What Circuit Split May Mean For FCA Kickback Liability

By **Li Yu, Ellen London and Gregg Shapiro** (August 28, 2023)

Li Yu

Ellen London

Gregg Shapiro

It is lunchtime on Friday.

The general counsel of your top client, a medical device company, is calling urgently to ask you how she should outline the company's financial exposure in a U.S. Department of Justice False Claims Act kickback investigation for the board of directors.

Or, imagine that you represent a qui tam relator or work at the DOJ, and you need to depose the defendant pharmaceutical company's 30(b)(6) witness in an FCA case alleging widespread kickbacks paid by the company to doctors as part of its "speaker program."

In both cases, you must wrestle with a 2010 amendment to the anti-kickback statute — Title 42 of the U.S. Code, Section 1320a-7b(g) — that creates FCA liability for any "claim that includes items or services resulting from [an AKS] violation."

Is the resulting-from provision just a function of time — that an offer or receipt of a kickback preceded the submission of claims — or does it require proof of some other causal connection between a kickback and a claim?

Or must the plaintiff prove but-for causation between the alleged kickback and the claim?

Interpreting this aspect of the AKS not only has challenged FCA practitioners, but it has also divided federal courts.

On July 14, in U.S. v. Teva Pharmaceuticals Inc.,[1] the U.S. District Court for the District of Massachusetts followed the U.S. Court of Appeals for the Third Circuit's 2018 decision in U.S. ex rel. Greenfield v. Medco Health Solutions Inc.,[2] and held that the government need not show but-for causation in an AKS and FCA case.

Just three months earlier, the U.S. Court of Appeals for the Sixth Circuit in U.S. ex rel. Martin v. Hathaway[3] followed the U.S. Court of Appeals for the Eighth Circuit in U.S. ex rel. Cairns v. D.S. Medical LLC,[4] and held exactly the opposite.

Recognizing the contrary interpretations, the district court in Teva has just certified for appeal its July 14 ruling and stayed the trial, which had been scheduled to begin in a few weeks.

Meanwhile, in January, a district court in the Eighth Circuit held that the government in an AKS and FCA case need not concern itself with the resulting-from provision at all and could instead prove causation using the false certification theory of causation that courts had endorsed prior to the 2010 AKS amendment.[5]

This growing divergence has significant ramifications for civil fraud cases, because the AKS

is one of DOJ's top enforcement priorities.[6]

Here, we begin by describing the origin of this AKS provision. We then elaborate on the diverging judicial constructions of the resulting-from provision and the interpretive steps leading to those constructions.

Next, we highlight how DOJ and defense attorneys are adapting their arguments in light of the circuit split.

Finally, we offer practical suggestions — on venue selection, pleading, discovery and settlement strategy — for attorneys who must address this issue in affirmative and defensive postures.

Origin of Section 1320a-7b(g)

In addressing causation in AKS and FCA cases before the 2010 amendment to the AKS, circuit court decisions like U.S. v. Rogan[7] and U.S. ex rel. Hutcheson v. Blackstone Medical Inc in the U.S. Court of Appeals for the First Circuit in 2011[8] held that a certification of compliance with the AKS was an express or implied prerequisite for seeking payment, even when the wrongdoers did not submit claims.

The U.S. Court of Appeals for the Seventh Circuit's 2011 Rogan decision also articulated an expansive view of FCA liability — a defendant is liable for all claims that violate the AKS even if the claims reflected "all the care [rendered]" or if the government "would have paid for the[] care" had "the patients [] gone elsewhere."[9]

When Congress added Section 1320a-7b(g) to the AKS, sponsors of the amendment wanted to correct a 2008 U.S. District Court for the Eastern District of Arkansas decision, U.S. ex rel. Thomas v. Bailey.[10]

In Thomas, the court held that, even when a surgeon at a hospital took kickbacks in exchange for using a particular medical device, the hospital's claims for the surgeries were not false under the FCA because the hospital was not aware of the kickback scheme and, therefore, could not have falsely certified compliance with the AKS.[11]

According to a sponsor of a 2009 bill with a provision that ultimately became Section 1320a-7b(g), the Thomas court inappropriately allowed the submission of a kickback-tainted claim by an innocent party to "launder[ ][it] into a 'clean' claim."[12]

The amendment was supposed to remedy this "problem by ... ensur[ing] that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves."[13]

The Conflicting Judicial Interpretations of Resulting-From Provision

Soon after the 2010 amendment, parties in FCA kickback cases proposed dueling interpretations of the new resulting-from language.

In 2014 in the U.S. District Court for the Southern District of New York, for example, the defendant in U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp. asked the court to construe the resulting-from provision as requiring proof of but-for causation, i.e., to create FCA liability, the "sale of [a] drug to a particular patient [must be] actually caused by the kickback scheme."[14]

The Kester court rejected this argument, noting that the legislative history made it completely clear that the purpose of the 2010 AKS amendment was "to correct Thomas's strict interpretation of the false certification theory" and "did nothing to alter the [pre-existing] false certification theory of [FCA liability]."[15]

In 2018, the Third Circuit in Greenfield issued the first appellate interpretation of the resulting-from language. Greenfield involved allegations that a specialty pharmacy paid remuneration to two foundations to induce them to refer Medicare patients.

The pharmacy defendant urged the Third Circuit to adopt a but-for causation standard, arguing that it was consistent with the U.S. Supreme Court's construction of "results from" in another statute, the Controlled Substances Act, or CSA.[16]

Like the Kester court, the Third Circuit rejected this construction as inconsistent with the intent of Congress in amending the AKS,[17] holding instead that Section 1320a-7b(g) merely requires proof of a link between a claim submitted to the government and "medical care that was provided in violation of the Anti-Kickback Statute (as a kickback renders a subsequent claim ineligible for payment)."[18]

Under Greenfield, the government and relators only need to show that specific claims involved a patient or provider who was "exposed to" a kickback.

After Greenfield, other district courts applied a similar causation standard. For example, in U.S. ex rel. Bawduniak v. Biogen IDEC Inc., the U.S. District Court for the District of Massachusetts held that relators need not show "that the physicians would not have prescribed [Biogen's] medication but for the kickbacks."

Instead, it was "sufficient to show that [Biogen] paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback."[19]

In 2019, the First Circuit cited Greenfield approvingly in assessing an FCA retaliation claim in Guilfoile v. Shields, opining that, given "the 'resulting from' language of the 2010 [AKS] amendment, if there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA."[20]

In July 2022, however, the Eighth Circuit in Cairns declined to follow Greenfield and instead adopted the but-for causation standard. In Cairns, the government had obtained a $5.4 million FCA judgment based on evidence that Medicare claims were tainted by kickbacks from an implant distributor.[21]

On appeal, the Eighth Circuit held that, given the Supreme Court's prior plain language interpretation of the CSA's results-from provision in Burrage, evidence of such taint was not enough for the resulting-from provision.

Instead, the Cairns court held that the government must prove the surgeon would not have used the implants "absent the illegal kickbacks."[22] While acknowledging "that the Third Circuit came out differently," the Eighth Circuit opined that Greenfield was wrong in "relying on legislative history" when the meaning of the statutory text was plain.[23]

The Sixth Circuit applied the same logic in the Martin case earlier this year.[24]

District courts elsewhere, however, largely have continued to follow Greenfield. In U.S. ex rel. Everest Principals v. Abbott Laboratories, for example, a court in the U.S. District Court for the Southern District of California acknowledged Cairns, but nonetheless found the relator's causation allegations sufficient because they establish a link between the kickback and the claim for reimbursement.[25]

In U.S. ex rel. Fitzer v. Allergan Inc., the U.S. District Court for the District of Maryland also declined to follow Cairns.[26]

The Fitzer court questioned the Cairns court's reliance on Burrage in an AKS case, given that "the [Burrage] Court explained that '[w]here there is no textual or contextual indication to the contrary, courts regularly read phrases like 'results from' to require but-for causality.'"[27]

Concluding that the context of the 2010 AKS amendment "indicates that Congress intended to make it easier, not harder, to bring (and ultimately prove) FCA claims" based on AKS violations, Fitzer followed Greenfield rather than Cairns.[28]

DOJ and Defense Bar Responses to the Circuit Split

In response to the circuit split, the DOJ has followed a two-pronged approach to FCA cases involving kickback allegations.

Outside of the Sixth and Eighth Circuits, the DOJ has argued for adherence to the Greenfield causation standard. That argument proved persuasive to the Teva court last month.[29]

Further, in a brief filed in June in another District of Massachusetts case, the DOJ cited the Supreme Court's recent decision in U.S. ex rel. Schutte v. SuperValu Inc., which invoked the need to construe words in their particular statutory context,[30] as further evidence that the Burrage court's interpretation of results-from language in the CSA should not control how courts construe the resulting-from provision in the AKS.[31]

Within the Eighth Circuit, in the recent Fesenmaier case, the DOJ successfully elided Cairns and reverted to the false certification theory prevalent before the 2010 AKS amendment.

In a pretrial ruling in Fesenmaier, the district court noted that the plaintiffs were seeking "to prove their case solely under a material-falsity theory," i.e., defendants sought "payment for services that ... violate a material condition of reimbursement [i.e., compliance with the AKS]."[32]

The court held that Cairns did not foreclose this false certification theory as a means of proving damages in an AKS/FCA case.[33]

Shortly after that decision, the Fesenmaier case went to trial. The jury found that the defendants' kickbacks caused the submission of 64,575 false claims to Medicare, and the court directed the entry of a $487 million judgment.[34]

FCA defendants, unsurprisingly, have advocated for the adoption of the but-for causation standard from Cairns and Hathaway. After the recent Teva decision, for example, the defendant promptly filed a motion to certify an interlocutory appeal on the proper standard of causation.[35]

On Aug. 14, the district court certified the interlocutory appeal and stayed the trial in Teva.[36]

Suggestions for FCA Practitioners

First, practitioners who represent qui tam relators or defendants in FCA cases involving alleged kickbacks should pay close attention to the choice of venue in such cases.

While a plaintiff's venue choice is typically accorded great weight on a motion to transfer,[37] there is an emerging "consensus view among district courts that a plaintiff's choice of forum is entitled to considerably less deference in qui tam cases."[38]

Thus, defense and relators' counsel should think carefully about the identities of key witnesses and their locations,[39] because courts view "convenience of both the party and non-party witnesses [as] probably the single-most important factor[.]"[40]

Second, in jurisdictions that have construed the resulting-from provision to require but-for causation, practitioners should refamiliarize themselves with the false certification theory in kickback cases.

Here, both relators' and defense counsel are well served to scrutinize the wording of any express certification of AKS compliance and any applicable statute, regulation or contract mandating AKS compliance.[41]

Further, because FCA decisions like Hutcheson addressed AKS violations under the false certification rubric before the Supreme Court's 2016 Escobar decision, it is important to think carefully about how to plead materiality or to challenge materiality allegations under Escobar.[42]

Third, in discovery, practitioners should pay close attention to evidence related to the practical and financial impact of alleged kickbacks. For example, in cases involving alleged kickbacks to patients, finding evidence that, absent the kickbacks, patients could not have afforded a treatment modality is strong proof of but-for causation.

Uncovering a defendant's internal analysis of the return on investment for alleged kickbacks likewise can help plaintiffs show that a kickback was a but-for or actual cause.[43]

Defense counsel, on the other hand, can focus on the government payers' responses to the alleged kickback arrangements.

Finally, for practitioners engaged in or anticipating settlement discussions, it is imperative to keep close track of the evolving case law. This is especially true in cases pending in jurisdictions that may be addressing this statutory construction issue squarely for the first time.

Understanding what standard governs the scope of false claims — and thus damages — is critical to deciding on what is an appropriate outcome.

Li Yu is a partner at DiCello Levitt. He previously served as senior counsel at the U.S. attorney's office for the Southern District of New York.

Ellen London is a shareholder at London & Stout PC. She previously served as an assistant U.S. attorney for the Southern District of New York and the U.S. District Court for the Northern District of California.

Gregg Shapiro is a founder at Gregg Shapiro Law. He previously served as affirmative civil enforcement chief at the U.S. Attorney's Office for the District of Massachusetts.

Disclosure: While working at the U.S. Attorneys' Offices, Ellen London and Li Yu were involved with U.S. ex rel. Kester v. Novartis, and Gregg Shapiro was involved with U.S. v. Teva and U.S. v. Regeneron.

[1] U.S v. Teva Pharms., Inc., No.20-11548, 2023 WL 4565105, at *4 (D. Mass. July 14, 2023).

[2] U.S. ex rel. Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89 (3d Cir. 2018).

[3] U.S. ex rel. Martin v. Hathaway, 63 F.4th 1043 (6th Cir. 2023).

[4] U.S. ex rel. Cairns v. D.S. Medical, LLC, 42 F.4th 828 (8th Cir. 2022).

[5] U.S. ex rel. Fesenmaier v. The Cameron Ehlen Group, Inc., No. 13-cv-3003, 2023 WL 36174 (D. Minn. Jan. 4, 2023).

[6] According to DOJ, AKS settlements accounted for nearly half of its total FCA recoveries in 2022. See https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022.

[7] U.S. v. Rogan, 517 F.3d 449, 453 (7th Cir. 2008) (upholding FCA liability under the "implied certification" standard – "government offers a subsidy … with conditions. When the conditions are not satisfied, nothing is due").

[8] U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 392-94 (1st Cir. 2011) (holding that attestations of AKS compliance in Medicare cost reports and provider agreements sufficed to create FCA liability under the "express certification" standard); see also McNutt v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1260 (11th Cir. 2005) (holding that "compliance with the [AKS] is necessary for reimbursement under the Medicare program"); U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 565 F. Supp. 2d 153, 159 (D.D.C. 2008) ("Legion other cases have held violations of AKS ... can be pursued under the FCA, since they would influence the Government's decision of whether to reimburse Medicare claims.").

[9] 517 F.3d at 453.

[10] U.S. ex rel. Thomas v. Bailey, No. 06 Civ. 465, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008).

[11] Id. at *13.

[12] 155 Cong. Rec. S10852, S10853, 2009 WL 3460582 (daily ed. Oct. 28, 2099).

[13] Id.

[14] U.S. ex rel. Kester v. Novartis Pharms. Corp., 41 F. Supp. 3d 323, 331-32 (S.D.N.Y. 2014).

[15] Id. at 334-35.

[16] 880 F.3d at 96 (citing Burrage v. U.S., 571 U.S. 204, 210-12 (2014)).

[17] See id. (citing H.R. Rep. No. 95-393, at 47 (1977)).

[18] Id. at 98.

[19] U.S. ex rel. Bawduniak v. Biogen Idec, Inc., No.12- CV-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018). See also U.S. ex rel. Heller v. Guardian Pharmacy, LLC, 521 F. Supp. 3d 1254, 1274 (N.D. Ga. 2021) (FCA relator must "show causation, or some 'link' between the payment of remuneration and the submission of false claims to establish FCA liability based on an AKS violation") (cleaned up); U.S. ex rel. Arnstein v. Teva Pharms. USA, Inc., 13 Civ. 3702, 2019 WL 1245656, at *24 (S.D.N.Y. Feb. 27, 2019) ("A link is required, but it is less than showing that the bribe succeeded in producing the prescription.") (cleaned up).

[20] Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019). Guilfoile involved an FCA retaliation claim in which plaintiff alleged he had been fired for raising concerns about an alleged kickback arrangement. On appeal, the First Circuit considered whether the plaintiff had "sufficiently plead[ed] that he ... was retaliated against based on conduct that reasonably could lead to a viable FCA action." Id. at 188.

[21] 42 F.4th at 833, 835.

[22] Id. at 835.

[23] Id. at 836.

[24] 63 F.4th at 1053 ("There's not one claim for reimbursement identified with particularity in this case that would not have occurred anyway....").

[25] U.S. ex rel. Everest Principals v. Abbott Laboratories, 622 F. Supp. 3d 920, 933 (S.D. Cal. 2022).

[26] U.S. ex rel. Fitzer v. Allergan, Inc., No. 1:17-cv-00668-SAG, 2022 WL 9974736 (D. Md. Aug. 23, 2022).

[27] Id. at *10 (quoting Burrage, 571 U.S. at 212). Of note, in the same term that it decided Burrage, the Supreme Court in Paroline v. U.S. declined to require "a showing of strict but-for causation" for imposing restitution "as a proximate result of" a crime based on "the statute's remedial purpose." 572 U.S. 434, 456-59 (2014).

[28] 2022 WL 9974736, at *10.

[29] 2023 WL 4565105, at *4.

[30] U.S. ex rel. Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1402 (2023) (quotation omitted).

[31] See United States' Surreply to Regeneron's Motion for Summary Judgment, U.S. v. Regeneron Pharms., Inc., No. 1:20-cv-11217, Dkt. 315 at 8 (D. Mass. June 8, 2023).

[32] 2023 WL 36174, at *2.

[33] See id. at *3.

[34] See Order, Fesenmaier, Dkt. 1042 (D. Minn. May 12, 2023).

[35] See Defendants' Memorandum of Law in support of Motion to Certify Interlocutory Appeal and Postpone Trial at 3-5, U.S. v. Teva Pharms. USA, Inc., Dkt. 196-1 (D. Mass. July 26, 2023).

[36] See Order, U.S. v. Teva Pharms. USA, Inc., Dkt. 235 (D. Mass. Aug. 14, 2023).

[37] D.H. Blair & Co. v. Gottdiener, 462 F.3d 95, 106-07 (2d Cir. 2006).

[38] U.S. ex rel. Roop v. Arkray USA, Inc., 2007 WL 844691, at *2 (N.D. Miss. Mar. 19, 2007); accord U.S. ex rel. Bassan v. Omnicare, Inc., 15-cv-4179 (CM), 2022 WL 72300, at *2 (S.D.N.Y. Jan. 7, 2022) (finding "Plaintiff's choice of forum is not entitled to particular deference" in FCA case).

[39] In weighing this factor, courts do not "merely tally the number of witnesses" in different venues, but instead "qualitatively evaluate the materiality of [their] testimony[.]" U.S. ex rel. State of Florida v. ApolloMD, Inc., 1:17-cv-20012-KMW, 2020 WL 1018736, at *5 (S.D. Fla. Aug. 3, 2020).

[40] Bassan, 2022 WL 72300, at *3; accord ApolloMD, 2020 WL 1018736, at *5.

[41] See Fesenmaier, 2023 WL 36174, at *3; accord Hutcheson, 647 F.3d at 392-94; U.S. ex rel. Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497, 535-39 (S.D.N.Y. 2014).

[42] Since 2016, several district courts have held that compliance with the AKS is material under Escobar. See, e.g., U.S. ex rel. Wood v. Allergan, Inc., 246 F. Supp. 3d 772, 817-18 (S.D.N.Y. 2017) (holding "that compliance with the AKS is a 'material' condition of payment"), rev'd on other grounds, 899 F.3d 163, 166 (2d Cir. 2018); U.S. v. America at Home Healthcare & Nursing Servs., Ltd., No. 14-cv-1098, 2017 U.S. Dist. LEXIS 94505, at *20-23 (N.D. Ill. June 20, 2017) (rejecting post-Escobar challenge to materiality of AKS violations in FCA case).

[43] See Arnstein, 2019 WL 1245656, at *39 (discussing the import of ROI analysis of defendant pharmaceutical company's "speaker program"); see also https://www.justice.gov/usao-vt/pr/electronic-health-records-vendor-pay-largest-criminal-fine-vermont-history-and-total-145 (discussing how defendant electronic health record software developer used ROI analysis to solicit kickbacks from opioid manufacturer).