

United States Senate
WASHINGTON, DC 20510

March 26, 2021

President Joseph R. Biden, Jr.
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear President Biden,

Today the country faces an unprecedented global pandemic. As you continue to respond to this crisis, we ask you to remember the ongoing opioid epidemic, which has worsened during the COVID-19 pandemic. Between June 2019 and May 2020, U.S. overdose deaths reached an all-time high, with more than 81,000 American lives lost, and we expect this number to grow.¹ Addressing the enormous challenges that face the health and wellbeing of our country requires strong, trusted leadership in our health agencies moving forward, particularly the future leadership of the Food and Drug Administration (FDA).

Since 1999, we have lost over 450,000 Americans to opioid-related overdose. It is clear that we are facing a devastating opioid epidemic, and 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 world's opioids.²³ The amount of prescription opioids sold in the US has nearly quadrupled since 1999 without a reported increase in pain. At the same time, overdose deaths involving opioids have also quadrupled since 1999.⁴ Opioid prescribing is clearly driving opioid overdose deaths.

The FDA has played a critical role in this overdose epidemic overseeing the approval of prescription opioids through its Center for Drug Evaluation and Research (CDER). In 1995, the FDA oversaw the first approval of OxyContin.⁵⁶ By 2001, the FDA updated opioid labels to allow use for “around-the-clock” treatment of moderate to severe pain, greatly perpetuating the opioid

¹ Centers for Disease Control and Prevention, *Overdose Deaths Accelerating During COVID-19* (Dec. 27, 2020), [https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid19.html#:~:text=Over%2081%2C000%20drug%20overdose%20deaths,Control%20and%20Prevention%20\(CDC\).](https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid19.html#:~:text=Over%2081%2C000%20drug%20overdose%20deaths,Control%20and%20Prevention%20(CDC).)

² Dina Gusovsky, *Americans consume vast majority of the world's opioids*, CNBC (updated Apr. 27, 2016), <https://www.cnbc.com/2016/04/27/americans-consume-almost-all-of-the-global-opioid-supply.html>

³ Centers for Disease Control and Prevention, *U.S. Opioid Dispensing Rate Maps* (updated Dec. 7, 2020), <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>.

⁴ *Understanding the Epidemic*, Centers for Disease Control and Prevention (updated Mar. 19, 2020), <https://www.cdc.gov/drugoverdose/epidemic/index.html>

⁵ Food and Drug Administration, *Development & Approval Process | Drugs* (updated Oct. 28, 2019), <https://www.fda.gov/drugs/development-approval-process-drugs>.

⁶ Food and Drug Administration, *Advisory Committees: Critical to the FDA's Product Review Process*, (updated May 4, 2016), <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/advisory-committees-critical-fdas-product-review-#:~:text=The%20primary%20role%20of%20an.and%20other%20public%20health%20issues>.

epidemic.⁷⁸ With roughly 222 people dying every day, the FDA should be doing everything it can to address the public health consequences of widely-available prescription opioids.

The FDA convenes an advisory committee of scientific experts when a matter is of significant public interest, highly controversial, or in need of a specific type of expertise. In 2014, The FDA approved Zohydro, a pure hydrocodone drug, despite an advisory committee strongly voting against approval by an 11 to 2 margin due to the known dangers of overdose and death.^{9 10} After the advisory committee pushback on Zohydro's approval, the FDA approved several opioids without seeking advisory committee guidance. While this has since changed, the decision to approve those drugs without the extra level of scrutiny about their safety and impact on public health has had lasting public health consequences. As we have seen during the review of COVID-19 vaccine products, independent expert input at public advisory committee meetings is a critical step to ensuring that the products authorized or approved by the FDA are safe and effective for use by the American people.¹¹

Until recently, the FDA continued to approve many new opioid products despite already having dozens on the market. Many of these newly approved drugs did not demonstrate meaningful clinical benefit beyond what was already available on the market. In approving new opioids, the FDA did not consider the wider threat to public safety or the real threat of increased addiction and overdose deaths that could result from these approvals. Despite the FDA's own advisory committee voting 19-10 to reclassify hydrocodone from a Schedule III to a Schedule II, it took several years for this critical change to be made. In the first year after hydrocodone-combination drugs were rescheduled, the number of opioid prescriptions fell by 26.3 million, which meant there were 1.1 billion fewer opioid tablets circulating within our communities.¹²

Unfortunately, the FDA has a long track record approving dangerous opioids without considering public health. A federal judge presiding over county and state cases against opioid manufacturers and distributors recently wrote, "It is accurate to describe the opioid epidemic as a man-made plague, 20 years in the making."¹³ Although some courts are holding opioid

⁷ Andrew Kolodny, MD, *How FDA Failures Contributed to the Opioid Crisis*, American Medical Association Journal of Ethics (Aug. 2020), <https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08>

⁸ Food and Drug Administration, *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse* (updated Dec. 30, 2020), <https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse>.

⁹ John Fauber, *Killing Pain: AGs Want FDA to Review Zohydro Approval*, MedPage Today (Dec. 11, 2013), <https://www.medpagetoday.com/publichealthpolicy/fdageneral/43374>.

¹⁰ David Pittman, *FDA Panel Gives Thumbs Down to Opioid*, MedPage Today (Dec. 7, 2012), <https://www.medpagetoday.com/painmanagement/painmanagement/36334>.

¹¹ Ravi Gupta, *During COVID-19, FDA's Vaccine Advisory Committee Has Worked To Boost Public Trust – It Can Still Do More*, Health Affairs (Feb. 26, 2021), <https://www.healthaffairs.org/doi/10.1377/hblog20210225.712221/full/>.

¹² Christopher Jones, P. Lurie, D. Throckmorton. *Effect of US Drug Enforcement Administration's Rescheduling of Hydrocodone Combination Analgesic Products on Opioid Analgesic Prescribing*. JAMA Network. (March 2016). <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2484293>

¹³ Jef Feeley, *Opioid-Industry Claims Proceed as Judge Cites 'Man-Made Plague'*, Bloomberg (Dec. 20, 2018), <https://www.bloomberg.com/news/articles/2018-12-20/opioid-industry-claims-proceed-as-judge-cites-man-made-plague>.

manufacturers and distributors accountable for their actions that caused this epidemic, it is clear the FDA missed clear signs about the risks and benefits of opioids, which allowed this crisis to take hold.¹⁴

Almost 30 years after the FDA first approved OxyContin, overdose deaths are the highest they have ever been, and are likely to continue to rise. It's clear that, in order to move forward and address this epidemic, we need new leadership at the FDA that will consider patients and public health when making decisions about drug approvals. The FDA needs to reverse its history of ignoring and overruling experts and advisory panels when approving these dangerous drugs, as well as other types of drugs that have failed to demonstrate the level of safety and efficacy to justify approval. The drug epidemic is multi-faceted, and we must help those struggling with substance use disorder by connecting them to care, educating our youth on the risks of drug misuse and abuse, and expanding access to behavioral health treatment. However, in order to be successful we also need to ensure that those who have played a role in creating this epidemic are held responsible, and the agency in charge of approving our medicines does so with a focus on protecting patients, and public health.

Thank you for your attention to ensuring the health and well-being of all Americans. We welcome the opportunity to discuss your efforts and how we can work together.

Sincerely,



Joe Manchin III
United States Senator



Margaret Wood Hassan
United States Senator

¹⁴ Christie C, Baker C, Cooper R, Kennedy PJ, Madras B, Bondi P. The President's Commission on combating drug addiction and the opioid crisis. Published November 1, 2017.



Angus S. King, Jr
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