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Courts Must Apply Correct Causal Standard In Kickback Cases

By **Matthew Dunn, Matthew O'Connor and Krysten Rosen Moller**
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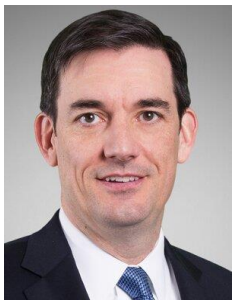

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In 2010, Congress amended the Anti-Kickback Statute to state that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim" for purposes of the False Claims Act.[1]

Congress did not state that any time there is an AKS violation, there is also an FCA violation. Likewise, Congress did not state that claims that might result from, could foreseeably result from, or were tainted by AKS violations are false.

Rather, the statutory language states that a claim is false or fraudulent under the FCA — one element of FCA liability — if it includes items or services resulting from the AKS violation.

Despite the clear statutory language and supporting legislative history, over recent years relators, the government and some courts have interpreted the "resulting from" language as having little to no practical meaning.

Plaintiffs have advocated for interpretations of the statute that, contrary to the plain language and Congress' intent, would completely collapse the distinct elements of AKS and FCA liability into each other and find defendants liable under the FCA even if no claims to the government actually resulted from the alleged AKS violation and the government suffered no loss.

This article explains why the statutory language requires but-for causation and how arguments to the contrary conflate the legal standards and could lead to severe, unintended real-world consequences.

Consider the statutory requirements of the FCA and AKS.

The FCA creates civil liability for knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the government.[2]

FCA claims may be premised upon an underlying violation of the AKS, a separate criminal statute.[3] However, to establish FCA liability in this manner, the plaintiff must establish: (1) the elements of an FCA violation; (2) the distinct elements of an

AKS violation; and (3) the linkage between the two set forth under Title 42 of the U.S. Code, Section 1320a-7b(g).

More specifically, a violation of the FCA requires that a plaintiff show: (1) falsity; (2) causation; (3) scienter; and (4) materiality.[4]

Separately, to prove a violation of the AKS, it must be established that the defendant(s): (1) knowingly and willfully; (2) offered or paid remuneration; (3) to induce the purchase, lease, order, recommendation or referral of any good, facility, service or item; and (4) such good, facility, service or item was one for which payment may be made in whole or in part under a federal health care program.[5]

A plaintiff can establish the first element of an FCA violation, falsity, if she establishes (1) all of the elements of the AKS violation and (2) that a claim submitted to the government includes items or services resulting from the AKS violation.[6] Then, the FCA plaintiff would also need to establish the other elements of an FCA violation set forth above.[7]

The "resulting from" language Is not superfluous, and is consistent with the entire purpose of the FCA — to prevent the submission of false claims to the government.

As demonstrated by the text of the statute, the requirement that FCA claims premised upon an underlying violation of the AKS must result fro the AKS violation creates a but-for causal standard.

First, the statute makes clear that there is a discrete "resulting from" requirement. The statute limits the application of Section 1320a-7b(g) to claims resulting from the violation of the AKS — it does not say, as it could have, that any AKS violation is an FCA violation.

In addition, the "resulting from" requirement is unique to subdivision (g) in Section 1320a-7b, and does not exist in Section 1320a-7b(b), which lays out the elements of an AKS violation. This shows that merely satisfying the elements of an AKS violation is not sufficient to establish an FCA violation.

The "resulting from" language establishes a distinct element that must be satisfied before an AKS violation creates a false claim under the FCA. This additional requirement makes sense given the different purposes of the FCA and AKS: The FCA targets only false claims for reimbursement, while AKS violations need not be linked to actual claims for reimbursement.

Second, this "resulting from" requirement must mean something. The U.S. Supreme Court has provided guidance on the language in other contexts, and has held that it "imposes ... a requirement of actual causality," i.e., but-for causation, in Burrage v. United States in 2014.[8]

This interpretation of "resulting from" as requiring but-for causation is also supported by the plain dictionary meaning of that term.[9]

The legislative history confirms that the use of "resulting from" in the statute was no mistake — proponents of the amendment to the AKS consistently used the language "resulting from" in their congressional statements.[10]

As the U.S. Court of Appeals for the Eighth Circuit has held in Cairns v. D.S. Medical LLC in 2022, when a plaintiff seeks to establish falsity or fraud under the FCA through a violation of the AKS, "it must prove

that a defendant would not have included particular 'items or services' but for the illegal kickbacks."[11]

This interpretation is most faithful to the text and purpose of the FCA, and would avoid absurd results that would come from requiring a lesser causal standard.

Other courts have incorrectly interpreted the "resulting from" language.

Although the Eighth Circuit has embraced a but-for standard, other courts and plaintiffs, including in cases post-dating the Eighth Circuit's decision in Cairns, have largely read the "resulting from" language out of the statute, or so greatly watered it down that the plain words have no teeth. The argument in support of this position has been framed in several ways.

First, in an amicus curiae brief in Martin v. Hathaway in 2022, the government has asserted that there must not be a but-for causal requirement to establish an FCA violation premised on an AKS violation because "the AKS contains its own nexus requirement ... [that] does not limit AKS liability to situations where the desired outcome of the kickbacks actually materializes."[12]

Similarly, plaintiffs have argued that they must only show that one purpose of the remuneration was to induce a prescription to establish an FCA violation.[13] In other words, once the illegal offer is made, the AKS violation is complete and FCA liability can be established.

These arguments have a fatal flaw in common. They conflate the FCA elements and AKS elements into a single inquiry.[14]

While these may be relatively noncontroversial points about establishing an AKS violation under Title 42 of the U.S. Code, Section 1320a-7b(b), i.e., an offer without acceptance may lead to AKS liability, they ignore the resulting-from requirement in Title 42 of the U.S. Code, Section 1320a-7b(g).

The AKS contains its own nexus requirement for establishing AKS liability and the one-purpose test has been adopted in multiple circuits to address the AKS element of inducement.[15] But plaintiffs' arguments about the AKS elements say nothing about the causal resulting-from requirement, which appears in a separate, distinct subsection of the statute and relates to an entirely different type of liability.

The issue is not what is required to prove AKS liability. Rather, the issue is what is required to prove that a claim was false to establish FCA liability, which, according to Section 1320a-7b(g), requires a claim that includes items or services resulting from the AKS violation.

Interpreting Section 1320a-7b(g) as requiring nothing more than what is required to establish AKS liability under Section 1320a-7b(b) is not only contrary to the distinct text and structure in the statute, but also Congress' intent.

Congress added a specific resulting from requirement in Section 1320a-7b(g) to delineate the universe of claims that could be rendered false. Moreover, this interpretation ignores the critical differences between the FCA and AKS.

The FCA and AKS are separate statutes, enacted for entirely different purposes, and Congress specifically set forth distinct causation standards: The FCA was enacted to right harms caused to the government from false claims that were submitted, whereas the AKS is an intent-based crime criminalizing even

offers of remuneration that are never accepted.[16]

For the same reasons, plaintiffs' arguments that civil liability under the FCA cannot require but-for causation because criminal liability under the AKS requires a lesser causal standard also fail.

Given the different purposes of the statutes, the fact that there are additional elements needed to establish FCA liability — "resulting from" and the other FCA elements — is entirely appropriate. In addition, the FCA, a civil statute, requires a lower burden of proof than the AKS.

Applying any standard other than but-for causation will have serious, real-world detrimental effects.

Ignoring or watering down the "resulting from" language in the AKS is not only inconsistent with the plain meaning and purpose of the statute — it could also result in serious, real-world detrimental effects for entirely innocent patients and physicians.

Let's take a hypothetical: A doctor treats patients for a life-threatening condition. Based on her clinical experience, she has prescribed the same pharmaceutical product for years. Then one day, a representative for the pharmaceutical company calls on the doctor and offers something that a relator's counsel alleges is a kickback, one purpose of which was allegedly to induce the doctor to keep prescribing the product that she has prescribed for years.

The doctor politely declines, never sees her visitor again, and continues treating patients as she always has, using the same drug; her behavior is not affected one iota. Nonetheless, under the theory espoused by the relators' bar, every subsequent prescription from this doctor for this drug is tainted by the kickback, and every associated reimbursement claim to a federal healthcare program is false.

What does such a scenario mean for the doctor? She cannot prescribe the drug to government-insured patients without submitting so-called false claims, even though she did nothing remotely wrong.

What does that mean for her patients? Since all of these legitimate prescriptions have supposedly been transformed into tainted ones, their medically appropriate, life-saving drug would, at least according to plaintiffs, be ineligible for reimbursement unless they find a new doctor to write the prescriptions.

This is, of course, an absurd result, and it demonstrates why the "resulting from" language is a critical requirement that should be vigorously enforced. Applying the but-for standard would avoid these unintended outcomes, while still ensuring that those with criminal culpability may be prosecuted under the AKS and that the government can recover civil damages under the FCA if claims actually resulted from that wrongdoing.

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[1] 42 U.S.C. § 1320a-7b(g).

[2] 31 U.S.C. § 3729(a)(1)(A).

[3] See 42 U.S.C. § 1320a-7b(b).

[4] U.S. ex rel. Petratos v. Genentech, Inc., 855 F.3d 481, 486–87 (3d Cir. 2017) (citing 31 U.S.C. § 3729).

[5] See 42 U.S.C. § 1320a-7b(b)(2); see also U.S. v. St. Junius, 739 F.3d 193, 210 n.18 (5th Cir. 2013).

[6] 42 U.S.C. § 1320a-7b(g).

[7] For instance, where a defendant is alleged to have "caused" the submission of false claims, Relator will have to satisfy both the "resulting from" requirement in 42 U.S.C. § 1320a-7b(g), which is the subject of this article, and the separate causation element in the FCA.

[8] Burrage v. United States, 571 U.S. 204, 210–11 (2014); see also United States v. Jeffries, 958 F.3d 517, 521 (6th Cir. 2020) ("[T]he phrase 'results from' is not ambiguous . . .").

[9] See United States ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 834 (8th Cir. 2022); The American Heritage Dictionary of the English Language 1497 (5th ed. 2016) (defining "result," "results," and "resulting" as "[t]o happen as a consequence" or "[s]omething that follows naturally from a particular action, operation, or course; a consequence or outcome"); Webster's Third New International Dictionary 1937 (2002) (defining "result," "results," and "resulting" as "to proceed, spring, or arise as a consequence, effect, or conclusion").

[10] See, e.g., 155 Cong. Rec. S10852–54 (daily ed. Oct. 28, 2009) (Sen. Leahy stating that purpose of amendment is to "ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action under the False Claims Act" and Sen. Kaufman stating that the claim must "result[] from" illegal kickbacks); 155 Cong. Rec. S13693 (daily ed. Dec. 21, 2009).

[11] Cairns, 42 F.4th at 836.

[12] Brief for the United States as Amicus Curiae in Support of Appellants at 21, U.S. ex rel. Martin v. Hathaway, No. 22-1463 (U.S. Sept. 13, 2022), ECF No. 30.

[13] See United States v. Narco Freedom, Inc., 95 F. Supp. 3d 747, 759 (S.D.N.Y. 2015).

[14] For example, in United States v. TEVA Pharms. USA, Inc., No. 13 CIV. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016), the court properly characterized the defendant's argument that "the [complaint] fail[ed] to . . . 'allege a factual nexus between the improper conduct and the resulting submission of a false claim to the government.'" However, the court then described prior AKS cases holding that a relator must only show that "one purpose" of the remuneration was to induce. Id.; see also U.S. ex rel. Everest Principals, LLC v. Abbott Lab'ys, Inc., No. 3:20-CV-286-W (AGS), 2022 WL 3567063, at *6 (S.D. Cal. Aug. 18, 2022) (citing TEVA and holding same).

[15] Courts have held that a plaintiff may demonstrate inducement, an element of the AKS (not the FCA), if "one purpose" of the defendant's actions were to provide unlawful remuneration. See United States v. W. Carl Reichel, Case No. 1:15-cr-10324-DPW, D.I. 244 at 5-6 (D. Mass. June. 17, 2016).

[16] See 42 U.S.C. § 1320a-7b(b); see also, e.g., Garg v. Covanta Holding Corp., 478 F. App'x 736, 741 (3d Cir. 2012) (holding that the statutory requirements of the FCA limit recovery to "fraudulent claims that cause or would cause economic loss to the government") (quoting Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 179 (3d Cir. 2001)).