Children's Health Defense™

NOTICE FOR EMPLOYERS, UNIVERSITIES AND OTHER INSTITUTIONS MANDATING COVID-19 VACCINES

August 31, 2021

This serves as notice that the requirement for any individual to be vaccinated against COVID-19 for employment or participation at a university or other institution violates federal law. The COVID-19 vaccines manufactured by Moderna and J&J are merely authorized, not approved or licensed, by the federal government; they are Emergency Use Authorization (EUA) only. They merely "may be effective."

Federal law 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) requires that the person to whom an EUA vaccine is administered be advised, "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." The reason for the right of refusal stems from the fact that EUA products are by definition experimental. Even if the FDA approves and licenses existing COVID vaccines, they will remain experimental and thus subject to the international requirement that informed consent is "absolutely essential." Nuremberg Code, Article 1; *Abdullahi v Pfizer, Inc.*, 562 F3d 163 [2d Cir 2009]. Phase III clinical trials for the Pfizer vaccine do not end until May 2, 2023[1]; and for the Moderna vaccine until October 27, 2022.[2]

EUA products are by definition experimental and thus require the right to refuse. Under the Nuremberg Code, the foundation of ethical medicine, no one may be coerced to participate in a medical experiment. Consent of the individual is "absolutely essential." A federal court held that the U.S. military could not mandate EUA vaccines to soldiers. Doe #1 v. Rumsfeld, 297 F.Supp.2d 119 (2003). The court held: "...the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." Id. at 135. No court has ever upheld a mandate for an EUA vaccine.

1 Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals - Full Text View - ClinicalTrials.gov

2 A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19 - Full Text View - ClinicalTrials.gov

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The U.S. Food and Drug Administration (FDA) approved a biologics license application for the Pfizer Comirnaty vaccine. However, there is a huge real-world difference between products approved under EUA compared with those the FDA has fully licensed.

- All existing Pfizer vials (in the hundreds of millions), remain under the federal Emergency Use Authorization (EUA) (meaning people have the "option to accept or refuse");
- The third or "booster" Pfizer shot is identical to the above and remains under the EUA with limited use to certain categories of people;
- BioNTech received FDA approval for people ages 16 and above under the name Comirnaty, but there are no Comirnaty doses available in the United States;
- In other words, there is currently NO FDA approved COVID-19 injection available anywhere in the United States. Every COVID shot in America remains under the EUA law and thus people have the "option to accept or refuse" them; and
- Even when an FDA approved COVID shot becomes available, individuals are protected by federal law and many states laws from being forced to get these shots based on their sincere religious beliefs or conscience rights.

The Pfizer injection is still considered experimental under U.S. law. There is a legal difference between products approved under authorization of emergency use (EAU) compared with those the FDA has fully licensed. The FDA issued another letter for the existing Pfizer shots which confirms they are still under EUA, are not fully approved, and has a liability shield. That means people must be told the risks and benefits, and they have the right to decline a medication that is not fully licensed.

It is typical for vaccines to be in clinical trials for 6-10 years before licensure[3]; COVID vaccines have been in trials for a matter of months. We simply do not have long-term safety data, and the short-term data indicate alarming injury and death rates, unprecedented for any other licensed vaccine. 4,406 deaths and 21,537 serious injuries have been reported after COVID vaccination to the Vaccine Adverse Event Reporting System (VAERS) between December 14, 2020 and May 21, 2021.[4]

COVID vaccines will remain de facto experimental for many years; courts may well require the right of refusal, as for Emergency Use Authorization vaccines, in work and education contexts

[3] Biopharmaceutical Research & Development:The Process Behind New Medicines; Available at: http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf
[4] The Vaccine Adverse Event Reporting System (VAERS) Request

because of this underlying reality. But even if courts were not to find these vaccines experimental, they would still have the duty to look at any vaccine mandate policy's necessity, proportionality, reasonableness, harm avoidance and non-discrimination based on the U.S. Supreme Court's landmark decision *Jacobson v Massachusetts*, 197 US 11 [1905]. There is reason to believe that some courts would find COVID vaccine mandates inconsistent with Jacobson.

The liability for forced participation in a medical experiment, including injury or death, may be incalculable. Medical and religious exemptions will be insufficient to overcome the illegality of EUA vaccine mandates. Children's Health Defense urges U.S. employers, universities and other institutions to respect and uphold the rights of individuals to refuse EUA COVID-19 vaccines.