United States Senate
WASHINGTON, DC 20510

August 26, 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 FDA reissued the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine.[1] This vaccine is currently available and used in the United States. At the same time, the FDA announced its approval of the biologics license application submitted by BioNTech Manufacturing GmbH for Comirnaty (COVID-19 Vaccine, mRNA) against COVID-19 for individuals 16 years of age and older.[2] According to the FDA, "there is not sufficient approved vaccine [Comirnaty] available for distribution" in the U.S.[3]

In the letter that reissued the EUA for the Pfizer-BioNTech COVID-19 vaccine, the FDA stated that Comirnaty and the Pfizer-BioNTech COVID-19 vaccines are "legally distinct with certain differences that do not impact safety or effectiveness."[4] That statement, together with the fact that the FDA issued two distinct letters – one extending the EUA for the vaccine used in the U.S. and the other granting the FDA approval of the Comirnaty vaccine used in Europe and other countries – has caused a great deal of confusion.

As I stated to you in my letter dated August 22, 2021, "I see no need to rush the FDA approval process for any of the three COVID-19 vaccines. Expediting the process appears to only serve the political purpose of imposing and enforcing vaccine mandates."[5] Because the FDA-approved Comirnaty vaccine is not generally available in the U.S., but the Pfizer-BioNTech COVID-19 vaccine will continue to be used in the U.S. under a reissued EUA, the FDA seems to be confirming my suspicion.

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[1] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration, Aug. 23, 2021 available at https://www fda.gov/media/150386/download.
[2] Letter to Amit Patel, BioNTech Manufacturing GmbH, from Mary Malarkey, Director, Office of Compliance and Biologics Quality, U.S. Food and Drug Administration, and Marion Gruber, Director, Office of Vaccines Research and Review, U.S. Food and Drug Administration, Aug. 23, 2021 available at https://www fda.gov/media/151710/download.
[3] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 5, Aug. 23, 2021 available at https://www.fda.gov/media/150386/download (See footnote 9).
[4] *Id.* at 2 (See footnote 8).
[5] Letter from Ron Johnson, U.S. Senator, to Janet Woodcock, Acting Commissioner, U.S. Food and Drug Administration, et al., Aug. 22, 2021.

In order to address the confusion created by the FDA's August 23, 2021 letters, I am asking that you expeditiously provide answers to the following 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"?

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."[6] 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?

I look forward to receiving a response to this limited number of questions no later than August 30, 2021. Your answers are crucial to Americans who will now be forced into making potentially life-altering decisions in response to the employer, military and educational mandates that your August 23, 2021 letters have triggered. I will also be sending you a more detailed follow-up letter to your inadequate response to my August 22, 2021 letter in the next few days.

Sincerely,

Ron Johnson
U.S. Senator

[6] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 5, Aug. 23, 2021 available at https://www.fda.gov/media/150386/download (See footnote 9).