United States Senate
WASHINGTON, DC 20510

October 7, 2021

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

On August 23, 2021, the Food and Drug Administration (FDA) reissued the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine and announced the approval of the biologics license application for Comirnaty that created confusion that you have failed to clarify. On August 26, 2021, I wrote you a letter seeking clarification regarding language in the FDA's EUA reissuance that Comirnaty and the Pfizer-BioNTech COVID-19 vaccines are "legally distinct with certain differences that do not impact safety or effectiveness," and that "[a]lthough COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA."[1]

I requested a response by August 30, as I assumed you would have this information readily available. However, more than one month later, you have failed to provide any response to that letter. Meanwhile, on September 13, 2021, the National Library of Medicine within the National Institutes of Health, reported, "[a]t present, Pfizer does not plan to produce any product with these new [Comirnaty National Drug Codes] and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution."[2] On September 22, 2021, the FDA reissued the EUA for the Pfizer-BioNTech COVID-19 vaccine, with the same language regarding availability limitations for individuals 16 years of age and older.[3]

As I previously noted, your answers are crucial to Americans who are being forced into making potentially life-altering decisions in response to employer, military, and school vaccine

[1] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 2, Aug. 23, 2021 archived copy available at https://web.archive.org/web/20210823142034/https://www fda.gov/media/150386/download (See footnote 8); *Id.* at 5 (See footnote 9). FDA appears to have removed the August 23, 2021 letter from its website and replaced it with a copy of the September 22, 2021 reissuance letter.
[2] Announcement, U.S. National Library of Medicine, Pfizer received FDA BLA license for its COVID-19 vaccine (Sept. 13, 2021), available at https://dailymed nlm nih.gov/dailymed/dailymed-announcements-details.cfm?date=2021-09-13.
[3] Letter to Amit Patel, BioNTech Manufacturing GmbH, from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 6, Sept. 22, 2021, available at https://www.fda.gov/media/150386/download (See footnote 12).

mandates. In the midst of these coercive mandates, your inability to answer basic questions shows a complete disregard for the many Americans who continue to seek clarity about the vaccines.

I, therefore, write to reiterate the questions from the August 26, 2021 letter and I request the following additional information below:

August 26, 2021 Questions

1. Why didn't the FDA grant full licensure for the Pfizer-BioNTech vaccine that is in use and available in the U.S.?

2. How are the Comirnaty and Pfizer-BioNTech COVID-19 vaccines "legally distinct" and what are the "certain differences"?[4]

3. There is no doubt that the FDA's action will lead to more vaccine mandates and increased pressure on those currently choosing not to get vaccinated. Your letter to Pfizer suggests that "there is not sufficient approved vaccine available for distribution."[5] Is there sufficient supply in the U.S. of the Comirnaty vaccine to ensure that those being vaccinated under mandates will be receiving the FDA-approved version? Or is it more likely (or certain) that they will be vaccinated using the vaccine administered under the reissued EUA?

4. If there is insufficient supply of Comirnaty vaccines for those succumbing to the coercion of mandates, isn't the FDA de facto endorsing vaccine mandates utilizing EUA vaccines?

5. Will individuals who receive either vaccine be afforded the same legal protections if they are injured by the vaccine? If not, why not?

Additional Questions

1. When will there be sufficient supply of Comirnaty in the U.S. for the population it is approved for?

2. Have any individuals received Comirnaty in the U.S. since its approval? If so, how many?

3. Will individuals for whom Comirnaty is approved be able to choose whether to receive Comirnaty instead of the EUA Pfizer-BioNTech vaccine?

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[4] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 2, Aug. 23, 2021 archived copy available at https://web.archive.org/web/20210823142034/https://www fda.gov/media/150386/download (See footnote 8)
[5] *Id.* at 5 (See footnote 9).

Please provide responses to these questions by no later than October 14, 2021. Thank you for your attention to this urgent matter.

Sincerely,

Ron Johnson
U.S. Senator