

U.S. Sen. Johnson: Continues to press the FDA, Pfizer, BioNTech on transparency and politicization of vaccine approval process

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WASHINGTON — On Thursday, U.S. Sen. Ron Johnson (R-Wis.) wrote letters to Albert Bourla, CEO of Pfizer and Dr. Uğur Şahin, CEO of BioNTech and Dr. Janet Woodcock, Acting Commissioner of the Food and Drug Administration (FDA). Sen. Johnson previously sent a [letter](#) to Dr. Woodcock on August 26, 2021, asking for clarity regarding two letters issued by the FDA – one extending the emergency use authorization (EUA) for the vaccine and the other granting the FDA approval of the Comirnaty vaccine – which caused a great deal of confusion. The FDA has yet to respond to that letter.

The senator wrote to Pfizer and BioNTech, “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.’ 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.’ 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. 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."

The senator asked the FDA to clarify the language in the FDA's August 23 reissued EUA for the Pfizer-BioNTech COVID-19 vaccine and the FDA's announcement of the approval of the biologics license application for Comirnaty.

"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 mandates," the senator wrote to the FDA. "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."

The letters can be found [here](#) and [here](#) and below.

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

55131 Mainz

Germany

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 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?

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

Sincerely,

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.”[\[6\]](#)

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.”[\[7\]](#) 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.[\[8\]](#)

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 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”?[\[9\]](#)

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.”[\[10\]](#) 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?

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

Sincerely,