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For the first time, the FDA may fine a drug maker for failing to post clinical trial results

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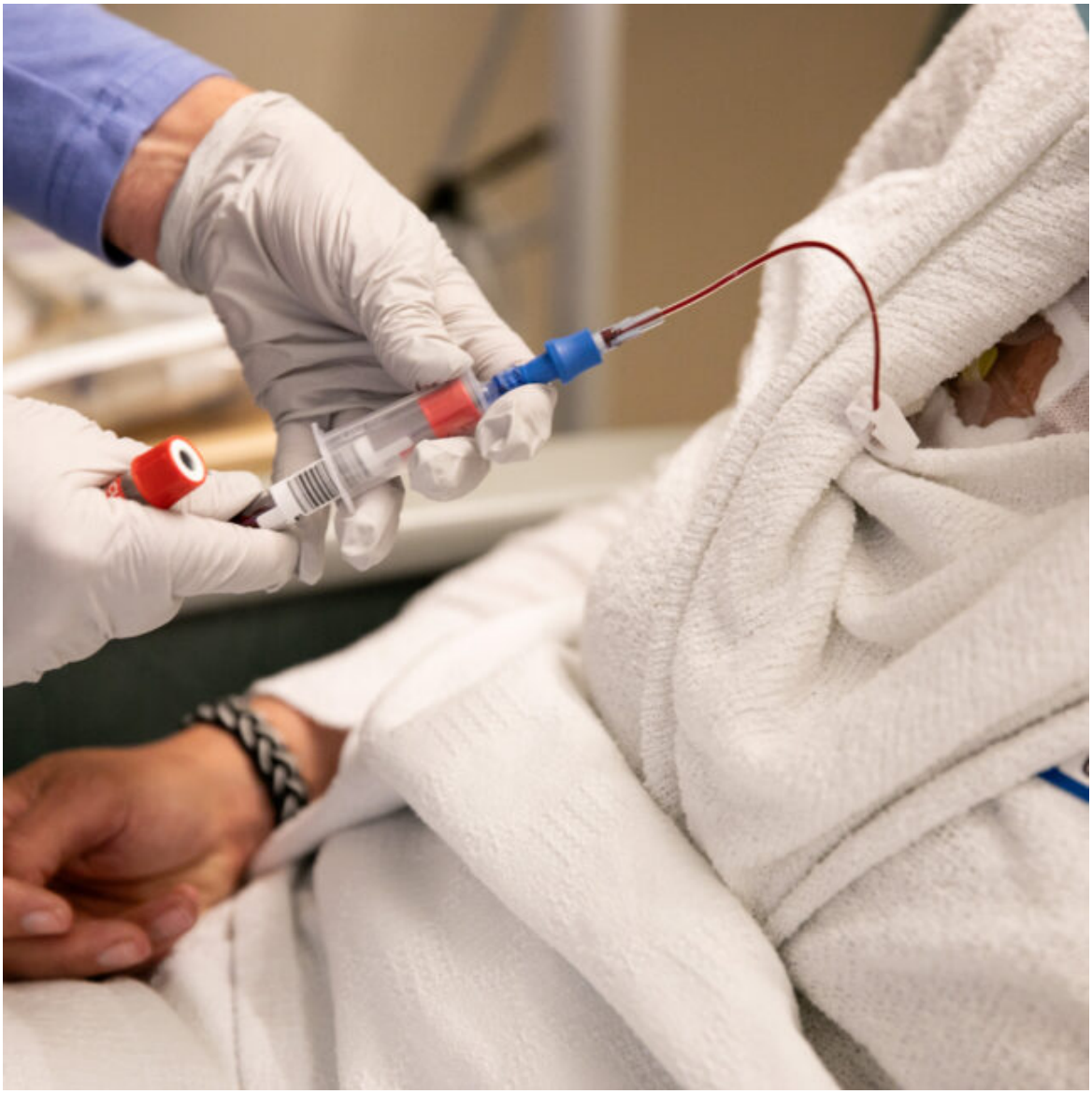

A patient participates in a clinical trial at Dana-Farber Cancer Center. *Kayana Szymczak for STAT*

The Food and Drug Administration is threatening to fine Acceleron Pharma

(XLRN) for failing to submit required information about a clinical trial to a federal registry, the first time the agency has taken such a step in response to ongoing calls for greater transparency into clinical studies.

In an April 27 letter sent to the drug maker, the FDA noted the results of a Phase 2 clinical trial that was run to test a pair of drugs for treating advanced kidney cancer. Although the agency contacted the company last July, the results have still not been posted. Acceleron now has until May 27 to post the data and an Acceleron spokesman wrote us that the company plans to do so.

"Being transparent about the results of completed clinical trials enables important advances in the development of medical products and helps ensure a safe, effective and efficient clinical research enterprise," Acting FDA Commissioner Janet Woodcock said in a statement.

The push for clinical trial transparency has been a long-running issue in the U.S. and abroad. Researchers maintain that without access to specific data, trial 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 no later than one year after the study's completion date unless a deadline extension is obtained. But enforcement has been weak.

The FDA has been under pressure to act.

A study last year in The Lancet found compliance was poor. And 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. In 2016, President Biden — when he was Vice President — threatened to cut funds to medical research institutions that fail to report results in a timely manner.

Last July, the FDA released final guidelines for penalizing trial sponsors that fail to register studies, do not report results to ClinicalTrial.gov, or submit false information. The guidance noted that any company or university that does not provide required information to ClinicalTrials.gov, the federal registry, may face a $10,000 fine for each infraction.

Nonetheless, the results for about 72% of nearly 9,900 clinical trials have not been reported to ClinicalTrials.gov, according to the latest data on Trials Tracker, a web site created by several U.K. researchers three years ago to keep tabs on FDA performance. The site estimates that the FDA could impose fines worth $19 billion by now, but has so far, not collected anything.

The letter to Acceleron is "a first, small step by FDA toward enforcing the law. It comes after FDA abdicated its enforcement responsibilities for many years," said Christopher Morten, deputy director of the Technology Law and Policy Clinic at the New York University School of Law. He also represents Universities Allied for Essential Medicines, an advocacy group pushing for greater disclosure.

He explained that trial results and protocols from thousands of clinical trials remain missing from ClinicalTrials.gov and, moreover, some of the trials concern the safety and effectiveness of medicines already approved by the FDA and on the market. For his reason, he argued that the FDA needs to step up enforcement to improve compliance and better inform the public.

"The FDA can and must send many more of these notices," Morten added, "and begin using its legal authority to impose monetary penalties on egregiously, chronically noncompliant trial sponsors."

We should note that, although Acceleron published the trials results in a medical journal two years ago, that did not meet the requirement for submitting results to

ClinicalTrials.gov, an FDA spokesman said. He explained that specific information is not always included in journal articles and concern about bias in scientific literature was a "key" reason for requiring results to be reported to the registry.

On a related note, a federal court judge last year ordered the U.S. government to crack down on wayward trial sponsors after finding federal research agencies had misinterpreted a law requiring them to collect and post clinical trial data. The ruling meant potentially hundreds of trial sponsors — namely, universities and drug and device makers — were on the hook to release previously unpublished data.

In general, the issue has generated attention from lawmakers and regulators elsewhere. Last year, the Danish Medicines Agency threatened to pursue sanctions — including prison sentences — against drug makers and universities that fail to publish study results in a European database, as required. In the U.K., a Parliamentary committee had called for sanctions on companies and universities that fail to report results.

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