January 27, 2021

The Honorable Xavier Becerra
Secretary of Health and Human Services-Designate
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Norris Cochran
Acting Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary-Designate Becerra and Acting Secretary Cochran:

We, the undersigned organizations, are writing to communicate our strong opposition to Dr. Janet Woodcock's potential nomination for Commissioner of the U.S. Food and Drug Administration (FDA). We strongly urge that her position as Acting Commissioner be a very short transition prior to President Joe Biden nominating a Commissioner who has a track record focused on public health. Serving as the Director of the FDA's Center for Drug Evaluation and Research (CDER) for more than 25 years, Dr. Woodcock presided over one of the worst regulatory agency failures in U.S. history. Since 1999, more than 500,000 Americans have lost their lives to opioid-related overdoses, and millions of Americans have developed opioid use disorder from use of prescription opioids.

As a federal judge presiding over hundreds of 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."[1] Much of the responsibility for the opioid crisis clearly rests with industry. But the fact that opioid manufacturers for decades disseminated false claims about the risks and benefits of opioids points to a dereliction of duty by CDER, the FDA division led by Dr. Woodcock.

The FDA's opioid regulatory failures under Dr. Woodcock's leadership have not gone unnoticed. In 2017, the *President's Commission on Combatting Drug Addiction and the Opioid Crisis* found that the opioid crisis was caused in part by "inadequate oversight by the FDA." [2] After coming to a similar conclusion, the National Academy of Sciences, Engineering and Medicine (NASEM) issued a report calling on the FDA to overhaul its opioid policies.[3] In 2019, Dr. Woodcock's failure to implement NASEM's opioid

[1] Feeley J. Opioid-Industry Claims Proceed as Judge Cites 'Man-Made Plague.' Bloomberg News. December 20, 2018. https://www.bloomberg.com/news/articles/2018-12-20/opioid-industry-claims-proceed-as-judge-cites-man-made-plague.. Accessed on January 26, 2021.
[2] Christie C., et al. The President's Commission on Combating Drug Addiction and the Opioid Crisis. Washington, DC: The White House; 2017.
[3] Bonnie RJ, Kesselheim AS, Clark DJ. A Report from the National Academies of Sciences, Engineering, and Medicine. JAMA. 2017;318(5):423-424.

recommendations prompted calls for her dismissal from the Chair of FDA's Anesthetic and Analgesic Drug Products Advisory Committee and Public Citizen.[4] That same year, appearing on the television program *60 Minutes,* former FDA Commissioner Dr. David Kessler sharply criticized the FDA's opioid decision-making, including a recent decision, made on Dr. Woodcock's watch, to approve a fentanyl analogue (Dsuvia) that is 1,000 times more potent than morphine.

In the face of mounting criticism of the FDA over its opioid decision-making, Dr. Woodcock has maintained a defensive posture, refusing to acknowledge past mistakes. For example, in response to a letter from Senator Maggie Hassan and Senator Edward Markey, in 2020 Dr. Woodcock defended past decisions, including its 1995 approval of OxyContin, despite evidence that Purdue Pharma improperly participated in drafting the agency's review of its own application.[5] Dr. Woodcock also defended the FDA's decision in 2001 to broaden the approved indication described in OxyContin's product labeling, which allowed Purdue to more explicitly promote OxyContin for conditions where risks outweigh benefits.

In its opioid decision-making, Dr. Woodcock, and the division she supervised, consistently put the interests of opioid manufacturers ahead of public health, often over-ruling its own scientific advisors and ignoring the pleas of public health groups, state Attorneys General, and outraged victims of the opioid crisis. Some examples of the FDA's improper decisions include approving Opana without adequate evidence of safety or long-term efficacy, approving Zohydro despite a vote of 11-2 against approval by a scientific advisory committee, and approving promotion of OxyContin for children as young as 11 years old.

During Dr. Woodcock's tenure, FDA also failed to work collaboratively with other federal agencies to address the opioid crisis. For nearly a decade, the FDA resisted efforts by the Department of Justice to up-schedule hydrocodone products until Congress required a vote on the topic by a scientific advisory committee. And FDA staff publicly criticized science-based opioid prescribing guidance from the Centers for Disease Control and Prevention, resulting in conflicting messages from the federal government in the midst of a public health crisis.

Recent reports that the pharmaceutical industry enthusiastically supports Dr. Woodcock's candidacy for FDA Commissioner do not surprise us because she consistently put the interests of opioid makers ahead of public health.[6] If Dr. Woodcock

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[4] Roza D. Public Citizen: Woodcock Must Step Down for FDA Opioid Reg Reform. Inside Health Policy. March 21, 2019. https://insidehealthpolicy.com/daily-news/public-citizen-woodcock-must-step-down-fda-opioid-reg-reform. Accessed January 26, 2021.

[5] Letter from Janet Woodcock, M.D., Director, FDA Center for Drug Evaluation and Research, to Senator Margaret Hassan, United States Congress. January 21, 2020; Department of Justice internal memo from Kirk Ogrosky on proposed indictment of Purdue Pharma, et al. October 6, 2006.

[6] Tong A. Endpoints poll: Janet Woodcock takes the (interim) helm at the FDA. And a large majority of our readers want her to stay there. Endpoints News. January 21, 2021. https://endpts.com/endpoints-poll-janet-woodcock-takes-the-interim-helm-at-the-fda-and-a-large-majority-of-our-readers-want-her-to-stay-there/. Accessed January 26, 2021.

is nominated for and confirmed as FDA Commissioner, all hope will be dashed that the FDA would begin to base opioid decisions on the best available science, correct past harmful opioid decisions, and finally implement the NASEM recommendations.

If you have any questions about our concerns, please contact Ms. Emily Walden at emily.walden@feduprally.org or at (502) 759-4116.

Sincerely,

Aidan's Promise, Inc
Advocates for the Reform of Prescription Opioids
Center for Popular Democracy's Opioid Network
End The Stigma
Families Against Deadly Drugs
The Fed Up! Coalition
Health GAP
Heroin Support
HOPES Unified Voices for Change
Hope2gether Foundation
James Place, Inc
Learn to Cope
Michael's Voice
National Coalition Against Prescription Drug Abuse
No First Time
P.A.I.N. (Prescription Addiction Intervention Now)
PharmedOut
Physicians for Responsible Opioid Prescribing
Prevent Opioid Abuse
Public Citizen
Relatives Against Purdue Pharma
Save the Michaels
Social Security Works
Southeast Florida Recovery Advocates, Inc.
The Spoon Movement
Steve Rummler HOPE Network
Stop Drug Deaths
STOPPNow
Teamsharing
Tunnel of Hope
Woodymatters

cc:
Tom Coderre, SAMHSA Acting Assistant Secretary
Ron Klain, White House Chief of Staff
Rachel Levine, HHS Assistant Secretary-Designate
Sean McCluskie, HHS Chief of Staff