United States Senate

April 27, 2022

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

In 2016, during your first tenure as Commissioner of the Food and Drug Administration (FDA), you 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*. Unfortunately, here we are five years later, two months into your second tenure at the FDA, and no meaningful progress has been made on any of these recommendations.

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. The National Academies' recommendations specifically for the FDA included:

- **Recommendation 6-1.** Incorporate public health considerations into opioid-related regulatory decisions.
- **Recommendation 6-2.** Require additional studies and the collection and analysis of data needed for a thorough assessment of broad public health considerations.
- **Recommendation 6-3.** Ensure that public health considerations are adequately incorporated into clinical development.
- **Recommendation 6-4.** Increase the transparency of regulatory decisions for opioids in light of the committee's proposed systems approach (Recommendation 6-1).
- **Recommendation 6-5.** Strengthen the post-approval oversight of opioids.
- **Recommendation 6-6.** Conduct a full review of currently marketed/approved opioids.
- **Recommendation 6-7.** Apply public health considerations to opioid scheduling decisions.

The report concluded by saying it would take years of aggressive, coordinated efforts to reverse the impacts of the drug epidemic. Unfortunately, while rates of fatal overdoses are up, the FDA continues to be behind the curve of the drug epidemic. Recent reports estimate that more than

105,000 Americans, including more than 1,500 West Virginians and 2,700 Hoosiers, died from drug-related overdoses in the last year. This is the highest number ever recorded. West Virginia continues to have the highest rate of overdose deaths in the country with 90 deaths per 100,000 people. This is almost triple the national average of 31.5 deaths per 100,000 people. Indiana's rate of overdose deaths is above the national average at 36.7 deaths per 100,000 people.

In your request to the National Academies you claimed to be "committed to action" to address the drug epidemic because you recognized "that this crisis demands solutions."[1] Sadly, despite the powers at its discretion to meaningfully address the opioid epidemic, the FDA has stood on the sidelines while the pharmaceutical industry continues to pursue profits over saving lives. One of the most commonsense recommendations from the National Academies was to have FDA develop and institute a new process for reviewing the safety and effectiveness of all approved opioids,[2] this has yet to be undertaken. Instead, the FDA appears to have done the opposite. Even while the National Academies study was ongoing, the FDA approved five new opioids and removed only one from the market.

Recently, the Office of National Drug Control Policy (ONDCP) released the National Drug Control Strategy, which reiterated many of the recommendations included in the National Academies report. Specifically, the National Drug Control Strategy highlighted that ONDCP will work with the FDA to explore whether to "create a requirement for training through the Opioid Analgesic Risk Evaluation Mitigation Strategy (REMS), pursuing a legislative solution if necessary."[3] The National Academies' report similarly recommended aggressively using REMS, authorities that are already available to the FDA, to support safe and effective use of opioids. But the FDA has yet to use those authorities.

We did not support your nomination because we did not believe you are the right person to fight back against the pharmaceutical industry or correct the culture at the FDA. Now that you have settled into your role, we implore you to prove us wrong and champion the needs of our nation at this crucial time.

Sincerely,

Joe Manchin III
U.S. Senator

Mike Braun
U.S. Senator

[1] A Proactive Response to Prescription Opioid Abuse. The New England Journal of Medicine. April 14, 2016. https://www.nejm.org/doi/full/10.1056/NEJMsr1601307.
[2] Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. National Academies of Sciences, Engineering, and Medicine 2017. The National Academies Press. https://doi.org/10.17226/24781.
[3] National Drug Control Strategy. https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf.