From The Epoch Times

Experts Want Labels for Pfizer, Moderna COVID-19 Vaccines Updated to Acknowledge Limitations

0:004:56

A coalition of experts is calling for U.S. officials to update the labels for the Pfizer and Moderna COVID-19 vaccines to acknowledge limitations to clinical trials, including stating clearly that the phase III trials that led to clearance didn't provide evidence of efficacy against death.

"Incomplete, inaccurate, or misleading labeling of any medical product can negatively impact the health and safety of Americans, with global ramifications considering the international importance of FDA [Food and Drug Administration] decisions," Peter Doshi, an associate professor at the University of Maryland School of Pharmacy whose expertise includes clinical trials, and eight other experts wrote in a petition.

The group, known as the Coalition Advocating for Adequately Labeled Medicines, sent the petition to the FDA, which authorized the vaccines in late 2020 and approved them in 2021.

The experts note that the clinical trials that led to the authorization "were not designed to determine and failed to provide substantial evidence of vaccine efficacy against SARS-CoV-2 transmission or death." As evidence, they cited the FDA's review memorandums, which stated, in part, that "data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination."

SARS-CoV-2 is the pathogen that causes COVID-19.

The FDA states on its website that "the scientific community does not yet know" if the vaccines will reduce such transmission.

“While language in labeling that states what a product has not been proven to do is uncommon, it is necessary when caregivers and patients may inaccurately assume something that is untrue,” the coalition stated, citing how Dr. Anthony Fauci, a former top U.S. health official; President Joe Biden; and others have falsely suggested that the vaccines prevent transmission and would lead to herd immunity.

People should also be informed that the efficacy of Pfizer’s vaccine wanes after just two months, according to the experts. They pointed to Pfizer’s interim results from the trial, which were available in April 2021 but not disclosed to the public until July 2021.

They also want the adverse event sections expanded to include sudden cardiac death, pulmonary embolism, and decreased sperm concentration, among other event types.

Studies from the FDA and others have found an association between one or both of the vaccines and the conditions.

“FDA’s mission is to advance public health in part by helping the public get accurate, science-based information. However, we are concerned that current FDA-approved labeling for the mRNA COVID vaccines is seriously out of date, and, thus, has potential to misinform providers and patients,” Kim Witczak, founder of Woody Matters and one of the signatories, told The Epoch Times via email.

The FDA, Pfizer, and Moderna didn’t respond to requests for comment.

Public Comments

Members of the public can add comments to the petition here.

Early comments support the petition.

“The very least you could do is properly label these medical products and give people informed consent, so they know the same risks that you know, which have been proven clinically and through many individual tragedies,” one comment said.

Another said the FDA should require the vaccine makers to update the labels “to ensure safety and efficacy.”

Previous Denial

The coalition submitted a petition in mid-2021 asking the FDA to not grant approval, a step above emergency authorization, to any of the COVID-19 vaccines until at least two years of follow-up had been completed.

They also urged regulators to ensure that “substantial evidence of clinical effectiveness that outweighs harms in special populations,” such as infants, pregnant women, and people who have recovered from COVID-19, and conduct an in-depth safety assessment of the spike proteins that the vaccines introduce into the body.

Illegitimate reasons for granting approval include bolstering public confidence and enabling vaccine mandates, according to the coalition.

The FDA responded on the same day that it granted approval to the Pfizer vaccine, saying the petition “does not contain facts demonstrating any reasonable grounds for the requested action.”

Emails that were later disclosed show that the FDA rushed its review of the vaccine because of a desire to enable vaccine mandates and with the hope that approval would lead to more people being vaccinated.