Cooley

DOJ Previews Enforcement Policies Aimed at Clinical Trial Fraud

December 20, 2021

On December 9, 2021, one of the nation's top healthcare prosecutors made clear that clinical trial fraud will be a major enforcement priority of President Joe Biden's Department of Justice. Speaking at the Food and Drug Law Institute's (FDLI) Enforcement, Litigation and Compliance Conference, Deputy Assistant Attorney General Arun G. Rao announced that the DOJ plans to turn up the heat on companies that fabricate clinical trial data or falsify medical records. While these are the fact patterns of two recent prosecutions in this area, any noncompliance impacting patient safety is likely to get a closer look by government regulators.

Rao supervises the DOJ's Consumer Protection Branch (CPB), which brings criminal and civil actions to enforce health and safety-related laws. The CPB works closely with the Food and Drug Administration to enforce the Food, Drug and Cosmetic Act (FDCA), the operative statute outlining the FDA's mandate to protect the public health. The FDCA includes civil and criminal penalties, and these cases often begin with a referral from the FDA to the DOJ outlining the legal violations. The CPB has expanded significantly in recent years, and now has more than 90 prosecutors and more than 100 support personnel equipped to bring FDCA enforcement actions. Rao highlighted recent prosecutions against companies and individuals who falsified clinical trial data – and promised that more enforcement actions are on the way.

Here's what you need to know.

Why the DOJ is focused on clinical trial fraud

According to Rao, clinical trial fraud has been and will continue to be a point of emphasis for the CPB, with a particular focus on cases in which companies have allegedly falsified clinical data. The CPB is devoting substantial attention to these cases both because they can pose immediate dangers to consumers and because fake studies can cause broader damage to "confidence in the healthcare industry as a whole." These comments echoed recent remarks from CPB Director Gustav Eyler. In late 2020, Eyler called clinical trial fraud a "key area of drug and device related enforcement," and warned that "bad research" can "do great harm – both to patients and to trust in the system." Eyler also discussed these topics at this month's FDLI conference.

The CPB's priorities dovetail with the FDA's focus on clinical trial data. Of note, Dr. Robert Califf, Biden's nominee for FDA commissioner who led the agency in 2016, has been deeply involved in data initiatives related to FDA applications. He will likely continue to focus on clinical trials and data issues if confirmed to head the FDA. In his prepared remarks at a Senate confirmation hearing last week, Califf rated patient and consumer protection among his top priorities and identified the need for a "systematic approach to evidence generation" to improve patient safety.

Enforcement in the clinical trial space helps maintain the public's trust in the FDA to determine the safety and efficacy of medical products. With heightened importance of the FDA's processes during the COVID-19 pandemic, clinical trial fraud has, and will continue to be, top of mind for government regulators.

Recent prosecutions

Rao highlighted two recent examples of the CPB's enforcement in the area of clinical trial fraud. First, he discussed a trial fraud scheme based at a facility called Unlimited Medical Research in Miami. According to the CPB, five individuals purported to conduct an asthma medication trial, reporting pediatric subjects' visits, trials and payments. But according to Rao, "none of these things happened." CPB has already secured multiple guilty pleas and significant prison terms – one doctor was sentenced to 63 months in prison – with at least one defendant awaiting trial.

Second, Rao discussed a clinical trial fraud scheme based at Tellus Clinical Research, also in Miami. In this case, eight individuals purported to perform trials intended to evaluate a number of medical conditions, including opioid dependency and diabetic nephropathy. CPB alleges that these conspirators wholly "invented" the information they submitted to the FDA, including trial data, medical records and the subjects themselves. This case is ongoing.

Potential penalties

Companies and individuals alleged to have committed clinical trial fraud face a range of civil and criminal penalties and remedies, depending on which charges prosecutors bring. In addition to possible FDCA felony violations, which can carry prison sentences of up to three years, prosecutors frequently bring wire and mail fraud charges where the penalties can escalate to up to 20 years of prison. FDCA and Title 18 charges – such as making false statements to the FDA – also carry heavy criminal fines.

Considering the DOJ's stated emphasis on clinical trial fraud, we urge companies to stay vigilant with their compliance efforts.

This content is provided for general informational purposes only, and your access or use of the content does not create an attorney-client relationship between you or your organization and Cooley LLP, Cooley (UK) LLP, or any other affiliated practice or entity (collectively referred to as "Cooley"). By accessing this content, you agree that the information provided does not constitute legal or other professional advice. This content is not a substitute for obtaining legal advice from a qualified attorney licensed in your jurisdiction, and you should not act or refrain from acting based on this content. This content may be changed without notice. It is not guaranteed to be complete, correct or up to date, and it may not reflect the most current legal developments. Prior results do not guarantee a similar outcome. Do not send any confidential information to Cooley, as we do not have any duty to keep any information you provide to us confidential. When advising companies, our attorney-client relationship is with the company, not with any individual. This content may have been generated with the assistance of artificial intelligence (AI) in accordance with our AI Principles, may be considered Attorney Advertising and is subject to our **legal notices**.

Key Contacts

Andrew D. Goldstein Washington, DC	agoldstein@cooley.com +1 202 842 7805
Daniel Grooms Washington, DC	dgrooms@cooley.com +1 202 776 2042
Natasha Leskovsek Washington, DC	nleskovsek@cooley.com +1 202 728 7131

Sonia Nath Washington, DC	snath@cooley.com +1 202 776 2120
Vince Sampson Washington, DC	vsampson@cooley.com +1 202 728 7140

This information is a general description of the law; it is not intended to provide specific legal advice nor is it intended to create an attorney-client relationship with Cooley LLP. Before taking any action on this information you should seek professional counsel.

Copyright © 2023 Cooley LLP, 3175 Hanover Street, Palo Alto, CA 94304; Cooley (UK) LLP, 22 Bishopsgate, London, UK EC2N 4BQ. Permission is granted to make and redistribute, without charge, copies of this entire document provided that such copies are complete and unaltered and identify Cooley LLP as the author. All other rights reserved.