UPDATED 08/09/2021

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:

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]

Once FDA approves the Covid Vaccine, track your Jab, record any concerns, gather evidence, and consider to hire an attorney to sue Big Pharma if you get sick. FDA approval will cause emergency status (EUA) to end, and at this point the government no longer protects the vaccine manufacturers from liability.

1. COVID-19 vaccines currently available, are **mRNA** vaccines.[3]
    1. What is an mRNA vaccine?[4]
    2. 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
    3. The Janssen Biotech, Inc, slightly different in using the viral vector to shuttle gene encoding, delivers 'S Antigen DNA'… "The viral vector shuttles the gene encoding the S antigen into a human cell."[5]
    4. And "the Oxford-AstraZeneca vaccine is based on the virus's genetic instructions for building the spike protein. But unlike the Pfizer-BioNTech and Moderna vaccines, which store the instructions in single-stranded RNA, the Oxford vaccine uses double-stranded DNA."[6]
2. All COVID-19 Vaccines are currently *only* approved as Emergency USE Authorizations (EUAs).
    1. 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."[7]
3. It has been made clear that not only is there a first for mRNA technology – there is also a first for the Lipid Nanoparticles used to transport the mRNA technology:"The vaccines, appropriately celebrated as a first for mRNA technology, are also a milestone for the nanoparticle field…" — meaning this is an unknown experiment. The article explains that historically this research has not been successful.

    And this first in science, which is a true experiment, is also one that is not transparent: "But details on how Moderna arrived at its optimal formulation in the first place are scant. Id.[8].

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

1. Long-term side effects, severe or minor, are unknown because there are no PRIOR approved mRNA vaccines in the U.S.
2. 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[9]. 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.*

Your Option to Refuse is based on Federal law over EUAs[10]. No one has the right to mandate an EUA approved vaccine.

1. Your Right to Informed Consent[11] is separate from the Option to Refuse, and is also based on Federal law over EUAs.
2. 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 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.
3. To be clear, the EEOC's guidance updated on May 28, 2021, related to language suggesting that vaccines may be "**required**" by employers, only states that "***federal EEO laws*** *do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated*…"[12] This is called a word game or word salad.
4. This is a limited statement **which does not include other federal law**, specifically 21 USCS § 360bbb-3 under the Food Drug and Safety Act, discussed above, which requires that EUA's are administered with the option to refuse and the right to informed consent, which requires both the benefits and the negatives of an EUA vaccine.
5. EEOC guidance relates to Title VII and discrimination laws, which for example does not relate to other potential lawsuits, such as under the ERISA statute at 29 U.S.C. 1132(a)(1(b) for arbitrary and capricious health plans mandating vaccines. Deciding that you choose a COVID-19 vaccine is a medical question to made with your doctor — not because of a mandate from an employer.
6. EEOC guidance recognizes that you may have a religious or medical exemption. Religious exemption, for example, can apply to those who oppose abortion based on their faith because the Johnson & Johnson vaccine, (the Jansen vaccine), uses retinal cells from a fetus that was aborted in 1985 and treated in a lab since; the Pfizer and Moderna vaccines test the mRNAs on fetal cell lines from an aborted fetus from 1973[13].

7. There is Potential Liability on Employers or Universities that Mandate Vaccines if an Employee or Student suffers any Side Effects or Death from a mandatory EUA vaccine.
    1. 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[14]
    2. 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.[15] On June 23, 2021 the CDC updated guidance recognizing that "Since April 2021, there have been more than a thousand reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (i.e., Pfizer-BioNTech, Moderna) in the United States." https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html.
    3. Despite this, the CDC recommends vaccination?? This is a serious condition and the question of whether the vaccine is appropriate for you, should be a discussion with your doctor, not your employer.
    4. Safety and Efficacy is based on a Cost Benefit analysis, but at the peak, March 16, 2020, CFR (Case Fatality Ratio) was highest in people aged 85 years or older (range 10%–27%), and was lower in people younger than 55 years (**<1%**).[16a]
    5. 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.[16b]
    6. On April 20, 2021 OSHA issued guidance 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."
    7. More recently, 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.*

8. 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?
9. Does your employer or university want to find out what the lack of informed consent from a mandate making available the option to refuse or the mandated disclosure of private health information means in civil litigation? Or when there is injury after mandating a EUA vaccine, or in worker's compensation court depending on the coverage?

8. Preliminary Research from the National Institutes of Health shows Immunity for those of who have had COVID-19.
    1. No studies yet exist on the long-term impact on someone getting an EUA COVID-19 Vaccine who has had COVID-19. **And there are reports of people with serious adverse reactions.[17]**
    2. CDC appears to ignore research such as the NIH study in early 2021[18] ,[19] 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…"[20]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."[21] – which obviously indicates that you are immune when you have already been infected.There are no long-term studies on what adverse events can happen to someone who already had COVID-19 and gets the vaccine.
    3. Children under 16 show 0 risk of infection or getting symptomatic from COVID-19.[22] In *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 188-189, (2nd Cir. 2009), the court, under the Alien Tort Statute, protected Nigerian children from an experimental vaccine that Pfizer was using on them without Informed Consent.
    4. And this is without getting to the question of currently available treatment options for COVID-19 and whether there is still an Emergency basis to authorize EUAs like the COVID-19 Vaccines. Hydroxychloroquine Has about 90 Percent Chance of Helping COVID-19 Patients, States Association of American Physicians and Surgeons (AAPS), April 28, 2020[23].
    5. "The Association of American Physicians and Surgeons (AAPS) presents a frequently updated table of studies that report results of treating COVID-19 with the anti-malaria drugs chloroquine (CQ) and hydroxychloroquine (HCQ, Plaquenil®)."[24]
    6. "A five-day course of ivermectin for the treatment of COVID-19 may reduce the duration of illness," by the National Library of Medicine, pub.med.gov,[25]
    7. The FDA reached a milestone of approving 1,000 original and supplemental generic drug applications to help in the treatment of patients with COVID-19 since the start of the pandemic. The Center for Drug Evaluation and Research prioritized the review of generic drug applications for potential treatments and supportive therapies for patients with COVID-19, such as antibiotics, sedatives used in ventilated patients, anticoagulants, and pulmonary medications.[26]

[1] "There are currently no licensed mRNA vaccines in the United States." https://www.covidhealth.com/article/understanding-explaining-mrna-covid19-vaccines

[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)."*

[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

[5] Janssen Biotech, Inc." https://www.janssencovid19vaccine.com/hcp/how-its-designed.html

… "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)."*

[6] https://www.nytimes.com/interactive/2020/health/oxford-astrazeneca-covid-19-vaccine.html

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

[8] 'Over more than 3 decades, promising lipids studied in the lab often failed to live up to their potential when tested in animals or humans. Positively charged lipids are inherently toxic, and companies struggled for years before landing on formulations that were safe and effective. When injected intravenously, the particles invariably accumulated in the liver, and delivery to other organs is still an obstacle. Reliably manufacturing consistent LNPs was another challenge, and producing the raw materials needed to make the particles is a limiting factor in the production of COVID-19 vaccines today.'

Without these lipid shells, there would be no mRNA vaccines for COVID-19, by Ryan Cross, Chemical & Engineering News, March 6, 2021. https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8

[9] 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*.

[10] 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

[11] (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

[12] "The federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID-19, subject to the

reasonable accommodation provisions of Title VII and the ADA and other EEO considerations discussed below. These principles apply if an employee gets the vaccine in the community or from the employer." https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

[13] Fetal Cell Lines Were Used to Make the Johnson & Johnson COVID Vaccine—Here's What That Means

3/4/2021, MSN.com, https://www.msn.com/en-us/health/medical/fetal-cell-lines-were-used-to-make-the-johnson-and-johnson-covid-vaccine%E2%80%94heres-what-that-means/ar-BB1efi8p

[14] 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/

[15] 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

[16a] https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html#print (citing f.n. 39.)

[16b] 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/

[17] Exclusive: Athlete Who Recovered From COVID Facing 'Very Different Future' After Second Dose of Pfizer Vaccine Triggers Myocarditis, by Megan Redshaw, 06/21/21, the Defender, Children's Health Defense https://childrenshealthdefense.org/defender/greyson-follmer-pfizer-vaccine-myocarditis/?utm_source=salsa&eType=EmailBlastContent&eId=faf15c81-fc5a-4174-bb39-70c908f37be8

[18] 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%2FesDTdKPA8V669M48HmlOBTkXVmFrGKu5pqJZAZE%3D&reserved=0

[19] *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

[20] 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

[21] 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.

[22] 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.

[23] https://finance.yahoo.com/news/hydroxychloroquine-90-percent-chance-helping-155637974.html

[24] https://finance.yahoo.com/news/hydroxychloroquine-90-percent-chance-helping-155637974.html

[25] https://pubmed.ncbi.nlm.nih.gov/33278625/

[26] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021