PERK
Protection of the Educational Rights of Kids

A SUMMARY OF EUA LAW, AUTHORIZATIONS, & POLICY

PRESCREENING REQUIREMENT

Patients should be screened prior to receipt of each vaccine dose, and those with a contraindication should not be vaccinated. A COVID-19 prevaccination questionnaire pdf icon[6 pages] is available to assist with screening. CDC https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

MODERNA

On December 18, 2020, the Moderna Vaccine was issued an Emergency Use Authorization (EUA) for emergency use of Moderna COVID 19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3). https://www.fda.gov/media/144636/download Page 1

The emergency use of Moderna COVID 19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). https://www.fda.gov/media/144636/download Page 5

The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19. The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA). https://www.modernatx.com/covid19vaccine-eua/recipients/ Page 1

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 16 years of age and older. (Pfizer fact sheet) https://www.fda.gov/media/144413/download Page 1

PFIZER

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 16 years of age and older, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3).
https://www.fda.gov/media/144412/download Page 1

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active

immunization to prevent COVID-19 in individuals 16 years of age and older. https://www.fda.gov/media/144413/download Page 1

JOHNSON & JOHNSON

On February 27, 2021, the FDA issued and Emergency Use Authorization for emergency use of Johnson and Johnson single dose vaccine. "Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the Janssen COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization."
https://www.fda.gov/media/146303/download
EUA fact sheet for healthcare providers: https://www.fda.gov/media/146304/download
Fact sheet for recipients and caregivers: https://www.fda.gov/media/146305/download

INFORMED CONSENT

"Emergency Use Authorization" means that any product with this designation must be voluntary. Under 21 U.S.C. § 360bbb-3, "Authorization for medical products for use in emergencies":

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed —
(I) that the Secretary [of Health and Human Services] 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.

FDA, CDC, and ACIP

The CDC admits that it is illegal and unethical to mandate PCR testing in schools.[19] Moreover, the States, and therefore public schools, cannot mandate the PCR test or COVID vaccines because the FDA and courts have found the federal preemption doctrine prevents States, and therefore public schools, from going outside the bounds of the Emergency Use Authorization law.[20]
[19] https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-testing.html
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

ACIP

CDC Advisory Committee on Immunization Practices (ACIP) meeting in August 2020, where ACIP Executive Secretary Amanda Cohn, MD stated:

"I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandated."[21]
[21] US Centers for Disease Control (September 2020), *August 2020 ACIP Meeting – COVID-19 vaccine supply & next steps.* https://www.cdc.gov/vaccines/videos/low-res/acipaug2020/Covid-19Supply-NextSteps_3_LowRes.mp4 (@1:14:40)

FULL LICENSURE EXPECTED IN 2022

The law is clear that States, cannot mandate experimental products and are preempted from mandating an EUA product.[22] The soonest the Moderna and Pfizer/BioNTech experimental vaccines could be considered by FDA for full licensure (in adults only) is when the trials are expected to conclude, on October 27, 2022 and January 31, 2023, respectively.

[22] See e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 570-71 (2001)

Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)external icon

Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)external icon

Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)external icon