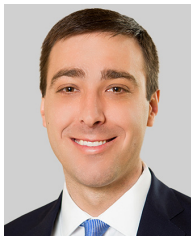
On September 27, a different Massachusetts federal district judge, Chief Judge F. Dennis Saylor, held in a similar case that the "resulting from" provision in the AKS *does* require but-for causation. In *United States v. Regeneron Pharmaceuticals*, the government alleges that Regeneron violated the AKS and caused the submission of false claims by funneling unlawful remuneration through a charitable foundation that provides co-pay assistance to patients prescribed Regeneron's drugs. Both the government and Regeneron moved for summary judgment, but the court denied both motions.

A claim for payment is per se false under the False Claims Act if it "result[ed] from" a violation of the Anti-Kickback Statute.

As to causation, the court first rejected the government's argument that the First Circuit's prior decision in *Guilfoile* had already resolved the issue. The court observed that *Guilfoile* did not elaborate on what a "sufficient causal connection" would entail and never specifically examined whether but-for causation is required. The court went on to explain why it viewed the Third Circuit's *Greenfield* decision as being "fraught with problems."

That was mostly because *Greenfield* had framed causation in terms of whether a particular patient was "exposed" to an illegal remuneration or referral. The court noted that the meaning of the term "exposed" is uncertain and does not derive from any statute or common law framework. Like the Sixth and Eighth Circuits, the court ultimately concluded that the plain meaning of "resulting from" requires but-for causation.

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At the same time, however, the court cautioned that even but-for causation does not require an act to be the *sole* cause, but only that it was a "substantial factor" in bringing about the harm. So, while the government would have to prove but-for causation, the court emphasized that it would not have to show that an AKS violation was the *only* reason a subsequent claim for payment was submitted. Finally, the court noted that causation could be established at trial "through circumstantial evidence and reasonable inferences."

Next step: the Supreme Court?

While not directly bearing on the circuit split, the conflicting district court decisions in *Teva* and *Regeneron* illustrate how the split will inevitably lead to inconsistent results in similar cases across different circuits. And, with the circuits already divided, there appears to be little prospect for consistency going forward without the Supreme Court's intervention.

On October 3, however, the Supreme Court denied a petition for certiorari in the *Martin* case from the Sixth Circuit. That said, now that the First Circuit appears poised to enter the fray as well, more petitions for certiorari are certain to follow.

Given the square circuit conflict, the prevalence and variety of AKS theories⁵ being pursued by relators and the government, and the scope of the potential exposure for FCA defendants, there is good reason to think the Supreme Court will eventually address the issue. If so, FCA defendants would be well served by a decision requiring plaintiffs to establish at least the ordinary but-for causation familiar to the common law, which would go a long way toward reining in exotic kickback theories that threaten to stretch the AKS beyond recognition.

Notes

¹ 42 U.S.C. § 1320a-7b(g).

² <https://bit.ly/40u2jPX>

³ <https://bit.ly/3FTKvDX>

⁴ <https://bit.ly/3FxFi9w>

⁵ <https://bit.ly/46LQYwV>