The Causation Trend in Anti-Kickback False Claim Cases: Courts' Rejection of Relators' Taint Theory Should "Cause" Them Concern at the Summary Judgment Stage of Qui Tam Litigation

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I. Introduction

The False Claims Act ("FCA")[1] permits a person, known as a "qui tam relator" (or more commonly, a "whistleblower"), to bring a lawsuit on behalf of the federal government when that person has information that a healthcare provider submitted false claims to the government. To sustain an FCA claim, a relator must prove that "(1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)."[2]

FCA cases often involve alleged violations of the federal Anti-Kickback Statute ("AKS"). Congress added specific language into the AKS in 2010, through the passage of the Patient Protection and Affordable Care Act ("PPACA"), to expressly provide that "a claim that includes items and services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."[3]

Partially because the phrase "resulting from" was not defined by the 2010 amendment, creative relators in FCA lawsuits based on alleged AKS violations have in recent years relied on a conflated "taint" theory of causation to advance their case. In essence, the theory goes like this: the provider participated in an unlawful kickback scheme; during the scheme, the provider submitted reimbursement claims to the government (as proven by aggregate Medicare or Medicaid claims data); at the same time, the provider certified that it was complying with all federal healthcare laws; and all claims the provider submitted during the scheme were "tainted" and thus false under the FCA.

Courts that have squarely addressed this "taint" theory since the passage of the 2010 amendment have consistently rejected it. In fact, the growing trend of courts is to require relators to produce evidence at the summary judgment stage of the lawsuit establishing an actual causal link between the alleged kickback scheme and the submission of false claims to the government. Merely asserting that all claims were "tainted" by kickbacks will not suffice.

II. Circuit Court Decisions

Two recent federal circuit court decisions arising from appeals in AKS-based qui tam lawsuits demonstrate this trend: *United States ex rel. King v. Solvay Pharms., Inc.*[4] and *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*[5]

In *King*, the relators – former sales representatives for the defendant pharmaceutical company, Solvay – claimed in their FCA lawsuit that Solvay orchestrated an off-label marketing and kickback

scheme to promote certain drugs, and this scheme "proximately caused physicians to prescribe these drugs for off-label uses to Medicaid patients."[6] [7] The district court granted summary judgment in Solvay's favor, and the relators appealed.

The Fifth Circuit Court of Appeals affirmed, first holding that there was insufficient evidence that the marketing scheme "*actually caused* off-label prescriptions to Medicaid patients."[8] The court then turned to the kickback portion of the scheme, where the relators alleged that Solvay illegally induced doctors to both promote and prescribe the subject drugs. Again, the court concluded that evidence of causation was lacking:

> Relators' evidence shows (1) physicians participating in Solvay programs in which they were compensated for consultations or presentations and (2) subsequent prescriptions by those physicians of Solvay's drugs to Medicaid patients. Nowhere, however, do Relators cite to evidence creating a genuine issue of material fact that such compensation, or any incidental benefits, caused those physicians to prescribe to Medicaid patients. . . . Although it is not an unreasonable inference that Solvay intended those programs to boost prescriptions, it would be speculation to infer that compensation for professional services legally rendered *actually caused* the physicians to prescribe Solvay's drugs to Medicaid patients.[9]

In effect, the court held that the relators' lawsuit was properly dismissed through summary judgment because they failed to establish that the alleged kickback scheme was the "but-for" cause of the submission of any false claims.[10]

In *Greenfield*, the relator was a former vice president of Accredo Health Group, Inc. ("Accredo"), a specialty pharmacy that delivered medication and provided in-home nursing care to hemophilia patients.[11] In his FCA lawsuit, Greenfield alleged that Accredo violated the AKS by making donations to two local charities which, in turn, recommended Accredo as a "preferred provider" of hemophilia-related services.[12] The district court granted summary judgment in Accredo's favor. In doing so, it rejected Greenfield's taint theory that "any and all claims submitted to the government for hemophilia patients, regardless of how they came to be customers of the defendants, violate the FCA because defendants certified their compliance with the AKS for each of those claims."[13] It held that Greenfield failed to meet the causation element of his claim because he did not show that Accredo received government payments "because of" or "as a result of" the alleged kickback scheme – effectively applying the *King* Court's "but-for" test.[14]

The Third Circuit Court of Appeals affirmed, although it took a different tack than the lower court. The issue, as the court framed it, was "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."[15] Greenfield cited data that Accredo "submitted claims for . . . federally insured patients during the relevant time period,"[16] and "insist[ed] that the taint of a kickback render[ed] every reimbursement claim false"[17] – thus advocating that no link was required. The court rejected Greenfield's "taint" theory.[18] On the other hand, it declined to adopt Accredo's – and the district court's – view that the relator must prove that the purported kickback scheme "actually caused" the submission of false claims.[19] Instead, it went with "something in between," setting out a "one claim" test.

The court explained that "[a] 'link' is required, but it is less than espoused by Accredo: For a[n] [FCA] violation, Greenfield must prove that at least one of Accredo's claims sought reimbursement for medical care that was provided in violation of the AKS. . . ."[20] To that end, the court emphasized that Greenfield could not overcome summary judgment "simply by demonstrating that Accredo submitted federal claims while allegedly paying kickbacks."[21] Instead, according to the court, there must be some "evidence that shows a link between the alleged kickbacks and the medical care received by at least one of Accredo's . . . federally insured patients."[22] The court concluded that because Greenfield presented no such evidence, the district court properly granted summary judgment in Accredo's favor.[23] Although the Third Circuit declined to adopt a "but for" causation test as the lower court did – and as the Fifth Circuit did in *King* – the decision is nonetheless notable due to its rejection of Greenfield's "taint" theory and its acknowledgement that, at the very least, some "link" is required between the alleged kickback scheme and the submission of purportedly false claims.[24]

III. Lower Court Decisions

Several district courts have also recognized that instead of relying on some theoretical "taint," a relator who bases an FCA lawsuit on AKS violations must establish a causal link between the alleged kickbacks and specific claims for government funds. For example, in *United States ex rel. Wall v. Vista Hospice Care, Inc.*,[25] the relator alleged that the defendants violated the FCA by falsely certifying compliance with the AKS. The underlying kickback scheme involved the defendants' alleged payment of incentive bonuses to employees in order to meet hospice admission and retention goals.[26] The district court for the Northern District of Texas granted the defendants' summary judgment motion because, in part, the relator failed to establish a causal link between the alleged kickback scheme and the actual submission of a false claim.[27] In so holding, the court emphasized that the relator "did not sufficiently link the payment of a bonus to a referral, patient, or claim[,]" and did not present "evidence of *any* claim that was false based on an AKS violation, asking the Court to assume that all claims submitted while Defendants were paying incentive bonuses were false."[28]

As noted in the introduction, Congress amended the AKS in 2010 to state "a claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim [under the FCA]."[29] District courts have concluded that the "resulting from" language of the AKS supports the conclusion that there must be a causal link between the alleged kickbacks and the submitted claims.[30]

For instance, in *Guilfoile v. Shields Pharm., LLC*,[31] the district court for the District of Massachusetts cited this statutory language in concluding that "[a]n illegal payment that violates the anti-kickback statute constitutes a false claim *only when it results* in a false claim being submitted to the government." There, the court dismissed the realtor's complaint[32] because he failed to allege sufficient facts "to show how the alleged anti-kickback violation could have led to the submission of false claims. . . ."[33] Likewise, in *United States ex rel. Fla. Sec'y of Anesthesiologists v. Choudry*,[34] the district court for the Middle District of Florida dismissed the relator's complaint, emphasizing that he "merely speculates that an unlawful kickback scheme exists and, by extension, asserts that all Medicare claims were 'tainted.'" Citing the AKS's express language, the court explained that "'a claim' is actionable under the [FCA] when 'it includes items or services *resulting from* a violation of

the [AKS].' While the defendants may have presented claims to Medicare, absent allegations that a claim is tied to a kickback, Relator fails to allege a plausible cause of action under [the FCA]."[35]

IV. Interplay with *Escobar*

It is worth noting here the possible interplay between these decisions and the Supreme Court's decision in *Universal Health Servs. v. U.S. ex rel. Escobar*,[36] which dealt, in part, with whether an "implied" false certification theory can be the basis of liability under the FCA.[37] In determining what Congress meant by the words "false" or "fraudulent" in the FCA, the Court looked to common law:

> Congress did not define what makes a claim 'false' or 'fraudulent.' But it is a settled principle of interpretation that, absent any other indication, Congress intends to incorporate the well-settled meaning of the common-law terms its uses. . . . And the term 'fraudulent' is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud.[38]

Citing this language, the Seventh Circuit Court of Appeals recently opined in *United States v. Luce*[39] that *Escobar* requires the application of all common law fraud principles in FCA cases, including causation. Further, the court observed "[t]he statutory language of the FCA does not suggest that Congress sought to depart from the established common-law understanding of causation in fraud cases."[40] That "common-law understanding," according to the court, "encompasses both cause in fact and legal cause."[41] Thus, the court concluded that the government or relator in an FCA lawsuit must prove that the defendant's alleged misrepresentations were both the "but for" and "proximate" cause of the government's damages (that is, the injury was "the type that a reasonable person would see as a likely result of his or her conduct.").[42] The Seventh Circuit's reasoning in *Luce* supports the argument that the above decisions requiring a causal link between the alleged kickback scheme and the submission of false claims to the government are consistent with – and, in fact, mandated by – *Escobar.*

V. Conclusion

These recent decisions provide an invaluable tool for providers defending FCA lawsuits premised on alleged AKS violations where the relator relies on a "taint" theory of causation. They make clear that merely citing aggregate Medicare or Medicaid claims data and theorizing that all claims submitted during the course of an alleged kickback scheme "must have" been false is insufficient to overcome a summary judgment motion regarding causation, a point the First Circuit Court of Appeals recently drove home in *United States ex rel. Booker v. Pfizer*:

> After six years of litigation, relators' only proffered evidence of actual false claims was aggregate data reflecting the amount of money expended by Medicaid for [the subject] prescription[] [drug]. . . . We have previously held comparable data insufficient on its own to support an FCA claim, even at the motion to dismiss stage. . . . Ultimately, summary judgment . . . is the put up or shut up moment in litigation, and a relator certainly must make a greater showing than is required in a pleading in order to get in front of a jury.[43]

For this reason, relators relying on a "taint" theory should have "cause" for concern at the summary judgment stage of qui tam litigation.

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[1] 31 U.S.C. §§ 3729-3733.

[2] *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009).

[3] 42 U.S.C. § 1320a-7b(g).

[4] 871 F.3d 318 (5th Cir. 2017).

[5] 880 F.3d 89 (3d Cir. 2018).

[6] 871 F.3d at 323.

[7] While physicians may legally prescribe drugs for all-label uses, pharmaceutical companies cannot legally promote their drugs for off-label uses.

[8] *Id.* at 329 (emphasis in original). *See also id.* at 330 (remarking that the relators had the "burden of producing evidence indicating that [allegedly improper lobbying] influence caused actual false claims . . . to be submitted for Medicaid reimbursement.").

[9] *Id.* at 332 (emphasis added).

[10] An action is the "but-for" cause of a harm if "the harm would not have occurred in the absence – that is, but for – the defendant's conduct." *Burrage v. United States*, 134 S. Ct. 881, 887-88 (2014).

[11] 880 F.3d at 91.

[12] *Id.*

[13] *United States ex rel. Greenfield v. Medco Health Sys., Inc.*, 223 F.Supp.3d 222, 228-29 (D.N.J. 2012).

[14] *Id.* at 230.

[15] 880 F.3d at 95.

[16] *Id.* at 93.

[17] *Id.* at 100.

[18] *Id.*

[19] *Id.* at 98.

[20] *Id.*

[21] *Id.* at 99.

[22] *Id.* at 100.

[23] *Id.*

[24] Note that two other Circuits have held similarly in FCA cases premised on allegations of unlawful off-label drug marketing. *See United States ex rel. Ibanez v. Bristol Myers Squibb Co.*, 874 F.3d 905, 917 (6th Cir. 2017) (affirming dismissal), *id.* at 916 ("[A]lthough relators allege defendants made false . . . statements in order to increase the number of . . . prescriptions, there are no allegations connecting these statements to any claim made to the government. . . . [R]elators . . . rely on a too-attenuated chain connecting alleged false statements to the submission of claims."); *Lawton ex rel. United States v. Takeda Pharm. Co.*, 842 F.3d 125, 132-33 (1st Cir. 2016) (affirming dismissal), *id.* at 131 ("While the complaint describes at considerable length . . . Takeda's marketing machinations, [it] falls well short of alleging, with the requisite amount of specificity, . . . how the Defendants' actions resulted in the submission of false claims."); *United States ex rel. Kelly v. Norvartis Pharm. Corp.*, 827 F.3d 5, 15 (1st Cir. 2016) (affirming dismissal). *But see U.S. ex rel. Dhillon v. Endo Pharms.*, 617 F. App'x 208, 214 (3d Cir. 2015) (unpub.), where the Third Circuit held, in an off-label marketing case, that a relator had established a "strong inference" that claims had been submitted as a result of the alleged scheme. *Dhillon* was not cited or discussed in the Third Circuit's subsequent *Greenfield* decision.

[25] 2016 WL 3449833, *1 (N.D. Tex. June 20, 2016).

[26] *Id.* at *9.

[27] *Id.* at *24-*25.

[28] *Id.* (emphasis in original).

[29] 42 U.S.C. § 1320a-7b(g) (emphasis added).

[30] The *Greenfield* Court, however, was not convinced by Accredo's argument to that effect. 880 F.3d at 96-98.

[31] 2017 WL 969329, *7 (D. Mass. Mar. 10, 2017) (emphasis added).

[32] In his complaint, the plaintiff asserted a retaliation claim under the FCA (alleging that his employment was terminated for investigating potential false claims), as well as several state law claims. *Id.* at *1.

[33] *Id.* at *8.

[34] 2017 WL 2604930, *7 (M.D. Fla. June 14, 2017).

[35] *Id.* at *7-*8 (emphasis in original). *See also United States ex rel. Brown v. Celgene Corp.*, 226 F.Supp.3d 1032, 1053 (C.D. Cal. 2016) ("Although the AKS does not itself establish a civil cause of action, it states 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 FCA. . . . Thus, Brown can establish an FCA claim by showing that (1) Celgene knowingly and willfully paid kickbacks to induce prescriptions of its drugs, and (2) claims for Celgene's drugs were presented to federal healthcare programs *as a result*.") (emphasis added), *id.* at 1057 (declining to determine whether the relator had "shown that any of the alleged kickbacks caused false claims" because he had not "identified any actionable kickbacks.").

[36] 136 S. Ct. 1989 (2016).

[37] Whether a claim is, in the first instance, "false" under the FCA is distinct from the issue of causation. A claim may be considered false under the FCA if it is factually or legally false. *See U.S. ex rel. Wilkins v. Untied Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). A factually false claim is one "in which a contractor or other claimant submits information that is untrue on its face," *United States v. Kellogg Brown & Root Servs., Inc.*, 800 F. Supp. 2d 143, 154 (D.D.C. 2011), such as "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010). On the other hand, a legally false claim is one that is "predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term." *Mikes v. Straus*, 274 F.3d 687, 696-97 (2d Cir. 2001). Legally false claims are further broken down into "express certification" and "implied certification" claims. An "express" certification claim "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Id.* at 698. An "implied" false certification claim "is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.*at 699. The *Escobar* Court held that the implied certification theory "can, at least in some circumstances, provide a basis for liability . . ." as long as the claim makes specific representations about a good or service (as opposed to merely requesting payment), and the defendant's failure to disclose noncompliance with the material statutory, regulatory, or contractual requirements makes those specific representations "misleading half-truths." 136 S. Ct. at 2001.

[38] Escobar, 136 S. Ct. at 2000 (internal citations, quotations, and alterations omitted).

[39] 873 F.3d 999, 1011-14 (7th Cir. 2017).

[40] *Id.* at 1012.

[41] *Id.*

[42] *Id.*

[43] 847 F.3d 52, 58 (1st Cir. 2017) (internal citations and quotations omitted). *See also United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (holding that an FCA relator cannot "merely . . . describe a private scheme in detail but then . . . merely allege . . . that claims requesting illegal payments must have been submitted, were likely submitted[,] or should have been submitted to the Government.").