

Vaccine Expert Explains FDA “Approval” of Comirnaty and Why Vaccine Makers Are Targeting Children

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Alix Mayer, Board President of Children’s Health Defense in California and an award-winning medical journalist, is herself vaccine injured. According to Mayer, the reason Covid vaccine manufacturers are trying to mandate the shot for children is to evade liability for injuries, because once a vaccine is on the childhood vaccination schedule, vaccine makers have immunity against lawsuits for injuries. The COVID shots currently have legal immunity against liability because they’re still under emergency use authorization (EUA). There are four standards required for EUA.

She explains the trickery behind the FDA limited approval of Comirnaty, in which the FDA claimed Comirnaty is interchangeable with the Pfizer shot, in an attempt to license both at the same time under Comirnaty. But a federal judge recently rejected the DoD claim that the two shots are interchangeable. In addition, FDA Biologics License Applications documents say that Comirnaty is really only “ready for approval.”



Link for video: <https://www.bitchute.com/video/JACccDM34JGP/>

STORY AT-A-GLANCE

- The reason our children are being targeted by COVID mandates is because vaccine makers want to get the shots onto the childhood vaccination schedule.
- Once a vaccine is added to the childhood schedule, the vaccine maker is shielded from financial liability for injuries, unless the manufacturer knows about vaccine safety issues and withholds that information.
- Products must satisfy four criteria in order to get emergency use authorization: There must be an emergency; a vaccine must be at least 30% to 50% effective; the known and potential benefits of the product must outweigh the known and potential risks of the product; and there can be no adequate, approved and available alternative treatments (drugs or vaccines). Unless all four criteria are met, EUA cannot be granted or maintained.
- According to a U.S. federal court decision, the Pfizer shot and BioNTech's Comirnaty are not interchangeable.
- Comirnaty is NOT fully approved and licensed. It's only "ready for approval." Comirnaty is licensed to be manufactured, introduced into state commerce, and marketed, but it's not licensed to be given to anyone, and it's not yet available in the United States. They're waiting for it to be added to the childhood vaccination schedule, to get the liability shield.

In this [interview](#), Alix Mayer explains why our children are being so aggressively targeted for the COVID-19 injection even though they're not at risk of serious SARS-CoV-2 infection and clarifies the status of Comirnaty.

Mayer, Board President of Children's Health Defense – California Chapter, is herself vaccine injured; not from the COVID jab, but from a series of vaccines she received 20 years ago. (Incidentally, Mayer grew up in the Oscar Mayer family in the 5th generation descended from the original Oscar Mayer, a German immigrant who started as a butcher boy. Despite Mayer's vaccine injury, her family does not share her views on vaccine safety issues.)

Mayer graduated from Duke University with a BA and from Northwestern University with an MBA in finance and management strategy. She worked for Apple in the mid-1990s. When she was 29, Apple promoted her to acting manager of worldwide customer research.

In preparation for a family trip to Bali, her doctor recommended getting six vaccines: hepatitis A vaccine, hepatitis B vaccine, diphtheria, tetanus, polio, and oral typhoid, which she did. Eventually, 13 years later, she finally realized it was these shots that triggered her health problems.

"They gave me brain damage and total disability," Mayer says. "I spent three years in my early 30s being 80% housebound, and I really I didn't know if I was ever going to get better."

I went through a whole bunch of diagnoses: lupus, chronic fatigue syndrome, Lyme disease . Ultimately, none of those made sense and none of the treatments made me any better, until we put the pieces together and figured out that I was actually vaccine injured.

It's literally just a cause and effect. If you look back at my history and lay out my vaccine schedule, you can see that my health declined two weeks after I got the vaccines.

I had encephalitis and encephalopathy ... digestive issues, hypersomnia – sleeping 16 hours a day – flu-like symptoms, a 24/7 migraine, joint pain. I really had no life at all in my early 30s until I went on a gluten-free diet. That started my health recovery.

I then became an award-winning medical journalist with a bunch of different blogs, and then a health consultant. In 2018, I retired from all that and joined Children's Health Defense”.

The COVID Jab Tragedy



While many vaccines have a questionable safety profile, especially when combined, data from the Vaccine Adverse Events Reporting System (VAERS) suggest there's never been a vaccine as dangerous as the experimental mRNA gene transfer injections for COVID.

What's more, while lack of transparency and accountability has been a chronic problem within the vaccine industry, the obvious hazards associated with vaccines are really being highlighted by the COVID jabs.

Many now know of someone who has been injured by the COVID jab, and most were injured so shortly after the shot that it's hard to deny a correlation. The staggering number of injuries reported among adults who have received the COVID shot in turn highlights the insanity of rolling it out to young children.

According to Mayer, the reason they're trying to mandate the COVID shot for children is to evade liability for injuries, because once a vaccine is on the childhood vaccination schedule, vaccine makers have immunity against lawsuits for injuries.

Vaccine Makers Want Zero Liability



Vaccine Liability Shield

The COVID shots currently have legal immunity against liability because they're still under emergency use authorization (EUA). If you think BioNTech's Comirnaty has been fully licensed, you'd be mistaken. Mayer explains:

"I put together a slide deck about Emergency Use Authorization (which you can see in the video interview above) because there is so much confusion over this and what's really going on. Once you understand the genesis of EUA and the standards they have to meet in order to keep these products on the market, then you understand the behaviors [we're now seeing]."

They're falling all over themselves to protect the EUAs for these products and also introduce other very confusing kinds of approval to get away with stuff. So, let me just start to clarify it right now.

This presentation is all about these three strangleholds that the vaccine makers and our government are never going to let go of ... These are the things they're guarding with their lives.

First of all, they need to guard the emergency ... so they cannot have any early treatments. Those cannot exist. They're also going for full liability protection, and children will be used as pawns to get them full liability protection.

Vaccine makers love EUA products because they have this huge liability shield. If you're injured by an EUA vaccine, you can't sue the manufacturer, you can't sue the person who gave it to you, you can't sue the institution where you got the shot.

*You must go through something called the **CICP**, the Countermeasures Injury Compensation Program, where they'll only cover unpaid medical expenses, and probably only for pharmaceuticals and lost wages.*

Now, if you're vaccine injured, let me tell you right now, you are not going to be using pharmaceuticals because they do not work for vaccine injury. They will make you sicker. You'll be on two dozen pharmaceuticals before you know it and you're going to be sick from those. They do not work. The only thing that's going to get you better if you're vaccine injured is natural treatments ...

That's the kind of treatment you're going to need, and that's not even covered, even if you were to get compensation. Everybody I know with chronic illness, whether it's a

child or an adult who has chronic fatigue syndrome, vaccine injury, Lyme disease, they're paying \$50,000 out of pocket per year.

If you can't work and you have to pay for your treatment out of pocket, I don't know how you ever get by. People suffer like crazy; they lose homes, they go into bankruptcy."

Since its inception, the Vaccine Injury Compensation Program (VICP), which pays for injuries caused by vaccines on the childhood vaccination schedule, has paid out about one-third of claims. It's a long, arduous process that oftentimes takes years and, in the end, rarely provides adequate compensation.

"If you do end up getting compensation ... they don't pay it out in one lump sum, they pay it out year by year, and they pretty much hope that whoever is injured is actually going to die of their injuries before they get compensated.

That's been said to me a bunch of times by people who've been through this horrible process. Now, the VICP has only compensated 3% of claims. And so far, there have been no approvals for [compensation] for COVID shot injuries," Mayer says. [Editor's note: The first COVID case was recently determined "eligible" for compensation, but the case has not yet been adjudicated.]

Stages of Liability: EUA

In her slide show, Mayer reviews each of the stages of product liability, and whether the mRNA shots can be mandated. As mentioned, vaccine makers have no liability as long as their product is under EUA, as the product is investigational.

"Investigational is a synonym for experimental," Mayer says. "And the word experimental ties it directly into the Nuremberg Code, which says that we cannot be experimented on [without consent]. We always have the right to accept or refuse a medical treatment.

[The Nuremberg Code] is not a law, but it's a code under which the whole world is supposed to be operating by. It is actually codified into some local and federal laws as well ... So, what everybody needs to know is that coercion and duress are considered de facto mandates and illegal. De facto means that it's basically the same as an outright mandate.

It's illegal medical segregation, medical apartheid [because that is a form of coercion or duress.] So, if you go to a restaurant and they demand your vaccine passport, only let you eat outside, and they might not let you use the bathroom, that's medical segregation.

That is illegal and I do not support businesses that do that, and you shouldn't either. Any access privileges that are different between the vaccinated and unvaccinated are illegal, and any visual indication of vaccine status like a sticker or a bracelet ... that's also illegal because that creates segregation and medical apartheid, [since they are all forms of coercion or duress.]"

Importantly, mass violation of the law does not make something legal.

"If we all drove 100 miles an hour on Interstate 80, would we watch the speed limit

signs suddenly changed to 100 miles per hour? No, it's not going to happen. Mass violation of the law has never made anything legal. And just because schools and businesses and our government are mandating these shots, it doesn't make it legal. It's all illegal.

Now, they know full well that it's illegal to mandate these [COVID shots]. President Biden knows it's illegal. But what they're counting on is that the court cases overturning their illegal mandates will take a while, and in that interim, people are going to be scared enough to get the shots. And unfortunately, it's worked".

Stages of Liability: Full Licensure and Childhood Scheduling

The next stage is full licensure (FDA approval). Once a product is fully licensed, the company becomes liable for injuries. At that point, the product can be legally mandated. Of course, knowing how dangerous the COVID shots are, no manufacturer wants to be financially liable for injuries. They'd be sued out of business.



This is the holy grail if you're a manufacturer of a COVID vaccine right now. You want it to be fully licensed, but not put on the market until you get it on the children's schedule. ~ Alix Mayer

To get immunity against liability again, the vaccine manufacturers need to get their product onto the childhood vaccination schedule. This will also allow government to mandate the shots. As noted by Mayer:

DOJ Redefines Medical 'Consequence'

In Doe v. Rumsfeld, the court held that service members could refuse an EUA product without punitive consequences such as dishonorable discharge or other punishments. Therefore, there were no consequences to refusing an EUA product, other than the natural consequence of possibly getting the disease.

However, in July 2021, the U.S. Department of Justice attempted to redefine the term "consequences" just for the COVID shot, to suggest that punitive consequences, like job loss or being separated from your working or learning location, are legal when a person refuses an EUA vaccine.

"But this type of consequence, a punitive consequence, has never been adjudicated," Mayer says. "That's not in any law. This is just an opinion from the DOJ. And it absolutely means nothing, except it came from our DOJ, so people give it a lot of authority.

They also stated twice – and this is so hard to understand because it's just beyond reason – that the right to accept or refuse an EUA product is 'purely informational.'

Literally, you can read that you could die by taking it, but it's purely informational. You cannot act on it. That's what the DOJ says. Again, it's not adjudicated, so it

doesn't mean anything. It's an opinion. It holds no legal weight at all. So, as we said before, these mandates are starting to be overturned".

Four Standards for EUA

There are four standards that must be fulfilled for an EUA. If any of these criteria are not met, EUA cannot be granted or maintained.

- 1. The secretary of Health and Human Services has to declare and maintain a state of emergency. If the emergency were to go away, all EUA products would have to come off the market. And that doesn't just mean vaccines. It also includes the PCR tests and even surgical masks. As of Dec. 29, articles began to appear showing the PCR tests are being*
- 2. Evidence of effectiveness. Historically, vaccines had to show a 70% or greater effectiveness, as measured by a fourfold increase in antibody levels, to qualify. For an EUA vaccine, the efficacy threshold is only 30% to 50%. In another departure from prior vaccine approvals, the COVID vaccine clinical trials relied on the RT-PCR test, not antibodies, to demonstrate effectiveness in the small "challenge phase" of the trials.*
- 3. The known and potential benefits of the product must outweigh the known and potential risks of the product. In the case of COVID shots, there's overwhelming evidence showing they do more harm than good.*
- 4. The last standard that must be met is there can be no adequate, approved, and available alternative treatments (drugs or vaccines). "This is why hydroxychloroquine and ivermectin were quashed," Mayer says. This is also another reason Comirnaty is not treated as a fully approved product in the U.S., because if it were, then all the other COVID shots that are under EUA would have to be removed from the market.*

Now, you probably heard that the Pfizer shot was 95% effective when it first rolled out, but that was relative risk reduction, not absolute risk reduction. Confounding these two parameters is a common strategy used to make a product sound far better than it actually is. The absolute risk reduction for Pfizer's shot was just 0.84%.³

For example, if a study divided people into two groups of 1,000 and two people in the group who didn't get a fictional vaccine got infected, while only one in the vaccinated group got infected, the relative risk reduction would be reported as 100%. In terms of absolute risk reduction, the fictional vaccine only prevented 1 in 1,000 from getting the infection – a very poor absolute risk reduction.

The take-home message here is that even though the minimal threshold for effectiveness is ludicrously low, in terms of absolute risk reduction, these shots still don't measure up. Within six months, even the relative risk reduction bottoms out at zero. What's more, there's evidence that the clinical trials were manipulated as well.

"I remember an analysis very early in lockdowns [that showed] if you added back all the probable cases of COVID to the clinical trial [data], the effectiveness went from 90% to between 19% and 29%",⁴ Mayer says.

"This is a four-legged stool", Mayer says. "If any one of these legs goes away, you have to take your EUA products off the market ... by law. I put [state of] emergency and [treatment] alternatives in red, because those are two of the things that they have a stranglehold on; those are things they are guarding like crazy.

This means that every variant that comes out, they must make it sound super scary to keep the emergency going. So, the variants serve a purpose. You have to think about these variants in the context of this crime, where they have to keep the emergency going to keep their products on the market.

You would think this emergency would stop maybe when we get to herd immunity, maybe if we get 90% vaccination uptake, maybe COVID is just going to go away, like smallpox did in the early 1900s [even though] only 5% of people were vaccinated . [But it won't] go away [until] the shots get full approval, and the manufacturers get a full liability shield".

Comirnaty's Quasi Approval

With regard to Comirnaty, is it or is it not fully approved and licensed? The answer is more complex than a simple yes or no. Mayer explains:

"Comirnaty's quasi approval is just for BioNTech. It doesn't have to do with Pfizer, and this is why I'm doing this presentation because I'm going to explain what's going on with that.

This is the race to get liability protection. Remember, that's the other stranglehold that they want. They really want to get this liability protection. Once the COVID shots are fully approved, the manufacturer has full liability.

There's all this confusion about Comirnaty. Was it fully approved? Is it on the market? Is it interchangeable with the Pfizer shot? And does it make the COVID shot mandate legal? It's all the same answer. NO, No, no!

According to infectious diseases pharmacist Bryan Alexander of PharmD, In terms of what is contained inside the vial of each they are identical. Pfizer and BioNTech simply formally "branded" or named their vaccine Comirnaty. Read the full article [here](#).

BioNTech is the German biotechnology company that partnered with Pfizer in bringing this COVID-19 vaccine to market.

"Pfizer Comirnaty" and "Pfizer BioNTech COVID-19 vaccine" are biologically and chemically the same thing. In a [joint media statement](#) released by Pfizer and BioNTech on Dec. 21, 2020, the companies explained, "The vaccine will be marketed in the EU under the brand name COMIRNATY, which represents a combination of the terms COVID-19, mRNA, community and immunity, to highlight the first authorization of a messenger RNA (mRNA) vaccine..." Marketed in the EU because if approved in the US, it would open the company up to law suites.

The FDA issued an intentionally confusing biological license application approval for

Comirnaty. It was an unprecedented approval to both license the Comirnaty shot, saying it's 'interchangeable' with the Pfizer shot. But they also said it's 'legally distinct'.

In that same approval, they retain the vaccine's liability shield by designating it EUA as well. They want it to be fully approved, but they want the liability protection, so they did this BS dual approval.

So, [Comirnaty] is licensed to be manufactured, introduced into state commerce, and marketed, but it's not licensed to be given to anyone, and it's not available in the United States. It's available in the U.K., New Zealand, and other places, but it is not available in the United States because they're really scared of liability.

Now, are you ready for this one? The BLA actually states that Comirnaty is only 'ready for approval.'⁵ It doesn't say it's approved anywhere in the document. And they buried this language in a pediatric section to confuse people even more.

Here's what they said, 'We're deferring submission of your pediatric studies for ages younger than 16. For this application, because this product is ready for approval for use in individuals 16 years of age and older, as pediatric studies for younger ages have not been completed'.

Why did they do this? Sixteen is a very important number. You would think the age break would be 18. That's a very typical age break for everything else that we do in this country. Why 16?

The reason they did 16 is because 16- and 17-year-olds are still on the children's vaccination schedule. And then the manufacturer gets full liability protection. That's why this is ready to be approved for 16 and up, not 18 and up".

Comirnaty Is Not Fully Licensed

This confusion is clearly intentional. On the one hand, the FDA claims Comirnaty is interchangeable with the Pfizer shot, yet it's also legally distinct. Courts have had to weigh in on the matter, and a federal judge recently rejected the DoD claim that the two shots are interchangeable. They're not interchangeable. That means Comirnaty vaccine is still EUA. It does not have full approval and it's not on the market.

"Military members involved in lawsuits are challenging the military's COVID vaccine mandate. They filed an amended complaint seeking a new injunction after the judge last month rejected the assertion that the Pfizer COVID shot and BioNTech's Comirnaty are interchangeable. So, we're still hammering on this legally, but a court has ruled that they are not interchangeable".

[Editor's note: This information is accurate at the time of the interview, but legal challenges are ongoing, and courts may issue new rulings. December 22, 2021, the U.S. Supreme Court announced⁶ it has slated January 7, 2022, to hear arguments challenging Biden's vaccine and testing mandates.] Read the case notes [here](#).

So, how do we know that Comirnaty is not being treated as fully approved?

1. First, the approval states you have the right to accept or refuse the

product. That means it's an EUA.

2. it's not available in the U.S. because Comirnaty does not have liability protection.
3. If it were available, it's an alternative [treatment] and all other EUA shots would have to come off the market.
4. The CDC Advisory Committee on Immunization Practices (ACIP) would have to recommend it for ages 16 to 18 and the CDC would have added it to the children's recommended schedule. That's how we know it's not fully approved and on the market.

Here is the label for Comirnaty. It says it's emergency use authorization. It doesn't say it's fully approved because it's not. But look at the safety information; they are recognizing myocarditis and pericarditis have occurred in some people who've received the vaccine, more commonly in males under 40 years of age than among females and older males.

So, this is saying that young men are getting heart inflammation. And what we know from all the anecdotal reports is 300 athletes have died or collapsed on the field, and children in schools have died of heart attacks. That's what's going on here.

And the reason they have to declare this is because they know it. They know it's happening. And the only way they can be sued is if they know there's a problem with their vaccine and they don't declare it. So, they declare it here, in very mild language as if it's not that big of a deal, but it's a very big deal. Young people are dying [from the shots] who have a 99.9973% chance of recovering from COVID!

DID YOU KNOW...

- ✓ Children have **minuscule risk** of severe COVID-19 with a recovery rate of 99.9973%
- ✓ US Government reports **18,461 deaths + 875,653 adverse reactions** from the shot as of 11.5
- ✓ An estimated **8% of US population** (including kids) is at **risk of anaphylactic shock** to COVID-19 vaccines with polyethylene glycol (PEG)
- ✓ **Alarming rates of myocarditis/pericarditis** (heart inflammation) is occurring in adolescents post-injection (similar to heart attack)

DON'T BE COERCED. IT CAN'T BE REVERSED.

Children's Health Defense

KIDS ARE NOT FOR SALE

The holy grail is to get the shot on the CDC recommended schedule for children, because then it gets full liability protection according to the 1986 Act. This is why they're going after our children when they have a 99.9973% recovery rate [from Covid.]

Every medical intervention has a risk benefit equation, and it doesn't calculate for kids at all. They should never be getting COVID shots. The shots don't prevent transmission. They don't prevent cases. They don't prevent hospitalization or death".



How you can help

Children's Health Defense has sued the FDA over the approval of Comirnaty, alleging that this is a "bait and switch" to convince people they are receiving a licensed vaccine, when in fact they are getting an EUA vaccine that cannot be lawfully mandated. Unfortunately, these kinds of legal cases can take a long time, and children are being needlessly harmed while we wait for legal clarification.

They also have a couple dozen other legal cases underway. If you want to help, please sign up to become a member on childrenshealthdefense.org. It's only \$10 for a lifetime membership.

"That really helps us with standing in our legal cases, because the more people we represent, the stronger our cases are," Mayer says. If you're in California, you can join the local chapter at ca.childrenshealthdefense.org. You can also help by purchasing Robert F. Kennedy Jr.'s book "[The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health](#)."

Read source article here:

<https://prepareforchange.net/2022/01/02/the-quazi-approval-of-comiranty-interview-with-a-lix-mayer-and-dr-mercola/>