For the first time, the FDA warns a trial investigator for failing to report study results

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By Ed Silverman Sept. 9, 2021*Adobe*

In a little noticed warning, the Food and Drug Administration threatened to fine the principal investigator of a clinical trial for failing to submit results as required by federal law, marking the first time the agency has widened its list of targets that could face penalties for such a violation.

Until now, the regulator had warned two different drug makers for failing to post study results to a federal database, ClinicalTrials.gov. Those moves came as a belated response to years of complaints that too many drug makers and universities do not follow requirements for reporting results, an issue that has riled countless researchers and transparency advocates.

In this instance, the regulator cited a Los Angeles surgeon, Andrey Petrikovets, who ran a study for University Hospitals Cleveland Medical Center, an academic center affiliated with Case Western Reserve University. The trial compared different pain regimens following vaginal pelvic floor reconstructive surgery, but published results were overdue, according to an Aug. 31 letter the FDA sent to the surgeon.

The study was completed in June 2018, and federal law required the results to be posted on the database a year later. The FDA wrote Petrikovets in July 2020 about his failure to do so, but he responded last November that he was very busy with the "Covid surge" and short-staffed, according to the FDA letter. By Sept. 1, however, the ClinicalTrials.gov site indicated the results were submitted.

We asked Petrikovets why the results were not posted sooner, instead of one day after the FDA letter was issued and will update you accordingly.

A University Hospitals spokesperson wrote us that "individual principal investigators are responsible for updating the information. Dr. Andrey Petrikovets reports to have corrected the information last week and FDA has acknowledged receipt of the information. The doctor is no

longer affiliated with University Hospitals. We follow-up with researchers if we find that they are out of compliance with reporting data for their studies. We provide detailed instructions on how to correct the records if they are unsure."

As noted previously, the push for transparency has been a long-running issue in the U.S. and abroad.

Researchers maintain that without access to specific data, results cannot be easily duplicated, which inhibits greater understanding of how medicines might work. And they argue this, in turn, can adversely affect treatment decisions and health care costs. A STAT investigation in 2015, for instance, revealed widespread inconsistencies in how top research universities report clinical trial data.

Under U.S. federal law, clinical trial sponsors are required to register applicable studies on ClinicalTrials.gov within 21 days after the first human subject is enrolled and submit certain summary results information for those trials. Generally, they must do so no later than one year after the study completion date, unless a deadline extension is obtained.

An analysis released in July found that just 58% of the trials run by drug makers met legal requirements for registering and disclosing results for medicines approved in 2016 and 2017. Still another recent analysis found just 40% of study results were reported to ClinicalTrials.gov within a required one-year deadline.

A study last year in The Lancet found compliance was poor. A study published two years ago in the New England Journal of Medicine found slow progress among drug makers and academic research centers in reporting results of human studies to ClinicalTrials.gov, and that the quality of the data was sometimes problematic. And an investigation published last year in Science found lackluster reporting results.

Indeed, enforcement has been weak.

The results for about 26% of more than 11,200 clinical trials have not been reported to ClinicalTrials.gov, according to the latest data on Trials Tracker, a website created by several U.K. researchers to keep tabs on FDA performance. The site estimates that the FDA could impose fines worth more than $23.2 billion by now, but has so far not collected anything.

"While we applaud the FDA for appropriately enforcing federal statutes, it is regretful that it takes public accountability to drive compliance. Clinical trial transparency is so much more than following minimal requirements," said Anthony Keyes, program manager for clinical research projects at Johns Hopkins University and a member of the Clinical Trials Registration and Results Reporting Taskforce, a consortium of members of academic medical centers, universities, hospitals, and nonprofits.

"All researchers, whether (working as) an individual or working at an institution, must respect the spirit of transparency at the heart of the federal statutes. It's not easy and there are competing

priorities, but it's worth it — for the benefit of the global scientific community, the public and, most importantly, our patients."

University Hospitals, by the way, has a poor reporting record, according to Trials Tracker, with just 21.4% — or three of 14 — studies submitted to ClinicalTrials.gov. However, the spokesperson for University Hospitals argued the institution has a large research portfolio and takes compliance issues "seriously," which includes working with researchers to meet reporting requirements.

The institution conducted more than 150 studies related to Covid-19 during the pandemic, which included being selected as a trial site for remdesivir, the Gilead Sciences (GILD) antiviral treatment, as well as trials for the Pfizer (PFE) vaccine.

"That the leading pharmaceutical and medical device manufacturers in the world trust UH with their clinical trials testifies to the success of our program in the critical performance areas of quality, documentation and timely completion. To state or imply otherwise would be grossly inaccurate. We are looking into the Trials Tracker site that you referenced, but would recommend that you not rely on the data reported."

About the Author Reprints

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