FDA-Approved COVID-19 Vaccines are Unavailable

Comirnaty [1] and Spikevax [2], the only FDA-approved COVID-19 vaccines, are unavailable. Available COVID-19 vaccines, including Pfizer-BioNTech [3], Moderna [4], and Janssen (Johnson & Johnson) [5], have not been approved by the U.S. Food and Drug Administrations and are under emergency use authorization (EUA).

Comirnaty and Spikevax are FDA-approved COVID-19 vaccines made by Pfizer for BioNTech and Moderna. They are approved as a 2-dose series for prevention of COVID-19. The Pfizer-BioNTech and Moderna COVID-19 vaccines have received EUA from the FDA to provide a 2-dose series to individuals; they are not FDA-approved. The FDA's Comirnaty and Spikevax approval letters facially state, the CDC: (1) explicitly distinguishes the Comirnaty and Pfizer-BioNTech vaccines; (2) expressly distinguishes that Comirnaty is approved and Pfizer-BioNTech is not FDA-approved but under EUA. **The Comirnaty and Pfizer-BioNTech COVID-19 vaccines are legally distinct** [6] **and have different ingredients**. [3] **Spikevax and Moderna COVID-19 vaccines are also legally distinct.** [7]

Under an EUA, the FDA may allow the use of unapproved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases when there are no adequate, approved, and available alternatives. [8] The FDA re-issued the EUA for the Pfizer-BioNTech and Moderna COVID-19 vaccines on 29 March 2022 because "there is no adequate, **approved**, and available alternative to the Pfizer-BioNTech [or Moderna] COVID-19 Vaccine[s] to prevent COVID-19." [6]

The Pfizer-BioNTech, Moderna, and Janssen Fact Sheets for Recipients and Caregivers specifically state, "It is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard of medical care." [3] [9] [10] Each COVID-19 vaccine is required to have a Fact Sheet for Healthcare Providers that reinforces the need for informed consent [11] by stating the vaccination provider must communicate to the recipient or their caregiver information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving each dose of a COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the COVID-19 Vaccine, which is not an FDA-approved vaccine.
- **The recipient or their caregiver has the option to accept or refuse the COVID-19 Vaccine**.

From a legal perspective, EUA vaccines cannot generally be mandated. Under Title 21 U.S. Code §355(i)(4) and related regulations, people must be told the product in question is not FDA approved and that receipt of the product is voluntary, and the person must agree to the receipt of drug, biologic, or medical product before it can be administered. [12] This is known as informed consent. Withholding informed consent because you have not been provided the full ingredients list, side effects, or seen peer reviewed studies of efficacy through full vaccine trials, is not a refusal to receive a vaccine, rather a legally distinct, procedural objection to informed consent Title 21 U.S. Code § 360bbb–3(e) (1) (a)(ii) reiterates that individuals must be informed of the option to accept or refuse administration of the product. [13]

Military members are typically protected by the same laws outlined above. However, Title 10 U.S. Code 1107a grants the President authority to waive informed consent for service members receiving EUA products only in the event the President determines, in writing, that informed consent is not in the interests of national security. [14] A Presidential waiver of informed consent has not been granted at this time. Informed consent is required to administer an EUA vaccine to a military member. In Doe #1 v. Rumsfeld, this requirement was upheld and the court held "Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." [15] Any directive from a government official that compels vaccination from a non-FDA approved vaccine is unlawful *per se*. Article 92 of the UCMJ states "[a] general order or regulation is lawful unless it is contrary to the Constitution, the laws of the United States, or lawful superior orders or for some other reason is beyond the authority of the official issuing it." Any order requiring COVID-19 vaccination through use of any vaccine other than Comirnaty or Spikevax is contrary to the laws of the United States, including but not limited to U.S.C. Title 10 § 1107a.

By law, receipt of an EUA vaccine is strictly voluntary for all Americans.

References

[1] U.S. Food and Drug Administration, Biologics License Application Letter from FDA to BioNTech Manufacturing GmbH, Silver Spring, MD, 2021.

[2] U.S. Food and Drug Administration, Biologics License Application Letter from FDA to ModernaTX, Inc, Silver Spring, MD, 2022.

[3] Pfizer-BioNTech, "Vaccine Information Fact Sheet for Recipients and Caregivers About Comirnaty (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Use In Individuals 12 Years Of Age and Older," 3 January 2022.

[4] Moderna US, Inc., "Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)," 31 January 2022.

[5] Janssen Pharmaceutical Companies, "Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)," 31 January 2022.

[6] Jacqueline A. O'Shaughnessy, Acting Chief Scientist, "Letter of Authorization (Reissued)," 3 January 2022. [Online]. Available: https://www.fda.gov/media/150386/download. [Accessed 24 January 2022].

[7] U.S. Food and Drug Administration, Letter of Authorization from FDA to ModernaTX, Inc, Silver Spring, MD, 2022.

[8] U.S. Food and Drug Administration, "Emergency Use Authorization for Vaccines Explained," 20 November 2020. [Online]. Available: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained. [Accessed 01 November 2021].

[9] Moderna US, Inc., "Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older," 31 January 2022.

[10] Janssen Pharmaceutical Companies, "Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older," 31 January 2022.

[11] Pfizer-BioNTech, "Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)," 31 January 2022.

[12] U.S. Code, "Title 21 U.S.C. §355. New drugs".

[13] U.S. Code, "21 USC 360bbb-3: Authorization for medical products for use in emergencies".

[14] U.S. Code, "10 USC 1107a: Emergency use products".

[15] *John Doe #1 v. Rumsfeld, --- F.Supp.2d ----, 2003 WL 22994225,* (D.D.C. Dec 22, 2003).