

To the Board of Health,

I received an email stating the Board of Health will be deciding about a possible mandate of the Covid-19 vaccine for all NSHE students.

As I am sure you are aware, the COVID-19 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. The Board of Health cannot lawfully require students to receive a COVID-19 vaccine that is being distributed under an EUA.**

#### **Federal Law Prohibits Mandating Products Granted EUA**

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, a novel viral vector vaccine platform.

The same section that authorizes the FDA to grant an EUA, Section 564 of the Federal Food, Drug, and Cosmetic Act (the "Act") **requires that the public have "the option to accept or refuse administration of the product."**

It also states 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."**

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 **requires that FDA ensure that recipients are informed ... that they have the option to accept or refuse the EUA product.**

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."**

#### **An Unlicensed and Unapproved Product Comes with Risk**

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.**

In fact, recent evidence shows **those who have been vaccinated still transmit the virus, and the majority of those getting sick are those who have been**

**vaccinated. In Provincetown, MA, they saw 500 new cases of infections within two weeks in which three-fourths of these cases were reported in fully-vaccinated individuals.**

So far, reported adverse reactions from the vaccine include, but are not limited to:

- **Death**
- **Neurological disorders**
- **Numbness**
- **Myocarditis**
- **Tingling**
- **Tremors**
- **TIAs**
- **Virus mutations**
- **Antibody mediated viral enhancement**

"No vaccine, even the regular vaccines,...ever stops infection." - Dr. Dan Stock

One of the vaccines was pulled from use by the CDC and FDA due to serious **fatal reactions**. 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**.

Furthermore, 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.**" 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.**"

### **Vaccine Mandates Violate the Act, the EUA, Public Policy and the Nuremberg Code**

By implementing a vaccine mandate, the Board of Health would be openly and deliberately **taking away each student's statutory guaranteed right** to decide whether to accept or refuse administration of the COVID-19 vaccines, **without any regard for the personal and autonomous right of each student to choose whether they want to receive an unapproved and unlicensed medical product -- effectively forcing each student to choose between facing expulsion or receiving an experimental medical treatment to which they do not consent.**

Patients are allowed to refuse all sorts of treatments from chemo, organ transplant, etc. All of these procedures can save and extend lives, but the individual is allowed to make a personal risk assessment.

**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:**

"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."

See also UNESCO Universal Declaration on Bioethics and Human Rights, Article 6(1) 15 i:

"Preventive ... 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."

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 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 safely prevent infection or transmission. Therefore, requiring that students receive these vaccines to prevent infection is unscientific.

Additionally, the Board of Health is failing to take into consideration that a significant portion of its student population is likely to have had SARS-CoV-2 and fully recovered. Aside from natural immunity due to previous infection, 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.

**The university 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 students. While manufacturers and vaccine administrators are protected by the PREP Act, the Board of Health is not.**

By taking away the students' ability to continue our education over a personal health decision, you are exerting a level of control over their lives that you have only over your own lives and those of your minor children. They are neither. We ask those of you involved in making this decision why you would consider a mandate for a virus with 99.98% survival rate, for which credible physicians around the country prove there are other effective treatments. A mandate has not been done for the common cold, influenza, or respiratory syncytial virus. Consider the rights your fellow American citizens should continue to have in making their own healthcare decisions.

For all of the foregoing reasons, we respectfully request that the Board of Health give serious consideration to the issues raised herein and vote no on any COVID-19 vaccine mandate since **requiring an unlicensed and unapproved product violates federal law, international laws, civil and individual rights, ethics, and public policy.**

Very truly yours,

Kim Benke

SOURCES:

1 <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 SARS-CoV-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-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid>

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

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<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04/03-COVID-Shimabukuro-508.pdf>

6 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>

7 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>.

8 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>.

9 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/download>;  
Fact Sheet for Recipients ... Janssen COVID-19 Vaccine available at <https://www.fda.gov/media/146305/download>.

10 <https://bit.ly/3qxerxs>