

False Claims Act Enforcement in 2021: A Look Ahead

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This is the sixth in our First 100 Days series examining important trends in white collar law and investigations in the early days of the Biden administration. Our previous entry discussed [ESG initiatives by the SEC](#). Up next will be a close look at pandemic-related fraud.

As expected, the Biden presidency has brought new leaders to the top posts of the Department of Justice (DOJ). What does this mean for False Claims Act (FCA) enforcement? We examine here recent FCA enforcement trends and predict increased pursuit of healthcare, cybersecurity, and pandemic fraud under the Biden Administration.

Recent Trends in FCA Enforcement

The Department of Justice's recent zeal in pursuing False Claims Act cases likely provides a measure of what to expect under the Biden Administration. Deputy Assistant Attorney General Michael Granston summarized the DOJ's recent enforcement priorities in a [December 2020 address](#) to the ABA Civil False Claims Act and Qui Tam Enforcement Institute. There, Mr. Granston identified the period between 2017 and 2020 as the most active period of enforcement in the Act's history as measured by the number of new matters opened. This trend of increased enforcement shows no sign of slowing, with the DOJ opening a record number of new matters in 2020, including 672 qui tam matters alone. Further, the DOJ recovered approximately \$11.4 billion in judgments and settlements under the Act between 2017 and 2020, the third highest amount recovered during any four-year term.

The vast majority of claims between 2017 and 2020 targeted the healthcare industry, with healthcare related claims constituting more than eighty percent of the total. Within the healthcare sphere the Department of Justice has specifically deployed the False Claims Act to address the ongoing opioid epidemic. These efforts have recently produced a variety of high profile settlements involving pharmaceutical companies accused of practices that encourage physicians to prescribe their opioid products. For example, in 2019 Insys Therapeutics, the manufacturer of an opioid spray, agreed to pay \$225 million to resolve civil and criminal allegations that it had provided kickbacks to providers. The DOJ's enforcement efforts have also targeted healthcare providers accused of writing medically unnecessary prescriptions for opioids as well as electronic medical record companies allegedly involved in opioid-related schemes.

Mr. Granston also identified the False Claims Act as a vehicle to combat schemes that contribute to rising drug prices. Such cases have included claims against pharmaceutical companies that allegedly cover the co-payments of Medicaid beneficiaries in violation of the Drug Rebate Statute. Additionally, the DOJ has recently pursued numerous claims against pharmacies for allegedly inflating drug prices reimbursed by federal programs.

Lastly, one notable statistic from 2020 FCA enforcement concerns not the activity targeted or amount recovered, but the sources of the matters themselves. In 2020, the Department of Justice opened 250 non-qui tam new matters. This is by far the greatest number of non-qui tam new matters since the 1990s, with an increase of more than 100 non-qui tam new matters as compared to 2019. In his remarks, Mr. Granston indicated that the Civil Division has begun expanding its reliance on data analysis to identify potential fraud cases. While the Civil Division will continue to rely on whistleblowers to identify potential FCA violations, the Division will also employ its own data analyses both to identify new cases and to assess whistleblower allegations.

New Leaders at the Department of Justice

The Biden Administration will bring significant changes to the Department of Justice, with new political appointees at the Department's helm. These new leaders will bring new ideas and possibly new priorities for FCA enforcement. President Biden has chosen DOJ veterans

for the top three posts, indicating a pro-prosecutorial sentiment shared among the Department's leaders.

Attorney General Merrick Garland took office on March 11, 2021. A.G. Garland served on the U.S. Court of Appeals for the District of Columbia Circuit from 1997-2021. Prior to his appointment on the D.C. Circuit, A.G. Garland spent nearly a decade at the DOJ, where he served as Principal Associate Deputy Attorney General (1994-1997), Deputy Assistant Attorney General for the Criminal Division (1993-1994), and Assistant U.S. Attorney in the U.S. Attorney's Office for the District of Columbia (1989-1992).

President Biden's pick to serve as Deputy Attorney General—the second highest-ranking official at the Justice Department—is Lisa Monaco. Most recently, Ms. Monaco co-chaired the Data Security & Privacy practice at a D.C.-based law firm. Prior to entering private practice, Ms. Monaco had a distinguished career in public service, serving as Homeland Security and Counterterrorism Advisor to President Obama (2013-2017), Assistant Attorney General for National Security (2011-2013), and holding various other roles at the Department of Justice, U.S. Attorney's Office, and FBI. Notably, as an Assistant U.S. Attorney, Ms. Monaco served on the Enron Task Force, co-leading the trial team in the prosecution of five former Enron executives.

As for the No. 3 post, President Biden has nominated Vanita Gupta to serve as Associate Attorney General. Ms. Gupta, a longtime civil rights lawyer, currently serves as the president and CEO of the Leadership Conference on Civil and Human Rights. From 2014-2017, Ms. Gupta served as Principal Deputy Assistant Attorney General and head of the DOJ's Civil Rights Division.

The appointee for Assistant Attorney General for the Civil Division remains to be announced. This post oversees the Commercial Litigation Branch and its Fraud Section—the branches generally responsible for FCA enforcement. Despite the personnel changes at the very top, leadership within the Commercial Litigation Branch and its Fraud Section will likely remain steady. Mr. Granston currently serves as head of the Commercial Litigation Branch and has worked within that branch for over twenty years, serving as the director of the Fraud Section from 2013-2019. Further, Jamie Yavelberg, another longtime Fraud Section veteran, recently stepped into the director role. The consistency of leadership within the branch of the DOJ that drives FCA enforcement indicates that there is little reason to expect a substantial departure from the DOJ's recent approach.

Combatting FCA Abuse by Qui Tam Relators

One notable feature of the DOJ's recent approach to the FCA has been to actively seek dismissal of frivolous qui tam claims under 31 U.S.C. § 3730(c)(2)(A). This approach is due in large part to a memorandum issued by then-Director of the Fraud Section Michael Granston in 2018 (the "Granston Memo") which encourages government attorneys handling FCA cases to seek dismissal of qui tam actions when such dismissal would serve the interests of the government. The Granston Memo identifies certain factors for government attorneys to consider when evaluating dismissal, including the government's interests in curbing meritless qui tams, preventing parasitic or opportunistic qui tam actions, and preserving government resources, among others. In the three-year period since the Granston Memo's circulation, the number of dismissals under § 3730(c)(2)(A) has more than doubled as compared to the thirty-year period prior.

The Granston Memo was motivated by record increases in qui tam actions filed over the last several years. Indeed, as stated above, the DOJ saw 672 new qui tam matters opened in 2020. For the last decade, annual totals of qui tam actions filed have exceeded 600. The ever-increasing number of qui tam actions does not reflect an increase in meritorious claims—if such were the case, we would expect to see a corresponding increase in the number of intervened cases. But the level of intervention has remained static while the number of qui tam filings has skyrocketed, reflecting relators' abuse of the FCA.

Assuming Mr. Granston continues in his role with the Commercial Litigation Branch, as we expect he will, it will be interesting to follow whether he will undertake additional efforts to encourage more dismissals or otherwise curb frivolous cases. Mr. Granston identified one such tool in his 2020 remarks, namely expanded reliance on data analysis to assess allegations that the government receives from relators. Such analysis should help the government identify meritless claims.

Predicting Future FCA Enforcement under the Biden Administration

Enforcement of the FCA under the Biden Administration will in large part reflect familiar priorities pursued in recent years. Namely, the False Claims Act will remain steadily enforced, primarily against the healthcare industry, and with a special emphasis on addressing the opioid crisis. Nonetheless, we also expect significant new developments as the DOJ begins to utilize the FCA as a tool to combat emergent cyber-security threats and fraud related to the coronavirus pandemic.

As Mr. Granston stated during his 2020 address, the DOJ's primary concern regarding enforcement of the False Claims Act remains to combat healthcare fraud, with a special emphasis on practices that allegedly exacerbate the opioid crisis. The Biden Administration has

not specifically commented on the efficacy of this strategy. Nonetheless, policy priorities identified by the Biden campaign show close conformity with existing DOJ priorities described in Mr. Granston's 2020 address. During the campaign, Mr. Biden released The Biden Plan to End the Opioid Crisis. Mr. Biden's plan promised to "demand accountability from pharmaceutical companies and others responsible for the opioid crisis accountable." Biden's plan goes on to promise that his administration will direct the DOJ to make actions within the healthcare industry that allegedly caused the opioid crisis a top investigative and enforcement priority. As to the FCA, this strategy closely mirrors actions already implemented by the DOJ in the last four years.

New FCA enforcement efforts under the Biden Administration will most likely focus in large part on addressing cybersecurity threats. Mr. Granston's 2020 address identified cybersecurity as an area of particular interest to the DOJ in determining where to pursue new FCA claims. President Biden's decision to appoint Lisa Monaco as Deputy Attorney General indicates that cyber security represents an area of particular concern to the Biden Administration. If confirmed, Ms. Monaco will bring extensive cybersecurity experience to her new role.

Finally, we expect significant new FCA enforcement in the area of coronavirus-related fraud. The DOJ has already suggested that the unprecedented scale of the federal government's COVID-19 relief efforts has created opportunities for fraud. Mr. Granston has stated that the DOJ will continue to closely monitor this area. We will continue to closely monitor this area as well, with the next installment of our First 100 Days series focusing on the Biden Administration's efforts to combat pandemic-related fraud.

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