May 25, 2021

Push back against Mandatory COVID-19 vaccinations! Here is information based on publicly available sources – that you can use to write a letter or with which to seek the assistance of legal counsel:

1) There are No Licensed COVID-19 Vaccines in the U.S presently[1]. All COVID-19 vaccines are currently approved only as Emergency Use Authorized (EUAs) only - and "approval" does not mean "licensed."[2]

    a. All COVID-19 vaccines currently available are **mRNA** vaccines.[3]
        i. What is an mRNA vaccine?[4]
        ii. According to the CDC, contain "mRNA vaccines have strands of genetic material called mRNA inside a special coating. That coating protects the mRNA from enzymes in the body that would otherwise break it down. It also helps the mRNA enter the dendritic cells and macrophages in the lymph node near the vaccination site." https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html

    b. All COVID-19 Vaccines are currently *only* approved as Emergency USE Authorizations (EUAs).

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[1] "There are currently no licensed mRNA vaccines in the United States." https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html.

[2] The most updated list of licensed vaccines in the U.S. is at FDA.gov. https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

[3] Moderna "The vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication." *See FDA letter 2/25/01 to Moderna granting "Emergency Use Authorization (EUA)".*

Pfizer Bio-NTech Covid-19 vaccine: "The vaccine contains a nucleocide-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication." *See FDA letter 2/25/01 to Pfizer Bio-NTech granting "Emergency Use Authorization (EUA)."*

Janssen Biotech, Inc. "The vaccine contains a recombinant, replication-incompetent human adenovirus serotype 26 (AD26) vector, encoding the SARS-CoV-2 viral spike (S) glycoprotein, stabilized in its pre-fusion form. It is an investigational vaccine not licensed for any indication." *See FDA letter 2/27/01 to Janssen Biotech, Inc. granting "Emergency Use Authorization (EUA)."*

[4] **mRNA Vaccines Are New, But Not Unknown** There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying them for decades. https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html

i. What is an Emergency Use Authorization? "Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives."[5]

c. There has never been, nor is there currently, a licensed mRNA vaccine in the United States[6].

2) There are No Long-Term Studies supporting Safety and Efficacy of EUA COVID-19 vaccines.

a. Long-term side effects, severe or minor, are unknown because there are no PRIOR approved mRNA vaccines in the U.S.

b. In 2020 the University of Pennsylvania did a mRNA Review, which can be summed up with this excerpt from the Review, that addresses the lack of sufficient data on mRNA vaccines in 2020, supporting the fact that all of the reliable data for both short-term and long-term trends will be based on the population who is now getting the COVID-19 vaccines[7]. This is the largest known experiment on Americans.

While there is not sufficient data to statistically test these observations, a few trends are seen in the data. First, the rate of adverse events and the rate of serious adverse events were higher after a subject's second injection compared to the first one. Second, subjects receiving higher doses of the vaccine reported more adverse events and more severe adverse events. There is a possible trend towards a reduced rate of adverse events in older subjects than in younger ones. ***There is not sufficient data to permit any conclusions about the comparative safety of specific vaccines.*** *While one study reported on mRNA influenza vaccines and another reported on a respiratory syncytial virus vaccine, there is not sufficient evidence to draw more generalized comparisons of the safety of mRNA vaccines compared to other types of vaccines.*

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[5] https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

[6] **mRNA Vaccines Are New, But Not Unknown** There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying them for decades. https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html

[7] ADVERSE EFFECTS OF MESSENGER RNA VACCINES An Evidence Review from the Penn Medicine Center for Evidence-based, Practice December 2020, director Nikhil K. Mull, MD (CEP) Lead analyst: Matthew D. Mitchell, PhD (CEP)Clinical review Patrick J. Brennan, MD. (CMO)http://www.uphs.upenn.edu/cep/COVID/mRNA%20vaccine%20review%20final.pdf at p.11, *Primary Studies*.

3) Your Option to Refuse is based on Federal law over EUAs[8]. No one has the right to mandate an EUA approved vaccine.

   a. Your Right to Informed Consent[9] is separate from the Option to Refuse, and is also based on Federal law over EUAs.

   b. The most recent relevant court decision in relation to an injunction application on an Emergency Authorized Vaccine (EUA) vaccine was *Doe v. Rumsfeld*, Civil Action No. 03-707, 2005 U.S. Dist. LEXIS 5573, *2-3, 2005 WL 1124589, where the United States District Court for the District of Columbia required that the EUA anthrax vaccine be only administered in the military on a voluntary basis "pursuant to the terms of a lawful emergency use authorization ("EUA") pursuant

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[8] According to the Section 564 of the Federal Food, Drug, and Cosmetic Act, a lawful application of the terms of a lawful emergency use authorization ("EUA") pursuant includes (e)(1)(A)(i)(III):

> (III) 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.

21 USCS § 360bbb-3
https://www.law.cornell.edu/uscode/text/21/360bbb-3

[9] (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown.

21 USCS § 360bbb-3
https://www.law.cornell.edu/uscode/text/21/360bbb-3

See also the FDA's guidance on the right to informed consent and the option to refuse:

How will vaccine recipients be informed about the benefits and risks of any vaccine that receives an EUA?

FDA must ensure that recipients of the vaccine under an EUA are informed, to the extent practicable given the applicable circumstances, that FDA has authorized the emergency use of the vaccine, **of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine,** and of any available alternatives to the product. Typically, this information is communicated in a patient "fact sheet." The FDA posts these fact sheets on our website.

https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

to section 564 of the Federal Food, Drug, and Cosmetic Act." This decision, as the earlier decision in *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 also found the EUA could not be mandated; recognizing the *option to refuse* under federal law governing EUAs.

c. <u>There is Potential Liability on Employers or Universities</u> that Mandate Vaccines if an Employee or Student suffers any Side Effects or Death from a mandatory EUA vaccine.

i. It is a violation of your privacy rights to be forced to declare whether you have been vaccinated or not. When a Virtue Hunter seeks this information, remind them of privacy rights of your own medical information, also known as PHI and PII[10]

ii. Ask about all updates on safety because you have the right to informed consent. For example, the CDC has recently put out information in April of 2021on reports of Myocarditis following mRNA vaccines.[11]

iii. And most recently, Luc Montagnier, a French virologist and recipient of the 2008 Nobel Prize in Medicine for his discovery of the human immunodeficiency virus (HIV), has recently exposed the dangers of the COVID-19 vaccines. Montagnier discussed the issue in an interview with Pierre Barnérias of Hold-Up Media earlier this month, which was exclusively translated from French into English for RAIR Foundation USA. The vaccines don't stop the virus, argues the prominent virologist, they do the opposite - they "feed the virus," and facilitate its development into stronger and more transmittable variants. These new virus variants will be more resistant to vaccination and may cause more health implications than their "original" versions.[12]

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[10] PHI is an acronym of Protected Health Information, while PII is an acronym of Personally Identifiable Information -- while you can always waive your privacy rights, you have the right to determine your own release of private medical information. https://www.hipaajournal.com/what-is-considered-phi/

[11] On May 17, 2021, the CDC stated: The VaST session on May 17, 2021, included several presentations on myocarditis following mRNA vaccines, from the Department of Defense (DoD), the Vaccine Adverse Event Reporting System (VAERS), and Vaccine Safety Datalink (VSD). There were also brief updates from the Veteran's Administration (VA) and the Clinical Immunization Safety Assessment (CISA) groups about their plans for future investigation of myocarditis. COVID-19 VaST Work Group Technical Report – May 17, 2021. https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR2-muRM3tB3uBdbTrmKwH1NdaBx6PpZo2kxotNwkUXlnbZXCwSRP2OmqsI

[12] Nobel Prize Winner Warns Vaccines Facilitate Development of Deadlier COVID Variants, Urges Public to Reject Jabs, by Veronika Kyrylenko, The New American, May 20, 2021: https://thenewamerican.com/french-nobel-prize-winner-warns-vaccines-facilitate-development-of-deadlier-covid-variants-urges-the-public-to-reject-jabs/

iv. On April 20, 2021 OSHA issued guidance this week that says, "If you require your employees to be vaccinated as a condition of employment (i.e., for work-related reasons), then any adverse reaction to the COVID-19 vaccine is work-related. The adverse reaction is recordable if it is a new case under 29 CFR 1904.6 and meets one or more of the general recording criteria in 29 CFR 1904.7."

v. Now, however, due to Administration virtue signaling, the language from OSHA appears to have been updated to state:
Are adverse reactions to the COVID-19 vaccine recordable on the OSHA recordkeeping log?
DOL and OSHA, as well as other federal agencies, are working diligently to encourage COVID-19 vaccinations. OSHA does not wish to have any appearance of discouraging workers from receiving COVID-19 vaccination, and also does not wish to disincentivize employers' vaccination efforts. As a result, OSHA will not enforce 29 CFR 1904's recording requirements to require any employers to record worker side effects from COVID-19 vaccination through May 2022. We will reevaluate the agency's position at that time to determine the best course of action moving forward.

vi. Are they arbitrarily changing the law - to fit virtue signaling…? The question would then become, can an agency change enforcement of a regulation without following the APA and putting out notice of a rule change?

vii. Does your employer or university want to find out what the lack of informed consent or making available the option to refuse or the mandated disclosure of private health information means in civil litigation when there is injury after mandating a EUA vaccine, or in worker's compensation court depending on the coverage?

d. Preliminary Research from the National Institutes of Health shows Immunity for those of who have had COVID-19.

i. No studies yet exist on the long-term impact on someone getting an EUA COVID-19 Vaccine who has had COVID-19.

ii. CDC appears to ignore research such as the NIH study in early 2021[13] ,[14] which is based on more recent research than the authorizations that the EUA approvals were based on for the current EUAs, when the CDC issued its guidance on recommended vaccinations. Preliminary Research shows those who have had Covid-19 do have T-cells that protect them from reinfection, which is greater than the six months some were led to believe.

Despite this, the CDC recommends vaccination "Even if you have already recovered from COVID-19, it is possible-although rare-that you could be infected with the virus that causes COVID-19 again..."[15]
And it appears the CDC is ignoring its own medical definition of immunity: "Immunity: Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."[16] - which obviously indicates that you are immune when you have already been infected.

iii. Children under 16 show 0 risk of infection or getting symptomatic from COVID-19.[17]
iv. And this is without getting to the question of currently available treatment options for COVID-19 and whether there is still a basis for an EUA.[18]

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[13] CD8+ T cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants - PubMed
https://na01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F33594378%2F&data=04%7C01%7C%7Cf496c029c7a546320c2508d8f90cf35b%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637533181300658523%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=daj%2FesDTdKPA8V669M48HmIOBTkXVmFrGKu5pqJZAZE%3D&reserved=0

[14] *Lasting immunity found after recovery from COVID-19*, National Institutes of Health, January 26, 2021
https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19?fbclid=IwAR0NvW6PWXlK4xIf7yTulxhYagh6qAaSL4cZbVCJXmjuON-q4Lsz6A9Wa24

[15] Frequently Asked Questions about COVID-19 Vaccination, "If I have already had COVID-19 and recovered, do I still need to get vaccinated with a COVID-19 vaccination?
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

[16] CDC, Definition of Terms https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm#:~:text=Definition%20of%20Terms,-Let's%20start%20by&text=Vaccine%3A%20A%20product%20that%20stimulates,or%20sprayed%20into%20the%20nose.

[17] See the Petition for a Temporary Restraining Order filed this week in the U.S. District Court for the Northern District of Alabama by America's FrontLine Doctors, 2:21-cv-00702, CLM.
[18] https://finance.yahoo.com/news/hydroxychloroquine-90-percent-chance-helping-155637974.html