

Congress of the United States
Washington, DC 20515

September 14, 2021

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

Dear Acting Commissioner Woodcock:

Select Subcommittee Republicans are conducting oversight of potential political interference with the U.S. Food and Drug Administration (FDA) by the Biden Administration. President Biden, instead of following the science, is attempting to distract from his numerous crises by playing politics and moving out ahead of the FDA and the Centers for Disease Control (CDC) when it comes to the science on coronavirus vaccine booster shots.

Without evidence and data, President Biden announced that booster doses of the mRNA vaccines would be available for Americans starting September 20, 2021.¹ Top scientists and researchers were stunned by this decision—particularly because the CDC and the FDA had not yet conducted their independent review of the data.² In fact, two vaccine manufacturers have not yet submitted the relevant data to the government agencies.³ The political manipulation and pressure to interfere with the science by President Biden's White House reportedly contributed to the decision of two top career scientists, Marion Gruber and Phill Krause, who were key in the vaccine process, to leave the FDA.⁴ They felt that the FDA was being sidelined by the Biden Administration and "what finally did it for them was the White House getting ahead of FDA on booster shots."⁵

Further, we now know that those same FDA scientists disagreed with the Biden Administration on the need for booster shots. In a paper published September 13, 2021, both

¹ Bob Herman, *FDA's top vaccine leaders are leaving*, Axios (Aug. 31, 2021), <https://www.axios.com/fda-vaccine-leaders-gruber-krause-leaving-2fbc4998-cd40-4864-b816-3a5ec81e9084.html>; Erin Banco, Sarah Owerwohle & Adam Cancryn, *Tensions mount between CDC and Biden health team over boosters*, POLITICO (Sept. 13, 2021), <https://www.politico.com/news/2021/09/13/cdc-biden-health-team-vaccine-boosters-511529>.

² Caitlin Owens, *The bureaucracy pushes back on Biden's booster plan*, AXIOS (Sept. 1, 2021), <https://www.axios.com/biden-coronavirus-vaccine-boosters-fda-cdc-4189df4c-e794-4e4f-af16-cce32f63b3d9.html>.

³ Erin Banco, Sarah Owerwohle & Adam Cancryn, *Tensions mount between CDC and Biden health team over boosters*, POLITICO (Sept. 13, 2021), <https://www.politico.com/news/2021/09/13/cdc-biden-health-team-vaccine-boosters-511529>.

⁴ Caitlin Owens, *The bureaucracy pushes back on Biden's booster plan*, AXIOS (Sept. 1, 2021), <https://www.axios.com/biden-coronavirus-vaccine-boosters-fda-cdc-4189df4c-e794-4e4f-af16-cce32f63b3d9.html>.

⁵ *Id.*

Krause and Gruber argued that “[c]urrent evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high.”⁶

In order for the Select Subcommittee to conduct legitimate oversight and enable a better response to the next pandemic, we request the following documents and information as soon as possible but no later than September 28, 2021.

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 American receiving booster shots.

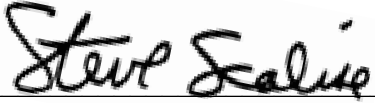
The Committee on Oversight and Reform is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. Further, the Select Subcommittee on the Coronavirus Crisis is empowered to investigate “preparedness for and response to the coronavirus crisis, including the planning for and implementation of testing, containment, mitigation, and surveillance activities.”⁷ Thank you in advance for your cooperation with this inquiry.

⁶ Phillip R Krause, *et.al*, *Considerations in boosting COVID-19 vaccine immune responses*, LANCET (Sept. 13, 2021), <https://els-jbs-prod-cdn.jbs.elsevierhealth.com/pb-assets/Lancet/pdfs/S0140673621020468-1631529799470.pdf>.


⁷ H. Res. 935 § 3(a)(4) (2020).

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Sincerely,



Steve J. Scalise
Ranking Member
Select Subcommittee on the
Coronavirus Crisis



James Comer
Ranking Member
Committee on Oversight and Reform

cc: The Honorable James E. Clyburn, Chairman
Select Subcommittee on the Coronavirus Crisis

The Honorable Carolyn Maloney, Chairwoman
Committee on Oversight and Reform