Whose Knowledge Counts? The Expanding Scope of Government Knowledge in FCA Cases

By Michael Wagner and Dan Grant on June 12, 2020

False Claims Act

Next week marks the four-year anniversary of the Supreme Court's landmark False Claims Act ("FCA") decision in *Universal Health Services, Inc. v. Escobar*, 136 S. Ct. 1989 (2016). In *Escobar*, the Court set a high bar for demonstrating the materiality of an alleged violation to the Government's payment decision, declaring that "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." In so holding, the Supreme Court confirmed that the question of government knowledge lies at the heart of FCA liability determinations, but it did not specifically address who counts as "the Government" for purposes of this materiality inquiry. The answer to this question has far-reaching consequences for both determinative legal questions and government discovery disputes. As discussed below, a number of circuits have made clear that the relevant scope of government knowledge includes both the payor agency and other agencies with regulatory oversight and enforcement responsibilities.

The Department of Justice ("DOJ") often takes the position that when assessing materiality and resolving discovery disputes the only relevant question is how the paying agency acted after it learned about the defendant's alleged conduct. DOJ therefore might attempt to argue that it is irrelevant whether the Food and Drug Administration ("FDA") or the Department of Health and Human Services Office of Inspector General ("HHS-OIG") investigated a relator's allegations and took no action because those are not the agencies that continued to pay the allegedly false claims. Likewise, DOJ might contend that a defendant has no need for discovery from the FDA or HHS-OIG for the same reason. Post-*Escobar*, however, a number of courts have cast doubt on this narrow scope of DOJ's preferred materiality analysis, instead expressing a willingness to consider knowledge of the Government more broadly beyond the paying agency.

To take one example, the First Circuit has held "even in an ordinary situation *not involving misrepresentation of regulatory compliance made directly to the agency paying a claim*, when 'the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.'" *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34-35 (1st Cir. 2017) (quoting *Escobar*, 136 S. Ct. at 2003) (emphasis added); ***see also D'Agostino v. ev3, Inc.***, 845 F.3d 1 (1st Cir. 2016). *Nargol* related to allegedly false statements the defendant made to the FDA that led to FDA approval of a defective hip replacement product. The relators informed the FDA about the defendant's allegedly false statements. Despite learning about the

defendant's conduct, the FDA did not withdraw or suspend product approval. The First Circuit explained that the "very strong evidence" of government inaction despite knowledge of alleged misrepresentations "becomes compelling when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position." *Nargol*, 865 F.3d at 35. Even though the FDA was not the paying agency, the First Circuit held that the FDA's inaction demonstrated the immateriality of any misrepresentation.

Similarly, in *United States ex rel. Petratos v. Genentech Inc.*, the relator alleged that providers submitted false claims to the Centers for Medicare & Medicaid Services ("CMS") because the defendant suppressed data that would have required the company to file adverse event reports to the FDA that could have resulted in changes to a drug's FDA label. 855 F.3d 481, 485 (3d Cir. 2017). The relator raised his allegations and disclosed "material, non-public evidence . . . to the FDA and Department of Justice." The Third Circuit held that since the relator "concede[d] that the expert agencies and government regulators have deemed [the alleged] violations insubstantial, . . . we do not think it appropriate for a private citizen to enforce these regulations through the False Claims Act." Additionally, the Third Circuit explained that even after receiving information from the relator, the FDA "continued its approval" of the drug, added indications, and did not initiate proceedings to enforce its adverse-event reporting rules or require the defendant to change the drug's FDA label. The court also noted that "the Department of Justice has taken no action . . . and declined to intervene in this suit." *Id.*

Finally, the Fifth Circuit has looked to the actions of other non-payor government actors to support a lack-of-materiality holding. In *United States ex rel. Harman v. Trinity Industries Inc.*, the Fifth Circuit summarized case law from a variety of circuits and concluded that they stand for the proposition that "continued payment by the federal government [(as a whole rather than just the paying agency)] after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." 872 F.3d 645, 663 (5th Cir. 2017). Although the crux of the court's holding regarding a lack of materiality turned on the knowledge and actions of the paying agency, it also looked to actions of other agencies in reaching its conclusion that the allegations were not material. For example, the court cited the non-intervention decisions of various state governments in parallel state FCA actions as evidence refuting the relator's assertion that various state governments considered the defendant's conduct material. In addition, the court noted that DOJ declined the relator's *Touhy* request to produce officials to testify, which "once again [sent] the message that the government did not believe itself to be a victim of any fraud, a position from which it has not to this day retreated." *See also United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017) (considering knowledge of the Defense Contract Audit Agency rather than the specific paying agency); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (examining "the subsidizing agency *and other federal agencies*" when assessing materiality (emphasis added)); *United States ex rel. Ubl v. IIF Data Sols.*, 650 F.3d 445, 447 (4th Cir. 2011) (explaining that there is "no reason why the government's knowledge would become irrelevant simply because the employees with the knowledge do not work for the particular agency that happens to pay the contractor's invoices").

This emerging line of cases is fully consistent with *Escobar*'s heightened materiality standard. Courts have recognized that "[t]he FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments." *D'Agostino*, 845 F.3d at 8. After all, "[a]s the interests of the government and relator diverge, [the FCA's] enlistment of private enforcement is increasingly ill served." *Harman*, 872 F.3d at 669-70. Applying these principles, there is no reason to limit the "government knowledge" inquiry to the payor agency alone, particularly

where other agencies with regulatory oversight and enforcement responsibilities have examined the alleged misconduct and deemed it unworthy of any corrective or enforcement action. In such cases, a government regulator's decision *not* to act despite knowledge of alleged misconduct just as clearly evinces a judgment about the immateriality of the conduct as a payor agency's decision to continue payment. It is heartening to see the courts of appeals acknowledging this truth, and one can only hope that courts wrestling with materiality questions will continue to consider broadly what relevant government agencies knew about a relator's allegations and how they reacted.

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