

2 Things Mainstream Media Didn't Tell You About FDA's Approval of Pfizer Vaccine

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Buried in the fine print of Monday's approval by the U.S. Food and Drug Administration of the Pfizer Comirnaty COVID vaccine are two critical facts that affect whether the vaccine can be mandated, and whether Pfizer can be held liable for injuries.

by [Robert F. Kennedy, Jr. & Meryl Nass, M.D., *The Defender*](#)

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Monday, the U.S. Food and Drug Administration (FDA) [approved](#) a [biologics license application](#) for the Pfizer Comirnaty vaccine.

The press [reported](#) that [vaccine mandates](#) are now legal for military, healthcare workers, college students and employees in many industries. New York City Mayor Bill de Blasio has now [required](#) the vaccine for all teachers and school staff. The [Pentagon](#) is proceeding with its [mandate](#) for all military service members.

But there are several bizarre aspects to the FDA approval that will prove confusing to those not familiar with the pervasiveness of the FDA's regulatory capture, or the depths of the agency's cynicism.

First, the FDA acknowledges that while [Pfizer](#) has insufficient stocks of the newly licensed Comirnaty vaccine available,

there is “a significant amount” of the Pfizer-BioNTech COVID vaccine – produced under [Emergency Use Authorization](#) (EUA) – available for use.

The FDA [decrees](#) that the Pfizer-BioNTech vaccine under the EUA should remain unlicensed but can be used “interchangeably” ([page 2, footnote 8](#)) with the newly licensed Comirnaty product.

Second, the FDA pointed out that both the licensed Pfizer Comirnaty vaccine, and the existing vaccine are “legally distinct,” but proclaims that their differences do not “impact safety or effectiveness.”

There is a huge real-world difference between products under an EUA compared with those that 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-licensed 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.

The program's parsimonious administrators have compensated [under 4% of petitioners](#) to date – and not a single COVID vaccine injury – despite the fact that physicians, families and injured vaccine recipients have reported more than [600,000 COVID vaccine injuries](#).

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.

When the Centers for Disease Control and Prevention's (CDC) Advisory Committee for Immunization Practices places a vaccine on the mandatory schedule, a childhood vaccine benefits from an generous retinue of liability protections.

But licensed adult vaccines, including the new Comirnaty, do not enjoy any liability shield. 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.

While the media has trumpeted that the FDA has approved COVID vaccines, the FDA has not approved the Pfizer BioNTech vaccines, nor any COVID vaccines for the 12- to 15-year age group, nor any [booster doses](#) for anyone.

And FDA has not licensed any [Moderna](#) vaccine, nor any vaccine from [Johnson & Johnson](#) – so the vast majority of vaccines available in the U.S., if not all, remain unlicensed EUA products.

Here's what you need to know when somebody orders 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.

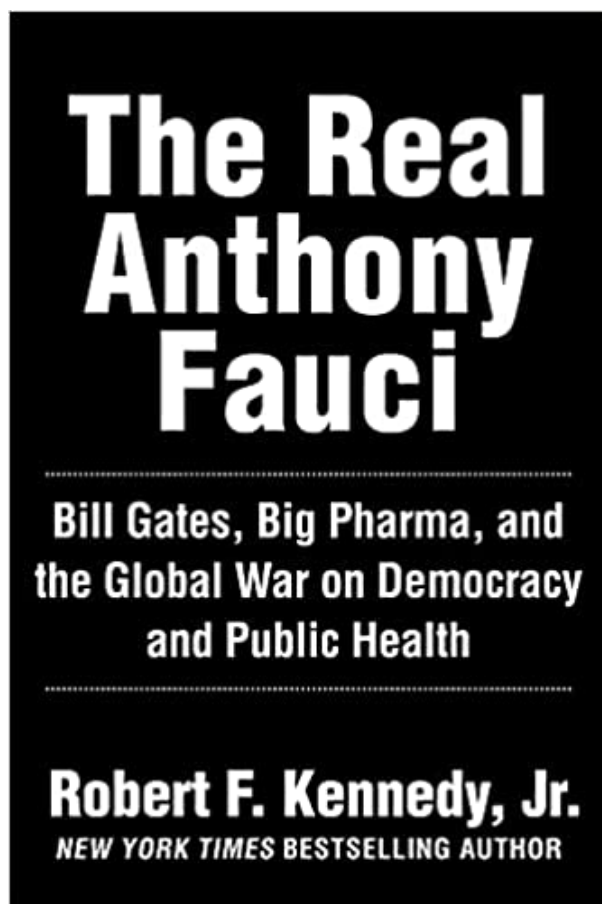
If it comes from Moderna or Johnson & Johnson (marketed as Janssen), you have the right to refuse.

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.

reputation as a resolute defender of the environment stems from a litany of successful legal actions.

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[The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health](#)

by [Robert F. Kennedy, Jr.](#)

[Now available for preorder.](#)

When the director of the National Institute of Allergy and Infectious Diseases (NIAID) since November 1984 and the leading architect of “agency capture”—the corporate seizure of America’s public health agencies by the pharmaceutical industry—happen to be the same man, conflicts of interest arise. Wearing both hats, Dr. Anthony Stephen Fauci, tasked with managing the COVID-19 pandemic in the US, peddled and back-pedaled his prescriptions as Pharma profits and bureaucratic powers grew and public health waned.

Working in tandem with his long-term partner, billionaire Bill Gates, to corral Americans toward a single vaccine solution to COVID, Dr. Fauci committed zero dollars to studying or promoting early treatment with various drug combinations that could dramatically reduce deaths and hospitalizations. Meanwhile, in an assault on our First Amendment guarantee of free speech, Dr. Fauci’s Silicon Valley and media allies dutifully censored criticism of his policies on mainstream social media and collaborated to muzzle any medical information about therapies and treatments that might end the pandemic and compete with vaccines.

After effectively abolishing the First Amendment right to free speech, Dr. Fauci subverted our Seventh Amendment rights to jury trials by arranging to shield reckless and negligent pharmaceutical corporations from liability for injuries from any COVID countermeasures, including vaccines. His lockdowns targeted First Amendment religious freedom by closing churches—while keeping liquor stores open as “essential businesses”—and abolishing century-old religious exemptions to vaccination. Dr. Fauci’s enforced quarantine trampled the Constitutional rights of assembly, of association, and to petition the government, and our Fifth Amendment protection against uncompensated taking of private property. His arbitrary mask and lockdown diktats, without public hearings or rulemaking, strangled our Fourth

and Fourteenth Amendment due process guarantees. His tracking and tracing initiatives bulldozed Constitutional rights to privacy and travel, and our Fourth Amendment protections against warrantless searches and seizures.

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