

Date: April 12, 2021

To: Whom It May Concern:

Re: Covid-19 Experimental Vaccine Candidates

Any compulsory Covid-19 vaccination requirement is a violation of federal law. I urge you to advise all students that they have the right to refuse or to take any COVID-19 vaccine. Any other action is contrary to federal law.

### **Covid-19 Vaccines are Experimental.**

Covid-19 vaccines are not approved by the FDA. The Covid-19 vaccines are only approved under an Emergency Use Authorization, for investigational use only.<sup>1</sup> Covid-19 vaccines lack requisite studies and are not approved medical treatment. The FDA's guidance on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances ... That they have the option to accept or refuse the EUA product ..."<sup>2</sup>

Title 21, Section 360bbb-3 of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") vests the Secretary of Health and Human Services with the permissive authority to grant Emergency Use Authorizations ("EUAs") providing that appropriate conditions designed to ensure that individuals to whom the product is administered are informed:

1. that the Secretary has authorized the emergency use of the product;
2. of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
3. **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.<sup>1</sup>

The right to avoid the imposition of human experimentation is fundamental, rooted in the Nuremberg Code of 1947, has been ratified by the 1964 Declaration of Helsinki, and further codified in the United States Code of Federal Regulations. In addition to the United States regarding itself as bound by these provisions, these principles were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. It is unlawful to conduct medical research, even in the case of an emergency, unless steps are taken to secure **informed consent** of all participants.<sup>3</sup>

The following Emergency Use Authorizations have been issued for Covid-19 vaccinations:

12/11/20 Moderna - FDA issued an EUA for emergency use of the Moderna mRNA COVID-19 vaccine for recipients 16 years of age or older.

12/18/20 Pfizer/BioNTech - FDA issued an EUA for emergency use of the Pfizer/BioNTech mRNA vaccine for recipients 18 years of age or older.

2/27/21 Johnson & Johnson - FDA issued an EUA for emergency use of the Johnson & Johnson COVID-19 vaccine (aka Janssen vaccine) for recipients 18 years of age or older.

Each of the above EUAs was issued in conjunction with a similar Fact Sheet from the FDA. For example, the Janssen fact sheet contains the following notice:

**“INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS”**

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website to obtain the Fact Sheet) prior to the individual receiving the Janssen Covid-19 Vaccine, including:

- FDA has authorized the emergency use of the Janssen Covid-19 Vaccine, which is not an FDA approved vaccine.
- ***The recipient or their caregiver has the option to accept or refuse the Janssen COVID-19 Vaccine.***
- The significant known and potential risks and benefits of the Janssen Covid-19 Vaccine, and the extent to which such risks and benefits are unknown.<sup>4</sup>

Clearly, any attempt to force anyone to take a Covid-19 vaccine is a violation of federal law and the conditions under which the Covid-19 vaccine has been authorized for use. The law is clear, experimental medical treatment cannot be mandated.

**Businesses are not shielded from liability with experimental agents.**

Under the 2005 PREP Act enacted by Congress, pharmaceutical companies that manufacture EUA vaccines are shielded from liability related to injuries and damages caused by their experimental agents. However, any employer, public school, or any other *entity or person* who mandates experimental vaccines on any human being is not protected from liability for any resulting harm. While vaccine manufacturers may be shielded from liability, your institution is not protected, and neither are you.<sup>5</sup>

You are hereby on notice that if you illegally or irresponsibly mandate EUA medical therapies on **students**, such as the experimental Covid-19 vaccine candidates, I may have no choice but to take legal action, and you may be personally liable for resulting harm.

I urge **your institution** to comply with the FD&C Act and the terms of the EUA and its accompanying Fact Sheet, and to advise all employees of their right to accept *or refuse* any Covid-19 vaccine. Any other course of action is contrary to federal law.

Thank you for your time and for protecting the best interest of your **students**.

Sincerely,

**Sign Name Here**

<sup>1</sup> <https://ca.childrenshealthdefense.org/wp-content/uploads/CDE-Superintendent-Letter0from-Childrens-Health-Defense-California-Chapter.pdf>

<sup>2</sup> <https://www.fda.gov/media/97321/download>

<sup>3</sup> 21 CFR § 50.24

<sup>4</sup> [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com)

<sup>5</sup> <https://childrenshealthdefense.org/defender/under-federal-law-can-your-employer-make-you-get-covid-vaccine/>