United States Senate
WASHINGTON, DC 20510

August 22, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Rockville, MD 20892

Rochelle P. Walensky, M.D., MPH
Director
Centers for Disease Control and Prevention
395 E Street SW
Washington, DC 20024

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

Dear Drs. Collins, Walensky, and Woodcock:

According to an article published on August 20, 2021 in *The BMJ*, the Food and Drug Administration (FDA) has decided "not to hold a formal advisory committee meeting to discuss Pfizer's application for full approval of its covid-19 vaccine."[1]

In a statement, the FDA reportedly told *The BMJ* that the agency did not believe a meeting was necessary because "t]he FDA has held numerous meetings of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) related to covid-19 vaccines, including a 22 October 2020 meeting to discuss, in general, the development, authorization, and licensure of covid-19 vaccines."[2] An FDA spokesperson added, "[t]he Pfizer BioNTech covid-19 vaccine was discussed at the VRBPAC meeting on 10 December 2020. If the agency had any questions or concerns that required input from the advisory committee members we would have scheduled a meeting to discuss."[3]

As you are well aware, I first raised the issue of vaccine safety signals coming from FDA and Centers for Disease Control and Prevention's (CDC) Vaccine Adverse Event Reporting System (VAERS) in a meeting with National Institutes of Health Director Collins on April 27, 2021. Since then, I have written four oversight letters on the subject of vaccine safety,

[1] Gareth Iacobucci, *Covid-19: FDA set to grant full approval to Pfizer vaccine without public discussion of data*, THE BMJ (Aug. 20, 2021), *available at* https://www.bmj.com/content/374/bmj n2086.
[2] *Id.*
[3] *Id.*

effectiveness, and adverse events.[4] To date, I have received little to no substantive response. This lack of transparency is unacceptable.

As of August 20, 2021, VAERS is reporting 12,791 worldwide deaths associated with the three Covid-19 vaccines available under an FDA Emergency Use Authorization (EUA). Of those deaths, 4,632 occurred on Day 0, 1, or 2 following vaccination. As the CDC and the FDA are quick to point out, VAERS reports do not prove causation. But this number of deaths, particularly with 36.2% occurring within 2 days of vaccination, should raise serious concerns.

It should also be noted that the 12,791 deaths related to Covid-19 vaccines reported on VAERS over the period of 8 months, compares to 8,966 deaths related to all other vaccines reported on VAERS since the inception of VAERS – a period of 31 years. And this does not raise alarm bells within your agencies, or cause you to reconsider assembling an independent safety panel of outside experts?

In addition to deaths, VAERS is also reporting 16,044 permanent disabilities, 51,242 hospitalizations, and 571,831 total adverse events related to the Covid-19 vaccines. I am receiving a growing number of letters from doctors and nurses detailing the vaccine injuries they are witnessing and treating, together with the suppression and censoring of this information they are experiencing.

Your agencies' dismissive attitude toward natural immunity has also been puzzling to say the least, and may increase the chances of vaccine injury in previously infected individuals. In its May 19, 2021 advisory, the FDA specifically discouraged Americans and their physicians from determining the status of their antibody immunity to SARS-CoV-2. It would seem to me that more medical information, not less, is the key to improving health outcomes related to any disease, including Covid-19.

Since the FDA's last VRBPAC public meeting, in addition to the VAERS data, there have been a number of safety concerns raised by highly qualified medical professionals and researchers. A petition signed by 31 medical professionals and submitted to the FDA argues there is no need to short circuit the full approval process, including public safety forums, since the EUA is making the vaccines available to anyone 12 years or older choosing to be vaccinated.[5] Some researchers are concerned about the unblinding of Pfizer's placebo group and

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[4] Ron Johnson, U.S. Senator, to Albert Bourla, Chief Executive Officer, Pfizer, July 1, 2021, https://www.ronjohnson.senate.gov/2021/7/sen-johnson-asks-moderna-and-pfizer-what-steps-they-ve-taken-to-assist-individuals-who-have-experienced-adverse-events-following-covid-19-vaccination; Ron Johnson, U.S. Senator, to Stéphane Bancel, Chief Executive Officer, Moderna, Inc., July 1, 2021, https://www.ronjohnson.senate.gov/2021/7/sen-johnson-asks-moderna-and-pfizer-what-steps-they-ve-taken-to-assist-individuals-who-have-experienced-adverse-events-following-covid-19-vaccination; Ron Johnson, U.S. Senator, to Francis Collins, Dir., National Institutes of Health, et al., July 13, 2021, https://www.ronjohnson.senate.gov/2021/7/sen-johnson-sends-letter-pressing-health-agencies-on-efforts-to-monitor-reports-of-adverse-reactions-to-covid-19-vaccines; Ron Johnson, U.S. Senator, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, July, 30, 2021, https://www ronjohnson.senate.gov/2021/7/sen-johnson-demands-biden-administration-release-all-data-from-cdc-slides-leaked-to-washington-post.

[5] *See* Linda Wastila, Peter Doshi, Hamid Merchant, and Kim Witczak, *Why we petitioned the FDA to refrain from fully approving any covid-19 vaccine this year*, THE BMJ (June 8, 2021), *available at*

how that will impact the reported trial results on safety and efficacy. Recent data coming out of the U.K. and Israel regarding vaccine efficacy raises a number of questions including: "Why isn't the same data regarding U.S. breakthrough cases available to the American public?" All these issues should be discussed in a transparent and public forum.

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. The observational phases of FDA approval take time, because there is no substitute for time in detecting and determining possible long-term harm. Additionally, we are already experiencing a severe health care worker shortage. Frontline doctors and nurses that are contacting me are expressing grave concerns about vaccine mandates which will only exacerbate the shortage.

Over the last year and a half, the decisions of federal health agencies have dramatically affected the lives of all Americans. The impact of these decisions has been felt in Americans' treatment options, employment, schools, housing and travel, and in countless other ways. The human toll of the social restrictions and economic devastation is incalculable. Unfortunately, your federal health agencies have not been transparent with the American people about how these life altering decisions have been made or what science and data they are based upon. I urge you to provide the information I have requested in my previous letters and to reconsider your decision not to assemble a VRBPAC public meeting prior to the granting of any final Covid-19 vaccine approval.

Sincerely,

Ron Johnson
U.S. Senator

https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/.