

FDA chief's long-promised opioid review faces skepticism

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U.S. Food and Drug Administration Commissioner Dr. Robert Califf speaks at a news conference at the Hubert H. Humphrey Building in Washington, Thursday, May 5, 2016. Califf says a comprehensive review of the opioid painkillers that triggered the nation's ongoing drug overdose epidemic is in the works. But he faces skepticism about the long-promised review from lawmakers, experts and advocates after years of delay. Credit: AP Photo/Andrew Harnik, File

As U.S. opioid deaths mounted in 2016, the incoming head of the Food and Drug Administration promised a "sweeping review" of prescription painkillers in hopes of reversing the worst overdose epidemic in American history.

Dr. Robert Califf even personally commissioned a report from the nation's top medical advisers that recommended reforms, including potentially removing some drugs from the market. But six years later, opioids are claiming more lives than ever, and the FDA has not pulled a single drug from pharmacy shelves since the report's publication. In fact, the agency continues putting new painkillers on the market—six in the last five years.

Now Califf is back in charge at the FDA, and he faces skepticism from lawmakers, patient advocates and others about his long-promised reckoning for drugs such as OxyContin and Vicodin, which are largely blamed for sparking a two-decade rise in opioid deaths.

"All the concerns that we had at the time on opioids are still there. We still have a really huge problem," said Richard Bonnie, a University of Virginia public health expert who chaired the committee that wrote the report.

Bonnie and his co-authors say the FDA seems to have incorporated several of their recommendations into recent decisions, including a broader consideration of a drug's public health risks. But they say there is more to be done.

In an interview with The Associated Press, Califf said a new internal review of opioids has been underway for months and that the public will soon "be hearing a lot more about this." While the review will look at past FDA decisions, Califf suggested the focus will be on future policy.

"It seems like people love sort of looking back and fault-finding, but I'm much more interested in learning so we can go forward and make the best decisions for what we need to do today," said Califf, who split his time between Duke University and working for Google after leaving the FDA in 2017 following President Donald Trump's election.

The 453-page report issued five years ago this month by the National Academies of Sciences laid out a strategy for reducing overprescribing and misuse of opioids, with particular focus on the FDA.

At the center of the recommendations was a proposal for the FDA to reassess the dozens of opioids being sold to determine whether their overall benefits in treating pain outweigh their risks of addiction and overdose. Those that don't should be removed from the market, the group said.



Dr. Robert Califf gathers his documents as the Senate Committee on Health, Education, Labor and Pension adjourn a hearing on the nomination of Califf to be commissioner of the U.S. Food and Drug Administration on Capitol Hill in Washington, Tuesday, Dec. 14, 2021. Califf, now head of the FDA, says a comprehensive review of the opioid painkillers that triggered the nation's ongoing drug overdose epidemic is in the works. But he faces skepticism about the long-promised review from lawmakers, experts and advocates after years of delay. Credit: AP Photo/Manuel Balce Ceneta, File

The lack of swift action underscores the glacial pace of federal regulation and the legal obstacles to clawing back drugs previously deemed safe and effective.

"It's really hard for the agency to get a drug taken off the market once it's been approved," said Margaret Riley, a food and drug law professor who consulted on the report.

Last year, U.S. overdose deaths soared to a record of 107,000, driven overwhelmingly by fentanyl and other illegal opioids.

Opioid prescriptions have fallen about 40% in the last decade amid restrictions by hospitals, insurers and state officials. But deaths tied to the medications remain at 13,000 to 14,000 per year. And studies suggest people who become addicted to opioids continue to start with prescription opioids, before switching to cheaper heroin and illegally made fentanyl.

"If Dr. Califf is serious about addressing the drug epidemic, the FDA should immediately implement" the report's recommendations, Sen. Joe Manchin of West Virginia said in a statement.

Manchin told the AP that he requested an update in April on the FDA's progress on the recommendations but didn't receive a response. He was one of five Democrats from hard-hit opioid states who voted against Califf's confirmation in February.

In response to questions about the recommendations, the FDA provided a list of actions it has taken on opioids, some which predated the report. The agency said it has acted on "nearly all" of the recommendations, by enhancing prescriber education and labeling, convening meetings and improving data collection.

"I think what you've seen is the agency grabbing at some of the low-hanging fruit and only to a certain level," Riley said.

Despite heightened scrutiny, the FDA continues putting new painkillers on the market. Many of the drugs have formulations designed to make them harder to misuse, such as hard-to-crush coatings that discourage snorting or injecting.



OxyContin pills are arranged for a photo at a pharmacy in Montpelier, Vt., Feb. 19, 2013. The head of the U.S. Food and Drug Administration says a comprehensive review of the opioid painkillers that triggered the nation's ongoing drug overdose epidemic is in the works. But FDA Commissioner Dr. Robert Califf faces skepticism about the long-promised review from lawmakers, experts and advocates after years of delay. Credit: AP Photo/Toby Talbot, File

Califf has said the FDA is bound by its regulations: Companies need only show that their drugs work better than a placebo, and the agency can't require new opioids to be safer or more effective than ones already on the market. He told Senate lawmakers in April that doing so might require legislation from Congress.

One of the report authors disagreed.

"I think the FDA has a lot of flexibility at this point to say, 'Look, given these circumstances we don't think that a placebo-controlled trial would be adequate,'" said Dr. Aaron Kesselheim, a lawyer and professor of medicine at Harvard Medical School.

As for older opioids like OxyContin, Califf says that as the agency gets more evidence on opioids' risks, it will "aggressively look at relabeling."

But delays in getting that evidence illustrate just how slowly the FDA process moves. It's been nearly 10 years since the agency required makers of long-acting opioids to conduct a dozen studies of their drugs' risks and effectiveness.

The main clinical trial looking at opioids for chronic pain has been delayed since 2019, due to repeated changes to its design. And results from seven other studies released in 2020 don't give a clear picture of whether the drugs are truly safe and effective for long-term use.

"We've got to have the data, and we can't accept excuses that it's hard to do," Califf said. "That's not going to be acceptable."

Riley said the data the FDA is seeking will be critical to providing the evidence needed to remove opioids from the market, which would likely face years of industry pushback.

"The question to me is whether the agency will actually have the gumption to use those tools to start pulling drugs," Riley said. "Do they have the will to do it?"

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