Legal Opinion Letter

Vol. 27 No. 3 April 6, 2018

Washington Legal Foundation
Advocate for Freedom and Justice®
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Washington, DC 20036
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Third Circuit Confirms that False Claims Act Liability Requires Actual Evidence of a False Claim

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It has always been the case that "[e]vidence of an actual false claim is the *sine qua non* of a False Claims Act violation." *See, e.g.*, *United States ex rel. Booker v. Pfizer*, Inc., 847 F.3d 52, 57 (1st Cir. 2017). The U.S. Court of Appeals for the Third Circuit recently set out one view of what that means in the context of a False Claims Act (FCA) suit premised on alleged violations of the Anti-Kickback Statute: the relator "must prove that at least one of [the defendant's] claims sought reimbursement for medical care that was provided in violation of the Anti–Kickback Statute (as a kickback renders a subsequent claim ineligible for payment)." *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 98 (3d Cir. 2018). Because the relator (the person who advances a public lawsuit in the name of the United States) could not link any alleged kickback violation to even a single federal claim for payment, the appellate court found that summary judgment was correctly entered for the defendant. *Id.* at 98-100.

The litigation began in 2012 when relator Steve Greenfield sued his former employer, Accredo Health Group, Inc.—a specialty pharmacy that delivers home care and blood-clotting medication to hemophilia patents. The complaint alleged that Accredo violated the False Claims Act by falsely certifying compliance with the Anti-Kickback Statute. The core of the alleged kickback scheme was financial donations for medical recommendations—more specifically, that Accredo made annual donations to at least two local hemophilia charities, and that those same charities in turn recommended Accredo as an approved provider and vendor.

During discovery, Greenfield learned that Accredo had submitted claims for 24 patients who were federally insured through Medicare. Greenfield could not, however, link any of those 24 patients (and the related federal payments) to the alleged Anti-Kickback Statute violations. In particular, the district court found no evidence that any patient was referred to or selected Accredo as a result of the charitable donations. As a result, the court entered summary judgment for Accredo.

The central issue on appeal 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." *Id.* at 95. The relator argued for "no link at all," because, in his view, it was enough that Accredo certified compliance with the Anti-Kickback Statute whenever it billed Medicare. *Id.* at 92 & n.3. The district court and Accredo were at the other extreme, "arguably requiring a causal relationship." *Id.* at 92-95.

The Third Circuit ultimately landed on "something in between." It held that, to prevail at summary judgment, relators need not necessarily prove that the alleged kickback violations were a but-for cause of *every* federally insured patient's decision to use the defendant's services, though they must provide evidence of "at least one" such patient and claim. *Id.* at 98-99.

In reaching that result, the Third Circuit forcefully rejected the relator's arguments for a more lenient evidentiary burden. The relator insisted that Accredo "necessarily violated the False Claims Act because all of its

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24 claims incorrectly certified that it did not pay any illegal kickbacks" and that "the taint of a kickback renders every reimbursement claim false." *Id.* at 98, 100. The Third Circuit "disagree[d]": "[a] kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Ibid.* Nor was it "enough … to show temporal proximity between [the] alleged kickback plot and the submission of claims for reimbursement." *Ibid.* In either case, the relator's theory amounted to nothing more than an inferential leap that illegal payments "must have been" submitted, "were likely" submitted, or "should have been" submitted. *Id.* at 98. Such conjecture falls short of the required "evidence of the actual submission of a false claim." *Ibid.*

The Third Circuit rooted its "at least one actual claim" requirement in its own precedent and that of its "sister circuits." For its part, the Third Circuit had previously terminated a relator's case at summary judgment when he could not show "a single claim … actually submitted" that was linked to the alleged wrongdoing. *Id.* at 99. The First, Seventh, and Ninth Circuits had likewise entered summary judgment for defendants when plaintiffs had "failed to carry [their] burden" without pointing to a single false claim that had actually been submitted. *Ibid.*

These principles foreclosed Greenfield's claim. According to the court of appeals, even assuming that Accredo had violated the anti-kickback law, the FCA requires more—Greenfield needed to "connect[]" those alleged kickbacks to at least one actual claim for federal reimbursement. *Id.* at 99-100. But he could not "point to at least one claim that covered a patient who was recommended or referred to Accredo by [the relevant charities]," or show that "that at least one of the 24 federally insured patients for whom Accredo provided services and submitted reimbursement claims was exposed to a referral or recommendation of Accredo by [the charities] in violation of the Anti–Kickback Statute." *Ibid*. And the Third Circuit was unwilling to accept probabilities or possibilities rather than actual evidence: because it was "impossible to rule out the chance that none of the 24 were [charity organization] members or that none of the 24 members were exposed to an illegal referral or recommendation," summary judgment was properly entered for defendant. *Ibid.*

The Third Circuit's holding reiterates the fundamental importance of requiring *qui tam* plaintiffs to *prove* that there was an actual false or fraudulent claim for payment submitted to the federal government. That cornerstone of FCA liability is front-and-center in the very name of the statute—the *False Claims* Act—and it is why courts have long recognized that "[e]vidence of an actual false claim is the *sine qua non* of a False Claims Act violation." *Booker*, 847 F.3d at 57; *see also, e.g.*, *United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 997 (9th Cir. 2002) ("It seems to be a fairly obvious notion that a False Claims Act suit ought to require a false claim").

The Third Circuit's holding also confirms that summary judgment should be an absolute backstop against relators who lack actual proof of actual false claims. At the motion to dismiss stage, many circuits (including the Third Circuit) do not necessarily require plaintiffs to plead the submission of an actual false claim, so long as they can "allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014). But summary judgment "is the put up or shut up moment in litigation." *Booker*, 847 F.3d at 58. By that point, relators (like Greenfield) have secured the opportunity to seek discovery, and if they *still* cannot "point to at least one claim" rendered false or fraudulent by the alleged kickbacks, the case should quite rightly be over. Speculation or inferences about claims for government payment simply cannot substitute for actual evidence and proof.

This case has broad implications for all defendants, but should prove particularly significant for pharmaceutical manufacturers. The decision is now another arrow in the quiver of any defendant confronted with a False Claims Act claim premised on alleged Anti-Kickback Statute violations. For pharmaceutical manufacturer defendants, as relators continue to steer clear of off-label promotion allegations (due to First Amendment hurdles) and to gravitate toward Anti-Kickback Statute allegations, this decision should be very helpful in restraining those relators and in curbing that litigation trend.

 ISBN 1056 3059