FDA advisor criticizes agency's response to opioid epidemic

Brian Dixon
6 February 2019

In a recent interview with the *Guardian*, the chair of the US Food and Drug Administration's (FDA's) opioid advisory committee, Dr. Raeford Brown, claimed the agency is manipulating data in favor of the pharmaceutical companies seeking approval for new opioid painkillers.

"They should stop considering any new opioid evaluation," Brown told the *Guardian*. "For every day and every week and every month that the FDA don't do the right thing, people drop dead in the streets. What they do has a direct impact on the mortality rate from opioids in this country."

According to the Centers for Disease Control and Prevention (CDC), deaths involving opioids are now six times higher than they were in 1999. Nearly 70 percent of the 70,200 deaths from overdoses in 2017 involved an opioid.

Brown says that he no longer has confidence that the regulatory agency is taking the opioid epidemic seriously.

As a case in point, Brown pointed to the recent approval of Dsuvia, a sublingual sufentanil pill (a more potent version of fentanyl) manufactured by the California pharmaceutical company AcelRx. While the drug was rejected in 2017 over safety concerns, the FDA eventually approved the drug in 2018 after excluding members of its own drug safety committee from attending the hearing.

The pharmaceutical industry has long criticized the FDA for lengthy approval processes. In response, the agency has developed a number of pathways to speed up the drug-approval process. This includes expedited approvals, where the agency reduces the number and size of clinical trials required for approval. As a result of these efforts, the FDA approved drugs an average of 60 days faster between 2011 and 2015 than its European counterpart, the European Medicines Agency.

Thus, the FDA has approved a number of drugs with limited data on their safety and efficacy. In turn, pharmaceutical companies have charged outrageous prices for treatments that may not even work and are potentially dangerous to patients.

Brown also criticized the "cozy, cozy relationships between the pharmaceutical industry and various parts of the FDA."

As a way to speed up the drug approval process, in 1992 the pharmaceutical industry began funding the salaries of agency reviewers in exchange for time limits on reviews. According to an article published this past June in ProPublica, 75 percent of the agency's scientific review budget came from the drug industry, an increase from 27 percent in 1993.

"You don't survive as a senior official at the FDA unless you're pro-industry," Dr. Thomas Marciniak, a former FDA medical team leader who retired in 2014, told ProPublica.

"The FDA has to pay attention to what Congress tells them to do, and the industry will lobby to get somebody else in there if they don't like you," Marciniak said.