

United States Senate

WASHINGTON, DC 20510

October 12, 2021

The Honorable Joseph R. Biden
President
The White House
Washington, D.C. 20500

The Honorable Lloyd J. Austin III
Secretary of Defense
U.S. Department of Defense
1000 Defense Pentagon
Washington, D.C. 20301

The Honorable Mark A. Milley
Chairman of the Joint Chiefs of Staff
9999 Joint Staff Pentagon
Washington, D.C. 20318

Dear President Biden, Secretary Austin and General Milley:

Multiple sources have alleged that the Department of Defense's (DoD) mandatory COVID-19 vaccinations may not be in accordance with Secretary of Defense Austin's August 24, 2021 memorandum (vaccine mandate) stating "[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."¹

On August 23, 2021, the FDA 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 [Emergency Use Authorization] EUA."² On September 13, 2021, the National Library of Medicine within the National Institutes of Health (NIH), 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."³ Again on September 22, 2021, the FDA stated, "there is not sufficient approved vaccine [Comirnaty] available for distribution to this population

¹ Memorandum from Secretary of Defense Lloyd Austin to Senior Pentagon Leadership, et al. (Aug. 24, 2021) (available at <https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF>).

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

³ 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>.

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[individuals 16 years of age and older] in its entirety at the time of reissuance of this EUA.”⁴ Absent a sufficient supply of the only approved COVID-19 vaccine, Comirnaty, it is not clear how DoD is complying with Secretary Austin’s assertion that mandatory vaccination will only occur with the fully-licensed vaccine.⁵

In order to understand the extent to which DoD service members subject to mandatory COVID-19 vaccination may have not received fully-approved vaccines as prescribed by Secretary Austin’s vaccine mandate, I request the following information:

1. How many vaccinations have been administered since Secretary Austin’s vaccine mandate?
2. Please provide the number of voluntary and mandated vaccinations administered to DoD service members using each vaccine by month:
 - a. Moderna – EUA;
 - b. Johnson and Johnson (Janssen) – EUA;
 - c. Pfizer-BioNTech – EUA; and
 - d. Comirnaty – FDA approved.
3. Please provide all orders issued to DoD personnel regarding DoD’s vaccine mandate.
4. Please provide all guidelines issued to DoD personnel regarding DoD’s vaccine mandate.
5. Please provide all documents and communications regarding DoD’s vaccine mandate, including but not limited to the development and implementation of the vaccine mandate.

Thank you for your attention to this urgent matter. Please respond no later than October 26, 2021.

Sincerely,



Ron Johnson
U.S. Senator

⁴ 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).

⁵ Memorandum from Secretary of Defense Lloyd Austin to Senior Pentagon Leadership, et al. (Aug. 24, 2021) (available at <https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF>).