

Revitalized Consumer Protection Branch Helps DOJ Civil Keep its Eye on the Ball: DOJ Will Fight COVID Fraud While Pursuing Pre-Existing Priorities

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In a speech on June 26, 2020 to the U.S. Chamber of Commerce, Principal Deputy Assistant Attorney General Ethan P. Davis reiterated the Department of Justice's commitment to fighting fraud and abuse in the coronavirus (COVID-19) era and beyond. Mr. Davis, the second in command of the United States Department of Justice (DOJ) Civil Division, identified six civil enforcement priorities and trumpeted the newly-revitalized Consumer Protection Branch's (CPB) role in fighting COVID-related fraud. While committing to using tools like the False Claims Act (FCA) to only target those who "knowingly failed to comply with material legal obligations and certifications," Mr. Davis' speech conveyed an image of a Civil Division that has the tools it needs to fight COVID-related fraud while keeping its focus on previously-identified priorities.

The Rise of the CPB

Per Mr. Davis, the CPB is "up-and-coming," and after tripling in size since 2017, is well-positioned to "play a key role" in fighting COVID-related fraud. By way of background, while the CPB is in the Civil Division, it does both criminal and civil work. Its investigations often run parallel to that of other DOJ components, and it is now "playing a much more significant role in the white collar space." In particular, the CPB works with the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) to enforce the Food, Drug and Cosmetic Act (FDCA) and Controlled Substances Act (CSA), which means it has oversight of large swaths of government spending.

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With that expertise, Mr. Davis made it clear that the re-tooled CPB will not pull any punches when it comes to companies or individuals looking to profit off the pandemic at the expense of consumer welfare. Indeed, the CPB has been “leading the charge” against companies peddling products that they falsely promise will prevent harm from the virus. Already, the CPB has obtained a temporary restraining order against an entity selling a fake vaccine, secured injunctive relief against marketing of supposed cures for COVID, and “shutter [ed] websites selling fake or unapproved treatments.”

But this is only the beginning—the CPB’s COVID and non-COVID enforcement is expected to expand going forward. Per Mr. Davis, the CPB “will vigorously pursue scammers” promising stimulus programs or government efforts. The Branch will also target the infrastructure facilitating the fraud like the telecommunications, marketing, and financial industries. Additionally, the CPB will continue monitoring and ensuring the safety and efficacy of new treatments and “related complications.” In particular, the CPB will target noncompliance with safety regulations, especially pharmaceuticals. Lastly, an ever-increasing number of preventative products and possible treatments are in clinical trial. The CPB will monitor such drug and medical device development for potential fraud, and will “vigorously pursue” companies *and their executives* for knowingly manipulating data, creating false data, and relaying false data.

Continuing Priorities Unrelated to COVID-19

While DOJ is using every tool in its kit to combat COVID-19 related fraud, it has made clear it continues to target non-COVID fraud. In concluding his remarks on the aggressive efforts with the FCA and by the CPB in the midst of the global pandemic, Mr. Davis made clear the DOJ’s pre-existing priorities remain.

First, civil opioid enforcement remains a primary DOJ priority per Attorney General Barr. The DOJ has used, and will continue to use, the FCA, CSA, and FDCA to crack down on the crisis and hold all participants in the distribution chain responsible—including pharmaceutical companies, doctors, and drug wholesalers. The CPB has also used forfeiture, civil injunctive, and penalty provisions of the CSA against pharmacies and individuals including pharmacists.

Second, the DOJ is committed to protecting the integrity of electronic health records by using the FCA to stop companies from corrupting the information submitted to physicians. To that end, Mr. Davis touted the fact that the DOJ recently entered into a \$118.6 million resolution with electronic health records vendor Practice Fusion that resolved allegations that the company received kickbacks from pharmaceutical companies in exchange for promoting opioid prescriptions with its software.

Third, Medicare Advantage, also known as Medicare Part C, will continue to be a hot bed for civil enforcement. With almost a third of Medicare beneficiaries opting to participate in Medicare Advantage plans, the Federal Government paid Medicare Advantage Organizations almost \$250 billion in 2019. While the DOJ’s record in FCA cases involving plans has historically been mixed, it has continued to challenge adverse rulings, intervene in *qui tams*, and even bring original cases in this space. Its persistence has proven fruitful, with settlements involving Medicare Advantage sometimes bringing staggering amounts back into the government fisc.

Fourth, the DOJ remains focused on its National Nursing Home Initiative, designed to reduce the subpar care the country's elderly population sometimes receives. Multiple investigations are already underway in several states.

Fifth, the DOJ anticipates increased fraud with dietary supplements given the perfect storm of developing science, ingredients imported from countries with little oversight, less regulation, and high profits. The CPB in particular will expand resources to target this emerging area.

Finally, the CPB is also increasing efforts to protect data privacy and security especially with the increased use of the Internet during the pandemic. For instance, last year the CPB and Federal Trade Commission entered into a \$5 billion settlement with Facebook entailing a comprehensive compliance overhaul to protect user privacy.

Conclusion

All in, Mr. Davis pledged that the Civil Division is fully-capable of walking and chewing gum at the same time. With the aid of its newly-revitalized CPB, it will fight newly emerging fraud related to the COVID crisis while also maintaining its previously-articulated enforcement priorities. Given the expanding role of the Civil Division, companies in highly-regulated industries—particularly the healthcare industry—must use extreme caution when working with or seeking funds from the Federal Government. In particular, given Mr. Davis' representations about wanting to use enforcement actions to combat true fraud, not those who act in good faith that may inadvertently violate regulatory requirements, companies should consider taking steps to bolster their compliance programs and take other measures to document their good faith compliance efforts.

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