



June 2, 2021

Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock,

Our organization is writing to express our deep concern regarding the recent approval requests from Moderna and Pfizer. Both have asked the FDA to give full approval to their Covid-19 vaccines, which to date only have Emergency Use Authority (EUA).

Their request should be promptly and fully denied.

Here are seven reasons for you to deny their requests for full approval:

1. This is the first-ever mRNA vaccine. It's never been used before and should not be rushed into approval. Long term effects are not known.
2. These vaccines are still in clinical trials and will be until late 2022 and 2023. The current vaccination program is a global experiment on the human population, including on those who were not part of the phases of the pre-distribution clinical trials.
3. The mRNA vaccines do not fit the CDC's definition of "vaccine" (provide immunity) or give CDC-defined "immunity" (prevent the disease).
4. By being called a "vaccine," the manufacturers are exempt from liability for the already more than 200,000 injuries and at least 4,863 deaths reported from the injection.
5. Employers, corporations, schools, and colleges are looking for such approval to mandate that their employees, students and others be injected with this investigational drug despite the dangers.
6. A mandate will lead to compulsion, coercion, and additional fear, forcing Americans to make an untenable decision. Those facing a mandate would be required to choose between the risks and dangers of the injection and the loss of education and income.
7. Already, OSHA reversed their decision to protect employees, removing the requirement that employers that require employees to take the coronavirus injection must report vaccine injuries as work injuries available for worker compensation. That requirement was removed on May 21.

A rush to approval would be dangerous to Americans. Federal approval of a drug typically takes years. “On average, it takes 10.5 years for a Phase I program to progress to regulatory approval.” And, according to J.P. Carroll, a drug in Phase I trials only had a 7.9% likelihood of approval. (*J.P. Carroll, BIOTechNOW, February 16, 2021, <https://www.bio.org/blogs/how-long-does-it-take-get-drug-approved>, accessed 06/02/21*) In addition, those approvals were not for an mRNA drug, which is a completely new type of drug. Furthermore, the long-term effects are not known.

If the FDA approves this “investigational drug”—the term used by Pfizer in one document for a medication which has not been approved by a regulatory agency—millions of Americans may be put in harm’s way. For many, their freedom and their right to engage in public life would also be threatened, curtailed, or eliminated.

Finally, we expect costly lawsuits would be the last resort used to protect the people the FDA chose not to protect. However, the many who could not afford to file a lawsuit would be vulnerable to the coercion unleashed by improperly rushed federal approval.

OUR REQUESTS:

First and foremost, **do not give FDA approval** to the investigational drugs (“vaccines”) manufactured by Pfizer, Moderna, or any other pharmaceutical company until the clinical trials are complete, the data analyzed, and the vaccine candidates have been fully and appropriately vetted.

Second, it is critically important for the FDA to follow due diligence requirements. The FDA should **recognize publicly the right of Americans to make a real choice, not a coercive choice.**

Third, the FDA must recognize the dangers such an approval would cause many Americans to face in a nation where employers, colleges, schools, and businesses just want to “get back to normal.” **Vaccine choice is an important American right. The FDA should not act in a way that directly or indirectly eliminates that right.**

If you wish to contact me, please do not hesitate to call 651-646-8935.

Sincerely,

Twila Brase, RN, PHN
President and Co-founder
Citizens’ Council for Health Freedom