

Prepare For DOJ's Pandemic-Related Enforcement Priorities

By **Elizabeth Scott, Angela Styles and Caroline Wolverton**

In remarks at the U.S. Chamber of Commerce's Institute for Legal Reform, Principal Deputy Assistant Attorney General Ethan Davis of the U.S. Department of Justice Civil Division elaborated on the focus of the DOJ's civil enforcement authority on fraud and illegal actions relating to COVID-19, including the Coronavirus Aid, Relief, and Economic Security, or CARES, Act stimulus programs, and consumer products marketed for use in addressing the virus.

Davis explained that private equity firms that invest in companies receiving CARES Act funds may be subject to enforcement activity if they take an active role in illegal conduct by one of their portfolio companies. Other enforcement priorities include the opioid crisis, electronic health records, Medicare Part C, nursing homes, fraud on the elderly, dietary supplements, and data privacy.

Recognizing the critical role private sector companies play in helping to bring an end to the pandemic and restart the economy, however, the DOJ will not target businesses that operate in good faith. And the DOJ will seek to dismiss COVID-19-related qui tam actions based on technical mistakes with paperwork or honest misunderstandings of the rules, as well as those aimed at companies that acted in good faith to take advantage of the regulatory flexibility certain federal agencies granted during this time of crisis.[1]

False Claims Act Enforcement Priorities With Respect to COVID-19

Echoing Attorney General William Barr's comments from earlier this year directing all U.S. Attorneys to prioritize the investigation and prosecution of Coronavirus-related fraud schemes[2], Davis made clear that the DOJ intends to actively use the False Claims Act, which is the federal government's most powerful civil enforcement tool, to combat those who would seek to exploit the COVID-19 crisis.

With violations potentially resulting in treble damages and civil penalties of up to \$23,331 per false claim or statement, the DOJ's prioritization effort is significant to the private sector, including companies receiving federal funds, and the resulting regulatory scrutiny and FCA exposure, for the first time in light of the pandemic.[3]

The Civil Division's fraud section has prioritized FCA enforcement actions for fraud relating to CARES Act stimulus programs in at least three specific areas:

1. Paycheck Protection Program and Main Street Lending Program

The DOJ will be looking for borrowers that knowingly submit false certifications, as well as lenders and borrowers that intentionally flout program requirements. Given its extraordinarily quick implementation and dissemination of more than \$500 billion in forgivable loans to businesses and nonprofits, the Paycheck Protection Program will likely be the focus of this effort. Actual eligibility for PPP loans under the program's size standards



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blended with the U.S. Small Business Administration's existing 7(a) loan requirements, and the accuracy of certification of need submissions by large and public companies, will likely occupy much of the DOJ's enforcement activity with respect to the PPP.

2. CARES Act Provider Relief Fund

A second focus of FCA enforcement will be providers that knowingly violate the terms and conditions on which funds are received, e.g., that the funds are for care of COVID-19 or presumptive COVID-19 patients.

3. Private Equity Firms

Finally, the DOJ will target private equity firms taking an active role in illegal conduct by their portfolio companies that receive CARES Act funds. Davis' statements with respect to investment firms make clear what many practitioners had viewed from the department's pre-pandemic case against private equity firm Riordan Lewis & Haden[4] as an increased willingness by the government to pursue the investment management firms backing health care companies and other entities that receive federal funds.[5]

Davis's remarks likewise provide important guidance regarding the level of participation and knowledge the government has deemed sufficient to pursue a private equity firm for its alleged conduct underlying an FCA scheme. Davis indicated the DOJ will target firms that take "an active role in illegal conduct by the acquired company."

Notwithstanding these areas of focus, Davis emphasized that the DOJ's enforcement efforts will avoid discouraging businesses operating in good faith from participating in stimulus programs and utilizing available regulatory flexibilities for development and distribution of COVID-19 tests, treatments and protective equipment.

Further, the DOJ does not intend to pursue enforcement actions against businesses that make "immaterial or inadvertent technical mistakes" or that honestly misunderstood government requirements. The DOJ wants to ensure that businesses are not discouraged from helping address COVID-19 by "unwarranted False Claims Act liability," and Davis noted more information on that point would be forthcoming.

Davis additionally indicated that the department may use its authority under the FCA to dismiss COVID-19 related qui tam actions based on paperwork mistakes or honest misunderstandings of the rules, as well as those aimed at companies that acted in good faith to take advantage of regulatory flexibility certain federal agencies granted during this national emergency.

Although the FCA provides the DOJ with authority to dismiss a qui tam action over a relator's objection, for decades that authority was rarely used. However, Davis confirmed that Deputy Assistant Attorney General Michael Granston's January 2018 memorandum outlining the circumstances under which department attorneys should consider moving to dismiss a qui tam action, including curbing meritless or opportunistic litigation, and preventing interference with agency policies and programs,[6] has had a meaningful effect.

He explained that in the two-plus years since the memo, the department has moved to dismiss approximately 50 qui tam actions, as compared to the approximately 45 qui tam actions the department moved to dismiss in the entire 30 years preceding its release.

Davis indicated the DOJ would use its dismissal authority with respect to COVID-19 to weed

out qui tam actions that are not in the interests of the U.S. because they are based on technical mistakes or honest misunderstandings of the rules. Further, the department may dismiss qui tam suits that seek to hold companies liable for taking advantage of discretionary enforcement policies designed to encourage private sector innovation — for example, discretionary measures aimed at making telehealth services more readily available.

While Davis' comments may provide some comfort for those companies engaged in efforts to combat COVID-19, whether an alleged FCA violation is the result of a technical mistake or honest misunderstanding is often hotly contested even in non-COVID-19 related cases, and defendants may face an uphill battle in convincing the government of their good intentions. Additionally, "knowing" under the FCA includes reckless disregard and deliberate ignorance, and Davis did not suggest that businesses can turn a blind eye to or intentionally avoid learning the requirements of the stimulus programs in which they participate.

Consumer Protection Priorities Related to COVID-19

The Civil Division's Consumer Protection Branch will focus its enforcement efforts on fraudulent and otherwise illegal tests, treatments and purported cures for COVID-19. It will pursue so-called scammers preying on the elderly with false promises of assistance through the CARES Act and other government programs and the infrastructure used in those scams, including facilitators in telecommunications, finance and marketing.

The Consumer Protection Branch will also take action against companies that flout safety requirements for COVID-19 treatments or related complications, particularly drugs and active pharmaceutical ingredients, and will act against fraud in clinical trials of drugs and medical devices for treating or preventing COVID-19.

As with FCA enforcement efforts, the Consumer Protection Branch will work with its agency and U.S. Attorney partners to ensure that the DOJ's actions are consistent with the increased regulatory flexibility afforded to companies developing and distributing COVID-19 tests, treatments and protective equipment, and will not target companies acting in good faith.

Other Areas of Anticipated Enforcement Activity

Davis made clear that the DOJ will continue to pursue fraud in areas other than COVID-19-related activities. The DOJ will continue to focus on the opioid crisis, electronic health records, Medicare Advantage, nursing home mistreatment, fraud on the elderly and dietary supplements.

The DOJ is increasing its focus on data privacy. Aware of businesses' growing accumulations of consumer data, the department is using its authority to enforce Federal Trade Commission Act civil penalties, as well as its other enforcement tools, to ensure data privacy and security.

For example, Davis cited the Consumer Protection Branch's recent role in pursuing and ultimately settling data privacy claims against Facebook Inc. for \$5 billion in civil penalties and the company's commitment to adopting robust compliance measures. He said moving forward the DOJ is committed to coordinating closely with the U.S. Federal Trade Commission and the DOJ's Antitrust Division to hold companies and individuals accountable for privacy law violations with respect to the acquiring, storing, or using of consumer data.

Focus on Third-Party Litigation Funding

Finally, as part of an information gathering exercise designed to bolster the DOJ's knowledge of who is behind qui tam suits, Davis announced that during their case intake interviews, DOJ lawyers will begin asking relators a series of questions regarding the role of third-party litigation funders in their cases.

These questions include (1) whether the relator or relator's counsel has any agreement with a third-party funder and, if so, whether such agreement is in writing; (2) the identity of the funder; (3) whether the relator has shared information relating to the qui tam action with the funder; and (4) whether the agreement entitles the funder to exercise direct or indirect control over the relator's litigation or settlement decisions.

DOJ lawyers will also ask the relator to inform them if the answers to these questions change at any point over the course of the litigation. These questions should provide the DOJ a view into important areas in which Davis admitted it currently lacks knowledge, including "whether and to what extent the funders are exercising control over relators' litigation and settlement decisions."

Indeed, third-party funding of qui tam suits raises a host of concerns. It can create a conflict of interest on the part of the relator, who may be incentivized to pursue the interest of the third-party funder even though the qui tam action is brought in the name of the U.S. Third-party funding of qui tam suits also enhances the risk that the confidentiality surrounding allegations of fraud will be breached in light of the relator's communications with the third-party funder.

Thus, third-party funding of qui tam suits poses a challenge to the DOJ's ability to fulfill its statutory obligation to protect the interests of the U.S. as the real party in interest in qui tam suits. The DOJ's planned questions are a significant first step in understanding the impact of third-party funding on qui tam suits and mitigating the concerns surrounding third-party funders' involvement.

Mitigating the Risk

With the DOJ's stated intention to avoid using its enforcement power to hold companies accountable for good faith errors, companies should take certain steps to mitigate the risk of liability, including identifying applicable program rules, staying abreast of such rules and actively on alert for any changes, and carefully documenting compliance efforts.

Where rules are ambiguous, companies should form a contemporaneous, reasonable understanding of what is required, document that understanding and the rationale for it, and communicate their understanding to the government if the issue arises — for example, in written correspondence with government officials, routine audits, U.S. Securities and Exchange Commission filings or other public reports.[7]

In addition, it is notable that Davis specifically mentioned two promising areas of potential DOJ control over relators in FCA suits — the exercise of dismissal authority in accordance with the Granston memo and inquiries of relators regarding third-party litigation funding of qui tam suits. The DOJ's actions going forward in both of these areas will be crucial to ensuring that the DOJ's good-faith enforcement policies are realized in practice.

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[1] Davis' remarks, given June 26, 2020, are available at <https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims>.

[2] See Attorney General William P. Barr, Attorney General William P. Barr Urges American Public to Report COVID-19 Fraud (Mar. 20, 2020), <https://www.justice.gov/opa/pr/attorney-general-william-p-barr-urges-american-public-report-covid-19-fraud>.

[3] Both the DOJ and private individuals or organizations, referred to as qui tam relators, can bring lawsuits in federal district court to recover damages and penalties for FCA violations.

[4] U.S. ex rel. Medrano v. Diabetic Care RX LLC, No. 15-62617-CIV-BLOOM (S.D. Fla. Feb. 16, 2018).

[5] Akin Gump's prior alert with respect to the Riordan, Lewis & Haden case is available at <https://www.akingump.com/en/news-insights/united-states-intervenes-in-suit-against-private-equity-firm.html>.

[6] Akin Gump's prior alert on the Granston Memo is available at <https://www.akingump.com/en/news-insights/departments-of-justice-memorandum-provides-guidance-for.html>.

[7] For a more comprehensive discussion of the steps companies can take to minimize their exposure to FCA liability in the aftermath of COVID-19 legislation, see Akin Gump's prior alert on the topic at <https://www.akingump.com/en/news-insights/reducing-false-claims-act-exposure-in-the-aftermath-of-covid-19-legislation.html>.