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June 17, 2021

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

Dear President Biden,

I write today concerning the lack of permanent leadership at the Food and Drug Administration (FDA), and the continued tenure of Dr. Janet Woodcock as interim commissioner. Just last week, the FDA granted approval for Aduhelm (aducanumab), a treatment for Alzheimer's, despite its advisory panel voting nearly unanimously against its approval, with no panel member voting in favor of approval. While the approval of a drug provides hope for the millions of Alzheimer's patients and their families, many scientists have second-guessed the scientific benefit of this approval. The FDA's, and in particular Dr. Woodcock's, decision to go against its advisory committee's decision yet again has resulted in at least three scientists resigning from the committee. In his resignation letter, Dr. Aaron Kesselheim noted that this approval was "probably the worst drug approval decision in recent U.S. history."[1] This brings into question the current interim leadership of Dr. Woodcock, at a time when strong, trusted leadership at our health agencies is most important. At a minimum, the agency should provide an explanation as to why it chose to go against its advisory committee's recommendations. Having a permanent agency head in charge to answer patients and doctors questions on this approval, as well as assure the general public of the FDA's commitment to public health, is imperative, and Dr. Woodcock is not the right person to lead the FDA.

This approval underscores the fact that more of the same leadership at the agency is not the answer. 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. The decision to approve 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.[2]

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[1] Aaron Kesselheim, MD, JD, MPH. Division of Pharmacoepidemiology and Pharmacoeconomics, Harvard Medical School and Brigham & Women's Hospital. https://twitter.com/akesselheim/status/1403675166803169283?s=20

[2] 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/do/10.1377/hblog20210225.712221/full/.

We are finally seeing a light at the end of the tunnel after an unprecedented global pandemic. As our country continues its path towards recovery and reopens after a year-long pandemic, we need to have permanent leadership at the FDA that prioritizes patients and public health, to keep our comprehensive response moving forward. The agency is currently considering whether to grant permanent approval to the three COVID-19 vaccines already in wide distribution, while reviewing new vaccines for potential approval. Without a permanent, confirmed commissioner in place to lead the FDA, important decisions that impact the country's response to COVID-19 will be slowed and prevent additional work to combat the ongoing drug overdose epidemic.

Over 600,000 Americans died of COVID-19 throughout the course of the pandemic. However, our country continues to battle an epidemic during the pandemic. In 2020, over 90,000 Americans died from drug related overdoses, which is the highest year of overdose deaths ever recorded, with over half of those likely involving an opioid or synthetic opioid.[3] This epidemic is headed in the wrong direction. The FDA has played a critical role in this overdose epidemic by overseeing continuous approvals of stronger and more addictive opioids since the initial approval of OxyContin in 1995 – and Dr. Woodcock has been there for all of it. Dr. Woodcock has repeatedly ignored public health concerns and shown a dereliction of duty by not working to end this epidemic. It is blatantly clear that we must do more to address the drug epidemic that is impacting every American.

In Fiscal Year 2021 (FY21), the FDA had a budget of $6.05 billion. For FY22, you are seeking $6.5 billion in funding for the FDA.[4] There must be a confirmed leader in place at the top of FDA to ensure this nearly 8 percent increase in funding is spent wisely and provides the resources our nation needs to recover from the pandemic, combat the ongoing opioid crisis, and restore public trust in the agency.

Time is crucial, as we could see new variants of COVID-19, new drugs being approved, while we're simultaneously losing roughly 246 lives every day to drug overdose. The FDA has been in crisis mode responding to the pandemic, and the latest controversial drug approval of Aduhelm has not helped the public gain confidence in the agency. With the agency resuming approvals of new vaccines, drugs, medical devices, and other new treatments, doctors and patients should feel confident in the agency tasked with overseeing their wellbeing. The FDA needs new leadership to be accountable for new drug approvals and to address the public health consequences of widely-available prescription opioids, as well as the numerous other health concerns facing our country. I hope the Biden Administration will examine the consequences of Dr. Woodcock's leadership and appoint someone more suited to lead our country out of this devastating pandemic.

Almost five months into your Administration, we still lack acceptable permanent leadership, making this one of the longest delays in almost 100 years for a new President to nominate a commissioner. While industry has benefited from the status quo over the last 35 years of Dr. Woodcock's tenure at the FDA, the people, patients and families suffering from the opioid

[3] Centers for Disease Control and Prevention. Provisional Drug Overdose Death Counts. (June 14, 2020), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[4] Department of Health and Human Services. Fiscal Year 2022 Budget in Brief. https://www.hhs.gov/sites/default/files/fy-2022-budget-in-brief.pdf

epidemic have not. We need urgency as the world emerges from the COVID-19 pandemic. You need to nominate a commissioner suited to address our public health challenges immediately, to set your agenda at this crucial agency for your first year, and give the Senate time to consider your nominee.

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

Sincerely,

Joe Manchin III
United States Senator