

August 11, 2022

Notice of Refusal of EUA Products

My child, _____, is a member of this school's _____
Print student name Sport

athletic team. The Department of Education has declared a policy for the 2022-23 school year which would require all unvaccinated student athletes to undergo twice weekly testing for COVID-19 in order to participate in school sports.

This policy is discriminatory and coercive, circumventing federal laws that protect the right for an individual to refuse the administration of a product which is authorized for emergency use only. As of the date of this letter there is no fully Food and Drug Administration (FDA) approved COVID-19 vaccine on the market, only products which have been granted Emergency Use Authorization (EUA).

While the FDA has approved the biologics licensing application submitted by BioNTech manufacturing for the Comirnaty mRNA vaccine for COVID-19 on August 23, 2021, with an update to include administration to children and adolescents 12 and up on July 8, 2022, the EUA for the currently manufactured and widely used alternative Pfizer BioNTech COVID-19 vaccine remains in place. The Comirnaty vaccine is *not available* for use, therefore only EUA vaccines can be taken.

Any coercion to receive an EUA vaccine is a violation of federal law.

According to the Comirnaty Vaccine Fact Sheet for Caregivers and Recipients anyone choosing not to take the vaccine has a right to do so under the EUA. The Fact Sheet states the following:

"WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE? Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care."

In *Doe et al. v. Austin*, U.S. Federal District Judge Allen Winsor of the U.S. District Court for the Northern District of Florida denied a preliminary injunction requested by 16 service members against the U.S. Military's COVID-19 vaccine mandate, however this judge rejected a claim by the U.S. Department of Defense (DOD) that the Pfizer-BioNTech COVID-19 vaccine being administered under Emergency Use Authorization is interchangeable with Pfizer's Comirnaty vaccine.

The judge's acknowledgment that "the DOD cannot mandate vaccines that only have an EUA" is significant for two reasons. One reason pertains to the difference in ingredients and manufacturing process between Pfizer's EUA vaccine and the approved Comirnaty vaccine, and the other pertains to the legal difference between a fully licensed vaccine and an EUA vaccine.

The latter reason would apply not just to the Pfizer-BioNTech vaccine, but also to the vaccines produced by Moderna and Johnson & Johnson (Janssen), both of which are authorized only as EUA products.

Under law, everyone has a right to refuse an EUA product.

Federal law Title 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) states:

... individuals to whom the product is administered are informed—

- (I) that the Secretary has authorized the emergency use of the product;
- (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; and
- (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. (emphasis added)

Under the Nuremberg Code, the foundation of ethical medicine, no one may be coerced to participate in a medical experiment. Consent of the individual is “absolutely essential.”¹ As long as the available vaccine being administered remains under Emergency Use Authorization with the clinical trials set to end in 2023, the Pfizer BIONTECH COVID-19 vaccine is considered experimental and investigational. The coercive nature of this policy therefore removes our right to full informed consent.

On August 11, 2022 the Centers for Disease Control (CDC) updated their guidance signaling that schools and other institutions no longer need to screen apparently healthy students and employees as a matter of course. The summary of guidance states:

Current priorities for preventing medically significant illness should focus on ensuring that persons 1) understand their risk, 2) take steps to protect themselves and others through vaccines, therapeutics, and nonpharmaceutical interventions when needed, 3) receive testing and wear masks **if they have been exposed**, and 4) **receive testing if they are symptomatic**, and isolate for ≥ 5 days if they are infected.

At all COVID-19 Community Levels (low, medium, and high), recommendations emphasize staying up to date with vaccination, improving ventilation, testing persons who are **symptomatic and those who have been exposed**, and isolating infected persons.

¹ <http://www.cirp.org/library/ethics/nuremberg/>

Testing for current infection. ...All persons should seek testing for active infection when they are symptomatic or if they have a known or suspected exposure to someone with COVID-19. When considering whether and where to implement screening testing of asymptomatic persons with no known exposure, public health officials might consider prioritizing high-risk congregate settings, such as long-term care facilities, homeless shelters, and correctional facilities, and workplace settings that include congregate housing with limited access to medical care. In these types of high-risk congregate settings, screening testing might complement diagnostic testing of symptomatic persons by identifying asymptomatic infected persons. **When implemented, screening testing strategies should include all persons, irrespective of vaccination status.** Screening testing might not be cost-effective in general community settings, especially if COVID-19 prevalence is low. (emphasis added)²

We hereby submit this notice of refusal of an EUA product, finding any and all threats to exclude my child from participation in school sports as an act of coercion and discrimination. We also refuse to adhere to any regular EUA testing for COVID-19 as this contradicts the current CDC guidance and is a violation of my child’s federally protected rights.

According to the (CDC) “People who are vaccinated may still get COVID-19.”³ If vaccination provides no protection from transmission, excluding unvaccinated students from participation is an arbitrary rule that is clearly discriminatory. Failure to regularly test those who have been vaccinated although they are just as capable of spreading the disease would theoretically place all students in equal danger.

Protections Under the Hawaii State Constitution

The Hawaii State Constitution, Article I, Section 2 states: “All persons are free by nature and are equal in their inherent and inalienable rights. Among these rights are the enjoyment of life, liberty and the pursuit of happiness...”

And Article I, Section 5 states: “No person shall be deprived of life, liberty or property without due process of law, nor be denied the equal protection of the laws, nor be denied the enjoyment of the person’s civil rights or be discriminated against in the exercise thereof because of race, religion, sex or ancestry.”

² https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e1.htm?s_cid=mm7133e1_w

³

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html>

Under the law my child has an equal right to enjoy the benefits of participation in school sports without adhering to coercive policies. Providing incentives to students who adhere to demands to be vaccinated (freedom from regular testing) presents serious violations of the right to free association and equal protection.

We, the undersigned, assume any and all risk associated with the choice to refuse the administration of the aforementioned EUA medical products, and enter into this binding contract to remove any and all liability from this school, the coaches and any associate organizations through which this sport may be sanctioned if my child gets sick and/or dies from COVID-19.

However, please note that failure to acknowledge and honor this Notice may result in civil claims against all those responsible for infringing upon the protected fundamental rights of my child.

_____ Dated: _____
Student Signature

_____ Dated: _____
Parent/Legal Guardian Signature

_____ Dated _____
Coach/Facilitator/Authorized Representative