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January 19, 2022

Dr. Janet Woodcock
Acting Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

On September 14, 2021, Select Subcommittee Ranking Member Scalise and I wrote to you requesting documents and information related to allegations of improper political interference at the U.S. Food and Drug Administration (FDA) by the Biden White House.[1] Since that request, reports continue to surface raising concerns about White House politicization of the FDA. Recently, two former high-ranking FDA officials—including one that resigned because of the alleged political interference by the Biden Administration at the FDA—raised concerns about the agency bypassing the standard process for making decisions related to booster shots for Americans.[2] If true, these short cuts undermine the integrity of our public health system and cause vaccine hesitancy. The President has repeatedly demonized unvaccinated Americans, which is outrageous given these allegations.[3] In addition to the prior questions and requests, we have new requests for information.

President Biden has called the ongoing pandemic, "a pandemic of the unvaccinated" and intimated that those who are not vaccinated are unpatriotic.[4] Instead of playing the blame game, President Biden should ensure the federal government is not cutting corners in the vaccine recommendations process.

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[1] Letter from Hon. Steve Scalise, Ranking Member, Select Subcomm. on the Coronavirus Crisis, H. Comm. on Oversight & Reform, Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform, to Janet Woodcock, Acting Commissioner, U.S. Food & Drug Admin. (Sept. 14, 2021).
[2] Philip R. Krause & Luciana Borio, *The Biden administration has been sidelining vaccine experts*, THE WASH. POST (Dec. 16, 2021); Emma Colton, *Critics question Biden FDA's approval of COVID boosters for children: 'Slap in the face to science*', FOX BUSINESS (Jan. 3, 2021).
[3] Remarks by President Biden on Fighting the COVID-19 Pandemic (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/; Shawna Chen, *Biden: It's "your patriotic duty" to get vaccinated*, AXIOS (Dec. 21, 2021).
[4] Id.

According to an article published in the *Washington Post*, the Biden FDA has made three key vaccination related decisions without convening a standing panel of outside scientific experts (the Panel) and again recently while authorizing booster shots for all children 12-15 years of age.[5] This is a deviation from the standard practice and is likely a result of ongoing scientific disagreement on the necessity of booster shots. As our September 14, 2021, letter to you noted, the White House preempted FDA and the CDC in their announcement of boosters for all adults. When the Panel was convened, there was significant dissention among the experts regarding whether booster shots were advisable for all Americans over the age of 18.[6] Also in September 2021, the Panel rejected, by a vote of 16 to 2, boosters for teens.[7] Since then, the data have not changed.[8] Teens remain at low risk of serious illness.[9] To achieve the White House's desired outcome this time around, the FDA dispensed with convening the Panel when it made the December 9, 2021, decision to allow boosters for ages 16 and 17, and the January 3, 2022, decision to allow boosters for ages 12-15.[10] The Panel was not going to do the White House's bidding so instead of engaging in a robust scientific dialogue, the Biden Administration made the calculated political decision to entirely cast aside the Panel. This has become a pattern with the Biden Administration—the Administration that repeatedly promised to follow the science.[11]

As the former FDA officials noted, deviating from the standard process undermines our public health framework and "[a]lthough some may find it convenient to make policy without their [expert] input, the long-term consequences will hurt public health."[12] The media and others were outraged when the prior administration deviated from standard processes.[13] Why should there not be the same outrage in these instances? One of these decisions—made without the Panel's input—allows teenagers to receive a third COVID-19 booster shot. Based on the Democrats' record of harming children over the course of the pandemic, it would be prudent to engage in thorough analysis of any decision related to COVID-19 effecting young people. [14] Instead, this White House and the agencies it controls have pushed forward without following the normal course.

On January 10, 2021, Dr. Marty Makary flagged vaccine transparency concerns related to the CDC's process.[15] According to Dr. Makary, "the CDC informed its Advisory Committee on Immunization Practices members that because it asked for 24 days of their time last year, the

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[5] Marty Makary MD, MPH (@MartyMakary), Twitter (Jan. 1, 2022 7:05 P.M.).
[6] Scalise & Comer letter, *supra* note 1.
[7] Marty Makary, *The Dangerous Push to Give Boosters to Teens*, WALL ST. J. (Dec. 21, 2021).
[8] *Id,*
[9] *Id.*
[10] Krause, *supra* note 2.
[11] Michael Shear & Benjamin Mueller, *Biden Promised to Follow the Science. But Sometimes, He Gets Ahead of the Experts,* N.Y. TIMES (Sept. 24, 2021).
[12] Krause, *supra* note 2.
[13] *Id.*
[14] Blake Hounshell & Leah Askarinam, *Pandemic Politics,* N.Y. TIMES, ON POLITICS NEWSLETTER (Jan. 4, 2022); Editorial Board, *Fresh Evidence the White House Put Teachers Unions Ahead of Science on School COVID Safety*, N.Y. POST (Dec. 26, 2021).
[15] Marty Makary, *The Feds' Booster Push Shows Public-Health Decisions Aren't Data-Driven*, N.Y. POST (Jan. 10, 2022).

CDC will do most of the work internally…"[16] The agency claims to be looking for a "feasible and sustainable" approach to meetings. Of course, this is a red herring since zoom has become ubiquitous through the course of the ongoing pandemic. Instead of being thorough and transparent, this Administration is shortcutting the standard vaccine recommendation process and in lieu, Dr. Walensky is determining, "what we thought people would be able to tolerate."[17]

The Committee on Oversight and Reform has an obligation to understand whether there is a valid reason the Biden Administration is circumventing the standard vaccine recommendation process. Since you did not respond to the September 14, 2021, letter I am reiterating the prior requests and adding new requests: numbers 8 through 10. Please provide the following documents and information as soon as possible but no later than February 2, 2022. Unless otherwise noted the requested time period is January 21, 2021, to the present:

1. All documents and communications relating to the study and implementation of a booster shot option for mRNA vaccine recipients.

2. All documents and communications between the FDA and the White House relating to booster shots.

3. All documents and communications related to President Biden's August 18, 2021, announcement that booster shots would be available for Americans beginning September 20, 2021.

4. All documents and communications relating to any effort by political appointees or White House personnel to review, revise, edit, delay, or prohibit publication of information related to booster shots.

5. All documents and communications related to the departure of FDA scientist Marion Gruber.

6. All documents and communications related to the departure of FDA scientist Phil Krause.

7. All documents and communications relating to any adverse employment action taken or considered against any employee, official, or contractor of the federal government for actions taken in the course of their employment related to the science of Americans receiving booster shots.

8. All documents and communications between or among employees at the White House, FDA, and/or CDC referring or relating to the decision not to convene additional meetings of the Vaccines and Related Biological Products Advisory Committee after September 17, 2021.

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[16] *Id*.
[17] Nathaniel Weixel, *Walensky: New CDC Guidance Is 'What We Thought People Would Be Able to Tolerate,'* THE HILL (Dec. 29, 2021).

9. All documents and communications between or among FDA employees and experts on the Vaccines and Related Biological Products Advisory Committee since September 17, 2021.

10. All documents and communications between any FDA employee and Dr. David Kessler at the White House.

The Committee on Oversight and Reform is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Further, the Select Subcommittee on the Coronavirus Crisis is empowered to investigate "preparedness for and response to the coronavirus crisis, including the planning for and implementation of testing, containment, mitigation, and surveillance activities."[18] Thank you in advance for your cooperation with this inquiry.

Sincerely,

James Comer
Ranking Member
Committee on Oversight and Reform

cc: The Honorable Carolyn Maloney, Chairwoman
Committee on Oversight and Reform

[18] H. Res. 935 § 3(a)(4) (2020).