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Pfizer's COVID Shot Granted Full Approval

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STORY AT-A-GLANCE -

- August 23, 2021, the U.S. Food and Drug Administration granted full approval to the COVID-19 mRNA injection developed by Pfizer/BioNTech, sold under the brand name Comirnaty, for use in people aged 16 and older
- Normally, the FDA will hold a formal hearing and allow for public and expert input before a drug is moved from emergency use authorization to full approval but, in this instance, no such hearing was held
- The notion that a "vaccine" that has killed more people in nine months than all other vaccines combined in three decades is considered safe stretches beyond the bounds of credulity and further undermines public trust in the FDA
- The approval is based on six months' worth of data from 44,047 people aged 16 and older. Half of them got the shots and half initially received a placebo. However, in early December 2020, Pfizer unblinded the control group and 93% of controls opted to get the real injection. This means we've had no control group since December 2020 and have nothing to compare the treatment group against
- The FDA's prescribing information for Comirnaty includes the risk of myocarditis and pericarditis, two types of heart inflammation that typically develop within seven days after the second injection

August 23, 2021, the U.S. Food and Drug Administration granted full approval[1] to the COVID-19 mRNA injection developed by Pfizer/BioNTech, sold under the brand name Comirnaty, for use in people aged 16 and older.

It's the fastest approval in history,[2] granted less than four months after Pfizer filed for licensing May 7, 2021.[3] It's also based on just six months' worth of data from 44,047 people aged 16 and older. Half of them got the shots and half initially received a placebo.

However, in the second week of December 2020, Pfizer unblinded the control group and 93% of controls opted to get the real injection[4] rather than remain in the control group for the remainder of the trial, which is slated to continue for another two years.

Pfizer CEO Albert Bourla commented on the FDA's approval, saying it "affirms the efficacy and safety profile of our vaccine," and that he's "hopeful this approval will help increase confidence in our vaccine …"[5]

According to STAT News,[6] public health officials hope the approval "will persuade some people who remain hesitant about the vaccine to get the shot," and will "make it easier for some public and private organizations to require vaccination."

FDA Ditches Public Hearing, Circumventing Established Norms

Normally, the FDA will hold a formal hearing and allow for public and expert input before a drug is moved from emergency use authorization to full approval, but nothing is normal when it comes to COVID.

In this instance, no such hearing was held, and an FDA spokesperson called it unnecessary, because the public had been allowed to comment on all three COVID-19 jabs — Pfizer's, Moderna's and Johnson & Johnson's — during a December 20, 2020, Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting. According to many, that isn't good enough.[7] As reported by The BMJ:[8]

> *"Kim Witczak, a drug safety advocate who serves as a consumer representative on the FDA's Psychopharmacologic Drugs Advisory Committee, said the decision removed an important mechanism for scrutinizing the data.*

'These public meetings are imperative in building trust and confidence especially when the vaccines came to market at lightning speed under emergency use authorization,' she said.

'The public deserves a transparent process, especially as the call for boosters and mandates are rapidly increasing. These meetings offer a platform where questions can be raised, problems tackled, and data scrutinized in advance of an approval.'

Witczak is one of the more than 30 signatories of a citizen petition calling on the FDA to refrain from fully approving any COVID-19 vaccine this year to gather more data. She warned that without a meeting 'we have no idea what the data looks like.'

'It is already concerning that full approval is being based on 6 months' worth of data despite the clinical trials designed for two years,' she said. 'There is no control group after Pfizer offered the product to placebo participants before the trials were completed.

Full approval of covid-19 vaccines must be done in an open public forum for all to see. It could set a precedent of lowered standards for future vaccine approvals.'"

Media Are Lying About Pfizer's FDA Approval

Before we go any further, let's clear up what the FDA actually approved, because they did not approve the Pfizer shot currently given. In the interview above, Dr. Robert Malone, the inventor of the mRNA vaccine platform, explains how we are being misled, yet again.

The injection that got the FDA approval is a Pfizer/BioNTech collaboration, to be sold under the brand name Comirnaty, and this injection is not currently available. Malone explains:

"The little trick that they've done here, is they've issued two separate letters for two separate vaccines. The Pfizer vaccine, which is what is currently available, is still under emergency use authorization and it still has the liability shield. Once again, the mainstream media have lied to you …

The product that's licensed is the BioNTech product, which is substantially similar but not necessarily identical, called Comirnaty, and it's not yet available. They haven't started manufacturing it or labeling it. And that's the one the liability waiver will no longer apply to.

So, the one that's actually licensed is not yet available, and when it does become available it will no longer have the liability shield. In the interim, the one that does have the liability shield is the Pfizer product and that is what is currently available and it's still under emergency use authorization."

What this means is, if you want to get the licensed COVID shot, you have to wait. This also means that if employers demand that employees get vaccinated because there's now a licensed COVID injection, employees should then demand to actually receive the FDA licensed Comirnaty,[9] not the emergency use only[10] Pfizer product that is currently being given.

FDA 'Tricking Us Into Giving Up Our Right to Refuse'

Now, while the two products are not necessarily identical, the FDA in its infinite wisdom has decreed that the two can be used interchangeably, but their legal statuses, however, are not interchangeable. As explained by Robert F. Kennedy Jr. and Dr. Meryl Nass in a recent article:[11]

"There is a huge real-world difference between products approved under EUA compared with those the FDA has fully licensed. EUA products are ***experimental*** *under U.S. law. Both the Nuremberg Code and federal regulations provide that no one can force a human being to participate in this experiment.*

*Under **21 U.S. Code Sec.360bbb-3(e)(1)(A)(ii)(III)**, 'authorization for medical products for use in emergencies,' it is unlawful to deny someone a job or an education because they refuse to be an experimental subject. Instead, potential recipients have an absolute right to refuse EUA vaccines. U.S. laws, however, permit employers and schools to require students and workers to take licensed vaccines.*

*EUA-approved COVID vaccines have an extraordinary liability shield under the **2005 Public Readiness and Preparedness Act**. Vaccine manufacturers, distributors, providers and government planners are immune from liability.*

The only way an injured party can sue is if he or she can prove willful misconduct, and if the U.S. government has also brought an enforcement action against the party for willful misconduct. No such lawsuit has ever succeeded.

*The government has created an extremely stingy compensation program, the **Countermeasures Injury Compensation Program**, to redress injuries from all EUA products …*

At least for the moment, the Pfizer Comirnaty vaccine has no liability shield. Vials of the branded product, which say "Comirnaty" on the label, are subject to the same product liability laws as other U.S. products …

Just as with Ford's exploding Pinto, or Monsanto's herbicide Roundup, people injured by the Comirnaty vaccine could potentially sue for damages. And because adults injured by the vaccine will be able to show that the manufacturer knew of the problems with the product, jury awards could be astronomical.

Pfizer is therefore unlikely to allow any American to take a Comirnaty vaccine until it can somehow arrange immunity for this product.

Given this background, the FDA's acknowledgement in its approval letter that there are insufficient stocks of the licensed Comirnaty, but an abundant supply

of the EUA Pfizer BioNTech jab, exposes the "approval" as a cynical scheme to encourage businesses and schools to impose illegal jab mandates.

The FDA's clear motivation is to enable Pfizer to quickly unload inventories of a vaccine that science and the Vaccine Adverse Events Reporting System have exposed as unreasonably dangerous, and that the Delta variant has rendered obsolete.

Americans, told that the Pfizer COVID vaccine is now licensed, will understandably assume COVID vaccine mandates are lawful. But only EUA-authorized vaccines, for which no one has any real liability, will be available during the next few weeks when many school mandate deadlines occur.

The FDA appears to be purposefully tricking American citizens into giving up their right to refuse an experimental product … Here's what you need to know when somebody orders you to get the vaccine: Ask to see the vial. If it says 'Comirnaty,' it's a licensed product.

*If it says 'Pfizer-BioNTech,' it's an experimental product, and under **21 U.S. Code 360bbb**, you have the right to refuse. If it comes from Moderna or Johnson & Johnson (marketed as Janssen), you have the right to refuse.*

The FDA is playing bait and switch with the American public — but we don't have to play along. If it doesn't say Comirnaty, you have not been offered an approved vaccine."

Approval by Captured Agency Hardly Affirms Safety

While the notion of full approval might sway some fence-sitters, especially if they don't understand that the licensed product is not what you get if you get a Pfizer shot right now, it's unlikely to influence those who have kept an eye on the skyrocketing number of adverse event reports logged into the U.S. Vaccine Adverse Events Reporting System (VAERS).

As of August 13, 2021, VAERS had logged 595,620 adverse events following COVID injection, including 54,142 hospitalizations and 13,608 deaths.[12] While these numbers are completely unheard of — with reported deaths from COVID-19 shots exceeding the reported death rate of more than 70 vaccines combined over the past 30 years — they may still be just the tip of the iceberg.

Previous investigations have shown VAERS reports account for a mere 1%[13,14] to 10%[15] of all vaccine-related injuries, which means the death toll from these jabs may be in the six-digits already.

The notion that a "vaccine" that has killed more people in nine months than all other vaccines combined in three decades is considered safe really stretches the bounds of credulity. It's simply not believable, and to many simply reaffirms the suspicion that the FDA is a captured agency working for the benefit of Big Pharma rather than safeguarding the public from dangerous drugs.

As noted by a commenter on BMJ associate editor Peter Doshi's article "Does the FDA Think These Data Justify the First Full Approval of a COVID-19 Vaccine?" republished by The Defender:[16]

> *"The Fraud and Death Administration has really outdone itself this time. Owned by pharma, serving pharma, to the extreme detriment to humanity. They deserve to be shuttered permanently, they are an organization of criminals."*

Risk of Heart Inflammation Acknowledged

The FDA didn't go so far as to give the Pfizer shot a completely clean bill of health, however. As reported by STAT News:[17]

> *"The FDA's prescribing information for the vaccine includes its associated risk of myocarditis and pericarditis, two types of heart inflammation that have appeared rarely among people who've received the mRNA vaccines, mostly within seven days after the second shot, health officials said. Men under 40*

appear to be at higher risk than women and older men, with the highest observed risk in boys age 12 to 17."

According to the Centers for Disease Control and Prevention, As of August 18, 2021, VAERS had received 1,339 reports of myocarditis or pericarditis in people under the age of 30 following COVID injection, with a majority of these cases being associated with the Pfizer shot.[18]

Pfizer's new Comirnaty package insert[19] also clearly states at the top of its first page under "Warnings and Precautions" that "postmarketing data demonstrate increased risk of myocarditis and pericarditis, particularly within seven days of the second dose."

Then, under Section 5.2 of the insert, Pfizer has added an entire section explaining the details of those adverse effects, and directing readers to a CDC webpage[20] that addresses those effects in adolescents and young adults.

Heart Inflammation Study Won't End Until 2025

In its approval letter for Comirnaty,[21] the FDA orders Pfizer/BioNTech to conduct research to investigate the risk of inflammation in and around the heart, as voluntary reporting mechanisms are insufficient:

"We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies: 4. Study C4591009, entitled 'A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-

> *19 mRNA Vaccine in the United States,' to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY."*

The FDA accepted Pfizer's suggested timetable for the post-approval study to evaluate incidence of heart and heart sack inflammation, which includes the submission of an interim report at the end of October 2023, a study completion date of June 30, 2025, and submission of a final report October 31, 2025.

Modern-Day Child Sacrifice?

The notion that the current Pfizer shot or the BioNTech product, Comirnaty, are "safe" is rather ludicrous in light of all this, and the idea that the FDA is even considering approving the shot for children as young as 12[22] — and are running trials on babies — is completely incomprehensible. Even worse, Fauci is pushing for infant approval by the end of the year.[23]

The myocarditis study for Comirnaty (which may or may not be as dangerous as the current Pfizer shot) won't be completed until four years from now, yet they see it fit to give this experimental injection to every last child in the United States? What are they thinking? Is it really wise to trade the risk of flu-like illness for heart damage? From the start of this pandemic, children have proven very resistant to SARS-CoV-2 infection and rarely ever suffer any significantly ill effects.

As reported by NPR,[24] Pfizer's youth trial, which includes children between the ages of 6 months and 11 years, doesn't even test "to see whether the vaccine actually prevents children from getting sick." Instead of assessing actual symptoms, the trial "will look at their blood to see if they are making the kinds of antibodies that have been shown to prevent disease."

In other words, all they're looking for is the antibody against the synthetic spike protein your body produces. But that antibody is not the best way to assess protection, as the protection is very narrow. Actual viruses contain several different proteins against which your body produces both antibodies and memory T cells when you're infected naturally.

This is why natural immunity is far more robust and long-lasting, and why the claim that vaccine-induced protection is superior to natural immunity is false. In my view, experimenting on children and not even doing a comprehensive job of it is simply unconscionable.

Do Data Justify Full Approval of Pfizer's COVID Jab?

In the morning of August 23, 2021, mere hours before the FDA announced its approval of the Pfizer shot, Doshi published a BMJ blog questioning whether available data could really support full approval. He wrote:[25]

> *"On 28 July 2021, Pfizer and BioNTech posted updated results for their ongoing phase 3 covid-19 vaccine trial. The preprint came almost a year to the day after the historical trial commenced, and nearly four months since the companies announced vaccine efficacy estimates 'up to six months.'*
>
> *But you won't find 10 month follow-up data here. While the preprint is new, the results it contains aren't particularly up to date. In fact, the paper is based on the same data cut-off date (13 March 2021) as the 1 April press release, and its topline efficacy result is identical: 91.3% … vaccine efficacy against symptomatic covid-19 through 'up to six months of follow-up.'*
>
> *The 20 page preprint matters because it represents the most detailed public account of the pivotal trial data Pfizer submitted in pursuit of the world's first 'full approval' of a coronavirus vaccine from the Food and Drug Administration. It deserves careful scrutiny."*

Doshi points out that while Pfizer has touted a 95% efficacy rate, and even higher against severe disease, this refers to relative risk reduction, not absolute risk reduction, which is actually an insignificant 0.7%[26] to 0.84%.[27] Moreover, "measuring vaccine efficacy two months after dosing says little about just how long vaccine-induced immunity will last," Doshi says.

6-Month Preprint Showed Evidence of Waning Immunity

Rapidly waning immunity is the proverbial elephant in the room, according to Doshi, who points to Israeli data showing Pfizer's shot went from a 95% effectiveness at the outset, to 64% in early July 2021 and 39% by late July, when the Delta strain became predominant. "This is very low," Doshi says, pointing out that the FDA's expectation for any vaccine is an efficacy rate of at least 50%.

> **"Waning efficacy has the potential to be far more than a minor inconvenience; it can dramatically change the risk-benefit calculus. ~ Peter Doshi"**

The FDA cannot claim it doesn't know the protection offered is pathetically short, as Pfizer's preprint, which contained six months' worth of data, showed evidence of rapidly waning immunity as early as March 13, 2021.

By the fourth month into the trial, efficacy had dropped from 96% to 90%, and one month after that, it was down to 84%. Curiously, while Pfizer had this data in April 2021, they didn't publish it until the end of July 2021. Still, that's what the FDA is basing its decision on.

What's more, this rapid drop in effectiveness could hardly be due to the emergence of the Delta variant, Doshi adds, because 77% of trial participants were in the U.S., where the Delta variant didn't become established until months after the data cut-off date.

> *"Waning efficacy has the potential to be far more than a minor inconvenience; it can dramatically change the risk-benefit calculus,"* Doshi writes.[28] *"And whatever its cause — intrinsic properties of the vaccine, the circulation of new variants, some combination of the two, or something else — the bottom line is that vaccines need to be effective.*
>
> *Until new clinical trials demonstrate that boosters increase efficacy above 50%, without increasing serious adverse events, it is unclear whether the 2-dose*

series would even meet the FDA's approval standard at six or nine months."

There's NO Control Group in This Mass Experiment

Making matters even worse, Pfizer, like all other COVID jab developers, went ahead and eliminated their control groups at the end of 2020. So, we're figuratively flying blind, having nothing to compare the vaccinated treatment group against.

This is a recipe for disaster, as it effectively hides side effects. If large numbers of people suddenly start developing a health problem, it can simply be written off as a new normal and/or can be blamed on some other environmental factor. Doshi comments on how this decision impacts our ability to evaluate any data coming out of these trials:[29]

"Despite the reference to 'six month safety and efficacy' in the preprint's title, the paper only reports on vaccine efficacy 'up to six months,' but not from six months.

This is not semantics, as it turns out only 7% of trial participants actually reached six months of blinded follow-up ('8% of BNT162b2 recipients and 6% of placebo recipients had ≥6 months follow-up post-dose 2.') …

This all happened because starting last December, Pfizer allowed all trial participants to be formally unblinded, and placebo recipients to get vaccinated. By 13 March 2021 (data cut-off), 93% of trial participants (41,128 of 44,060 …) were unblinded, officially entering 'open-label followup' …

So despite this preprint appearing a year after the trial began, it provides no data on vaccine efficacy past six months, which is the period Israel says vaccine efficacy has dropped to 39%.

It is hard to imagine that the <10% of trial participants who remained blinded at six months (which presumably further dwindled after 13 March 2021) could constitute a reliable or valid sample to produce further findings."

With the approval of Comirnaty, a formal package insert[30] has been released, and in section 6.1, they clearly state they've not had placebo participants since December 2020, not even among teenagers:[31]

> *"Section 6.1 — Upon issuance of the Emergency Use Authorization (December 11, 2020) for COMIRNATY, participants were unblinded to offer placebo participants COMIRNATY. Participants were unblinded in a phased manner over a period of months to offer placebo participants COMIRNATY."*

While a formal package insert now exists for Pfizer's mRNA shot, the Centers for Disease Control and Prevention will not issue Vaccine Information Statements (VIS) for it, but will continue to use online fact sheets. (The use of online fact sheets is why all package inserts for the COVID shots have been completely blank.)

If You're 'Vaccinated' You May Be High-Risk for COVID

As discussed in yesterday's lead article (August 30, 2021), data are now mounting showing people over the age of 50 who are "fully vaccinated" actually make up the bulk of COVID-19 related hospitalizations and deaths in that age group. One possible explanation for this is that antibody dependent enhancement is afoot, which makes people more prone to serious illness rather than less.

To be on the safe side, I recommend considering yourself "high-risk" for severe COVID if you've received one or more shots, and implement known effective treatment at the first sign of a respiratory infection.

Options include the Zelenko protocol,[32] the MATH+ protocols[33] and nebulized hydrogen peroxide, as detailed in Dr. David Brownstein's case paper[34] and Dr. Thomas Levy's free e-book, "**Rapid Virus Recovery**." Whichever treatment protocol you use, make sure you begin treatment as soon as possible, ideally at first onset of symptoms.

Sources and References

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