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What To Expect From FCA Investigations This Year

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The year-end announcement by the U.S. Department of Justice of its False Claims Act recovery statistics shows that 2017 was another year of aggressive FCA enforcement, with more than $3.7 billion in total recoveries and health care fraud cases again leading the pack.[1] Of the $3.7 billion in settlements and judgments, $3.4 billion related to lawsuits filed under the qui tam provisions of the False Claims Act. Those lawsuits resulted in $392 million in payments to qui tam whistleblowers, also called "relators."

The DOJ also recovered a total of $2.4 billion dollars in settlements and judgments from the health care industry alone, which includes pharmaceutical manufacturers, medical device companies, hospitals, nursing homes, laboratories and physicians accused of a variety of wrongdoing, such as allegations of paying "kickbacks" to health care providers to induce the use of certain goods or services reimbursed by the government, providing unnecessary or inadequate care, or overcharging for goods or services reimbursed by governmental health care programs. This is the eighth consecutive year that the DOJ's civil health care fraud settlements and judgments have exceeded $2 billion.

There's no question that the investigation and filing of False Claims Act cases — and health care fraud cases in particular — will continue apace in 2018. But beyond the numbers, what can companies expect in terms of what DOJ will prioritize and whether it will seek dismissal of meritless qui tams (as it recently suggested), and how can companies best position themselves once they are faced with an FCA investigation? The analysis below draws both on comments made at a panel discussion among civil fraud chiefs from five large U.S. Attorney's offices at a medical device litigation conference in New York City on Dec. 6, 2017, as well as my own experience investigating and litigating FCA cases as an assistant United States attorney in the U.S. Attorney's Office for the Southern District of New York.

The Priority Cases

Civil fraud supervisors from the Southern and Eastern Districts of New York, the District of New Jersey, the District of Massachusetts, and the Eastern District of Pennsylvania presenting at the conference on medical device litigation confirmed the high priority of health care fraud cases given the vast amounts of government money spent on health care. The DOJ attorneys explained that although cases involving kickbacks, medically unnecessary tests and procedures, and pricing continue to be a priority, a number of new types of cases are emerging (e.g., via whistleblower and law enforcement referral). In particular,

the panel pointed to a new wave of cases involving opioids, retention of overpayments, improper payments to patients (as opposed to doctors), and research fraud. With regard to this last category of cases, the panel gave the example of a pharmaceutical company discovering information during its development and testing of a product but choosing to conceal this information from the U.S. Food and Drug Administration, which could have affected government reimbursement decisions.

Additionally, the panelists emphasized their increasing use of data analytics to review health care companies' billing and claims practices, and how such analytics are used to select or prioritize targets of FCA investigations. This is not surprising, as many districts in the wake of the mortgage crisis reviewed data from the U.S. Department of Housing and Urban Development to select or prioritize targets of mortgage fraud investigations. Multiple panelists noted that companies in the health care arena should be looking at their data and should assume the DOJ is looking at it as well. If clear red flags emerge from a company's data alone, and the company has either not detected them or failed to investigate them, it is both more likely to find itself the target of an investigation and will have difficulty explaining its inaction once the DOJ is engaged.

In terms of naming individuals in FCA suits and settlements, as set forth by the DOJ in the Yates memo,[2] it became clear throughout the panel discussion that this practice occurs unevenly across districts. While the SDNY frequently names an individual in cases (where there is no voluntary disclosure by the company), other districts appear to have more varied practices. One supervisor AUSA panelist noted that, as a practical matter, an individual may be more likely named in a case involving a smaller company because in larger companies the responsibility for the misconduct may be more diffused and difficult to isolate.

In my own experience, it often was easier to identify one or two individuals who had primary responsibility within a small company, yet in those cases I often found that a single attorney attempted to represent both the company and the individual executive. In addition to the conflict dual representation presents, such an approach sends a bad message to the DOJ, suggesting that the company is not taking seriously either the investigation or the DOJ's intention to identify responsible individuals. Counsel for smaller companies hinder their advocacy efforts if they assume that DOJ priorities do not apply to their clients or assume that their clients are entitled to leniency based solely on their size. As discussed further below, a better approach is for counsel to be proactive, engage the DOJ early and often, conduct its own investigation and present the DOJ with its own assessment.

A Decline in Meritless Qui Tams?

A broad FCA development for 2017 was the announcement on Oct. 30 by Michael Granston, director of the commercial litigation branch of the fraud section of the DOJ's civil division, that the government will now move to dismiss qui tam actions when it determines that the case has no merit. Granston made the announcement at a meeting of the Health Care Compliance Institute in Washington, D.C.[3] Under the FCA the government has 60 days to decide whether to intervene in a qui tam action or let a relator move forward and pursue the claim herself, although in practice many courts routinely grant extensions of time and allow the government years to decide whether to intervene. Historically, the government intervenes in a small percentage of FCA cases, but takes no action to dismiss the cases in which it declines to intervene.[4] Based upon our review, the government has filed a motion to dismiss in less than 1 percent of the qui tam actions filed in the last 10 years. Relators increasingly elect to pursue their cases even without intervention, given the potential upside recovery. Many of these cases, however, are meritless and costly to defend against. Moreover, cases of dubious merit can also tax the government's resources as the DOJ continues to monitor those cases.

Nevertheless, companies should not expect to see a wave of dismissal motions in 2018. After all, the DOJ relies on relators to bring cases, and relators' counsel are almost akin to clients in that they can bring multiple matters to the same office or offices. Individual U.S. attorney's offices across the country thus stand to benefit from treating relators favorably, both in terms investigating and pursuing their cases and seeking favorable relator share awards once a case is resolved. An office with a reputation for successful FCA cases and favorable treatment of relators can expect to attract even more relators, who often have a choice between several districts in deciding where to file a qui tam action. Information about various districts is freely shared across the network of relators' counsel and through the Taxpayers Against Fraud Education Fund (a members-only whistleblower attorney network). A U.S. attorney office might therefore be concerned that repeatedly moving to dismiss meritless qui tams could lead to a reduction in qui tams filed in its district.

Additionally, motions to dismiss can be filed only with the approval of DOJ headquarters in Washington, D.C., and obtaining such approval requires a memo from the individual U.S. attorney office outlining the reasons that a dismissal motion is warranted, as well as an often lengthy period of discussion and deliberation within the DOJ. This initial process alone might be viewed as a bureaucratic headache with little upside for an already-busy U.S. attorney's office. Further, any motion to dismiss is likely to be contested at the district court and (if the motion succeeds) at the appellate level. Indeed, as an AUSA I was involved in a recent case in the SDNY in which the government persuaded the relator's counsel to voluntarily dismiss a qui tam in light of the relator's fugitive status. The government nevertheless faced a motion by this realtor (who remained a fugitive) after the case settled seeking a share of the recovery. Although the motion was denied, the case remains on appeal.[5] An office might therefore decide it simply is not worth either the risk of deterring other, meritorious qui tam suits or the expenditure of resources to evaluate, internally clear, and move to dismiss potentially meritless relator suits.

In short, while a flurry of DOJ dismissal motions directed at meritless qui tams would save judicial resources as well as the resources of those defending against such suits, and possibly deter filing meritless qui tams in the future, the DOJ is more likely to weigh the risks and drain on its own resources in filing such motions, and to conclude that it should take such action in only a rare and extreme case. In 2018 we should therefore expect a continuation of the trend of FCA lawsuits, with little respite provided by the DOJ in the form of motions to dismiss meritless qui tam cases.

Common Mistakes in Responding to FCA Investigations

In light of the continuing wave of FCA cases, the panel of civil fraud chiefs also addressed common mistakes in responding to such investigations, mistakes that I repeatedly witnessed during my tenure in the civil frauds unit of the SDNY. As explained further below, two common missteps highlighted by the panelists were that companies tend to overstate both their cooperation and the strength of internal controls and compliance programs. At best, these mistakes suggest that defense counsel is uninformed as to what cooperation entails and what robust compliance programs look like. At worst, such overstatements can devastate the company's and the defense counsel's credibility.

Safeguarding the company's credibility when dealing with the DOJ should always be at the forefront of defense counsel's mind. Once credibility is lost, it is nearly impossible for counsel to regain it, and it becomes far more difficult to negotiate effectively with the government, as I have witnessed repeatedly. Counsel should engage DOJ early and often, and try to obtain as much information as they can, while being courteous and respectful. The time between the first DOJ contact and a suit or settlement can be lengthy, and defense counsel should use that time to build rapport and credibility.

Note that before the DOJ files suit, it typically invites the company in and delivers a presentation summarizing the strength of its case, and typically allows defense counsel to return and deliver a counter-presentation. A strong counterpresentation that exposes weaknesses or other litigation risks in the government's case and highlights a company's otherwise exemplary record can be very persuasive, but only if credibility is intact by the time the parties reach that stage. Even those defense attorneys who are former DOJ attorneys themselves, and therefore may start out with a presumption of credibility, too often squander it by overreaching on facts or making repeated reference to their own time in the office. Even worse, some former DOJ attorneys have on occasion suggested that the government's case is meritless and would not have been brought during their tenure. Needless to say, such insults quickly thwart constructive dialogue. However, in my experience, DOJ attorneys appreciate defense counsel respectfully pointing out litigation risks for the government, as they want to "get it right" and don't want to learn of weaknesses only after their case has been made public.

Misconstruing Cooperation

Too many defense attorneys, accustomed to hard-fought civil litigation, also assume that a failure to fight equals cooperation. As the DOJ panelists reiterated, merely responding to a subpoena without contesting it does not equal cooperation. Defense attorneys instead should thoroughly familiarize themselves with existing DOJ guidance on factors considered in assessing a company's cooperation, such as that provided by U.S. Attorney's Manual 9-28.000[6] and the "Yates memo."[7] Although some of the DOJ guidance on corporate cooperation is facially directed toward criminal matters, the same basic principles apply in the civil context. This has been made clear in both the Yates memo and a 2016 speech by Acting Associate Attorney General Bill Baer on the civil False Claims Act and qui tam enforcement.[8]

Companies that seek cooperation credit must meet a threshold requirement of disclosing all facts relating to the individuals involved in the wrongdoing. As Baer explained, cooperation goes beyond "doing what the law requires" in terms of responding to subpoenas, and cannot be shown by "one-sided presentations and white papers." Rather, it involves prompt, fulsome responses to requests and "necessitates a focused presentation of relevant information demonstrating the actual conduct that is the subject of the investigation, even where such a presentation stretches beyond the price information that may be have been requested by the government."

In addition, as explained by Baer and reiterated by the Dec. 6 panel, cooperation typically involves prompt remediation, identifying key documents and making key witnesses available to the government. All of that said, cooperation does not necessarily involve a costly and wide ranging internal investigation, nor does it require the company to waive the attorney-client privilege. Where the appropriate scope of an internal investigation is unclear based on the government's inquiry, the best approach is usually for the company's attorney to have a conversation with the DOJ attorney about their expectations regarding scope. In most cases a candid and courteous approach results in counsel gaining information on the DOJ perspective that will make the internal investigation more focused and efficient.

Mischaracterizing the Strength of a Compliance Program

Companies also risk their credibility when, in negotiating with the DOJ, they tout "robust compliance programs" which, upon further inquiry, are robust on paper alone. Here, too, defense counsel must consult the relevant existing guidance from the DOJ and the investigating agency before characterizing the company's compliance program. As the panelists pointed out, both the DOJ[9] and the U.S. Department of Health and Human Services Office of Inspector General[10] have provided written

guidance on how to evaluate the strength of a corporate compliance program. The DOJ guidance was issued in February of 2017 and includes 11 topic areas of evaluation, with multiple questions within each topic.

Broadly speaking, the DOJ guidance suggests looking at (among other things):

- an analysis and remediation of the underlying misconduct;
- conduct by senior and middle management that encouraged or discouraged the misconduct;
- the role and resources of the compliance function;
- training and communications that address the risk in the area where misconduct occurred;
- effectiveness of a confidential reporting mechanism; and
- incentives and disciplinary measures, and periodic testing, review and improvement of the compliance function.

The panelists elaborated that in assessing the compliance function, they consider who the compliance officer reports to (the board of directors as opposed to a business function), how the officer is compensated (e.g., are bonuses based on purely business objectives), and where the officer is physically and organizationally positioned within the company. They further stated that they inquire whether the compliance function identified issues on its own (in the particular case that drew DOJ attention), and how it handled any issues it was able to identify. The HHS-OIG compliance guidance provides additional detail for various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment supplies.

The key takeaway is that while the categories of health care priority cases may be shifting slightly, what the DOJ expects in response to its investigations has not. Now, as ever, companies benefit from taking a proactive approach internally, by crafting a compliance program that meets DOJ expectations, and by investigating in the event the company is alerted to a misconduct issue either internally or from the DOJ. By being proactive, companies may also be able to persuade the government to decline to intervene in qui tam actions, resulting in the potential for less financial exposure and liability. For instance, in qui tam actions that the government declined to intervene in 2017, recovery was only $425,767,335 in settlements and judgments. For the qui tam actions in which the government intervened or otherwise pursued, recoveries amounted to $3,011,269,763.

In sum, companies benefit from taking a proactive approach, by engaging DOJ attorneys with courtesy and candor to properly scope their investigation and to work toward a prompt and fulsome presentation of facts. Whether the goal is cooperation or convincing the DOJ that the case should not be brought, one must have command of the facts and the necessary credibility to persuasively present them.

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[1] Press Release, Dep't of Justice, Justice Department Recovers Over $3.7 Billion in False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), available at: https://www.justice.gov/opa/pr/justice-department-recovers-over-3.7-billion-false-claims-act-cases-fiscal-year-2017.

[2] Sally Quillian Yates, U.S. Department of Justice, Office of the Deputy Attorney General, "Memorandum on Individual Accountability for Corporate Wrongdoing," (September 9, 2015), 1-7, available at: https://www.justice.gov/archives/dag/file/769036/download.

[3] David M. Glaser, Esq., RACmonitor, Developing Story: DOJ Will Dismiss Qui Tam Cases Lacking Merit (Part II) (Dec. 14, 2017), available at: https://www.racmonitor.com/developing-story-doj-will-dismiss-qui-tam-cases-lacking-merit-part-ii.

[4] Based upon our review, the government has filed a motion to dismiss in less than 1% of the qui tam actions filed in the last ten years. See also Jonathan T. Broillier, Note, Mutiny of the Bounty: A Moderate Change in the Incentive Structure of Qui Tam Actions Brought Under the False Claims Act, 67 OHIO ST. L.J. 694 (2006) (noting that the government exercises its option to dismiss qui tam actions in "exceptionally rare instances").

[5] United States v. L-3 Commc'ns Eotech, Inc., 232 F. Supp. 3d 583 (S.D.N.Y. 2017), appeal docketed, No. 17-621 (2d Cir. Mar. 2, 2017).

[6] Principles of Federal Prosecution of Business Organizations, available at: https://www.justice.gov/usam/usam-9-28000-principles-federal-prosecution-business-organizations

[7] Sally Quillian Yates, U.S. Department of Justice, Office of the Deputy Attorney General, "Memorandum on Individual Accountability for Corporate Wrongdoing," (September 9, 2015), 1-7, available at: https://www.justice.gov/archives/dag/file/769036/download.

[8] Press Release, Dep't of Justice, Acting Associate Attorney General Bill Baer Delivers Remarks on Individual Accountability at American Bar Association's 11th National Institute on Civil False Claims Act and Qui Tam Enforcement (June 9, 2016), available at: https://www.justice.gov/opa/speech/acting-associate-attorney-general-bill-baer-delivers-remarks-individual accountability.

[9] Evaluation of Corporate Compliance Programs, U.S. Department of Justice, Criminal Division, Fraud Section, available at:https://www.justice.gov/criminal-fraud/page/file/937501/download.

[10] Compliance Guidance, Office of Inspector General, U.S. Department of Health & Human Services, available at: https://oig.hhs.gov/compliance/compliance-guidance/index.asp.