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10 Key FCA Developments Of 2016

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Law360, New York (January 31, 2017, 1:05 PM EST) --2016 was another active year in the land of False Claims Act enforcement. The U.S. Department of Justice continued to set recovery records and turned its eye more keenly on enforcement of individuals. We heard from the Supreme Court not once, but twice, on FCA issues. Per-claim penalties increased as of Aug. 1, opening the door for higher recoveries and bigger whistleblower awards in the future. And courts across the country continued to wrestle with a host of FCA issues from statistical sampling, Rule 9(b)'s pleading requirements, and the public disclosure bar. Here's a closer look at some of the FCA highlights from 2016.

1. DOJ Collects Big False Claims Act Dollars — Again

It was another banner year for the DOJ's False Claims Act collections. The department announced in December that it had obtained more than $4.7 billion in settlements and judgments related to the FCA for fiscal year 2016, making it the third-highest year in history for FCA recoveries and bringing the DOJ's annual average recoveries to almost $4 billion since 2009. The largest recoveries came from industries that continue to be the hallmark of the department's FCA focus: $2.5 billion from the health care industry (drug and medical device companies, hospitals, nursing homes, labs, and physicians) and $1.7 billion from the financial industry, primarily from housing and mortgage fraud. The DOJ also identified procurement fraud as a significant area of recovery and specifically highlighted an $86 million settlement to resolve claims relating to the April 2010 Deepwater Horizon explosion. Not surprisingly, 2016 was also a big year for whistleblowers who filed 702 qui tam suits last year. Of the $4.7 billion in recoveries obtained by the DOJ, over half, $2.9 billion, related to lawsuits filed by whistleblowers.

2. Increased Focus on Individuals

In its year-end review of significant FCA recoveries, the DOJ also highlighted recoveries against individuals. In doing so, the department specifically referenced the Yates memo and its "reinforce[ment of] the Department's commitment to use the [FCA] to deter and redress fraud by individuals as well as corporations." The increased focus on individual liability in FCA matters was center stage in June, when Acting Associate Attorney General Bill Baer delivered remarks at the American Bar Association's 11th National Institute on Civil False Claims Act and Qui Tam Enforcement. Baer noted that, at the outset of every FCA investigation, DOJ "attorneys are instructed to focus on both the company and the individuals who may be responsible for the bad conduct," regardless of whether the matter is brought by a whistleblower or a referral from a law enforcement partner. In every case, the "inquiry into individual misconduct now proceeds in tandem with the underlying corporate

investigation."

And so, it is not surprising that, in a growing number of FCA resolutions, the DOJ is requiring executives to make substantial monetary payments to resolve personal liability. The DOJ identified multiple recoveries against individuals in 2016 that were in excess of $1 million, including three in excess of $5 million: $10.3 million against the founder and president of a Maryland-based splint supplier; $9.35 million against the former owner and chief executive officer of a Nashville drug testing laboratory; and $8.5 million against the founders of two Wisconsin testing labs.

Consider also the example of the DOJ's settlement with the former CEO of Tuomey Healthcare announced last year. In 2015, Tuomey unsuccessfully challenged a jury verdict of $237 million, a verdict that, at the time it was handed down, eclipsed the hospital's annual revenue and was believed to be the largest damages award ever against a community hospital. The company ultimately entered into a corporate settlement with the DOJ for $72.4 million, but the former CEO was not included in that settlement. This past September 2016, he finally settled with the DOJ for $1 million and agreed to a four-year period of exclusion from participating in federal health care programs.

3. Per-Violation Penalties Increased

2016 also saw an increase in per claim penalties under the FCA. Penalties increased as of Aug. 1, 2016, for violations occurring after Nov. 2, 2015, from the old range of $5,500 to $11,000 per claim to the new range of $10,781 to $21,563. Per claim penalties are trebled under the FCA's damages provisions. And, of course, increases in penalties necessarily will lead to greater financial rewards for whistleblowers, who receive up to 30 percent of the total amount of the government's recovery.

4. Supreme Court 1.0 — Escobar

On June 16, 2016, a unanimous U.S. Supreme Court approved the use of the implied false certification theory of FCA liability. (Universal Health Services Inc. v. United States. ex rel. Escobar, 136 S. Ct. 1989 (U.S. June 16, 2016)). The court held that implied certification will succeed as a theory of liability where (1) the claim makes specific representations about the goods and services being provided and (2) the defendant's failure to disclose noncompliance with material statutory, regulatory or contractual requirements makes those misrepresentations misleading. The court then provided guidance on the appropriate materiality standard, which has already become the focus of post-Escobar decisions in the lower courts (see discussion below). In shifting the focus to the facts and circumstances surrounding a misrepresentation, rather than regulatory and contractual strictures, the court stressed that the materiality standard is "demanding," and that the FCA is not an "all-purpose" antifraud statute, or a vehicle for punishing "garden-variety breaches of contract or regulatory violations."

5. Supreme Court 2.0 — State Farm

In a second unanimous FCA decision in 2016, the Supreme Court affirmed the lower court's interpretation of the FCA's seal requirement to dismiss a complaint, holding that a violation of the seal requirement does not mandate dismissal of a relator's complaint. (State Farm Fire & Casualty Co. v. United States ex rel. Rigsby, --- S. Ct. --, No. 15-513, 2016 WL 7078622 (U.S. Dec. 6, 2016)).The court also held that "the question whether dismissal is appropriate should be left to the sound discretion of the district court," and did not announce any specific standard to guide the lower courts, specifically noting that the standard "can be discussed in the course of later cases." The court provided specific guidance only on potential sanctions available to FCA defendants when relators violate the FCA's requirement that complaints be kept under seal for a minimum of

60 days. In addition to dismissal, the court noted that remedial tools such as “monetary penalties or attorney discipline remain available to punish and deter seal violations even when dismissal is not appropriate.”

6. Post-Escobar Roundup

In a post-Escobar world, lower courts have begun weighing in on both the test announced by the Supreme Court and on the practical application of the court’s holding with respect to materiality. There is already disagreement whether the court’s opinion in Escobar constitutes a new, mandatory two-part test with respect to every implied certification claim, with at least one district court finding that it does not. See Rose v. Stephens Institute, 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016), appeal filed, No. 16-80167 (9th Cir. Nov. 7, 2016) (relying on language that Escobar court would not resolve whether implied certification is viable for “all claims”). Other courts disagree and have held plaintiffs to that two-part test. See, e.g., United States ex rel. Handal v. Ctr. Emp’t Training, 2016 U.S. Dist. LEXIS 105158 (E.D. Cal. Aug. 8, 2016); United States ex rel. Doe v. Health First, Inc., 2016 U.S. Dist. LEXIS 95987 (M.D. Fla. July 22, 2016); United States ex rel. Creighton v. Beauty Basics Inc., 2016 WL 3519365 (N.D. Ala. June 28, 2016). Courts are also grappling with the application of Escobar’s guidance on the materiality standard.

Three courts of appeal have also considered materiality since the Supreme Court handed down Escobar, again with mixed results. See United States ex rel. Miller v. Weston Educ., Inc., 840 F.3d 494 (8th Cir. 2016) (false statement is material if a reasonable person would likely attach importance or defendant knew or should have known that the government would attach importance to it); United States v. Sanford-Brown, Ltd., 840 F.3d 445 (7th Cir. 2016) (relator failed to meet “the independent element of materiality” due to lack of evidence that government’s decision to pay would likely or actually have been different had it known of alleged noncompliance); United States ex rel. Escobar v. Universal Health Servs., Inc., 842 F.3d 103 (1st Cir. 2016) (on remand, court held that materiality is “demanding” and concluded that materiality had sufficiently been pled); United States ex rel. D’Agostino v. ev3, Inc., 2016 WL 7422943 (1st Cir. 2016) (for liability to exist, fraudulent representation must be material to the government’s payment decision). In addition to these cases, numerous district court cases have been decided with courts across the country applying, with expected variation, the post-Escobar materiality standard and making it likely that there will be much more to come on this standard in 2017.

7. One Step Closer to Guidance on the Use of Statistical Sampling

On Oct. 26, 2016, the Fourth Circuit heard arguments on a much watched case involving the use of sampling evidence in FCA case. In United States ex rel. Michaels v. Agape Senior Community Inc., involving Medicare reimbursements for hospice care, the district court refused to allow the use of statistical sampling by the relators to prove liability. The parties engaged in mediation and, when the defendants and relators reached a settlement, the government, which had declined to intervene in the case, objected to the settlement. The district court ultimately certified two issues for interlocutory review: (1) whether the government has an unreviewable veto over FCA settlements and (2) whether statistical sampling can be used to establish liability. At argument, the court of appeals, noted that the district court’s opinion presented as an evidentiary ruling that could have been revisited later in the proceedings and may, therefore, not be appropriate for interlocutory review in the first instance.

Although there is a growing acceptance that statistical sampling is an appropriate tool to establish damages in FCA cases, the use of statistical sampling to establish damages has raised concerns for FCA defendants for some time, particularly in the health care context. Although these methods provide courts with a way to review claims in cases where looking at each claim is untenable, they also raise questions of how a plaintiff can meet its burden of proving that each FCA violation is supported by a false claim, which is a statutory precursor

to recovery. Even if used as a practical necessity in large FCA cases, there is a balancing concern that extrapolation of statistical evidence will short-circuit factual and procedural safeguards for proving liability. The Agape case is the first time a court of appeals will consider the issue of statistical sampling to prove liability in an FCA case, and many will be watching for a decision in 2017.

8. Anti-Kickback Statute Safe Harbors Revised

On Dec. 7, 2016, the U.S. Department of Health and Human Services' Office of Inspector General published a final rule regarding revisions to the safe harbors available under the federal Anti-Kickback Statute and the Civil Monetary Penalties Law. As violations of the Anti-Kickback Statute constitute a per se violation of the FCA, understanding the revisions to the Anti-Kickback Statute and the related Civil Monetary Penalties Law (which allows for imposing civil penalties on anyone violating the Anti-Kickback Statute) are imperative to also avoiding also FCA risk.

The revisions to the Anti-Kickback Statute, effective as of Jan. 6, 2017, modified numerous safe harbor provisions, including those that apply to referral services, cost-sharing waivers by pharmacies and emergency ambulance services, federally qualified health centers, Medicare advantaged organizations, Medicare coverage gap discount programs, and local health care related transportation programs. The Civil Monetary Penalties Law similarly prohibits a person from offering or providing any remuneration to a Medicare or Medicaid beneficiary that is likely to influence the beneficiary's selection of a particular provider, subject to a limited number of exceptions. The revisions narrowed the definition of "remuneration" by providing exceptions for copayment reductions for outpatient services, certain Affordable Care Act-mandated exceptions, including items or services that promote access to care, retailer rewards programs, waivers of cost-sharing with respect to filling generic drug prescriptions under certain circumstances, and certain financial-need based exemptions.

9. Rule 9(b) Continues To Be Actively Litigated

Relators and defendants continued to do battle over the specificity of allegations brought in FCA complaints. As in prior years, this area of FCA jurisprudence elicited few bright lines and decisions were decidedly fact-driven depending on the particular case before each court. A number of courts of appeal decided cases involving Rule 9(b)'s pleading requirements. The Ninth Circuit overturned dismissal in a pair of cases dealing with particularity questions, while the Sixth and Seventh Circuits both dismissed complaints and seemed to hold relators to a higher pleading standard.

See United States. ex rel. Driscoll v. Todd Spencer M.D. Medical Group, Inc., No. 13-17624, 2016 WL 4191896 (9th Cir. Aug. 9, 2016) (Ninth Circuit reversed dismissal of the relator's complaint because certain claims were pled with sufficient particularity); United States v. United Healthcare Insurance Co., et al., 832 F.3d 1084 (9th Cir. Aug. 10, 2016), amended at No. 13-56746, 2016 WL 7378731 (9th Cir. Dec. 16, 2016) (relator's allegations satisfied 9(b) because they alleged "the who, what, when, where, and how of the misconduct charged"); United States ex rel. Sheldon v. Kettering Health Network, 816 F.3d 399 (6th Cir. March 7, 2016) (affirmed dismissal of case pled in part on personal knowledge for failure to plead with sufficient particularity); United States ex rel. Hanna v. City of Chicago, 834 F.3d 775 (7th Cir. Aug. 22, 2016) (affirmed grant of summary judgment for defendant for failure to plead with sufficient particularity); United States ex rel. Presser v. Acacia Mental Health Clinic, LLC, 836 F.3d 770 (7th Cir. Sept. 1, 2016) (Rule 9(b) requires pleading sufficient context regarding why specific conduct violates the law). Similarly, district courts came down on both sides of the particularity requirement. In one case, the district court held that it was sufficient to plead particular details of an alleged scheme to defraud and allegations regarding the likelihood that the claims were actually submitted. United States ex rel. Ramsey-Ledesma v. Censeo Health, LLC, 2016 WL 5661644 (N.D. Tex. Sept. 30, 2016). By and large, though, district courts determined that more specific factual pleading is required to satisfy Rule 9(b).

See Jallali v. Sun Healthcare Group, 2016 WL 3564248 (S.D. Fla. July 1, 2016) (9(b) not satisfied when the relator failed to allege the who, what, where, when, and why of any fraudulent submissions); United States ex rel. Witkin v. Medtronic, Inc., No. 11-10790-DPW (D. Mass. May 23, 2016) (complaint failed to satisfy Rule 9(b) where relator did not connect allegations of fraudulent promotion to any false claims for reimbursement); United States ex rel. Chase v. Lifepath Hospice, Inc., et al., 2016 WL 5239863, at *7 (M.D. Fla. Sept. 22, 2016) (complaint insufficient where scheme described with detail, but allegations lacked facts as to "time, place, and substance" of alleged fraud).

10. Public Disclosure Bar Continues to Be a Defendant's Tool for Dismissal

Another area of activity in 2016 was the FCA's public disclosure bar, with a handful of circuits weighing in on the issue and, to defendants' delight, most finding dismissal appropriate in light of previous publicly disclosed facts. In United States ex rel. May v. Purdue Pharma L.P., 811 F.3d 636 (4th Cir. Jan. 29, 2016), the Fourth Circuit affirmed dismissal of the action, holding that facts learned from an attorney representing another client were sufficient to trigger the public disclosure bar. See also United States ex rel. Beauchamp v. Academi Training Center, LLC, 816 F.3d 37 (4th Cir. Feb. 25, 2016) (where relator files amended pleading, date when claims arise for purposes of public disclosure bar is governed by the date of the first pleading to particularly allege the relevant fraud). In United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294 (3d Cir. Feb. 2, 2016), the Third Circuit reversed dismissal, even though it agreed that the allegations had been publicly disclosed via FOIA reports that the court agreed were government reports for purposes of the FCA.

Nevertheless, the court held that the district court relied on the wrong standard for when a relator was an original source and reversed dismissal applying the post-ACA amendment standard where, to qualify as an original source, a relator's knowledge must be independent of public sources, not all information in the public domain. The Sixth Circuit affirmed dismissal in United States ex rel. Advocates for Basic Legal Equality, Inc. v. U.S. Bank, N.A., 816 F.3d 428 (6th Cir. Mar. 14, 2016), where the conduct at issue had previously been publicly disclosed in a consent order with the Office of the Comptroller of the Currency and in an interagency report by the Federal Reserve, OCC, and Office of Thrift Supervision. Lastly, the D.C. Circuit upheld dismissal of an FCA suit in U.S. ex rel. Oliver v. Phillip Morris USA, Inc., 826 F.3d 466 (D.C. Cir. June 21, 2016), where the transaction at issue had been publicly disclosed under the "civil hearing" prong of the public disclosure bar because an inter-office memorandum discussing pricing practices was posted to a public website, along with millions of other documents, as part of a separate litigation.

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