



Expectations for white collar enforcement under the Biden Administration

White Collar Alert

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The senior leadership that will be responsible for white collar enforcement under the Biden Administration is starting to crystalize. In January 2021, President Joseph R. Biden, Jr. announced several key nominations for the US Department of Justice (DOJ), including DC Circuit Judge Merrick Garland for Attorney General, veteran prosecutor Lisa Monaco for Deputy Attorney General, and Gary Gensler – former Chair of the Commodity Futures Trading Commission (CFTC) – for Chair of the US Securities and Exchange Commission (SEC). While confirmation hearings for these nominees remain pending, many anticipate a surge in white collar enforcement activity once this team is in place.

In this alert, we analyze six key areas where the Biden Administration may focus its enforcement efforts: (1) securities fraud; (2) foreign corruption and anti-money laundering; (3) fraud on the government; (4) cryptocurrency; (5) antitrust; and (6) life sciences.

1. Securities fraud

If confirmed as SEC Chair, Mr. Gensler is expected to be a staunch enforcer of the securities laws given his record as CFTC Chair in the years following the 2008 financial crisis. We anticipate that the DOJ and the SEC both will be more active in pursuing securities investigations with a renewed focus on large Wall Street firms and public company

disclosures – eg, scrutiny of financial statements and accounting practices, disclosures related to the impact of COVID-19, and disclosures related to environmental, social, and governance (ESG) factors (see our recent alert here). We also anticipate that the successful SEC Whistleblower Program – which paid a record \$175 million to 39 whistleblowers in 2020 – will continue leading to significant securities enforcement actions, including DOJ “related actions.”

Insider trading enforcement is also likely to increase, especially if Congress and President Biden enact the proposed Insider Trading Prohibition Act, which would codify insider trading law in a statute for the first time, resolve uncertainty in the courts, and create incentives for more insider trading prosecutions. Given the recent events surrounding GameStop stock, we also expect closer scrutiny of market commentary on social media platforms, of short-selling practices, and actions to deter market manipulation.

For securities fraud and other types of white collar cases, the Biden Administration may return to a focus on prosecuting individuals deemed responsible for corporate wrongdoing. At DOJ, a long line of Deputy Attorneys General have issued policy memoranda addressing that topic. In the Obama Administration, the Yates Memo required companies to “identify all individuals involved in or responsible for the misconduct” before receiving any cooperation credit from DOJ. Under President Trump, Rod Rosenstein eschewed the practice of Deputy Attorneys General issuing eponymous policy memos in favor of capturing policy changes formally in what is now known as the Justice Manual. No matter the format, it is reasonable to expect that Ms. Monaco will continue to build upon the principles and incentives concerning individual prosecution in white collar cases. Indeed, as a former prosecutor on the Enron Task Force, Ms. Monaco’s early career focused on holding individuals accountable for alleged securities violations and corporate crime. That experience may influence the new Administration’s approach.

2. Foreign corruption and anti-money laundering

We expect that under the Biden Administration the DOJ and SEC likewise will increase their focus on foreign corruption and money laundering. We anticipate more robust enforcement, more active cases, and a sustained emphasis on cooperation and self-reporting.

The recently passed Kleptocracy Asset Recovery Rewards Act (KARRA) may bolster corruption enforcement because it closes some of the gaps in the current whistleblower programs for foreign government corruption information. Under the SEC Whistleblower Program, whistleblowers who provide information regarding bribery prohibited by the Foreign Corrupt Practices Act (FCPA) may receive rewards for a successful prosecution. Part of the National Defense Authorization Act for Fiscal Year 2021 (NDAA), KARRA establishes a pilot whistleblower reward program “to support U.S. Government programs and investigations aimed at restraining, seizing, forfeiting, or repatriating stolen assets linked to foreign government corruption and the proceeds of such corruption.” While FCPA prosecution is limited to those who give bribes – rather than those who receive them – whistleblower information provided pursuant to KARRA need only lead to restraining, seizing, forfeiting, or repatriating foreign assets to potentially be eligible for a reward. As such, KARRA strengthens the government’s ability to pursue FCPA cases, as well as related civil forfeiture actions, by encouraging tips to help recover assets connected to foreign corruption.

Anti-money laundering (AML) enforcement will also take center stage as the Anti-Money Laundering Act of 2020 (AMLA) is implemented. Another part of the NDAA, the AMLA is one of the most substantial and sweeping legislative reforms to AML and combating-the-financing-of-terrorism (CFT) laws since the USA Patriot Act of 2001. Among other tools, the AMLA: (1) creates a non-public registry that tracks the beneficial owners of certain companies; (2) enhances the AML Whistleblower Program akin to the Dodd-Frank Act’s SEC Whistleblower Program; (3) expands US regulators’ statutory authority to seek documents from foreign financial institutions; (4) modernizes the existing AML/CFT regime to account for emerging finance markets and patterns and expanding the resources and tools to counterthreats, including increased penalties and inter-agency information sharing; (5) increases penalties for Bank Secrecy Act (BSA) and AML violations; (6) allows Suspicious Activity Report (SAR) sharing with foreign affiliates; (7) establishes priorities to govern AML/CFT policy; and (8) creates an annual reporting requirement to apprise Congress of all DOJ settlements involving the Bank Secrecy Act (BSA) (see our recent alert here).

3. Fraud on the government

The False Claims Act (FCA) historically has been one of the government's top weapons against fraud. 2020 saw DOJ's lowest FCA recoveries in years, but FCA cases and recoveries will likely increase substantially under the new administration. One major focus will be companies and individuals who benefit from – or act as gatekeepers for – COVID-19 stimulus programs, including Paycheck Protection Program (PPP) loans, Main Street Lending Program loans, other relief found in the proposed Coronavirus Aid, Relief, and Economic Security Act (CARES Act), and any other relief enacted by Congress. In addition to a surge of pandemic-related *qui tam* actions by FCA whistleblowers, DOJ may receive a steady stream of referrals from inspectors general who monitor relief funds for potential fraud, including the Special Inspector General for Pandemic Recovery created by the CARES Act.

Other areas of focus may include cybersecurity, healthcare, and life sciences (described further below). As for healthcare-related fraud, DOJ may also receive referrals and develop cases through the FCA Working Group that it recently formed with the HHS Office of Inspector General.

One lingering question is whether DOJ policy will shift away from the 2018 Granston Memo, which has led to DOJ moving to dismiss a substantial number of *qui tam* actions pursuant to 31 U.S.C. § 3730(c)(2)(A) – about 50 since 2018, versus approximately 45 in the 30-year period pre-Memo. If so, such a shift may incentivize more FCA filings by prospective *qui tam* relators.

4. Cryptocurrency

In recent years, DOJ has shown increasing interest in pursuing crimes relating to or involving cryptocurrency. Actions by DOJ at the end of 2020 suggest that government interest in cryptocurrency is only increasing.

Significantly, the Attorney General's Cyber-Digital Task Force released a cryptocurrency enforcement framework in October 2020 which provides an overview of crimes in which cryptocurrency may play a role, the resources available to the government to combat those crimes, and the difficulties faced by the government in doing so (see our recent alert here). Recent enforcement actions involving cryptocurrency brought against individuals and companies provide further insight into DOJ's focus. For individuals, DOJ has actively pursued charges against traders and promoters who are alleged to have misrepresented the profitability of cryptocurrency investments. For companies, DOJ's scrutiny has fallen to examining the strength and appropriateness of anti-money laundering policies and procedures. DOJ under the Biden Administration has shown no signs of slowing down, with several announcements of cryptocurrency-related charges since President Biden took office.

5. Antitrust

News reports suggest that the Biden Administration is already showing strong interest in antitrust enforcement and policy which, if true, suggests an expanded role for DOJ going forward. The Biden Administration is said to be in discussions about the formation of a role within the White House focused on competition and antitrust policy.

One area of interest is likely to be the tech industry, which was already under intense scrutiny, as evidenced by DOJ's civil antitrust lawsuit against Google filed in October 2020.

While the Biden Administration has yet to announce who will head the Antitrust Division, DOJ may draw on the experience of Merrick Garland, who once taught an antitrust course at Harvard Law and participated in several antitrust decisions on the DC Circuit. Within DOJ's toolbelt as it pursues antitrust violations will be the opportunity to offer deferred prosecution agreements to resolve criminal antitrust matters, a policy change implemented in July 2019 which was utilized several times under the William Barr-led DOJ. If they are enacted, newly proposed broad changes to US antitrust laws by the incoming head of the Senate Antitrust Subcommittee, Senator Amy Klobuchar, may also bolster the Biden Administration's efforts.

6. Anti-Kickback Statute and False Claims Act

DOJ recovered over \$2.2 billion from FCA cases in 2020, more than \$1.8 billion of which came from settlements and judgments involving the healthcare industry. DOJ is expected to continue its laser-like focus on the life sciences industry under Merrick Garland, with pharmaceutical companies and medical device manufacturers expected to receive significant attention.

Anti-Kickback Statute (AKS) cases have been the bread and butter of DOJ enforcement in the life-sciences sector for decades, and such cases will surely continue apace under the new Administration. Particular areas to watch for AKS enforcement are:

- **Speaker programs and HCP engagement:** 2020 saw a number of cases brought against manufacturers concerning HCP engagement, including as to sponsored research, and HHS-OIG's recent "Special Fraud Alert" on speaker programs (see our recent alert here) suggests that these cases will continue to be a priority.
- **Electronic health records/clinical decision support:** The Practice Fusion settlement from early 2020 demonstrates that DOJ and regulators are keenly interested not only in how the government incentive programs surrounding electronic health records (EHR) services may be the subject of fraud, but also that it sees potential kickbacks in the relationships between manufacturers, EHR providers, and physicians.
- **Telemedicine:** When CMS relaxed reimbursement rules for telemedicine in March 2020 in part as a reaction to the COVID-19 pandemic, the use of telemedicine increased significantly and – not surprisingly – so did DOJ scrutiny, as evidenced by Operation Rubber Stamp in October 2020, which alleged a nationwide kickback scheme against more than 80 individuals involving over \$4.5 billion.
- **Patient and practice support:** DOJ's investigation of manufacturer donations to co-pay assistance charities appears to be winding down, but it filed three related lawsuits last year and HHS-OIG continues to look unfavorably on programs and conduct that – in its view – undermine the cost-sharing incentives built into federal programs like Medicare. DOJ will continue to scrutinize any manufacturer programs that support physicians and their practices to determine whether such programs provide a "substantial independent benefit" that could implicate the AKS.

We also expect DOJ – along with FDA and other agency partners – to continue to focus on issues concerning data integrity and current Good Manufacturing Practices (cGMP). Of course, notwithstanding the specific legal theory or facts in a particular case, DOJ interest is almost always animated by assessing whether one or more of three factors are implicated by the conduct at issue: whether independent clinical decision making was affected, whether public dollars were wasted, or whether patient safety was implicated.

Takeaways

- Public companies can expect scrutiny of their financial statements and disclosures;
- Focus on insider trading issues, focused on COVID-19 issues and beyond, is likely to increase.
- Regulators will likely place a greater emphasis on pursuing fraud claims, as well as a renewed focus on individual accountability.
- US regulators – particularly DOJ – will increasingly focus on preventing the criminal use of digital assets and blockchain technology.
- DOJ may find itself with new tools at its disposal to pursue criminal antitrust claims.
- The life sciences industry can expect continued scrutiny, particularly in relation to AKS enforcement.
- Companies should consider refreshing their risk assessments and compliance programs to ensure they are accounting for changes to their business due to the pandemic and shifting enforcement priorities.

Conclusion

In sum, we expect white collar enforcement activity to substantially increase across a range of subject-matter areas, with a diverse set of industries in the government's crosshairs. Not only will the government take a more aggressive posture, but the proliferation of whistleblower programs and the creation of new enforcement tools means that prosecutors will be armed with more information and resources than ever. Companies should remain vigilant as risks shift and consider

taking steps to ensure they adapt their compliance programs and controls accordingly.

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