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Gov't watchdog: many gaps in FDA's oversight of drug safety

January 14 2016, byMatthew Perrone

The Food and Drug Administration is speeding up its review of new drugs, yet often fails to keep track of safety issues with those medicines once they reach patients, according to government investigators.

A new Government Accountability Office report released Thursday outlines a host of shortcomings in FDA's system for tracking drug safety issues, including incomplete, outdated and inaccurate information. At the same time, the agency is making significant use of mechanisms to streamline its reviews, especially for drugs to treat deadly diseases like cancer.

The new findings come as FDA leaders emphasize the speed and efficiency with which agency scientists can approve experimental drugs. Last year the agency approved 45 first-of-a-kind drugs—the highest number in 19 years—with most reviewed in approximately eight months. More than half received some form of specialized review to speed their path to market.

But the GAO says the agency often fails to keep track of follow-up studies required for such high-priority drugs.

For instance, GAO found that the FDA was late in reviewing more than half of the 1,400 follow-up studies it had requested or required of drugmakers between 2008 and the fall of 2013. Those studies are critical for spotting safety issues that may not emerge until after patients start taking the drugs.

Congresswoman Rosa DeLauro, D-Conn., who commissioned the report, said the findings suggest the FDA is "shifting more of the safety risk to consumers."

"The GAO report clearly highlights that FDA is not doing its due diligence in tracking drug safety issues and post-market studies that are critical in ensuring patient safety," DeLauro said in a statement.

The Department of Health and Human Services, which oversees the FDA, said the agency is conducting internal evaluations to improve its computerized tracking system, which it acknowledged is challenging to update.

The FDA also revealed to GAO investigators that the majority of potential safety issues identified by staffers had not been uploaded to its archival drug tracking system.

"Given the high workload of its review staff it had prioritized identifying, assessing and addressing potential safety issues over administrative tracking," the GAO reported, based on interviews with FDA officials.

The report recommends FDA develop comprehensive plans for overhauling its database so it can be more easily updated with accurate, timely information.

The GAO found that a quarter of all drug applications approved by the FDA used at least one pathway to speed review, based on data from late 2006 to 2015. The FDA currently has four systems for expediting drug reviews. Features of those programs include shorter study requirements for promising new drugs and extra meetings with FDA staff.

Earlier in the week, a Senate panel voted to endorse President Obama's

nominee to be the next FDA Commissioner, Dr. Robert Califf. A prominent cardiologist and researcher, Califf is a leading authority on designing drug studies. He is currently the FDA's second-highest ranking official.