

Department of Justice

Office of Public Affairs

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Doctor, Clinic Owner and Staff Charged with Falsifying Clinical Trial Data

In an indictment unsealed today, a federal grand jury in Miami charged a Florida medical doctor and three others for their roles in an alleged scheme to falsify clinical trial data.

According to court documents, Dr. Martin Valdes, 64, of Coral Gables, Florida, Fidalgis Font, 53, of Miami, Julio Lopez, 54, of Miami, and Duniel Tejeda, 35, of Canon City, Colorado, were charged in a six-count indictment returned by a federal grand jury on Feb. 23, 2021. Each defendant was charged with conspiracy to commit mail and wire fraud and at least one substantive count of mail fraud. In addition, Valdes and Font were charged with money laundering and Valdes was further charged with making a false statement to inspectors with the U.S. Food and Drug Administration (FDA).

"The public must be able to rely on the accuracy and honesty of clinical trial data, which is essential to ensuring the safety of drugs approved for patient use," said Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division. "The defendants undermined that process and put patients at risk. The Department of Justice will pursue and prosecute those who put personal profit before public health."

According to the indictment, from at least February 2014 through at least July 2016, the defendants fabricated clinical trial data for profit while working at Tellus Clinical Research, a medical clinic based in Miami. The indictment alleges that the defendants knowingly enrolled subjects in clinical trials when those subjects failed to meet eligibility criteria, falsified subject laboratory results, falsified subject medical records, and falsely represented that subjects were taking the drugs being studied when in fact they were not. Valdes served as primary investigator for the clinical trials conducted at Tellus, Font was the owner of the business, and Lopez and Tejeda were senior Tellus employees.

"Reliable and accurate data from clinical trials is the cornerstone of FDA's evaluation of a new drug," said Catherine A. Hermsen, FDA Assistant Commissioner for Criminal Investigations. "Compromised clinical trial data could impact the agency's decisions about the safety and effectiveness of the drug under review. We will continue to monitor, investigate and bring to justice those whose actions may subvert the FDA approval process and endanger the public health."

"Falsifying clinical data is a violation of the public's trust and it endangers the safety of consumers," said Ariana Fajardo Orshan, U.S. Attorney for the Southern District of Florida. "Those who enrich themselves while compromising public health in this way commit serious crimes and will be prosecuted."

If convicted of conspiracy to commit mail and wire fraud or mail fraud, each defendant faces a maximum penalty of 20 years' imprisonment. If convicted of money laundering, Valdes faces a maximum penalty of 20 years' imprisonment, and Font faces a maximum of 10 years' imprisonment. If convicted of making a false statement to the FDA, Valdes faces a maximum of five years' imprisonment. A federal district court judge will determine any sentence after considering the U.S. Sentencing Guidelines and other statutory factors.

Assistant Director Clint Narver, Trial Attorney Lauren M. Elfner, and Trial Attorney Joshua Rothman of the Justice Department's Consumer Protection Branch are prosecuting the case. The FDA's Office of Criminal Investigations,

Miami Field Office, investigated the case, and the U.S. Attorney's Office of the Southern District of Florida provided critical assistance.

Additional information about the Consumer Protection Branch and its enforcement efforts may be found at www.justice.gov/civil/consumer-protection-branch. For more information about the U.S. Attorney's Office for the Southern District of Florida, visit https://www.justice.gov/usao-sdfl.

An indictment is merely an allegation and all defendants are presumed innocent until proven guilty beyond a reasonable doubt in a court of law.

Attachment(s):

Download tellus indictment.pdf

Topic(s):

Consumer Protection Health Care Fraud

Component(s):

Civil Division

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