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The Causation Conundrum: The Growing Circuit Split Surrounding Causation and Kickback–Premised False Claims Act Cases

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With the Supreme Court having issued its decision in *United States ex rel. Schutte v. SuperValu, Inc.* regarding scienter under the False Claims Act (FCA) in June 2023,[1] the question naturally turns to the next "big ticket" issue in FCA jurisprudence, which may also find itself before the high court. One candidate is the issue of what is required to prove causation in FCA actions premised on kickback and referral schemes under the Anti-Kickback Statute (AKS). This issue has divided circuits, with the Third Circuit requiring merely some causal connection,[2] and the Sixth and Eighth Circuits requiring "but-for" causation between the alleged kickback and the claim for payment.[3] The First Circuit is set to join this growing split,[4] having granted an interlocutory appeal on the issue following decisions from two judges in the District of Massachusetts that landed on opposite sides of the split.[5]

This circuit split has major implications for health care providers, pharmaceutical manufacturers, and other entities operating in the health care environment. Both the government and qui tam relators have brought FCA cases premised on alleged kickback schemes, and these FCA cases pose significant potential liability. For example, Teva Pharmaceuticals USA, Inc.—one of the plaintiffs in the aforementioned Massachusetts cases—is facing potential liability upwards of $10 billion dollars from an FCA suit premised on an alleged kickback scheme.[6] A higher, but-for standard for causation would be a key tool for FCA defendants to defend against such cases.

Background on FCA and AKS-Predicated FCA Actions

An FCA action requires a showing of: (1) a false statement or fraudulent course of conduct (i.e., falsity), (2) that is made with scienter, (3) that was material, (4) causing the government to pay out money or forfeit moneys due.[7] FCA actions can be predicated on violations of a myriad of laws and regulations, including those in the health care space such as the AKS. To establish falsity in an AKS-predicated FCA action, a plaintiff has historically needed to show that the defendant: (1) "knowingly and willfully," (2) offered or paid remuneration, (3) "to induce" the purchase or ordering of products or items for which payment may be made under a federal health care program.[8]

In 2010, Congress added the following language to the AKS at 42 U.S.C. § 1320a-7b(g): "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]."[9] Most courts have agreed that the AKS, therefore, imposes an additional causation requirement on FCA claims premised on AKS violations.[10] While courts generally agree that some causation must be shown, courts are divided both on how to define "resulting from" and the applicable standard for proving causation.

The Growing Circuit Split

In its 2018 decision—*United States ex rel. Greenfield v. Medco Health Sols., Inc.*—the Third Circuit was faced with the question of "what 'link' is sufficient to connect an alleged kickback scheme to a subsequent claim for reimbursement: a direct causal link, no link at all, or something in between."[11] The Third Circuit ruled out the "no link at all" approach, finding that a relator "may not prevail on summary judgment simply by demonstrating that [the defendant] submitted federal claims while allegedly paying kickbacks."[12] However, the court also rejected a direct, "but-for" causation standard. In rejecting a but-for standard, the Third Circuit did not perform any statutory interpretation for the phrase "resulting from."[13] Rather, the court looked to the legislative history and concluded that a but-for standard would be contrary to the intent of the AKS's drafters and "would dilute the [FCA]'s requirements vis-à-vis the [AKS], as direct causation would be a precondition to bringing a [FCA] case but not an [AKS] case."[14] The Third Circuit ultimately concluded that a defendant must demonstrate "*some connection* between a kickback and a subsequent reimbursement claim" to prove causation.[15]

Four years after the *Greenfield* decision, the Eighth Circuit was faced with the same question of how to interpret "resulting from" under 42 U.S.C. § 1320a-7b(g).[16] In *United States ex rel. Cairns v. D.S. Med. LLC*, the Eighth Circuit declined to follow the Third Circuit, and instead it held that, "when a plaintiff seeks to establish falsity or fraud through [42 U.S.C. § 1320a-7b(g)], it must prove that a defendant would not have included particular 'items or services' *but for* the illegal kickbacks."[17] Unlike the Third Circuit, the Eighth Circuit in *Cairns* based its decision on statutory interpretation.[18] The court noted that the Supreme Court had previously interpreted the "nearly identical phrase, 'results from,' in the Controlled Substances Act."[19] In that case—*Burrage v. United States*—the Supreme Court had interpreted "results from" to require but-for causation.[20] The Eighth Circuit followed the Supreme Court's lead and found that the government's arguments could not overcome the plain language meaning of "resulting from."[21]

This past April, the Sixth Circuit issued its decision in *United States ex rel. Martin v. Hathaway*, joining the split and siding with the Eighth Circuit in adopting a but-for causation standard.[22] As with the Eighth Circuit, the Sixth Circuit decided based on statutory interpretation, stating "[t]he ordinary meaning of 'resulting from' is but-for causation," and the legislative history does not "overcome the ordinary meaning of the text."[23] The Sixth Circuit similarly cited to *Burrage* for support of its statutory interpretation.[24] The Sixth Circuit additionally reasoned that "reading causation too loosely" would mean that "[m]uch of the workaday practice of medicine might fall within an expansive interpretation of the [AKS]" and would fail to "protect doctors of good intent," whereas but-for causation "still leaves plenty of room to target genuine corruption."[25] Notably, in October 2023, the Supreme Court denied certiorari in *Martin*, allowing the circuit split to continue growing.[26]

All Eyes on the First Circuit

As mentioned above, two judges in the District of Massachusetts ruled on this causation issue in mid-2023, landing on opposite sides of the split.[27] In July 2023, Judge Nathaniel Gorton granted the government's motion for partial summary judgment in *United States v. Teva Pharms. USA, Inc.*, adopting the Third Circuit's standard from *Greenfield* that just "some connection" between a kickback and subsequent reimbursement claim is all that is required for causation under 42 U.S.C. § 1320a-7b(g).[28] Judge Gorton stated that he was following the First Circuit's guidance on this issue from its 2019 decision, *Guilfoile v. Shields*.[29] Of note, *Guilfoile* only addressed whether the plaintiff had adequately pled an FCA *retaliation* claim rather than an FCA violation; however, Judge Gorton found this to be a distinction without a difference.[30]

Just two months later, in *United States v. Regeneron Pharms., Inc.*, Judge Dennis Saylor was faced with the same question of what causation standard should apply. Judge Saylor found that *Guilfoile* (and, therefore, *Greenfield*) was not binding because the First Circuit in *Guilfoile* had expressly stated that the issue before that court "was 'not the standard for proving an FCA violation based on the AKS, but rather the requirements for pleading an FCA retaliation claim.'"[31] Judge Saylor then analyzed the decisions and supporting rationales in each of *Greenfield*, *Cairns*, and *Martin*.[32] Ultimately, Judge Saylor was persuaded by the statutory interpretation analysis of *Cairns* and *Martin* and applied a but-for standard.[33]

Following Judge Gorton's ruling in *Teva*, the defendant moved to certify for interlocutory appeal the issue of what causation standard applies under 42 U.S.C. § 1320a-7b(g).[34] Judge Gorton granted this motion on August 14, 2023,[35] staying trial and sending the issue to the First Circuit, which officially certified the appeal on November 17, 2023.[36] In *Regeneron*, the government similarly moved to certify the issue for interlocutory appeal, with Judge Saylor granting the motion on October 25, 2023, and the First Circuit certifying the appeal on December 11, 2023.[37] With these two certifications, the First Circuit is poised to join the circuit split—on one side or the other—in 2024.

Conclusion and Key Takeaways

The First Circuit appears to be the next battleground for the ongoing dispute over what standard applies for proving causation under 42 U.S.C. § 1320a-7b(g). The Supreme Court declined to grant certiorari on this issue in *Martin* this past year. However, the growing confusion and disagreement among district and circuit courts over this issue, coupled with the issue's import in FCA jurisprudence, make it a strong bet to be the next FCA issue decided by the Supreme Court. In fact, the issue could be before the Supreme Court soon after the First Circuit joins the split. From a practical standpoint, until this split is resolved, FCA practitioners must pay close attention to choice of venue in AKS-predicated FCA actions.

As noted above, a higher, but-for standard for causation would be an important tool for FCA defendants. But-for causation would allow a defendant to argue that even if they had acted with an intent to induce referrals, no actual referrals resulted from the conduct, which would allow the defendant to avoid FCA liability altogether. Alternatively, but-for causation may allow a defendant to argue that FCA damages are lower than the full amount of referrals made where the government is unable to prove that all of the referrals "resulted from" the improper arrangement.

While awaiting a decision from the First Circuit, practitioners should also be aware of open questions here, including whether the Supreme Court's holding in *SuperValu* will have a marked impact on arguments for but-for causation. As noted above, the Sixth Circuit's and Eighth Circuit's decisions to apply but-for causation were rooted in statutory interpretation, and particularly in the Supreme Court's prior interpretation of the phrase "results from" in the Controlled Substances Act.[38] In *SuperValu*, however, the Supreme Court stated that words must be construed in their particular statutory context.[39] Plaintiffs—including the government in *Regeneron*—have begun to cite to this portion of *SuperValu* as evidence that the Sixth Circuit's and Eighth Circuit's analyses were flawed and but-for causation is improper.[40] The court in *Regeneron* was not convinced, but it remains to be seen whether the argument will gain force as this circuit split continues to grow.

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[1] 598 U.S. 739 (2023).
[2] *United States ex rel. Greenfield v. Medco Health Sols., Inc.,* 880 F.3d 89, 98-100 (3d Cir. 2018).
[3] *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052-55 (6th Cir. 2023); *United States ex rel. Cairns v. D.S. Med. LLC,* 42 F. 4th 828, 834-36 (8th Cir. 2022).
[4] *United States v. Teva Pharms. USA, Inc*., No. 23-cv-08028, Judgment (1st Cir. Nov. 17, 2023) (granting petition to appeal).
[5] *United States v. Regeneron Pharms., Inc*., No. 20-cv-11217, Memorandum & Order, at *21 (D. Mass. Sept. 6, 2023) (denying the government's motion for partial summary judgment and finding the government must prove "but-for" causation) [hereinafter, *Regeneron* Decision]; *United States v. Teva Pharms. USA, Inc*., No. 20-cv-11548, Memorandum & Order, at *6-7 (D. Mass. July 14, 2023) (granting the government's motion for partial summary judgment and finding that the government need only prove some "causal connection") [hereinafter, *Teva* Decision].
[6] *Teva*, No. 20-cv-11548, Opp. to Government's Motion for Partial Summary Judgment, at *16, n.8 (D. Mass. May 24, 2023).
[7] 31 U.S.C. § 3729(a)(1)(A), (B).
[8] 42 U.S.C. § 1320a-7b(b)(2)(B).
[9] *Id.* § 1320a-7b(g) (emphasis added).
[10] There have been at least a few courts that declined to require proof of causation. *See, e.g.*, *United States ex rel. Kester v. Novartis Pharm. Corp*., 41 F. Supp. 3d 323, 332-35 (S.D.N.Y. 2014) (finding "Congress gave absolutely no indication … it intended … to limit the [FCA's] reach where kickbacks were concerned" and that "any claim connected in any way to an [AKS] violation [is] ineligible for reimbursement").
[11] 880 F.3d at 95.
[12] *Id.* at 99.
[13] *See generally id.*; *see also* 42 U.S.C. § 1320a-7b(g).
[14] *Greenfield*, 880 F.3d at 96-97.
[15] *Id.* at 100 (emphasis added).
[16] *Cairns*, 42 F.4th at 834.
[17] *Id.* at 836 (emphasis added).
[18] *Id.* at 834-36.
[19] *Id.* at 834.
[20] 571 U.S. 204, 210-213 (2014); *Cairns,* 42 F.4th at 834.
[21] *Cairns,* 42 F.4th at 835-36.
[22] 63 F.4th at 1052-55.
[23] *Id.* at 1052-53.
[24] *Id.* (citing *Burrage*, 571 U.S. at 210-11).
[25] *Martin*, 63 F.4th at 1054-55.
[26] 144 S. Ct. 224 (2023).
[27] *See supra* note 5.
[28] *Teva* Decision, at *12-13.
[29] 913 F.3d 178, 190 (1st Cir. 2019) (citing *Greenfield*, 880 F.3d at 96-98).
[30] *Teva* Decision, at *13.
[31] *Regeneron* Decision, at *14 (citing *Guilfoile*, at 190).
[32] *See id.* at *15-21.
[33] *Id.* at *21.
[34] *Teva*, No. 20-cv-11548, Motion to Certify Interlocutory Appeal (D. Mass. July 26, 2023).
[35] *Id.*, Order (D. Mass. Aug. 14, 2023) (allowing defendant's motion).
[36] *See supra* note 4.
[37] *United States v. Regeneron Pharms., Inc*., No. 20-cv-11217, Order (D. Mass. Oct. 25, 2023) (allowing plaintiff's motion); No. 23-cv-08036, Judgment (1st Cir. Dec. 11, 2023).

[38] *Cairns,* 42 F.4th at 834-36 (analyzing *Burrage*, 571 U.S. at 210-13); *Martin*, 63 F.4th at 1052-53 (same).
[39] 598 U.S. at 754-55.
[40] *United States v. Regeneron Pharms., Inc*., No. 20-cv-11217, Government's Surreply to Regeneron's Motion for Summary Judgment, at *8 (D. Mass. June 8, 2023).

