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Justice Department Enforcement Priorities Focus on CARES Act Fraud

By Jaime L.M. Jones*

The author reports on the current enforcement priorities of the U.S. Department of Justice.

At a recent U.S. Chamber of Commerce, Institute for Legal Reform meeting, Principal Deputy Associate Attorney General Ethan Davis set forth the current enforcement priorities of the U.S. Department of Justice ("DOJ"),[1] clarifying for corporations accessing stimulus funds or otherwise dealing with government programs or acting in regulated industries how it is focusing its efforts to target fraud in the midst of the COVID-19 pandemic.

While Davis underscored DOJ's commitment to using the False Claims Act ("FCA") and other "weapons in [its] arsenal" to fight fraud against the various pandemic stimulus programs, he also emphasized DOJ's commitment to exercise enforcement discretion in cases lacking the hallmarks of bad corporate intent.

PAYCHECK PROTECTION PROGRAM

With respect to the department's pandemic-related enforcement priorities, it is clear that the DOJ plans to leverage the FCA to protect the "vast amounts of federal funds" being injected into the economy.

In that regard, the Civil Division lawyers are partnering with the Inspector General of the Small Business Administration to identify potential fraud in the Paycheck Protection Program. This sentiment was echoed by statements made recently to the American Bar Association Grant Law & Procurement Fraud Committee by the Executive Director of the Pandemic Response Accountability Committee—the independent oversight body established by the Coronavirus Aid, Relief, and Economic Security Act ("CARES" Act)—that the government is focused not just on prosecuting stimulus-related fraud on the back end but on leveraging data analytics and other monitoring efforts to root it out in the first instance.

Individuals and entities must abide by many certifications, attestations, and obligations when accessing funds under the Paycheck Protection Program,

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[1] Davis' prepared remarks are *available at* https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

Main Street Credit Facility, and healthcare provider relief fund, among others. DOJ intends to leverage those commitments to pursue treble damages and penalties under the FCA against companies and individuals that knowingly violate the program requirements or other relevant laws and regulations.

At the same time, companies and healthcare providers should feel confident that DOJ will not pursue enforcement on the basis of "immaterial or inadvertent technical mistakes" or against those who "honestly misunderstood the rules, terms, and conditions or certification requirements." This commitment is consistent with recent statements made by others within DOJ and of course consistent with the plain language of and prevailing body of FCA jurisprudence.

For example, while committing his office to using the FCA aggressively to pursue fraud in the pandemic, U.S. Attorney for the Eastern District of Texas Stephen Cox—who is on the leading edge of efforts by the U.S. Attorneys to fight pandemic-related fraud—recently announced the policy of his office, which will not bring cases based on "technical mistakes" or against those who "honestly misunderstood regulatory or certification requirements."

WHISTLEBLOWER LAWSUITS

Consistent with these commitments, it is expected that DOJ will use its authority, consistent with the principles outlined in the "Granston Memo," to dismiss meritless whistleblower lawsuits or those that are inconsistent with agency policies and guidance. Thus far, DOJ has made motions to dismiss approximately 50 *qui tam* lawsuits in the wake of the Granston Memo, as compared with only 45 motions to dismiss such suits in the preceding 30 years, as evidence that it will wield its dismissal authority when appropriate.

As it relates to pandemic-related enforcement, the department will analyze under Granston in particular those whistleblower attempts to attack actions that are the subject of regulatory waivers by relevant government agencies or that allege conduct perceived to be inconsistent with nonbinding agency guidance.

For example, the Department of Health and Human Services, Office of the Inspector General, recently announced that it will not pursue enforcement against certain COVID-19-related arrangements that may otherwise constitute illegal remuneration under the Anti-Kickback Statute. Whistleblowers who seek to profit from companies and providers that act in good faith to take advantage of the flexibility offered by the agency may be the subject of a Granston dismissal motion, according to Davis.

Despite the comfort offered by indications that the DOJ will not pursue conduct that arises from mistaken interpretations of regulations and proactively

dismissing meritless whistleblower suits, those that have been the subject of DOJ scrutiny under the FCA know that it can take years, at significant cost and distraction to even large corporations, for the government to investigate concerns that fraud may have occurred and to distinguish good-faith efforts to comply in the face of regulatory complexity or ambiguity from actionable fraud. At the same time, companies that accept funds today must consider how government enforcement priorities and policies may shift under future administrations.

PRIVATE EQUITY FIRMS

Private equity firms and investors may face increased risk under the FCA, particularly those that invest in the healthcare or life sciences sectors or other highly regulated industries. Based on DOJ's prepandemic pursuit of a compounding pharmacy and its private equity fund owner alleged to have accepted kickbacks that tainted claims filed with Tricare, it is apparent that DOJ is looking to bring similar actions to combat perceived fraud related to the CARES Act.

In particular, private equity firms have an obligation to come up to speed on the myriad complex laws and regulations that are designed to prevent fraud in highly regulated industries, and those firms that take an active role in the conduct of their portfolio companies will be pursued under the FCA to the extent violations occur.

SHAM COVID-19 PRODUCTS

Finally, DOJ has and will continue to undertake specific enforcement efforts to target those that promote and sell unauthorized or sham COVID-19 tests and treatments.

Aside from those actions the department can pursue civilly, it can leverage criminal actions under the Food, Drug, and Cosmetic Act as well as other criminal statutes. Such enforcement actions may be brought not just against the makers and marketers of phony COVID-19 products but also against companies whose technologies are used in such scams, such as the telemarketing companies, payment processors, and advertising agencies.

OTHER ENFORCEMENT PRIORITIES

Aside from the pandemic-focused enforcement priorities, the Civil Division is expected to have a continued focus on other areas that have received considerable attention in recent years.

For example, DOJ has emphasized issues of noncompliance with current good manufacturing practice ("cGMP") regulations in the manufacture of drugs and active pharmaceutical ingredients. Companies must pay particular attention to compliance in this area, as the Food and Drug Administration

recently announced that it is restarting inspections of manufacturing facilities. There will also most likely be a focus on dietary supplement manufacturers, especially because they import many ingredients from markets such as China and India, with demonstrated failures in cGMP compliance.

Other areas of continued enforcement focus or particular relevance to the life sciences industry include clinical trials fraud and data integrity issues and actions against those in the opioid supply chain related to that epidemic.

In the healthcare sector, continued enforcement actions under the FCA against electronic health records ("EHR") companies is anticipated. Recent actions in that space have included settlements resolving claims that EHR companies caused providers falsely to certify compliance with Meaningful Use requirements and allegations that EHR vendors accepted kickbacks in exchange for pushing prescribers to write more opioid prescriptions.

Separately, providers and plans that submit unsupported diagnosis codes to increase reimbursement under the Medicare Advantage program will face continued FCA litigation and enforcement. There will also be a focus on pursuing allegations of substandard care provided by nursing homes, including under the FCA.

Finally, data privacy is an emerging area of emphasis. For example, the recent $5 billion penalty against one social media company, and DOJ's cooperation with the Federal Trade Commission in the pursuit of that case, are a warning to all companies that acquire, store, or use consumer data that they will be subject to carefully coordinated enforcement scrutiny.