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Health Care Enforcement Year in Review and 2019 Outlook: Civil Litigation Developments and Settlements

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As in years past, the False Claims Act (FCA) remained a powerful health care enforcement tool in 2018, and FCA investigations and litigation persisted, fueled mainly by hundreds of lawsuits filed annually by relators, including 645 new *qui tam* actions initiated in FY 2018. An earlier post in our blog series analyzed data associated with these FCA litigation trends. Last year brought abundant, notable FCA case law developments and civil settlements, in addition to numerous Department of Justice (DOJ) policy changes, which we discussed in a prior post. This post covers 2018's most significant developments in FCA litigation and settlements, some of which are likely to influence the prosecution and defense of FCA cases for years to come.

Key FCA Civil Litigation Developments

Courts Continued to Grapple with the Application of Escobar

Consistent with the trend from last year, Courts of Appeals and federal district courts continued to apply the Supreme Court's 2016 decision in *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), which endorsed the theory of "implied false certification" under the FCA. As we covered in detail, the Court premised this theory on a "rigorous and demanding" element of "materiality," requiring that the alleged violation of a statute, regulation, or contract that gives rise to an FCA violation be "material" to the government's payment decision and that the provider or contractor must know that it is material. The Court's materiality analysis centered on "the likely or actual behavior" of the agency that made the payment decision. The Court also rejected the view that "materiality is too fact intensive to dismiss False Claims Act cases on a motion to dismiss . . . " so the stage was set for litigating the central issue of what is required, at the pleading stage, to allege materiality and survive a motion to dismiss.

As expected, extensive litigation concerning materiality has ensued. All but one U.S. Courts of Appeals – and dozens of federal district courts in every circuit – have grappled with this issue. In 2018, the central issues confronted by the Courts of Appeals were the significance of the

government's payment decisions and whether DOJ or relators need to plead that the alleged violation did or would have influenced the government's payment decision.

Several Courts of Appeals, including the First, Third, and Fourth Circuits, have held that the complaint must plead plausible facts showing that the alleged violation impacted or, if known, would have impacted the government's payment decision. Two circuits, however, decided that relators need not plead that the alleged violation did or would have impacted the government's payment decision (or that the government would have paid claims even in the face of material violations). These cases presented an opportunity to revisit *Escobar*.

In particular, the *certiorari petition* in a Ninth Circuit case, *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017) – which was discussed in a post last month – merited close attention. In Campie, the relators alleged violations of good manufacturing practices by a pharmaceutical manufacturer with respect to HIV drugs. FDA had some actual knowledge of the alleged violations but never withdrew approval of the drugs, and the government never ceased paying for the drugs.

The Supreme Court asked for the Solicitor General's views of the materiality standard under the FCA in connection with this petition. In November 2018, the Solicitor General filed an *amicus curiae* brief discussing whether the relators' FCA case should be dismissed. The Solicitor General agreed with the Ninth Circuit that the case should not be dismissed at the pleadings stage, but acknowledged that, given the government's continued payments, the relators "face[d] an uphill battle in alleging materiality sufficient to maintain their claims." Further, the Solicitor General argued that dismissal was not warranted based on case-specific circumstances, such as the dispute over the extent and timing of the agency's "actual knowledge" of the alleged violations at the time of payment, and potential reasons for the government to keep paying claims even in the event of actual knowledge of material violations.

The Solicitor General suggested circumstances where a violation of legal or contractual requirements is "material" (and thus actionable) even if the government continued to pay claims after the agency had actual knowledge of the alleged violations. First, the "government's knowledge of allegations that contractual or legal requirements have been violated" obtained through a *qui tam* FCA complaint cannot be equated with "government knowledge that violations have actually occurred." Second, "the government may have a variety of reasons for continuing to pay that entity for goods or services," including keeping federal programs operating, ensuring compliance with the government's own legal and contractual obligations, or determining that the alleged violation is not sufficiently serious to warrant a refusal to pay, and thus immaterial under *Escobar*. Finally, the Solicitor General, like the Ninth Circuit, rejected the defendants' argument that in the face of continued payment by the government, a relator must plead the reasons for such continued payment to overcome a presumption of immateriality. Notably, the Solicitor General also informed the Court that, if the case is remanded, the United States will exercise its authority under Section 3730(c)(2)(A) of the FCA to dismiss the case, which we described in a prior post in this blog series.

On January 7, 2019, the Supreme Court denied *cert.* in *Campie*, which means that the Ninth Circuit's decision on materiality will remain intact and that the case will be remanded at which time DOJ will presumably seek to dismiss it. Also on January 7th, the Supreme Court denied *cert.* in *U.S. ex rel. Harmon v. Trinity Industries*, which we covered in a previous post. In *Trinity Industries*, the relator sought Supreme Court review of the impact of continued government payments on the materiality standard, which was the basis for the Fifth Circuit's decision to reverse a jury award of $664 million against Trinity Industries due to the lack of materiality, and to enter a judgment for Trinity Industries to

end the case. The Supreme Court also denied *cert.* in *Trinity Industries* on January 7, 2019, thus the Court will not consider the issue of materiality in the 2018-2019 term.

Another closely watched case in 2018 was the Sixth Circuit decision in *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.,* No. 17-5826 (6th Cir. June 11, 2018.). In the second appeal, in this case, the court reversed the lower court and held that a complaint sufficiently alleged fraud as to the timing of need certifications for home health services. Medicare requires a completed and dated plan of care, signed by a physician "[b]efore the claim for each episode for services is submitted for the final percentage prospective payment." Relator alleged that defendant Brookdale, a home health provider, submitted bills for home health services where the physician's signature on the certification was not obtained at the time the plan of care was established or "as soon thereafter as possible," as set forth in the regulations.

A divided panel held that a relator adequately alleged that defendant submitted home health claims with plans of care that were "untimely" signed and certified by physicians. Over a vigorous dissent, the two judges in the majority held that the relator was not required to plead facts about whether or how any violation of this regulation had ever affected past government payment decisions, and that this pleading deficiency could not weigh against finding materiality. The home health provider filed a petition for *writ of certiorari*, asking the Supreme Court to review the Sixth Circuit's decision, on November 20th.

A few takeaways from these case law developments are clear. First, as we have discussed since the *Escobar* decision, the government's knowledge of the allegations – both what it knew and when – and regulatory and payment history are central materiality issues. If the relator or DOJ has not alleged facts to support materiality, or has not pleaded why payment continued in light of actual knowledge, this argument might serve as the basis for a dismissal (and should be preserved in any instance given that the Supreme Court might hear these issues in the future). Second, if litigation is a possibility, it is critical that counsel develop – through aggressive discovery – a clear understanding of actual government knowledge of the alleged (or similar) conduct and any government payment history.

Appellate Courts Issued Numerous Decisions Addressing FCA Cases Based on Alleged Lack of Medical Necessity

In 2018, a number of appellate courts decided cases involving FCA claims based on allegations that health care procedures or services reimbursed by Medicare or Medicaid were medically unnecessary. A central question in these cases is whether medical judgments – often the subject of competing medical expert opinion – can be "objectively false" and thus actionable under the FCA. As we discussed last year, over the last couple of years, several district courts have held that differences of clinical judgment about medical necessity cannot be "objectively false" under the FCA because "differences of opinion between physicians and medical experts about which reasonable minds could differ" cannot prove falsity under the FCA. Examples of such cases include *United States v. AseraCare Inc.,* 176 F. Supp. 3d 1282 (N.D. Ala. 2016) and *United States ex rel. Polukoff v. St. Mark's*, No. 16-cv-00304, 2017 U.S. Dist. LEXIS 8167 (D. Utah Jan. 19, 2017). As a result, several district courts dismissed FCA allegations that were based on the alleged lack of medical necessity.

However, several appellate courts pushed back last year by reversing district court decisions and finding instead that medical judgments can be "false" under the FCA. First, in *Polukoff*, the Tenth Circuit Court of Appeals revived a relator's FCA lawsuit, deciding that a physician's medical

judgment about the medical necessity of heart procedures can be "false or fraudulent" under the FCA. The relator alleged that a physician failed to comply with guidance from the American Heart Association and American Stroke Association regarding the medically appropriate use of a heart procedure called a PFO closure. As we explained in a discussion of the court's decision, the court found that medical judgments can be "false" for at least three reasons:

- Courts must read the FCA broadly to reach all types of fraud.
- Just because the allegedly false statement is stated as an opinion does not mean it is incapable of being false.
- Claims for medically unnecessary treatment are actionable under the FCA.

The court also found that a physician's certification that a procedure was medically necessary is "false" under the FCA if the procedure was not "reasonable and necessary" as defined by the Medicare Program Integrity Manual. Since the court's broad decision as to "falsity" could expose more physicians to FCA liability, the court pointed to the Supreme Court's statement in *Escobar* that the FCA elements of materiality and knowledge should prevent abuse of the statute. In October 2018, the Tenth Circuit rejected a request for rehearing, so the case is proceeding in the district court, which recently entered a scheduling order.

Because the Tenth Circuit adopted a broad definition of "false and fraudulent," the decision may shift the inquiry in FCA cases based on medical necessity from "falsity" to two other elements of the FCA: knowledge and materiality. The Tenth Circuit's decision may also open the door to future FCA claims based on a physician's alleged failure to follow manual provisions, medical society guidelines, and other guidance that are not embodied in regulations or in a National Coverage Determination.

Second, the Sixth Circuit Court of Appeals reversed a trial court's judgment of acquittal following a trial in which a jury found a cardiologist guilty of health care fraud (18 U.S.C. § 1347) and making false statements in violation of 18 U.S.C. § 1035, and remanded the case back to the district court. *United States v. Paulus*, No. 17-5410 (6th Cir. June 25, 2018). There, a cardiologist allegedly committed health care fraud and made false statements by exaggerating the extent of blockages in his patients' arteries (measured using angiograms), and then he performed and billed federal health care programs for medically unnecessary cardiac stent procedures. After a trial and jury conviction, the trial court found that the cardiologist's assessment of the degree of blockage is a subjective medical opinion, not an objectively verifiable fact, so the jury could not conclude beyond a reasonable doubt that the cardiologist made a false statement. The Sixth Circuit reinstated the jury's verdict and held that a patient's degree of blockage is a fact capable of proof or disproof.

Both the Tenth Circuit and Sixth Circuit decisions may result in more cases alleging a lack of medical necessity based on a "battle of the experts" to prove "falsity." All eyes are on the *AseraCare* case, noted above, which was appealed to the Eleventh Circuit Court of Appeals in 2016 after the district court threw out a jury verdict against the hospice provider on the basis that falsity cannot be proven by differences of medical opinion. The Eleventh Circuit's decision is one to watch for in 2019 because it will be interesting to see how the court addresses FCA claims based on alleged lack of medical necessity.

Notable Civil Settlements in 2018

DOJ reported that FCA federal recoveries, including settlements and judgments, amounted to over $2.8 billion in the government's fiscal year 2018. Of that total, over $2.5 billion related to health care and life sciences, the ninth consecutive year with such recoveries over $2 billion and the second

highest amount for the last four reported years. Of the health care recoveries, $1.9 billion resulted from *qui tam* cases, and there were 446 new health care *qui tam* filings, down slightly from the last two years.

Health care and life sciences settlements involved drug and device manufacturers, hospitals, Medicare Advantage plans, pharmacies, and laboratories. The largest settlement, for $625 million, was with AmerisourceBergen Corp. and its subsidiaries, and it involved resolution of allegations that it repackaged and resold cancer drugs to profit from "overfill" in the original packaging.

Two other significant settlements concerned allegations that pharmaceutical manufacturers violated the FCA by paying kickbacks to Medicare beneficiaries through their patient assistance programs (PAPs). In late 2017, United Therapeutics Corp. became the second pharmaceutical manufacturer to settle allegations of this nature when it agreed to pay $210 million to resolve claims that it improperly supported a charitable foundation's patient assistance program that helped patients afford copayments for hypertension drugs. This trend continued in 2018 with additional settlements involving some of the nation’s largest pharmaceutical manufacturers, including Pfizer as well as another manufacturer that paid $360 million. The settlements are notable for at least two reasons. First, neither the settlement agreements nor the press releases mention *qui tam* cases, which are the catalyst for most health care fraud investigations. Instead, the Boston U.S. Attorney’s Office apparently initiated these high-profile investigations. Second, each announced settlement has involved a Corporate Integrity Agreement (CIA) that specifically addresses the implementation of controls and monitoring activities designed to ensure that the PAPs to which the manufacturers donate operate independently. These CIAs provide useful insight into the government’s continuing expectations for relationships between PAPs and manufacturers. Given that two manufacturers have already announced settlements in principle and others have disclosed the existence of investigations, additional settlements are likely to occur in 2019.

On the provider side, an independent physician association agreed to pay $270 million to resolve a voluntary disclosure it made to the government and *qui tam* claims that it engaged in improper practices, including alleged "one way" chart reviews that supposedly increased reimbursement from Medicare Advantage plans paid on a risk-adjusted basis. Also, former hospital chain Health Management Associates, LLC agreed to pay over $216 million in a civil settlement (in addition to a $35 million criminal monetary penalty) to resolve allegations that it billed government health care programs for inpatient services that should have been billed as less-costly observation or outpatient services, paid illegal remuneration to physicians in return for patient referrals to HMA hospitals, and inflated claims for emergency department facility fees. To underscore DOJ's commitment to strict civil enforcement of the Anti-Kickback Statute, William Beaumont Hospital, a regional hospital system based in the Detroit, Michigan area, agreed to an $84.5 million settlement to resolve allegations of improper relationships with eight referring physicians intended to induce patient referrals.

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