FDA Accountability for Public Safety Act

The Problem

In 2020, more than 90,000 people died from a drug overdose, the highest amount ever recorded, with over 51% of those involving an opioid or synthetic-opioid. That's 246 people dying of an opioid overdose every day. It is clear that we are facing a devastating opioid epidemic. It is also clear that the opioid market is flooded with pills. The U.S. makes up only 4.6% of the world population, but consumes 80% of the opioids. Misuse and abuse of prescription drugs costs the country an estimated $78.5 billion a year in lost productivity, medical costs and criminal justice costs.

The FDA plays a critical role in this epidemic as the agency overseeing the approval of these drugs. The FDA convenes an advisory committee of scientific experts when a matter is of significant public interest, highly controversial, or in need a specific type of expertise. With so many people dying every day, it seems clear that the FDA should seek the counsel of its expert panel and adhere to its recommendations with regard to approving dangerously addictive opioids.

In recent years, however, the FDA has either ignored its advisory committee's recommendations or failed to seek its counsel. In 2013, the FDA approved the very powerful opioid, Zohydro, despite the advisory committee voting 11-2 against approval of the drug due to their concerns about the safety of the drug. And since that time, two new opioid medications, Targiniq and Hysingla, have been approved without an advisory committee meeting at all. This is a dangerous precedent.

While the FDA's opioid action plan has made steps in the right direction and the Comprehensive Action and Recovery Act (CARA) requires the FDA to seek the advice of their advisory committees in the approval of new opioids, this legislation will hold them to that promise and work to keep unnecessary, dangerous opioids off the market.

The Solution: The FDA Accountability for Public Safety Act will ensure that the experts' voices are heard when the FDA considers new, dangerous opioid medications. It would:

1. Strengthen the language included in CARA to ensure that both new opioids and already-approved opioids seeking approval for expanded labeling are subject to advisory committee review and recommendation before the FDA makes a decision about approval.

2. Require the FDA Commissioner to make the final decision regarding drug approval if the advisory committee does not approve of an opioid due to concern over consumer health and safety.

3. Require the FDA to submit a report to Congress that includes medical and scientific evidence regarding patient safety that clearly justifies why they ignored the advisory committee's recommendation. It must also include any conflicts of interest that FDA officials involved in the decision may have.

4. Prohibit the marketing of the drug until the report is submitted to Congress.