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DOJ Increases Focus on Clinical Trial Fraud

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While speaking at the Food & Drug Law Institute's Enforcement, Litigation and Compliance Conference in December, Deputy Assistant Attorney General Arun Rao identified clinical trial fraud as one of four key areas of enforcement focus by the Consumer Protection Branch of the U.S. Department of Justice ("DOJ").[1] Rao warned against the "dangerous consequences" of research fraud (often referred to as "research misconduct"), which he said serves to "undermine confidence in the health care industry as a whole."

Rao's remarks come at a time of increasing focus on scientific misconduct in clinical trials. Rao cited two recent clinical trial fraud enforcement actions in southern Florida that involved allegedly fabricated data, and he suggested that more enforcement actions may be on the way.

The COVID-19 pandemic will likely intensify such enforcement efforts. The Food and Drug Administration ("FDA") and other agencies (including the National Institutes of Health ("NIH") and the Office for Human Research Protections) have published guidance on the conduct of clinical trials during the COVID-19 pandemic to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice ("GCP"), and minimizing risks to trial integrity. The extensive government funding of clinical trials and basic science research during the pandemic will only increase regulators' interest in investigating allegations of potential data integrity issues. Accordingly, all organizations involved in basic science research, and especially clinical trials, should look to identify and address key areas of enforcement risk.

Legal Risk Areas Related to Clinical Trials

Scientific misconduct in clinical trials raises a number of risks, including criminal prosecution, FDA regulatory enforcement, and False Claims Act liability, in addition to reputational damage.

The Department of Health and Human Services ("HHS"), Office of Research Integrity ("ORI") defines ***fraud and research misconduct*** as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."[2] This definition would potentially include recording false, fabricated or misleading data, failing to disclose data that would normally be reported, submitting misleading reports regarding the conduct of the trial, and submitting false data to government agencies and/or for consideration for publication in journals. In addition to fraud, other investigative risk areas include foreign influence, conflicts of interests, and kickbacks, both foreign and domestic. Although ORI only has jurisdiction over research funded by HHS, the concept of research misconduct is well known to other parts of HHS and of the federal government, including FDA. Moreover, the receipt by many companies during COVID of federal funds for drug development means that ORI jurisdiction may, in many cases for the first time, extend to these sciences companies

Foreign influence cases typically arise when an investigator utilizes U.S. federal funds for their research while also maintaining undisclosed affiliations with other international institutions or universities, or when investigators inside commercial entities have undisclosed ex-U.S. affiliations that lead them to share their employer's technology without

[1] DOJ, "Deputy Assistant Attorney General Arun G. Rao Delivers Remarks at the Food & Drug Law Institute's (FDLI) 2021 Enforcement, Litigation and Compliance Conference," (Dec. 9, 2021), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-arun-g-rao-delivers-remarks-food-drug-law-institute-s.
[2] Department of Health and Human Resources Office of Resource Integrity, "Definition of Research Misconduct," https://ori.hhs.gov/definition-research-misconduct.

authorization. DOJ views such undisclosed relationships as problematic because they can potentially lead to investigators "double-dipping" by receiving both federal and foreign funds, as well as transferring to foreign institutions proprietary information funded by the U.S. and by U.S. companies. DOJ has increased its focus on foreign influence cases in recent years, including through the launch of its China Initiative in 2018 to counter economic espionage and trade secret theft by agents or operatives of the People's Republic of China.

While organizations are often familiar with professional norms regarding ***conflicts of interest***, such conflicts can also give rise to government actions. The Financial Disclosure by Clinical Investigators regulation (21 C.F.R. § 54) requires that commercial applicants that submit marketing applications for drugs, biologics or devices submit disclosures regarding various factors related to investigators' compensation and investigators' personal financial interests. It is important that clinical trial sponsors, and research institutions and their investigators, identify and disclose personal and financial conflicts of interests consistent with the Part 54 FDA regulations. Failing to do so may represent, among other things, providing false information to federal authorities.

Potential ***kickbacks*** involving exchanges of value to researchers and research institutions may likewise lead to enforcement actions under the Anti-Kickback Statute ("AKS") or the Foreign Corrupt Practices Act ("FCPA"). The AKS forbids offering or accepting financial remuneration or other benefits in return for referring services or devices that are covered under a federal health care program. The FCPA similarly forbids improper payments to foreign government officials, which can include individuals affiliated with foreign government-controlled corporations, medical centers or universities. Organizations should accordingly ensure that they have implemented comprehensive trainings, policies and bookkeeping procedures, as well as audits, to identify and prevent any improper payments to researchers, research institutions, clinical trial vendors (such as CROs), as well as government agents.

Conclusion

Recent statements by the DOJ make clear that clinical trial fraud is an agency priority, and industry sponsors of research, as well as researchers and research institutions, can expect more enforcement actions in the future. In order to minimize legal risk, manufacturers should act now to ensure trial sites and investigators have adequate training and procedures in place, and that those compliance protocols are tested and audited. They should also promptly investigate any potential data integrity issues or other allegations of misconduct in clinical trials or basic science research. Please consult your usual Ropes & Gray attorney for guidance on minimizing your risk.