United States Senate
WASHINGTON, DC 20510

October 7, 2021

Albert Bourla, DVM, Ph.D.
Chief Executive Officer
Pfizer
235 East 42nd Street
New York, NY 10017

Uğur Şahin, M.D.
Chief Executive Officer
BioNTech
An der Goldgrube 12
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Dear Drs. Bourla and Şahin:

On August 23, 2021, the U.S. Food and Drug Administration (FDA) announced the approval of the biologics license application for BioNTech's Comirnaty (COVID-19 Vaccine, mRNA).[1] On the same day, the FDA also announced it had reissued the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine.[2] The announcement of an approved vaccine under the name Comirnaty has been used to justify vaccine mandates. The simultaneous reissuance of the EUA for the Pfizer-BioNTech vaccine has created confusion and concern among the American people. I write to request information on the vaccine as authorized under the EUA and the approved Comirnaty product.

When the FDA made its August announcement it stated "[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"[3] On September 13, 2021, the National Library of Medicine within the National Institutes of Health, reported, "[a]t present, Pfizer does not plan

[1] 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.
[2] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration, Aug. 23, 2021 archived copy available at https://web.archive.org/web/20210823142034/https://www fda.gov/media/150386/download. (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).
[3] *Id*. at 5 (See footnote 9).

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."[4] 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.[5] Based on these statements it appears that individuals who are required to be vaccinated under President Biden's and the Department of Defense's vaccine mandates may not be able to receive the fully licensed and approved vaccine.

In order to better understand the use of Comirnaty and the Pfizer-BioNTech COVID-19 vaccine, please provide the following information:

1. Please explain why an EUA is still required for the Pfizer-BioNTech COVID-19 vaccine for individual 16 years of age and older given it has been 45 days since the approval of the Comirnaty vaccine for this group.

2. Since the August 23, 2021 approval of the biologics licensure application for the Comirnaty vaccine, please provide:

    a. The total number of doses of Comirnaty manufactured to date;
    b. The total number of doses of Comirnaty shipped in the U.S. to date, including a breakdown of the number of doses shipped to each state;
    c. The number of doses of the Pfizer-BioNTech COVID-19 vaccine manufactured since August 23, 2021; and
    d. The total number of doses of the Pfizer-BioNTech COVID-19 vaccine shipped in the U.S. since August 23, 2021, including the number of doses shipped to each state.

3. Does Pfizer or BioNTech provide guidance on the mixed use of Comirnaty or the EUA Pfizer-BioNTech COVID-19 vaccine for a single two-dose regimen? If so, please provide that guidance.

4. Given the FDA believes there are limited supplies of the Comirnaty vaccine, does Pfizer or BioNTech recommend that providers prioritize use of the approved Comirnaty vaccine for the initial two-dose regimen rather than single booster doses? If so, please explain why. If not, why not?

[4] 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.
[5] 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).

Please provide the requested information by no later than October 21, 2021. Thank you for your attention to this urgent matter.

Sincerely,

Ron Johnson
U.S. Senator