

Here's Why No One Can Force You to Take Pfizer's Newly 'Approved' Comirnaty Vaccine

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When the FDA announced full approval of Pfizer's Comirnaty COVID vaccine, the media predicted an avalanche of mandates — but the FDA's own Fact Sheet for the vaccine states it is "your choice to receive or not receive" the vaccine.

On Aug. 23, the U.S. Food and Drug Administration (FDA) issued its [approval](#) (also known as a license) for Pfizer's Comirnaty [COVID](#) vaccine.

The [FDA documents](#) related to the vaccine's approval are as [difficult to understand](#) as the new brand name is to pronounce.

According to the FDA, although [Pfizer's](#) Comirnaty vaccine is now approved, considerable amounts of the vaccine [will remain](#) under Emergency Use Authorization (EUA).

Also, the approval of the Comirnaty vaccine was limited to adults over age 16 receiving their first two doses.

Vaccination with the EUA Pfizer-BioNTech or the Comirnaty vaccine in the 12- to 15-year age group, or providing a third booster dose of either, are still considered an unapproved use — however, those uses remain authorized under EUA.

FDA made some [clear but cagey statements](#) about the differences between the Comirnaty vaccine and the Pfizer-BioNTech EUA vaccine.

For example:

"The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness."

What does that statement mean? What, specifically, are the "certain differences" that make the two vaccines "legally distinct"?

The FDA did not explain this in any of the documents provided last week to the public.

Here's my latest with [@NassMeryl](#)... Buried in fine print of Monday's approval by FDA of Pfizer Comirnaty COVID vaccine are 2 critical facts that affect whether vaccine can be mandated + whether Pfizer can be held liable for injuries. <https://t.co/QtpHufCKDI>

— Robert F. Kennedy Jr (@RobertKennedyJr) [August 25, 2021](#)

Two important facts about EUA drugs and vaccines

We know there are some important differences between EUA drugs and vaccines, and fully licensed drugs or vaccines.

We also know these two facts about EUA products:

1. EUA vaccines are designated as [experimental](#) or investigational products under U.S. law. As such, they [cannot be mandated](#). You have the right to refuse, without suffering consequences.
2. EUA vaccines have a [huge liability shield](#) that protects everyone involved with the product from being sued. If you are injured by an EUA vaccine, the only way to obtain compensation for damages is to apply to the [Countermeasures Injury Compensation Program](#) (CICP), which might cover unpaid medical expenses and lost wages only. However, only 3% of claims made have been compensated, and so far the program has approved [no claims](#) for COVID vaccine injuries.

Some say the CICP, which is run through the U.S. Department of Health and Human Service and does not give petitioners the right to a judge or jury, withholds due process from injured Americans.

Yet this is the only pathway by which an injured party can seek help after receiving an EUA vaccine or drug.

It's right there in the fact sheet — FDA says it's 'your choice'

Legally, in order to mandate a vaccine, the vaccine must be fully approved. However, once a vaccine for use in adults moves from an EUA product to a licensed everyday product, it loses its liability shield.

We believe it is likely the FDA was instructed to find a way to both license the Pfizer vaccine — so mandates would be legally supported — while also retaining the vaccine's liability shield.

The FDA could not find a way to do this under existing law. So instead, as we [reported Aug. 24 in The Defender](#), the agency chose to create confusion regarding the legal status of the two Pfizer-BioNTech vaccines.

In a document we discuss here for the first time — the [fact sheet](#) required to be given to recipients of either the Comirnaty or Pfizer-BioNTech COVID vaccine — the FDA acknowledges the facts we have just presented.

But the FDA also has added something new — the final sentence of the fact sheet states:

“This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.”

According to this fact sheet, the FDA also has designated the licensed Comirnaty vaccine as an EUA product. By doing so, the FDA has guaranteed the Comirnaty vaccine the same liability shield as the EUA Pfizer-BioNTech vaccine.

However, that means the Comirnaty vaccine cannot be mandated. The FDA admits this in the fact sheet, where it states:

“WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

“Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.”

The fact sheet is FDA’s admission, buried in the fine print, that no one can currently be mandated to receive any COVID vaccine in the U.S., as all remain under the EUA.

This fact sheet for vaccine recipients is key to avoid being forced to accept an experimental vaccine.

We suggest you print it out, highlight the relevant passages and present it to anyone who tries to force vaccinations on employees.

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