EFFECTIVE Act

The Problem

Recent reports estimate that more than 106,000 Americans, including more than 1,400 West Virginians and 2,750 Hoosiers, died from drug-related overdoses in the last year. This is the highest number ever recorded in a single 12-month period. West Virginia continues to have the highest rate of overdose deaths in the country with 81.4 deaths per 100,000 people. This is nearly triple the national average of 28.3 deaths per 100,000 people. Indiana's rate of overdose deaths is just above the national average at 36.7 deaths per 100,000 people.

In 2016, during Dr. Califf's first tenure as Commissioner of the Food and Drug Administration (FDA), he asked for a report on what more the FDA could be doing to address the drug epidemic. In 2017, the National Academy of Sciences, Engineering and Medicine (National Academies) completed and published its report, *Pain Management and the Opioid Epidemic*.[1]

The report was meant to help the FDA develop a regulatory framework for the review, approval and monitoring of opioids that "balances individual need for pain control with considerations of the broader public health consequences of abuse and misuse." It also included several recommendations to the FDA directly, as well as several other broad recommendations for policymakers on how to take meaningful steps to stem the tide of drugs flooding communities in America. Unfortunately, here we are six years later, and no meaningful progress has been made on any of these recommendations.

In an April 28, 2022 hearing in the Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies to review the FY23 FDA budget request, Dr. Califf, responded to questions regarding the status of implementing these recommendations with a request for more authority. Specifically, Dr. Califf stated that the FDA needed additional legal authority to allow the FDA to require a new drug application to have "superiority" to those on the market.

On February 16, 2023 the FDA released yet another report on the 2017 National Academies recommendations. The *External Review of FDA Regulation of Opioid Analgesics Final Report*[2] states that the FDA "should consider seeking from Congress certain additional authorities regarding opioid analgesic approvals and review of the advertising and promotion for such products, as well as additional resources to implement such authorities to strengthen oversight of prescription opioid analgesics." Again, here we are six years later with no action taken by the FDA to implement these recommendations.

The Solution

Senator Manchin and Senator Braun's Ensuring the FDA Fully Examines Clinical Trial Impact and Vitalness before Endorsement (EFFECTIVE) Act would allow the FDA to deny a new drug application for an opioid analgesic drug on the basis of the drug not being clinically superior to other commercially available drugs. This authority would help provide further authority to the FDA so they can review the public health impact of every new opioid approval and deny new drug applications even if the pharmaceutical company sponsored clinical trials apparently show "safety" of the drug.[3] Importantly, this bill fulfills a request from Dr. Califf to ensure that the FDA is able to fully implement the recommendations from the National Academies report It's past time the FDA consider public safety, instead of standing on the sidelines while the pharmaceutical industry continues to pursue profits over saving lives. This bill would help ensure that the FDA has all the tools necessary to implement the commonsense recommendations from the National Academies report.

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[1] https://nap.nationalacademies.org/catalog/24781/pain-management-and-the-opioid-epidemic-balancing-societal-and-individual

[2] https://www.fda.gov/media/165238/download

[3] https://www.manchin.senate.gov/newsroom/press-releases/manchin-braun-bill-to-address-incorrect-marketing-of-dangerous-opioids