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FDA: Vaccines Don't Have to Prevent Infection or Transmission

COVID VACCINES

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The U.S. Food and Drug Administration in White Oak, Md., on July 20, 2020. (Sarah Silbiger/Getty Images)

Vaccines don't have to prevent infection or transmission to be cleared in the United States, the country's top regulatory agency said in a new document.

"It is important to note that FDA's authorization and licensure standards for vaccines do not require demonstration of the prevention of infection or transmission," Dr. Peter Marks, a top official at the U.S. Food and Drug Administration (FDA), said in the document.

Marks was writing as he rejected nearly all recommendations from a group of experts that advised the FDA to update the labels for the Pfizer and Moderna COVID-19 vaccines.

Vaccines are traditionally known as drugs that prevent an illness. The U.S. Centers for Disease Control and Prevention (CDC) for years said a vaccine is a product that "produces immunity" while vaccination is an injection of an infectious organism "in order to prevent the disease." The agency changed its definitions after people correctly noted that COVID-19 vaccines do not prevent infection.

The Coalition Advocating for Adequately Labeled Medicines, a group of experts, had called for the FDA to make clear that the COVID-19 vaccines don't prevent infection or transmission.

"There is a widespread (but inaccurate) notion that efficacy against infection and transmission have been established by substantial evidence, and that these vaccines contribute to herd immunity," the group said, pointing to claims from President Joe Biden, the head of the CDC, and Dr. Anthony Fauci that vaccinated people would not get sick or infected.

Biden, for instance, falsely said in 2021 that "you're not going to get COVID if you have these vaccinations."

"To remedy this situation, language clarifying that phase III trials were not designed to determine and failed to provide substantial evidence of vaccine efficacy against SARS-CoV-2 transmission or death must be added to labels," the coalition said. SARS-CoV-2 causes COVID-19.

While it's uncommon to include in product labeling what a product has not been proven to do, there are cases where it's necessary due to inaccurate assumptions, the coalition said. They pointed to the FDA stating that the influenza medicine Tamiflu "has not been shown to prevent serious complications of influenza" after the drug's manufacturer said it reduced complications by nearly half.

Marks rejected the request, writing that the petitioners included "selected statements by U.S government officials suggesting that vaccination against COVID-19 may prevent infection or transmission" but omitted statements from Fauci and others that later acknowledged vaccines don't prevent infection or transmission.

"In responding to your Petition, we are not agreeing or disagreeing with any of the statements that are selected in the Petition," Marks said. "Rather, we are observing that the statements referenced by the Petition do not demonstrate a commonly held belief that the clinical trials provided substantial evidence of efficacy against SARS-CoV-2 transmission. We are not convinced that there is any widespread misconception about this."

The head of the CDC, Dr. Rochelle Walensky, is among those maintaining to the present day that the vaccines at one point completely prevented transmission and symptomatic illness.

Trial data showed high efficacy against symptomatic illness but not 100 percent efficacy. Real-world data has shown lower effectiveness. The trials were not designed to measure transmission, the FDA has said in various documents.

Authorization Standards

Marks also said that the FDA can authorize or approve a vaccine even if there's no "demonstration of the prevention of infection of transmission."

"A vaccine can meet the licensure standard if the vaccine's benefits of protecting against disease outweigh the vaccine's risks for the licensed use," he added. "There is no requirement that the vaccine also prevents infection with the pathogen that can cause the disease or transmission of that pathogen to others."

Emergency use authorization (EUA) can be granted "without any evidence that the vaccine prevents infection or transmission," he also said.

EUAs were given to the Pfizer and Moderna COVID-19 vaccines in late 2020 due to a March 2020 declaration by then-Health Secretary Alex Azar under the Public Readiness and Emergency Preparedness (PREP Act) Act. The vaccines were later approved, though the FDA reverted to emergency authorization this month when it switched all existing COVID-19 vaccines from the companies to the updated, unproven bivalent formulations.

Linda Wastila, a professor in the Department of Practice, Sciences, and Health Outcomes Research at the University of Maryland School of Pharmacy, said she was surprised by Marks' assertion.

"I am totally flabbergasted that the FDA responded that proof of prevention of infection and transmission is not necessary for an EUA vaccine," Wastila, who is part of the coalition, told The Epoch Times via email. The comment "makes me wonder if the FDA has ANY standards of safety and efficacy of the EUA vaccines," she added.

Under the PREP Act, an emergency authorization can be given for a product used to diagnose, treat, or prevent a disease or condition when officials conclude that the product "may be effective" in diagnosing, treating, or preventing the disease or condition and "the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product."

That assessment is based on "the totality of scientific evidence available ... including data from adequate and well-controlled clinical trials."

No clinical trial efficacy data has been made public for the bivalent vaccines.

The FDA did not respond to a request for comment. Marks noted that the FDA cleared the vaccines "for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2."

"The vaccines are not licensed or authorized for prevention of infection with the SARS-CoV-2 virus or for prevention of transmission of the virus, nor were the clinical trials supporting the approvals and authorizations designed to assess whether the vaccines prevent infection or transmission of the virus," he said.

Lack of Safety Data

Other proposed changes that were rejected, included making clear that the FDA authorized a new Pfizer vaccine formulation with a different buffer without requiring studies to evaluate the efficacy or safety.

Kim Witczak, founder of Woodymatters and another member of the coalition, criticized the response letter.

"Honest communication and transparency is key to trusting our regulatory agencies. However, the FDA's response to the citizen petition shows they are not really interested in transparency and sharing more information with the public," she told The Epoch Times in an email. "With an experimental rushed product, safety is paramount and the public deserves the good, the bad and ugly in real time."

The FDA only accepted a single proposal. It added some data from a trial to the labeling for the new Pfizer bivalent vaccine.

Before this month, the labels did not include any data from trials, because the FDA authorized the new vaccines as boosters without any trial data.

After the fall 2022 authorizations, Pfizer and Moderna announced that trials showed the bivalent triggered higher levels of neutralizing antibodies than the old vaccines. Antibodies are thought to protect against COVID-19. Pfizer said the data showed a favorable "safety profile" while Moderna said that "no new safety concerns were identified." The coalition said the labeling "should be updated to reflect current data."

While granting authorization for the bivalents as regular shots, the FDA updated the health care provider and recipient fact sheets for Pfizer's bivalent to include the safety data Pfizer announced. But it did not include any immunogenicity data or any data on Moderna's vaccine.

"FDA has not conducted an evaluation of the data that is referenced in the press release," Marks said.

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