Citizen Petition Urges FDA Against Premature Full Approval of Covid Vaccine

Many open, unanswered questions surrounding the efficacy and safety of COVID-19 vaccines must be answered before the FDA considers granting a full approval

BALTIMORE, MARYLAND, UNITED STATES, June 8, 2021 /EINPresswire.com/ -- On June 1st, a group of 27 clinicians, researchers, and consumer advocates filed an urgent Citizen Petition with the Food and Drug Administration (FDA) aimed at preventing the agency from prematurely granting full approval to any COVID-19 vaccine. (Pfizer and Moderna are currently seeking full approval through Biologics License Applications (BLAs).)

The group said there is no legitimate reason to rush an approval. They outlined the many open, unanswered questions surrounding the efficacy and safety of COVID-19 vaccines, detailing how those data must be collected before the FDA considers granting any vaccine a full approval.

> “Despite widespread adoption of these COVID-19 vaccines, many unanswered questions remain about their effectiveness and safety which only can be answered in time and with proper and necessary studies.”
>
> *Linda Wastila*

Currently, three COVID-19 vaccines are available in the United States under Emergency Use Authorizations (EUAs). The petition explains that, even without a full approval, vaccines will remain available for all who want them because EUAs do not carry any expiration date; thus, COVID-19 vaccines can continue to be lawfully provided under EUA even after the SARS-CoV-2 public health emergency no longer exists.

The petition states that premature FDA approval of any COVID-19 vaccine could negatively impact the health and safety of US residents, with global ramifications considering the international importance of FDA decision, and risks setting a precedent of lowered standards for

future vaccine approvals.

They write: “We are concerned that the premature licensure of a COVID-19 vaccine can seriously undermine public confidence in regulatory authorities, particularly if long-term safety issues were to emerge following licensure.”

The petition outlines eight efficacy and safety measures that must be met before serious consideration is given to granting full FDA approval:

1. Completing at least 2 years of follow-up of participants originally enrolled in pivotal clinical trials, even if the trials were unblinded and now lack a placebo control. All vaccine manufacturer phase 3 trials were already designed with this planned duration.

2. Prior to including in the list of populations for which a vaccine is approved, ensuring there is substantial evidence that clinical effectiveness outweighs harms in special populations including: infants, children, and adolescents; those with past SARS-CoV-2 infection; immunocompromised; pregnant women; nursing women; frail older adults; and individuals with cancer, autoimmune disorders, and hematological conditions.

3. Requiring thorough safety assessment of spike proteins being produced in-situ by body tissues following vaccine administration, and spike proteins’ full biodistribution, pharmacokinetics, and tissue specific toxicity.

4. Completion of vaccine biodistribution studies from administration site and safety implications of mRNA translation in distant tissues.

5. Thorough investigation of all severe adverse reactions reported following COVID-19 vaccination, such as deaths, reported in VAERS and other pharmacovigilance systems.

6. Assessment of safety in individuals receiving more than two doses.

7. Inclusion of gene delivery and therapy experts in the Vaccines and Related Biological Products Advisory Committee (VRBPAC), in recognition of the fact that the novel COVID-19 vaccines work on the premise of gene delivery, in contrast to conventional vaccines.

8. Enforcing stringent conflict of interest requirements to ensure individuals involved in data analysis and BLA-related decision making processes have no conflict of interests with vaccine manufacturers.

The petition says a COVID-19 vaccine should be fully approved when—and only when—substantial evidence demonstrates the benefits of a specific product outweigh the harms for the indicated, recipient population.

They petitioners explain the following are invalid reasons to approve a COVID-19 vaccine:

• To ensure vaccines are accessible after the public health emergency has ended. COVID-19 vaccines with an emergency use authorization (EUA) can be lawfully used after the expiry of the SARS-CoV-2 public health emergency declaration. (This is made clear by the many products for Ebola and Zika viruses which still have active EUAs.)

• To ensure adequate access to vaccines across the population. Full approval is not necessary to assure access to COVID-19 vaccines. EUAs for COVID-19 vaccines have enabled, and continue to enable, their widespread use.

• To enable vaccine mandates. Consideration of vaccine mandates is outside of FDA's purview. Furthermore, a mandate should only be considered once the evidentiary conditions are met for a BLA (demonstrating that benefits outweigh harms).

• To bolster public confidence. Like mandates, approving a medical product in order to bolster public confidence is backward logic and is outside the FDA's purview."

The 20-page petition from Linda Wastila and 26 co-authors can be downloaded here and is open for public comment. When FDA responds, it will be public on the regulations.gov docket (Docket ID: FDA-2021-P-0521).

LINKS

1) Commentary in British Medical Journal Opinion
https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/

2) Linda Wastila et al. Citizen Petition (Docket ID: FDA-2021-P-0521):
https://downloads.regulations.gov/FDA-2021-P-0521-0001/attachment_1.pdf

3) To comment on the Linda Wastila et al. Citizen Petition:
https://www.regulations.gov/commenton/FDA-2021-P-0521-0001

4) To read others comments on the Linda Wastila et al. Citizen Petition:
https://www.regulations.gov/document/FDA-2021-P-0521-0001/comment

5) Main FDA docket for Linda Wastila et al. Citizen Petition (Docket ID: FDA-2021-P-0521):
https://www.regulations.gov/docket/FDA-2021-P-0521/document

6) Press Release - Spanish
https://faculty.rx.umaryland.edu/pdoshi/files/2021/06/CP-Press-Release-Spanish.pdf

7) Press Release - Italian
https://faculty.rx.umaryland.edu/pdoshi/files/2021/06/CP-Press-Release-Italian.pdf

8) Press Release - German
https://faculty.rx.umaryland.edu/pdoshi/files/2021/06/CP-Press-Release-German.pdf

9) Press Release - Chinese (traditional)
https://faculty.rx.umaryland.edu/pdoshi/files/2021/06/CP-Press-Release-Chinese-traditional.pdf

10) Press Release - Chinese (simplified)
https://faculty.rx.umaryland.edu/pdoshi/files/2021/06/CP-Press-Release-Chinese-simplified.pdf

11) Press Release - Urdu
https://faculty.rx.umaryland.edu/pdoshi/files/2021/06/CP-Press-Release-Urdu.pdf

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