Updates

The Department of Justice (DOJ) recovered more than $3 billion in settlements and judgments from civil cases involving the False Claims Act (FCA) in the fiscal year ending September 30, 2019, according to statistics released by DOJ on January 9, 2020. DOJ's recoveries for the last fiscal year were slightly higher than in FY 2018 and reflect a robust level of enforcement against companies in healthcare and government contracting consistent with past years.

A large majority of these recoveries in the past fiscal year—about $2.6 billion—concerned the healthcare and life sciences industries, a modest increase from the prior year. DOJ recovered $252 million in defense contract cases—more than double the prior year's figure—while the total for settlements and judgments in non-defense, non-healthcare cases dropped.

Following is an overview of DOJ's FCA statistics for 2019, which reflect the government's priorities in the use of its primary civil remedy to combat fraud. It also addresses some of the key developments relevant to FCA investigations and litigation occurring in the last year.

Highlights From 2019's FCA Enforcement Statistics

Since 1986, when Congress amended the FCA, DOJ has recovered more than $62 billion under the statute, according to DOJ's announcement releasing its annual update to its civil fraud statistics. DOJ has obtained more than $2 billion in FCA cases each year since 2009.

Among the key takeaways from the newly released statistics:

- **Settlements and Judgments Are Mostly Consistent With Prior Years.** The government's recovery of about $3 billion in FCA settlements and judgments in FY 2019 is a slight (about $151 million) increase from FY 2018, when it obtained $2.9 billion. FY 2018 represented a roughly $500 million decrease from the prior year, and was the first time in eight consecutive years that FCA recoveries fell below $3 billion. Overall, the government's total FCA recoveries in FY 2019 are mostly consistent with those obtained in recent years, showing that the risks for companies that are subject to potential exposure under the statute remain significant.
- ***Qui Tam* Suits Remain Steady.** In 2019, 636 new *qui tam* cases were filed, according to DOJ's statistics. That is an average of about 12 cases per week. By comparison, 646 new *qui tam* cases were filed in FY 2018 and 681 in FY 2017.
- **Healthcare Recoveries Increase.** As in prior years, the large majority of DOJ's settlements and judgments under the FCA related to healthcare, including actions brought against drug and medical device manufacturers, managed care providers, hospitals, pharmacies, and physicians. FY 2019 was the 10th consecutive year that DOJ's civil healthcare fraud recoveries exceeded $2 billion. DOJ's recovery of $2.6 billion in FCA healthcare cases in FY 2019 reflects a modest upward trajectory. In FY 2018, the value of FCA recoveries in healthcare cases totaled roughly $2.53 billion, which was moderately higher than the previous year's figure of about $2.14 billion. According to DOJ, two of the largest recoveries in the healthcare industry this past year came from settlements with opioid manufacturers.
- **Department of Defense Recoveries Bounce Back.** Recoveries in defense procurement fraud-related cases bounced back after a drop in FY 2018. DOJ's figures show that FCA settlements and judgments in Department of Defense (DOD) cases totaled approximately $252 million in FY 2019. That is more than double the $107 million recovered in FY 2018, which was a sharp drop from FY 2017's total of $220 million. According to DOJ, 53 new DOD-related FCA cases were filed in 2019, up from 47 in 2018. Forty of those cases were initiated by *qui tam* relators.
- **Other Areas.** DOJ recovered about $196 million in non-defense, non-healthcare FCA cases in FY 2019, compared to approximately $260 million in 2018. The new figure reflects a drop-off in total recoveries in this category compared to past years.
- ***Qui Tam* Suits Continue to Generate Cases.** Lawsuits brought by relators under the FCA's *qui tam* provisions continue to be the source of most of the government's settlements and judgments. Of the $3 billion in FCA recoveries reported in FY 2019, about $2.2 billion arose from *qui tam* cases. However, the total value of share awards paid to relators dropped markedly during the past fiscal year to about $271 million, compared to roughly $341 million in FY 2018 and $536 million the year before that.

FCA Enforcement Developments and Case Law in 2019

Behind the numbers are several developments occurring in the last year relevant to enforcement and judicial interpretation of the statute that will likely continue to play out this year.

DOJ's Increased Use of Dismissal Authority

DOJ's press release notes that, during the past year it "made increasing use" of its statutory authority to seek dismissal of *qui tam* actions "to help prioritize and protect the expenditure of government resources." The so-called "Granston Memo," codified in Section 4-4.111 of the Justice Manual, directs DOJ attorneys to consider whether the government's interests are served by seeking dismissal of a *qui tam* suit under 31 U.S.C. § 3730(c)(2)(A), citing various factors. In a December 19, 2019, letter to Senator Chuck Grassley, DOJ noted that it has filed motions to dismiss in 45 FCA cases since January 2018, accounting for less than 4% of the 1,170 *qui tam* suits filed during that period. The U.S. Circuit Courts of Appeals are split as to the proper standard of review for such motions, and further litigation on that topic is likely in 2020.

Post-*Escobar* Issues

Lower courts in 2019 continued to address various FCA-related questions left open by the Supreme Court's 2016 opinion in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989. Courts continue to grapple with what evidence is necessary to establish that false claims are material to the government's payment decisions. Also, the circuits are split as to the proper standard for a motion to dismiss under Rule 9(b) and whether the FCA's first-to-file bar, which precludes a *qui tam* suit based on the facts underlying a pending action, is jurisdictional. The U.S. Supreme Court has so far declined to address such issues.

Restrictions on Use of Sub-Regulatory Guidance

Recent developments illustrate the increasing limitations on the use of sub-regulatory guidance in enforcement of the FCA.

In *Azar v. Allina Health Services et al.*, 139 S. Ct. 1804, the Court held that notice-and-comment rulemaking must be used for any Medicare issuance that establishes or changes a "substantive legal standard" governing the scope of benefits and other matters. Although *Allina* was not an FCA case, it appears likely to have a significant impact on healthcare FCA cases, which are routinely grounded on alleged violations of sub-regulatory guidance issued by federal agencies, as demonstrated by an October 31, 2019, memorandum issued by the U.S. Department of Health and Human Services' (DHS) deputy general counsel advising agencies to conform their practices to *Allina*.

The judicial application of *Allina* in FCA cases has started. A federal district court in Pennsylvania recently stated that a relator's claims failed as a matter of law because the Center for Medicare and Medicaid Services' (CMS) sub-regulatory guidance that he alleged had been violated was a substantive legal standard that required notice-and-comment rulemaking. *Polansky v. Executive Health Resources, Inc., et al.*, Final Memorandum No. 12-CV-4239 (E.D. Pa.) (Nov. 5, 2019).

Also, on October 9, 2019, President Trump issued Executive Order 13892, which, among other things, prohibits agencies from using guidance documents to "impose new standards of conduct" on persons outside the executive branch "except as expressly authorized by law or as expressly incorporated into a contract." The executive order effectively models DOJ's approach under the so-called "Brand Memo" limiting DOJ's use of guidance documents in affirmative civil cases.

DOJ Cooperation Credit Guidance

In May 2019, DOJ issued guidance giving DOJ civil attorneys express discretion to award credit to cooperative defendants in FCA cases. The guidance, codified in section 4-4.112 of the Justice Manual, identifies various factors that DOJ will consider when defendants self-disclose misconduct, cooperate with FCA investigations or settlements, or take effective remedial measures. The implications of the guidelines in settlements will continue to play out.

Statute of Limitations

In a May 2019 decision, the Supreme Court resolved a circuit split regarding the FCA's statute of limitations in a way that favors relators. In *Cochise Consultancy, Inc. et al. v. United States ex rel. Hunt*, 139 S. Ct. 1507, the Court held that relators have up to 10 years to file suit against defendants in cases in which the government declines to intervene, provided that the suit is filed within three years of the government knowing, or having reason to know of, the relevant facts. The Court also held that relators' knowledge of the facts is irrelevant to the statute of repose.

DOJ-HUD Memorandum of Understanding

In October 2019, DOJ and the U.S. Department of Housing and Urban Development (HUD) issued a Memorandum of Understanding (MOU) setting prudential guidance on the use of the FCA against Federal Housing Administration (FHA) lenders. The MOU sets forth criteria for when violations of FHA program requirements should be enforced administratively by HUD rather than be referred to DOJ for potential FCA litigation.

Procurement Collusion Strike Force

Also, on November 5, 2019, DOJ announced the formation of a Procurement Collusion Strike Force focusing on combating procurement-related antitrust crimes such as bid-rigging conspiracies and related fraudulent schemes. The strike force will be an inter-agency partnership consisting of DOJ prosecutors from the Antitrust Division and U.S. Attorneys' Offices, FBI investigators, the DOD Office of Inspector General, the U.S. Postal Service Office of Inspector General, and other federal offices of inspector general. The strike force will focus on investigating and prosecuting antitrust crimes in procurement, grant, and program funding.

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