Pfizer's 'Fully Approved' Comirnaty Vaccine is Still Not Available in the U.S.

On August 23, 2021, the US Food and Drug Administration (FDA) approved Pfizer's biological licensing application (BLA) for its COVID-19 vaccine named COMIRNATY for people aged 16yrs and older. At the time, vaccine hesitancy was persistent and the acting FDA Commissioner Janet Woodcock said that granting full approval to the vaccine might "instill additional confidence" in people to get vaccinated.

But it backfired, fuelling speculation over why there was no COMIRNATY-labelled vaccine available. Now, eight months have passed, and Americans are still being administered with the Pfizer BioNTech-labelled vaccine, which is under emergency use authorization (EUA). The reasons why remain uncertain, and as I discovered, the explanations offered by various US authorities have only added to the confusion.

Searching for COMIRNATY in the US

Pfizer's information hotline says it has no specific information on when COMIRNATY will be available. The CDC's website states that COMIRNATY is "not orderable." And a branch of the US Department of Health and Human Services (HHS) overseeing the Strategic National Stockpile (SNS), indicated that it was simply because Pfizer did not have time to change the labels. A spokesperson from HHS said, "Given the urgency of vaccinations to protect as many people as possible as quickly as possible, the company continued to ship its vaccine with the EUA label rather than taking valuable time to re-label the vials."

But Pfizer says this is not the case. In a statement, Pfizer said its "COMIRNATY-branded vaccine has been available to ship since late last year." So, what is the truth, and does it even matter what is written on the vaccine's label?

According to the FDA, the BioNTech-labelled vaccine under EUA can be used "as if the doses were the licensed vaccine" because both vaccines have the "same formulation and can be used interchangeably without presenting any safety or effectiveness concerns."

Pfizer said, "in terms of its ingredients and how it is made, the FDA-approved vaccine is no different from the vaccine that has been administered, to date. The EUA and BLA products are manufactured using the same processes, but they may have been manufactured at different sites or using raw materials from different approved suppliers."

Cody Meissner, professor of Paediatrics at Tufts University School of Medicine in Boston and FDA advisory committee member told me the vaccine's label is inconsequential. He said, "The vaccine that people are getting, whether it says COMIRNATY on it or not, is the Pfizer BioNTech vaccine. There's no question in my mind, as far as I know, that there's any difference

whatsoever, I think it's just a semantic difference."

The FDA now appears to have deprioritized the outstanding issue of vaccine labels. In a recently updated EUA guidance document for industry, the FDA deleted the item "how these vaccines will be labeled" from its list of matters it continues to consider.

Is there a legal distinction?

According to the FDA, the two Pfizer COVID-19 vaccines are legally distinct. An FDA spokesperson said, "There are two formulations of the Pfizer-BioNTech COVID-19 vaccine authorized for emergency use for individuals 12 years of age and older, and these same formulations are also approved under the COMIRNATY license for individuals 16 years of age and older."

Peter Meyers, emeritus professor at George Washington University Law School told me the only difference in American law between an EUA or licensed COVID-19 vaccine is that "the statute specifically says that the physician who gives you the vaccination must tell you, that for an emergency use vaccination, that it's optional, discretionary, it's not mandatory that you get it."

This raises debate about whether Americans have been receiving EUA vaccines with informed consent, particularly in the wake of vaccine mandates. "If the government or your employer wants to mandate it, they can do that, according to the most recent and authoritative decision from the Federal Office of Legal Counsel. It doesn't make any difference if it's an emergency use or permanent approval. It's only the person who gives you the vaccine, who must inform you [it's optional]," said Meyers.

He said the EUA and BLA status of the vaccine also does not alter the liability protections afforded to the vaccine

manufacturers for the covid-19 vaccines, with one exception – wilful misconduct.

“If the manufacturer does a large-scale test of the vaccine, finds out that it causes some very serious health problem, and then hides that from the federal government or the FDA, that would be wilful misconduct,” said Meyers.

Brook Jackson, the whistle-blower who provided The BMJ with evidence of falsified data in Pfizer’s pivotal mRNA trial has already filed a lawsuit for false claims against Pfizer (and its trial site operators) alleging they “deliberately withheld crucial information from the United States that calls the safety and efficacy of their vaccine into question” and “concealed violations of both their clinical trial protocol and federal regulations, including falsification of clinical trial documents.”

Vaccine waste

As of May 2, 2022, the CDC website shows approximately 728 million COVID-19 vaccines have been delivered to various states and 576 million of them have been administered to Americans, all EUA-labelled. Therefore, at least 152 million COVID-19 vaccines are sitting in vaccine centres unused, discarded or expired.

Pfizer’s vials have a shelf life of nine months at –90 °C to –60 °C, which suggests that much of the EUA product distributed to various US states would have expired given that the nation’s supply of covid-19 vaccines a year ago, was reported to be 800 million doses.

The FDA can decide to extend the shelf life of the vaccine. According to its website, the agency has already issued several extensions of expiry dates on various COVID vaccines in 2021. Had it not been for these extensions, presumably millions of vials would have gone to waste.

The CDC claims it keeps track of COVID-19 vaccine wastage via its Vaccine Tracking System, but did not respond to questions on how much had been wasted. Also, the HHS could not provide data on the expiry dates or batch numbers of distributed vials, a task that it oversees.

Now, as the demand for COVID-19 vaccines falls among Americans, it's reasonable to expect the wastage will increase. State health departments are tracking millions of wasted doses, including expired vials. One report found that nearly 1.5 million doses in Michigan, 1.45 million in North Carolina, 1 million in Illinois and almost 725,000 doses in Washington could not be used.

Despite persistent investigation, it is still not clear why FDA-approved COMIRNATY-labelled vials are not being distributed and administered to Americans. The organizations charged with manufacturing, approving, coordinating and tracking the vaccines seem to be operating in silos.