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## Top Cases And Developing Trends In FCA Litigation: Part 1

By Andy Liu, Robert Rhoad and Jason Lynch (February 7, 2019, 11:02 PM EST)

It was another year of interesting developments under the federal False Claims Act.[1] Based on our collective decades of experience investigating and litigating these cases at all stages, we compile below what we view as the most important recent developments and the implications of these decisions for FCA jurisprudence in the coming months.

## **U.S. Supreme Court Takes Up FCA Statute of Limitations**

An FCA plaintiff only has six years to bring her case, except that she will get three years after "facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances," even if that means more than six years after the action accrues, but only to a maximum of 10 years.[2]

This is one of several FCA provisions born of a simple idea but ambiguously drafted. Although the three-year provision maps easily onto a case brought by the government, what about qui tam cases brought by relators? May they avail themselves of the provision?

The federal appeals courts have reached a three-way split on the question. The U.S. Court of Appeals for the Fourth Circuit,[3] U.S. Court of Appeals for the Fifth Circuit[4] and U.S. Court of Appeals for the Tenth Circuit[5] have all held that the statute of limitations in Section 3731(b)(2) applies only in cases brought by the government or in which it has intervened. The Third[6] and Ninth[7] circuits allow a relator to rely on Section 3731(b)(2) in a declined case, but hold that the limitations period is triggered by the relator's knowledge of the alleged fraud, not by the government's knowledge.

In United States ex rel. Hunt v. Cochise Consultancy Inc.,[8] the U.S. Court of Appeals for the Eleventh Circuit adopted a third reading: Not only may a relator rely on Section 3731(b)(2) in a declined case, but the limitations period is triggered by the government's knowledge of the alleged fraud.



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The U.S. Supreme Court has granted certiorari. The U.S. solicitor general was not asked for his views on

the propriety of review and the government does not seem to have weighed in on any of the abovecited cases, so the government will unveil its position it its merits brief.

Whatever the outcome, the Supreme Court's reasoning may shed light on how it views the role of relators vis-à-vis the government under the FCA. This could inform issues such as the government's authority to dismiss qui tam actions under Section 3730(c)(2)(A), the government's discretion to settle cases over relators' objections under Section 3730(c)(2)(B) or relator-share disputes under Section 3730(d).

## U.S. Supreme Court Won't Address Government Knowledge of Allegations and Its Impact on Materiality

Second only to the above case that the Supreme Court will take are the two cases that it won't take: Gilead Sciences Inc. v. United States ex rel. Campie and United States ex rel. Harman v. Trinity Industries Inc.[9] Both cases implicate perhaps the most important emerging issue under Universal Health Services v. United States ex rel. Escobar: When the government already knows about the allegations brought by an FCA plaintiff, and has continued to pay the defendant nonetheless, how does that affect the materiality analysis?

Although the results in Gilead Sciences and Trinity Industries Inc. may seem at odds, the differences in procedural posture may reconcile the two.

In Gilead Sciences, the defendant marketed three drugs for use in HIV treatment. The U.S. Food and Drug Administration monitored the production of those drugs and even sent letters warning of potential regulatory violations. Yet at no point did FDA rescind its approval of Gilead's medicines. The U.S. Department of Justice did not intervene in the relator's suit. On that record, the U.S. Court of Appeals for the Ninth Circuit found no government knowledge of the defendant's violations as the government continued to pay.

The Supreme Court asked the solicitor general for his views. The solicitor general, not surprisingly, agreed: "Most of the circumstances on which petitioner relies do not necessarily show relevant government knowledge." [10]

The growing dispute is over whether the government knew of violations or merely of allegations. The Supreme Court in Escobar spoke in terms of "actual knowledge that certain requirements were violated." [11] Yet the solicitor general endorsed a "holistic inquiry," [12] which in our view should at least consider government knowledge of allegations.

While such knowledge may not be per se sufficient, neither should it be per se insufficient to dismiss a case. We regret that the Supreme Court will not be giving further guidance on how to account for government knowledge of allegations, which we have found common in FCA cases.

The Ninth Circuit and the solicitor general emphasized that Gilead Sciences was at the "pleading stage." But Escobar made clear that materiality is not too fact intensive to be examined on a motion to dismiss.[13] Thus, we think it cannot be enough that "the parties dispute exactly what the government knew and when,"[14] for that is inevitable at the pleading stage. Courts must always determine whether a given complaint has alleged plausibly and particularly the facts necessary to support materiality.[15]

For defendants disappointed in the solicitor general's ultimate position, there is at least helpful language in his brief from a defendant's perspective:

Petitioner correctly emphasizes (Reply Br. 5) that, even at the pleading stage, an FCA relator cannot rest solely on "conjecture" or "speculation." A relator's burden is to plead with particularity facts from which a fact finder might plausibly infer that the relevant misstatements were material. And given Escobar's holding that not every violation of a federal payment condition is material, see 136 S. Ct. at 2003, a complaint may be inadequate as to materiality even though it adequately alleges a violation.[16]

This is merely what Escobar demands, but it gives some comfort to hear the solicitor general agree that "conjecture" and "speculation" are not enough, and to reiterate that not all violations are material violations.

By far the most surprising turn of events was when the government promised that, were the case remanded, the DOJ would move to dismiss it under 31 U.S.C. Section 3730(c)(2)(A). The solicitor general cited the "merits" of the case, but also cited the "burdensome discovery and Touhy requests" that might follow if the case proceeds.[17] It is welcome news to hear the government suddenly interested in the discovery burdens in meritless qui tam cases, which have been born by defendants for decades while the DOJ rarely used Section 3730(c)(2)(A).

But are "discovery burdens" really the grounds on which the DOJ wants to rely? After Escobar made clear that materiality as an essential element of liability, won't every FCA case warrant discovery into what the relevant agency knew and when they knew it? If the government moves to dismiss every case in which discovery might be sought from its agencies, that will leave precious few cases proceeding. Instead, especially given the solicitor general's contemporary derogation of the merits of Gilead Sciences, it is more likely that discovery in this case would show that the government did not find the alleged falsity to be material. By staking its case on discovery burdens, the government may be proving too much.

Finally, we found an interesting footnote in the solicitor general's brief, in which he claimed that the government has "means short of dismissal" to undercut a relator's case.[18] It seems that the solicitor general has in mind an agency declaration to the effect that the alleged violations were not material. This approach, if undertaken, would surely draw fire from the relators' bar. There is also authority for the proposition that the qui tam provisions were meant to remedy fraud that the government knew about but didn't want to address, which would require the courts to step in between relators and the government. We shall see.

The Trinity Industries case revolved around highway guardrails, which were reimbursed in part by the U.S. Federal Highway Administration. The producers of such guardrails sought FHWA safety certifications, which all 50 states relied upon in approving the guardrails for installation. The relator in Trinity Industries essentially alleged that the company modified the guardrails without telling the government.

The issue was that the government already knew this before the relator brought suit: Trinity and the relator had met separately and repeatedly with the FHWA, which had been made aware of every alleged defect. The FHWA issued an official memorandum in which it "validated that the [relevant guardrail] was crash tested" and that it was "eligible for Federal reimbursement," such that there was "an unbroken chain of eligibility for Federal-aid reimbursement" during the relevant time period.

In the face of all this, the district court refused to dismiss the case and the relator took the case to trial. In the end, the relator obtained a \$575 million judgment in treble damages, \$138 million in statutory penalties and \$19 million in attorneys' fees and costs. Yet the Fifth Circuit vacated the entire judgment because the "continued approval of reimbursement" by the FHWA precluded any finding of damages or, more fundamentally, of materiality.

How do we reconcile the Trinity Industries and Gilead Sciences opinions? While seemingly at odds, the Fifth Circuit in Trinity Industries in fact drew "guidance" from the Gilead Sciences opinion. The principal difference is procedural posture: The court in Gilead was at the pleading stage, whereas the Trinity court had the benefit of a developed record.

As we noted above, however, it is not enough for a court to deny a motion to dismiss merely because no evidence has been adduced. That would contradict Escobar, in which the court went out of its way to say that materiality — which must be alleged with particularity under Rule 9(b) — is not too fact intensive to resolve on a motion to dismiss. Because the Supreme Court won't take either case, lower courts will have to continue wrestling with the issue.

## Courts are Requiring More of FCA Plaintiffs Alleging "Tainted Claims"

The FCA often serves as a cause of action for violations of other statutes. The Anti-Kickback Statute,[19] for example, is frequently a mere predicate to an FCA case even though it provides its own civil remedies.[20] As the theory goes, claims that are "tainted" by AKS violations render those claims "legally false" for FCA purposes.

This theory was actually codified by the Affordable Care Act.[21] That is rare among FCA predicate statutes, however. Most plaintiffs are merely alleging a "taint" with no express statutory basis for saying so. The fact that the AKS is statutorily linked to the FCA makes the following cases all the more interesting.[22]

In United States ex rel. Greenfield v. Medco Health Solutions, the relator alleged that a pharmacy illegally donated to certain charities in order to receive patient referrals and then allegedly falsely certified that it had complied with the Anti-Kickback Statute when seeking reimbursement.[23] The defendant obtained summary judgment in the district court because the relator "failed to provide evidence of even a single federal claim for reimbursement ... that was linked to the alleged kickback scheme."[24] Specifically, the district court found no causal link between the pharmacy's donations and a patient's decision later to use the pharmacy.[25]

While affirming the judgment, the U.S. Court of Appeals for the Third Circuit nonetheless rejected the district court's requirement of "proof that the underlying medical care would not have been provided but for a kickback." [26] Instead, the Court of Appeals read from the legislative history of the FCA and AKS an intent "to reach a broad swath of 'fraud and abuse' in the federal healthcare system," and held that neither statute "requires a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider." [27]

Notably, the Third Circuit expressly rejected the argument that "the taint" of the alleged kickbacks automatically "renders every reimbursement claim false." Rather, on summary judgment at least, it is not enough for an FCA plaintiff to show merely that the defendant "submitted federal claims while allegedly paying kickbacks." [28] In other words, "[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."[29] Accordingly, an FCA plaintiff must demonstrate "at least one claim that covered a patient who was recommended or referred" in violation of the Anti-Kickback Statute.[30] Failing "evidence ... link[ing the] alleged kickback scheme to any particular claim," an FCA defendant is entitled to summary judgment.[31]

The government filed an amicus brief in the appeals court, "contending the [district court] erred to the extent it required [the relator] to prove that patients chose [the defendant] because of HSI/HANJ's referrals and recommendations. In [the government's] view, all that needed to be shown was a claim that sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute.[32] Though the government clearly lost on that point, it did not appeal to the Supreme Court.

In Carrel v. AIDS Healthcare Foundation, three former employees alleged that the incentives offered to AHF employees and patients were unlawful kickbacks that rendered AHF's claims for reimbursement false.[33] The district court dismissed most of the relators' claims under Rule 9(b). Later the court granted summary judgment to AHF on the remaining claims based on the employee exemption in the AKS. The Eleventh Circuit affirmed on the AKS-exemption holdings.

The appeals court then analyzed the dismissed claims under Rule 9(b). Eleventh Circuit precedent requires — perhaps more stringently than in its sister circuits — particular allegations about the actual submission of false claims.[34] Applying that test to the claims in Carrel, the court found them insufficiently pled.

Although the relators had participated in the provision of health care services and were privy to "financial review meetings," they "failed to explain how their access to possibly relevant information translated to knowledge of actual tainted claims presented to the government."[35] Ultimately, they alleged a number of "background factors" but not that they "ever converged and produced an actual false claim."[36] Relators were not permitted to "rely on mathematical probability to conclude that [AHF] surely must have submitted a false claim at some point."[37]

These are welcome developments indeed. Plaintiffs should not be allowed merely to allege the violation of a different statute — especially one that prescribes its own civil remedies — and then bring an FCA action on the theory that the claims are "tainted" and thus false. 2018 has given defendants more ammunition to fight off these types of allegations.

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- [1] 31 U.S.C. Section 3729.
- [2] 31 U.S.C. Section 3731(b)(2).
- [3] United States ex rel. Sanders v. North American Bus Industries Inc., 546 F.3d 288 (4th Cir. 2008).
- [4] United States ex rel. Erskine v. Baker, 213 F.3d 638 (5th Cir. 2000) (per curiam) (unpublished).

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[5] United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah, 472 F.3d 702 (10th Cir. 2006).
[6] United States ex rel. Malloy v. Telephonics Corp., 68 F. App'x 270 (3d Cir. 2003).
[7] United States ex rel. Hyatt v. Northrop Corp., 91 F.3d 1211 (9th Cir. 1996).
[8] United States ex rel. Hunt v. Cochise Consultancy Inc., 887 F3d 1081 (11th Cir 2018).
[9] Gilead Sciences Inc. v. U.S. ex rel. Campie, No. 17-936 (S. Ct.); U.S. ex rel. Harman v. Trinity Indus.,
No. 17-1149 (S. Ct.).
[10] Br. at 11.
[11] 136 S. Ct. 1989, 2003 (2016).
[12] Br. at 17.
[13] 136 S. Ct. at 2004 n.6.
[14] Br. At 10.
[15] See Escobar, 136 S. Ct. at 2004 n.6.
[16] Br. at 14.
[17] Br. at 15.
[18] Br. at 16 n.*.
[19] 42 U.S. Code Section 1320a-7b.
[20] 42 U.S. Code Section 1320a-7a(a)(7).
[21] 42 U.S. Code Section 1320a-7b.
[22] U.S. ex rel. Greenfield v. Medco Health, 880 F.3d 89 (3d Cir. 2018); Carrel v. AIDS Healthcare
Foundation Inc., 898 F.3d 1267 (11th Cir. 2018).
[23] 880 F.3d 89, 91-92 (3d Cir. 2018).
[24] Id. at 91.
[25] Id. at 95.
[26] Id. at 100.
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[27] Id. at 96-97.

[28] Id. at 99-100.
[29] Id. at 100.
[30] Id.
[31] Id.
[32] Id. at 93.
[33] 898 F.3d 1267 (11th Cir. 2018).
[34] See id. at 1275 (collecting cases).
[35] Id. at 1277-78.

[36] Id. at 1277.

[37] Id.