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Did FDA Really Approve the Pfizer COVID Vaccine? Wait. What?

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The pressure is building. "Take the vaccine."

Many people are looking for a successful way to refuse the COVID vaccine in situations where the shots are mandated. I fully support such efforts.

Some people believe they can make the argument that the FDA didn't actually give full approval to the Pfizer vaccine on August 23rd. Therefore, these people can refuse the vaccine on the grounds that it is still experimental, meaning it has only been granted Emergency Use Authorization.

I'll discuss that practical strategy later in this article.

But first, I need to analyze the claim that the FDA didn't truly approve (license) the Pfizer vaccine.

OK. Here we go.

The first FDA document I'll reference is *"Comirnaty and Pfizer-BioNTech COVID-19 Vaccine,"* dated August 23, 2021. The document opens with this statement:

> "On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals."

"The FDA approved" means full approval. The FDA has fully approved the Pfizer-BioNTech COVID vaccine.

And this vaccine "will now be marketed" as the Comirnaty vaccine.

They are the same vaccine, medically speaking. The ingredients are the same.

The FDA document ALSO says the vaccine will continue to be available under the prior Emergency Use Authorization (EUA), for uses that are not yet fully approved. For example, injecting children 12-15, and as a third dose for certain immunocompromised people.

The full approval and the EUA status are riding together, side by side. The EUA status covers uses of the vaccine not covered under full approval.

The rest of this FDA document offers links. One of the links leads to an FDA news release, dated August 23, titled, *"FDA Approves First COVID-19 Vaccine."* The release states:

> "Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty…"
>
> "To support the FDA's approval decision today, the FDA reviewed updated data from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population."

The FDA, in this news release, is again asserting that the Pfizer vaccine is now approved, and makes a clear distinction between the prior EUA and this new approval.

Next, we move to a letter, also dated August 23, sent from the FDA to BioNTech Manufacturing GmbH, and Pfizer Inc. The letter is marked, *"BLA Approval."* BLA stands for "Biologics License Application." Here are key quotes:

> "Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA."
>
> "We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany…Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA…You may label your product with the proprietary name, COMIRNATY…"

The FDA officially licensed this vaccine. This is approval. It is not merely a continuation of Emergency Use Authorization (EAU).

And now we come to another key FDA document, *a letter sent to Pfizer Inc. on August 23, 2021* (addressed to Ms. Elisa Harkins). It also mentions the full licensure (approval) of the vaccine:

> "On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older."

This letter is further acknowledgement that the vaccine has been fully approved.

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Now we enter the thick weeds of the letter, during a discussion of how Emergency Use

Authorization will continue to be used. The language is very dense. It's taken me a while to separate out the strands.

To help you with what I'm going to untangle, understand that the FDA is making a distinction between what we could call the "old Pfizer vaccine" and the "new Pfizer vaccine." They are identical in their ingredients. They are the same vaccine. But the "old vaccine" vials were granted Emergency Use Authorization (EUA) before the August 23rd FDA full licensure of the vaccine; and the "new vaccine" vials will certainly be used under full licensure (approval).

Splitting hairs? Yes. But in order to understand what the FDA is saying in this letter, you have to grasp the distinction between "the old" and "the new."

The "old" vaccine is labeled "Pfizer-BioNTech COVID-19 vaccine," and the "new" vaccine is labeled "COMIRNATY." Again, they are exactly the same vaccine.

The FDA letter to Pfizer (the one addressed to Ms. Elisa Harkins) states:

> "On August 23, 2021, having concluded that revising this EUA [Emergency Use Authorization for the vaccine] is appropriate to protect the public health or safety…FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses **that are not included in the approved BLA**." [emphasis added]

The "old vaccine" will continue to have EUA status: it can be injected in people 12 and older, and it can be used as a third dose for certain immunocompromised individuals.

The "new vaccine"—which has full FDA approval—CONTINUES TO ALSO HAVE EUA STATUS—and therefore it too can be injected in people 12 and older, and used as a third dose for certain immunocompromised individuals.

Strange? Yes. The "new" and fully approved vaccine retains its former EUA status. It's BOTH fully approved and certified as an emergency experimental product.

I believe the FDA reasoning goes this way: the agency wants to make sure vials carrying the label of the "new" fully approved vaccine can be injected into people to whom the full approval doesn't apply—people between 12 and 15, and certain immunocompromised people, as a third shot. In other words, people covered under EUA status.

If you continue to read this FDA letter, you'll see this reasoning spelled out.

Bottom line, and my conclusion: The FDA has fully approved the "new vaccine" AND it has also retained the Emergency Use Authorization (EUA) for the "new vaccine." Both.

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So what does all this mean for people who want to find a workable reason for refusing the vaccine?

For example, suppose you work for a major corporation or a government agency, and you're

told you must get the shot. You say, “No, I won’t take the shot, because the FDA never approved it. It’s still an experimental medicine, because it only has EUA status.”

I believe you’ll lose. You’ll be told, “The FDA HAS approved it.”

Suppose you take a somewhat different approach. You say, “I’ll need to see the actual vial containing the vaccine you want to inject me with. Is it labeled ‘Pfizer-BioNTech COVID-19 vaccine’ (the ‘old’ vaccine) or ‘COMIRNATY’ (the ‘new’ vaccine)?”

Your boss says, “What difference does it make? Either way, it’s the same vaccine.”

And you say, “Not legally speaking. I understand it may take some time for the new shipments of the COMIRNATY to arrive. I won’t take the Pfizer-BioNTech shot because it only has Emergency Use Status, and therefore it’s an experimental medicine. Under federal law, I have the right to refuse an experimental medicine. I’m invoking that right.”

Will that fly?

I’m giving you non-lawyer opinions here. Understand this.

It’s possible this approach could buy you time. Maybe your boss will suddenly become a bit nervous—he tells you he’s going to talk to his company/agency attorneys, and he’ll get back to you.

Or maybe he threatens to fire you on the spot, and he tells you to hire (and pay through the nose for) a lawyer. You do. Do you think your argument will stand up in court? I don’t. Maybe I’m wrong. I’d like to be wrong about that.

Maybe your lawyer will suggest other approaches. A religious exemption, for example. Or, depending on the circumstances, a medical exemption.

But after reading the FDA documents I’ve cited above, I say that if you think the FDA hasn’t actually approved the vaccine, you’re mistaken.

This country, and other countries, are being split into the vaccinated and the unvaccinated. Communities are dividing. Families are dividing and fracturing. It isn’t a pretty picture.

Here in America, we’re used to living life as usual and believing that coercion isn’t going to come to our front doors. Despite the lockdowns and the mask mandates and the vast financial destruction of the past year, many people still think things are “all right.”

That’s not true.

I support all legal efforts to keep freedom of choice alive. I support the unions that are demanding NO VACCINE MANDATES. I also support those governors who are defending their states against COVID restrictions and vaccine mandates. People who criticize these governors because they aren’t perfect or are partially compromised are barking up the wrong tree. We need all the help we can get.

However, as far I’m concerned, putting all our eggs in the basket of court cases, legal filings, unions, and governors is shortsighted, to say the least.

Freedom always needs more. Freedom needs brave business owners to stay open and

maskless, despite government edicts. Freedom needs parents to keep showing up at school board meetings, to demand an end to COVID restrictions and mandates.

Most of all, freedom needs patriots, in the best sense of the word, to do what people in Europe and Australia are doing: come out in the street in great numbers. Over and over.

Not by the thousands. By the millions.

For as long as it takes.

The enemies of freedom have to feel the heat. They have to see that the people can't be forced beyond a certain point.

Whether we like it or not, whether we know it or not, the day is coming when, not the minority, but the majority of us will know we are living under tyranny.

Not just insanity; tyranny.

We will know it in ways that are undeniable.

Some of us already know it.

We're all living through a test of faith. Each individual; and whatever he/she has faith IN. How deep is that faith? How strong?

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The author of three explosive collections, THE MATRIX REVEALED, EXIT FROM THE MATRIX, and POWER OUTSIDE THE MATRIX, Jon was a candidate for a US Congressional seat in the 29th District of California. He maintains a consulting practice for private clients, the purpose of which is the expansion of personal creative power. Nominated for a Pulitzer Prize, he has worked as an investigative reporter for 30 years, writing articles on politics, medicine, and health for CBS Healthwatch, LA Weekly, Spin Magazine, Stern, and other newspapers and magazines in the US and Europe. Jon has delivered lectures and seminars on global politics, health, logic, and creative power to audiences around the world. You can sign up for his free NoMoreFakeNews emails here or his free OutsideTheRealityMachine emails here.

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