Employer/School Name

Manager/Supervisor/Superintendent/Principal

Address

NOTICE

RE: COVID19 Vaccine Mandate

Dear, _____

I am writing in regard to the COVID19 Mandate. I understand that you intend to require vaccination to all students/employees. As I am sure you are aware, the COVID19 vaccines are presently authorized under emergency use authorization ("EUA")

It is a violation of Federal Law to mandate receipt of a product that is only available pursuant to an EUA. Employer Name or School cannot require employees/students to receive a COVID19 vaccine that is being distributed under an EUA.

Emergency Use Authorization of COVID-19 Vaccines

In December 2020, the FDA granted EUA for two COVID-19 vaccines, one sold by Moderna and the other by Pfizer. Both are based on an RNA technology never before used in a licensed vaccine. In February 2021, the FDA granted EUA for a third COVID-19 vaccine sold by Janssen. This is a novel viral vector vaccine platform. The clinical trials that the FDA will rely upon to decide whether to license these vaccines are underway, but they are far from complete.

The EUA applications for these experimental vaccines were based on data which supports that these products may reduce certain symptoms of COVID-19 for some individuals, but the FDA's EUA authorizations made clear that there is no evidence the COVID-19 vaccines can prevent recipients from becoming infected with and transmitting the virus.

1 As the FDA explains, at the time of the EUA approval, the data was "not available to make a determination about how long the vaccine will provide protection, **nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 [i.e., the virus that causes COVID-19] from person to person."**

2 In fact, the FDA Briefing Documents for the COVID-19 vaccines supporting the grant of an EUA list the following as still unknown:

- "[e]ffectiveness in certain populations at high-risk of severe COVID-19,"
- "[e]ffectiveness in individuals previously infected with SARS-CoV-2,"

- "effectiveness against asymptomatic infection,"
- "effectiveness against long-term effect of COVID-19 disease,"
- "effectiveness against mortality," and
- "effectiveness against transmission of SARS-CoV-2."3

The FDA Briefing Documents also make clear much is **unknown** about the safety of these products, including,

- "[a]dverse reactions that are very uncommon,"
- adverse reactions "that require longer follow-up to be detected," and
- whether the vaccines will cause "[v]accine-enhanced disease."4

As a result, the authorization letters for both COVID-19 vaccines expressly provide that the vaccines are each "an investigational vaccine **not licensed** for any indication" and require that **"[a]ll promotional material relating to the COVID-19 Vaccine clearly and conspicuously … state that this product has not been approved or licensed by the FDA**, but has been authorized for emergency use by FDA."5

Reflecting that these vaccines have not yet been demonstrated to be safe and effective, use of one of them was recently paused by the CDC and FDA due to serious reactions that have proven fatal in some cases.6 This exemplifies why the authorization letters for the COVID-19 vaccines, in accordance with federal law, expressly provide that these vaccines cannot be required and must remain optional.

Federal Law Prohibits Mandating Products Granted EUA

The same section that authorizes the FDA to grant an EUA, Section 564 of the Federal Food, Drug, and Cosmetic Act (the "Act"), codified at 21 U.S.C. 360bbb-3, requires that the public have "the option to accept or refuse administration of the product." 21 U.S.C. 360bbb-3(e). It even provides that the Secretary of HHS is to "ensure that individuals to whom the product is administered are informed" of "the option to accept or refuse administration of the product." (Id.)

The FDA and CDC's guidance and regulations reflect the statutory prohibition from mandating that an individual receive a product that has only been granted EUA. For example, the FDA guidance entitled *Emergency Use Authorization of Medical Products and Related Authorities* provides that:

> For an unapproved product [such as the COVID-19 vaccines], the statute [21 U.S.C. 360bbb-3] requires that **FDA ensure that recipients are informed … [t]hat they have the option to accept or refuse the EUA product…7**

Similarly, when responding to an inquiry regarding whether the COVID-19 vaccines can be required, the Executive Secretary of the CDC's Advisory Committee on Immunization Practices ("ACIP"), Dr. Amada Cohn, publicly stated that "under an EUA, vaccines are **not allowed to be mandatory**. Therefore, early in the vaccination phase individuals will have to be consented and

cannot be mandated to be vaccinated."8 Dr. Cohn then reaffirmed to the FDA's Vaccine and Related Biological Products Advisory Committee that no organization, public or private, can mandate COVID19 vaccines:

> Organizations, such as hospitals, with licensed products do have capability of asking their workers to get the vaccine. But in the setting of an EUA, patients and individuals will have the right to refuse the vaccine.9

The EUAs for the COVID-19 Vaccines Repeats this Prohibition

The EUA letters for Pfizer, Moderna, and Janssen provide that each:

> COVID-19 Vaccine is authorized for emergency use with the following product specific information required to be made available to the vaccination providers and recipients, respectively (referred to as 'authorized labeling'):
>
> • Fact Sheet for Health Care Providers Administering Vaccine … [and]
>
> • Fact Sheet for Recipients and Caregivers.10

These facts sheets each provide that the receipt of the vaccine must be optional. The Fact Sheets for Healthcare Providers for the three COVID-19 vaccines state that: "The recipient or their caregiver **has the option to accept or refuse** [the] COVID-19 Vaccine."11 Similarly, the Fact Sheets for Recipients and Caregivers for each COVID-19 vaccine state on the first page: **"It is your choice to receive the [] COVID-**19 Vaccine."12

The Fact Sheet for Recipients and Caregivers for each of the COVID-19 vaccines also set forth in sequence the information required to be provided to recipients of the vaccine pursuant to section 564 of the Act, including "the option to accept or refuse administration of the product" and "the consequences, if any, of refusing administration of the product." **21 U.S.C. § 360bbb3(e)(1)(A)(ii).** All of the COVID-19 vaccine fact sheets provide the required information in sequence, including telling potential recipients: "It is your choice to receive or not receive the [] COVID-19 Vaccine," and that if "you decide to not receive it, it will not change your standard of medical care."13

Your Employer or School **Vaccine Mandate Violates the Act, the EUA, Public Policy and the Nuremberg Code**

By implementing its vaccine mandate, Your Employer or School is deliberately taking away each employee's/student's statutorily guaranteed right to decide whether to accept or refuse administration of the COVID-19 vaccines. Your Employer or School is doing so openly, without any regard for the personal and autonomous right of each employee/student to choose whether they want to receive an unapproved and unlicensed medical product.

Your Employer or School is effectively forcing each employee/student to choose between facing expulsion/termination from Your Employer or School or receiving an experimental medical treatment to which they do not consent.

The right to informed medical consent is considered a fundamental, overriding principle of medical ethics and international law, first laid down by United States government jurists in the

Nuremberg Code. See e.g., The Nuremberg Code (1947), 313 BMJ 1448 (1996) ("The voluntary consent of the human subject is absolutely essential. This means that the person…[is] able to exercise free power of choice, without the intervention of any element of…coercion."); 14 see also UNESCO Universal Declaration on Bioethics and Human Rights, Article 6(1).15

Public policy further demands that uncoerced consent is required. Congress made this plain in the Act by assuring that individuals can make their own medical decisions when it comes to EUA products, even during times of emergency. The only exception Congress granted for allowing an EUA to be mandated is a Presidential order requiring members of the armed forces to receive the product.16

The clear policy choice made at the highest levels of government to protect the individual's right to choose is further supported by the fact that whether COVID-19 vaccines are actually safe and effective is not yet known and will not be known until, at the earliest, the Phase III clinical trials are completed. The FDA-approved study protocols for the COVID-19 vaccines' timelines for collecting safety and efficacy data from trial participants is approximately two years. (Moderna's calls for 759 days of data collection, Pfizer's 742 days, and Janssen's 24 months.) When these companies submitted applications for an EUA, they had only accumulated data from study participants for a median of 6 to 8 weeks, i.e., less than 10% of the full study period.

Additional Considerations

As explained above, these vaccines have not been proven to prevent infection or transmission. Therefore, requiring that employees/students receive these vaccines to prevent infection is unscientific. It is also nonsensical to not require faculty and staff, some of whom may have a risk of severe COVID-19, while requiring healthy, people to receive this experimental product. To the extent the Your Employer or School policy permits faculty, staff, and other individuals to choose or refuse vaccination, but does not allow that same choice for other employees/students, this may raise equal protection issues.

Additionally, Your Employer or School is failing to take into consideration that a significant portion of its employee/student population is likely to have had SARS-CoV-2 and fully recovered. Putting aside the immunity conferred by having been previously infected, there have been concerns raised by medical professionals that vaccinating those recently infected can lead to serious injury or death by causing antigen specific tissue inflammation in any tissues harboring viral antigens.17 Your Employer or School should consider whether it might be liable for any damages, poor health outcomes, and loss of life due to mandatory COVID-19 vaccination policies forced upon its employees/students. While manufacturers and vaccine administrators are protected by the PREP Act, Your Employer or School is not.

For all of the foregoing reasons, we respectfully request that Your Employer or School give serious consideration to the issues raised herein and withdraw its COVID-19 vaccine mandate forthwith since requiring an unlicensed and unapproved product violates federal law, international laws, civil and individual rights, and public policy.

Sincerely,

_____

First, Middle Last Name

1 See https://www.fda.gov/media/144416/download, https://www.fda.gov/media/144673/download, and https://www. fda.gov/media/146338/download ("Data are limited to assess the effect of the vaccine against transmission of SARSCoV-2 from individuals who are infected despite vaccination."). 2 "FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine" available at https://www.fda.gov/news-events/press-announcements/fda-takes-additionalaction-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (emphasis added) . 3 "FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine" available at https://www.fda.gov/media/144245/ download; "FDA Briefing Document Moderna COVID-19 Vaccine" available at https://www.fda.gov/ media/144434/download;

"FDA Briefing Document Janssen COVID-19 Vaccine" available at https://www.fda.gov/media/146217/download. 4 Id. 5

See https://www.fda.gov/media/144416/download, https://www.fda.gov/media/144673/download at 9, and https://www.fda.gov/media/146303/download.

6 See https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04/03-COVID-Shimabukuro-508.pdf at 21.

7 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 (emphasis added)

. 8 Advisory Committee on Immunization Practices' August 26, 2020 Summary Report available at https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508 .pdf at 56 (emphasis added).

9 The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting Transcript of October 22, 2020 available at https://www.fda.gov/media/143982/download at 156.

10 FDA's EUA letter for Pfizer COVID-19 vaccine available at https://www.fda.gov/media/144412/download;

FDA's EUA letter for Moderna COVID-19 vaccine available at https://www.fda.gov/media/144636/download;

FDA's EUA letter for Janssen COVID-19 vaccine available at https://www.fda.gov/media/146303/download.

11 Fact Sheet for Healthcare Providers Administering … Moderna COVID-19 Vaccine available at https://www.fda.gov/media/144637/download; Fact Sheet for Healthcare Providers Administering … Pfizer-BioNTech COVID-19 Vaccine available at https://www.fda.gov/media/144413/download; Fact Sheet for Healthcare Providers Administering … Janssen COVID-19 Vaccine available at https://www.fda.gov/media/146304/download.

12 Fact Sheet for Recipients … Moderna COVID-19 Vaccine available at https://www.fda.gov/media/144638/download;

Fact Sheet for Recipients … Pfizer-BioNTech COVID-19 Vaccine available at https://www.fda.gov/media/144414/ down load; Fact Sheet for Recipients … Janssen COVID-19 Vaccine available at https://www.fda.gov/media/146305/ download. 13 Id.

14 https://history.nih.gov/display/history/Nuremburg+Code.

15 http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html ("[P]reventive … medical intervention is only to be carried out with the prior, free and informed consent of the person concerned… The consent … may be withdrawn … at any time and for any reason without disadvantage or prejudice.").

16 See 10 U.S.C. § 1107a available at https://www.law.cornell.edu/uscode/text/10/1107a.

17 See https://noorchashm.medium.com/a-letter-of-warning-to-fda-and-pfizer-on-the-immunological-danger-of-covid-19-vaccination-in-the-7d17d037982d.