

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

Updated: July 25, 2022

This letter serves as notice that the requirement for any individual to be vaccinated or boosted against COVID-19 for employment or participation at a university or other institution violates federal law.

Federal law 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) requires that the person to whom an Emergency Use Authorization (EUA) vaccine is administered must 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." In fact, both the FDA and CDC reflect upon the statutory prohibition from mandating that an individual receive a product that has only been granted EUA. Specifically, "[f]or an unapproved product, the statute requires that FDA ensure that recipients are informed ... that they have the option to accept or refuse the EUA product." (Emphasis added)¹ The reason for the right of refusal stems from the fact that EUA products are by definition experimental.

Emergency Use Authorization (EUA) of COVID-19 Vaccines. In December 2020, the Food and Drug Administration (FDA) granted EUA for two COVID-19 vaccines, Moderna and Pfizer and in February 2021, granted EUA for a third COVID-19 vaccine sold by Janssen (aka Johnson & Johnson). All 3 vaccines were rapidly developed in less than a year and rushed to market, bypassing the usual clinical development rules and regulations required to ensure safety and efficacy, thus making them "experimental." In fact, Phase III clinical trials are ongoing: the Pfizer trials are scheduled to end until May 2, 2023²; and the Moderna trials will continue until

¹ FDA's Emergency Use Authorization of Medical Products and Related Authorities – Guidance for Industry and Other Stakeholders available at https://www.fda.gov/media/97321/download; COVID-19 Vaccine EUA Recipient/Caregiver Fact Sheets | CDC

²Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals - Full Text View - ClinicalTrials.gov

October 27, 2022.³ Despite the standard practice for all human research that requires clinical ethics committees and safety monitoring boards throughout the process, here there are none.

Typically, vaccine clinical trials require a 6–10-year process before FDA approval for licensure is granted,⁴ however, these COVID-19 vaccines have been in trials for only a matter of months. Although the long-term risks and complications remain unknown, it is abundantly clear even in the short term that the risks of COVID-19 vaccination outweigh any purported benefit.⁵ In fact, the FDA has acknowledged that the existing data show "known serious risks of myocarditis"—a potentially fatal heart condition—from the COVID vaccines,⁶ and the Centers for Disease Preventions and Control (CDC)'s own data show that there has been an increased risk of myocarditis, especially in young males following COVID-19 vaccination.⁷ Myocarditis is a serious heart condition, and far from a minor inconvenience.⁸ In a peer-reviewed scientific article publish on June 25, 2022, researchers confirmed, "The largest associations are observed for myocarditis following mRNA-technology vaccination in persons aged 18 to 24 years. Estimates of excess cases attributable to vaccination also reveal a substantial burden of both myocarditis and pericarditis across other age groups and in both males and females." And in an unprecedented response to an 80% increase in athletes who have died suddenly over the past year with no prior history of heart disease, the European Society of Cardiology issued

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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

⁴ Biopharmaceutical Research & Development: The Process Behind New Medicines; Available at: http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf

⁵ Myocarditis following mRNA Covid-19 vaccination: A pooled analysis - PMC (nih.gov); See <u>COVID-19 and</u> All-Cause Mortality Data by Age Group Reveals Risk of COVID Vaccine-Induced Fatality is Equal to or Greater than the Risk of a COVID death for all Age Groups Under 80 Years Old as of 6 February 2022, independent analysis by Kathy Dopp, MS and Stephanie Seneff, PhD.

⁶ FDA, Letter to Pfizer Inc., Aug. 23, 2021, p. 6.

⁷ CDC Awardee COVID-19 Vaccination Planning Meeting; Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination | Clinical Infectious Diseases | Oxford Academic (oup.com); Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods | medRxiv. See also Children's Hospital at the University of Washington's Report on their findings of 35 cases of myocarditis in children within one week after receiving the second dose of the Pfizer mRNA vaccine; FDA briefing document for VRBAC meeting on Moderna's EUA request for use of COVID-19 vaccine in children 6 months through 17 years of age, at pp. 19-20 (discussing 26 studies showing vaccine increases risk of myocarditis/pericarditis in young males) 178-179 (acknowledging risks).

⁸ Katie A. Sharff, et al., Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large integrated Health System: A Comparison of Completeness and Timeliness of two Methods, medRxiv 2021.12.21268209; DOI: https://doi.org/10.1101/2021.12.21.21268209; Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods | medRxiv See also Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines | Nature Communications

⁹ Le Vu, S., Bertrand, M., Jabagi, MJ. *et al.* Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines. *Nat Commun* **13**, 3633 (2022); <u>Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines | Nature Communications https://doi.org/10.1038/s41467-022-31401-5</u>

recommendations on June 17, 2022, to prevent and monitor sudden cardiac death in athletes.¹⁰ In short, these problems are not going away anytime soon.¹¹

COVID-19 vaccines pose a significant threat to an individual's health. To date, the CDC's VAERS data released on July 15, 2022, show 1,350,950 reports of adverse events from all age groups following COVID-19 vaccines, including 29,635 deaths and 246,676 serious injuries between December 14, 2020, and July 1, 2022. Of the 29,273 reported deaths, 19,150 cases are attributed to Pfizer's COVID-19 vaccine, 7,850 cases to Moderna, and 2,577 cases to Johnson & Johnson (J&J). Of the total 13,705 reported deaths in the U.S. as of July 15th, 7% occurred within 24 hours of vaccination, 15% occurred within 48 hours of vaccination, and 54% occurred in people who experienced an onset of symptoms within 48 hours of vaccination. Notably, it is well documented that fewer than 1% of all adverse events are ever reported to the CDC's VAERS, which means that the number of those individuals who have been injured or have died is even greater.¹²

To date, there is no FDA approved COVID-19 vaccine, just a bait and switch to confuse unsuspecting Americans. Although the FDA has recently approved the Pfizer and Moderna COVID-19 vaccines under the brand names Comirnaty and Spikevax respectively, both the FDA and the CDC confirm that neither vaccine is currently available for use in the United States.¹³ The current lack of availability of the approved vaccines is significant because individuals still have a legal right to either accept or refuse the "experimental" vaccine under the EUA, including the ability to claim an exemption. This means that if these FDA fully licensed and approved vaccines were currently available, these manufacturers and *those mandating the COVID-19 vaccines and boosters* would be immediately stripped of their liability shield granted to them under the EUA¹⁴ could be held legally responsible under the same product liability laws as other U.S. products for any injuries or deaths caused by their product.¹⁵

Further, regardless of whether these COVD-19 vaccines are licensed or not, they cannot be mandated under Title VII. In essence, employee vaccine religious exemption requests must be accommodated where a reasonable accommodation exists without due hardship to the

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¹⁰ Silvia Castelletti, et al., "Indication and utility of cardia genetic testing in athletes," 16 June 2022, European Journal of Preventative Cardiology DOI: 10/1093/eurjpc/zwac080; <u>Up to 80% of athletes who die suddenly had no EurekAlert! 5-fold increase in sudden cardiac and unexplained deaths among FIFA athletes in 2021 – America's Frontline Doctors (americasfrontlinedoctors.org)</u>

¹² See Search Results from the VAERS Database (medalerts.org);

Harvard-Vaccine-Injury-Study-Page-6-Reveals-1-Percent-Rate Substack); Electronic Support for Public Health-Vaccine Adverse Event Reporting System (ESP:VAERS) (ahrq.gov)

¹³ <u>FDA letter no SpikeVax available.pdf</u> (see page 7, footnote 11.); <u>IIS COVID-19 Vaccine Related Code | CDC (archive.ph)</u>; <u>IIS COVID-19 Vaccine Related Code | CDC (archive.ph)</u> <u>Moderna COVID-19 Vaccine Health Care Provider Fact Sheet (fda.gov)</u>

¹⁴ 2 Things Mainstream Media Didn't Tell You About FDA's Approval of Pfizer Vaccine • Children's Health Defense (childrenshealthdefense.org)

¹⁵ Investigational New Drug (IND) Application | FDA

employer.¹⁶ Many individuals who hold sincere religious beliefs against receiving the COVID-19 vaccine are entitled to seek a religious exemption under the law. Any policy denying unvaccinated individuals the opportunity to seek a religious or medical exemption is illegal.¹⁷

Title VII of the Civil Rights Act of 1964 (Title VII) prohibits discrimination based on religion. Title VII provides that "[i]t shall be an unlawful employment practice for an employer ... to fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's race, color, religion, sex, or national origin." [emphasis added]. Under Title VII, employers have a legal duty to provide exemptions and accommodations for those individuals who raise objections to receiving employer-mandated vaccines based upon sincerely held religious beliefs, practices, or observances. Specifically, an employer is prohibited against religious discrimination in employment and cannot "limit, segregate, or classify" "in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his [or her] status as an employee."19 These protections apply regardless of whether the religious beliefs or practices in question are traditional, organized, or uncommon as the term "religion" is broadly defined for purposes of Title VI.²⁰ Refusal to offer religious exemptions to individuals is a direct violation of federal law. Indeed, any organization that intentionally deprives individuals of their fundamental First Amendment Right to Religious Freedom and is deliberate discrimination.

Mandating "experimental" vaccines is a direct violation of the Nuremberg Code. At this point, any employer or college/university that continues to mandate "experimental" COVID-19 vaccines and boosters for its employees, students, or applicants, will constitute a clear and egregious violation of the Nuremberg Code. Specifically, the Nuremberg Code, a universal legal norm and the foundation of ethical medicine, prohibits the "human experimentation" of any kind of medical procedure deemed to be "experimental" whereby the recipients are classified as "human subjects." Furthermore, the Nuremberg Code categorically requires the voluntary informed consent of all participants "without the intervention of any element of force, fraud, deceit, or duress." This means that every individual has the right under the Nuremberg Code to refuse the experimental COVID-19 vaccine without coercion, especially since the scientific evidence clearly shows that healthy individuals are not at an elevated risk of serious illness or death should they become infected with COVID-19. Understand that any

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¹⁶ Title VII and Employee Rights | Justia

¹⁷ Questions and Answers: Religious Discrimination in the Workplace | U.S. Equal Employment Opportunity Commission (eeoc.gov); see also States With Religious and Philosophical Exemptions From School Immunization Requirements (ncsl.org)

¹⁸ 42 U.S.C. § 2000e 2(a)(1).

¹⁹ 42 U.S.C. § 2000e-2(a)(1), (2).

²⁰ Burwell v. Hobby Lobby, Inc., 573 U.S. 682, 725 (2014); See also Church of Lukumi Babalu Aye., Inc. v. City of Hialeah, 508 U.S. 520, 531. (1993).

²¹ Emergency Use of an Investigational Drug or Biologic | FDA

²² Nuremberg Code, Article 1; *Abdullahi v Pfizer, Inc.*, 562 F3d 163 [2d Cir 2009]. <u>Nuremberg Code - history - Office of NIH History and Stetten Museum</u>

²³ Nuremberg Code - history - Office of NIH History and Stetten Museum; Covid-19 — Navigating the Uncharted (nejm.org)

violation of the Nuremberg Code constitutes a "crime against humanity." The liability for forced participation in a medical experiment, not to mention liability for injury from such coerced medical intervention, may be incalculable. Medical and religious exemptions will be insufficient to overcome the illegality of EUA vaccine mandates.

The COVID-19 vaccine does not prevent infection with or transmission of COVID-19 and increases susceptibility to the other variants. The health and safety for all members of your community must be paramount, yet the intended goal of preventing outbreaks of COVID-19 is outdated and unattainable.²⁴ As recent as July 13, 2022, Dr. Fauci admitted in a televised interview that "COVID-19 vaccines . . . don't protect overly well . . . against infection "25 Even the CDC has admitted on its own website that people who have been vaccinated may contract and spread COVID-19 to others and has gone even further to say, "[v]accine breakthrough infections are expected."²⁶ (Emphasis added). In other words, any impression that vaccinated individuals cannot contract or spread COVID-19 is false because they can and do spread the virus. Moreover, over time, COVID-19 vaccination appears to *increase* the risk of contracting other variants, rendering healthy individuals whose vaccinations are up to date *more* likely to spread the virus.²⁷ Thus, since there is no basis in science or public health for mandating COVID-19 vaccine boosters, Children's Health Defense legal team strongly urges U.S. employers, colleges/universities, and other institutions to do the right thing by dropping its discriminatory COVID-19 booster mandate, and respect the rights of individuals to refuse the experimental EUA COVID-19 vaccines and boosters.

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²⁴ Vaccine Breakthrough Infections: The Possibility of Getting COVID-19 after Getting Vaccinated (cdc.gov)

²⁵ Fauci admits that COVID-19 vaccines do not protect 'overly well' against infection | Fox News

²⁶ Vaccine Breakthrough Infections: The Possibility of Getting COVID-19 after Getting Vaccinated (cdc.gov)

²⁷ BMJ 2022;377:01506; Covid-19: Omicron sub variants driving new wave of infections in UK | The BMJ