UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

PETITION FOR ADMINISTRATIVE ACTION TO REMOVE AN EMERGENCY USE AUTHORIZATION CONDITION FOR COVID-19 VACCINES	**:**	**Docket No.:**

CITIZEN PETITION

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CITIZEN PETITION

This petition for administrative action is submitted on behalf of Informed Consent Action Network[1] ("**Petitioner**") pursuant to 21 C.F.R. § 10.30 and related and relevant provisions of law (including the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act) to request that the Commissioner of Food and Drugs (the "**Commissioner**") take the actions listed below to remove certain conditions that are part of the emergency use authorizations ("**EUA**") for all COVID-19 vaccines.

In blatant violation of the EUAs for the COVID-19 vaccines, public health authorities and other stakeholders, when promoting COVID-19 vaccines, are not including the language required by the vaccines' "Conditions Related to Printed Matter, Advertising, and Promotion" in the "Condition of Authorization" section described in the EUA (the "**EUA Advertising Conditions**").

For example, and as detailed below, the U.S. Department of Health and Human Services ("**HHS**"), the Director of the U.S. Centers for Disease Control ("**CDC**"), and various additional stakeholders are promoting COVID-19 vaccines authorized pursuant to EUA but are failing to comply with the EUA Advertising Conditions. Because these other federal health authorities, including the FDA's parent department, HHS, are failing to comply with the EUA Advertising Conditions, the conditions should be lifted so as to not create precedent that blatant violations of EUA conditions are tolerated.

A. ACTION REQUESTED

1. Remove the following EUA Advertising Condition in Moderna's COVID-19 vaccine EUA:

> All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that:
>
> This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older, 12 through 17 years of age, 6 years through 11 years of age, or 6 months through 5 years of age as appropriate; and
>
> The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.[2]

[1] Including, but not limited to, on behalf of its members that work for the Petitioner.

[2] https://www.fda.gov/media/144636/download.

2. Remove the following EUA Advertising Condition in Pfizer-BioNTech's COVID-19 vaccine EUA:

> All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:
>
> This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older, in individuals 5 through 11 years of age, or in individuals 6 months through 4 years of age as appropriate; and
>
> The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.[3]

3. Remove the following EUA Advertising Condition in Janssen's COVID-19 vaccine EUA:

> All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that:
>
> This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine; and
>
> The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.[4]

[3] https://www.fda.gov/media/150386/download.

[4] https://www.fda.gov/media/146303/download.

4. Remove the following EUA Advertising Condition in Novavax's COVID-19 vaccine EUA:

> All descriptive printed matter, advertising, and promotional material relating to the use of the Novavax COVID-19 Vaccine clearly and conspicuously shall state that:
>
> This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and
>
> The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.[5]

B. STATEMENT OF GROUNDS

5. Section 564 of the Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 360bbb-3, governs any issuance of an EUA for a medical product. This federal statute makes clear the criteria for issuance of authorization for unapproved products and that conditions of authorization may be established to protect the public health.

6. The Secretary of Health and Human Services, who is responsible for ensuring that these conditions are made clear and are met, has delegated these responsibilities to the U.S. Food and Drug Administration ("**FDA**").

7. The FDA has granted EUAs for four COVID-19 vaccines sold by Moderna, Pfizer, Janssen, and Novavax (the "**COVID-19 Vaccines**").[6]

8. These emergency use authorizations granted by the FDA to Pfizer (most recently on July 8, 2022), Moderna (most recently on June 17, 2022), Janssen (most recently on May 5, 2022), and Novavax (on July 13, 2022), each include the conditions detailed in paragraph 1 through 4 above related to printed matter, advertising, and promotion (the "**EUA Advertising Conditions**").

9. Although these EUAs are made public by the FDA, it is apparent that not all stakeholders, including public health agencies on both the federal and state levels, and vaccination providers, are abiding by the EUA Advertising Conditions.

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[5] https://www.fda.gov/media/159902/download.

[6] Each of the four COVID-19 vaccine EUAs have been signed by Jacqueline A. O'Shaughnessy, Ph.D., Acting Chief Scientist of the FDA.

10. There are hundreds, if not thousands, of social media posts regarding COVID-19 Vaccines being publicly shared by health agencies in almost every state across the country, as well as emails, newsletters, mailings, and other communications by health agencies, promoting COVID-19 vaccines to the public that do not include the required language that these vaccines are not approved or licensed by the FDA.

11. For example, in a tweet posted on June 18, 2022 by Dr. Rochelle Walensky, the Director of the CDC, on the @CDCDirector Twitter account, there is a video of her stating: "We

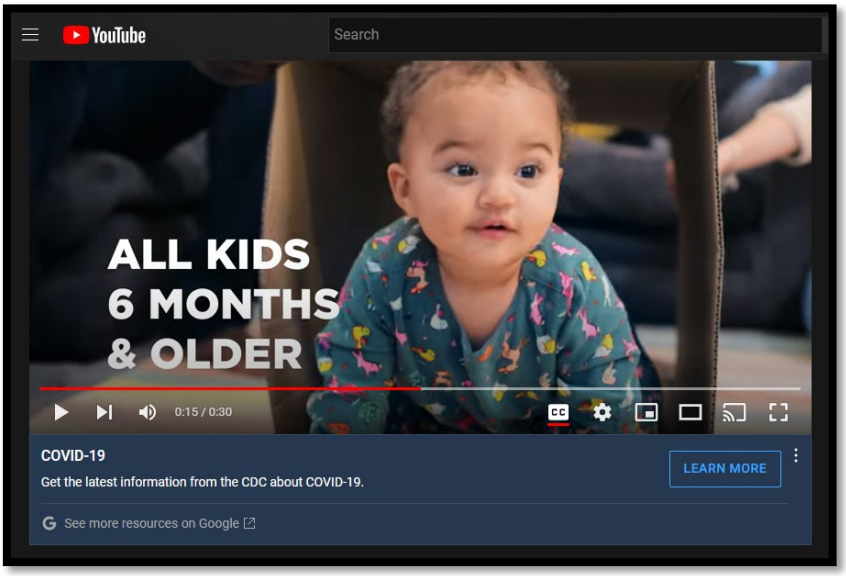
now know based on rigorous scientific review that the vaccines available here in the United States can be used safely and effectively in children under 5." Dr. Walensky then states: "We have taken another important step together on our fight against COVID-19 by making safe and effective vaccines available for our little ones."[7]

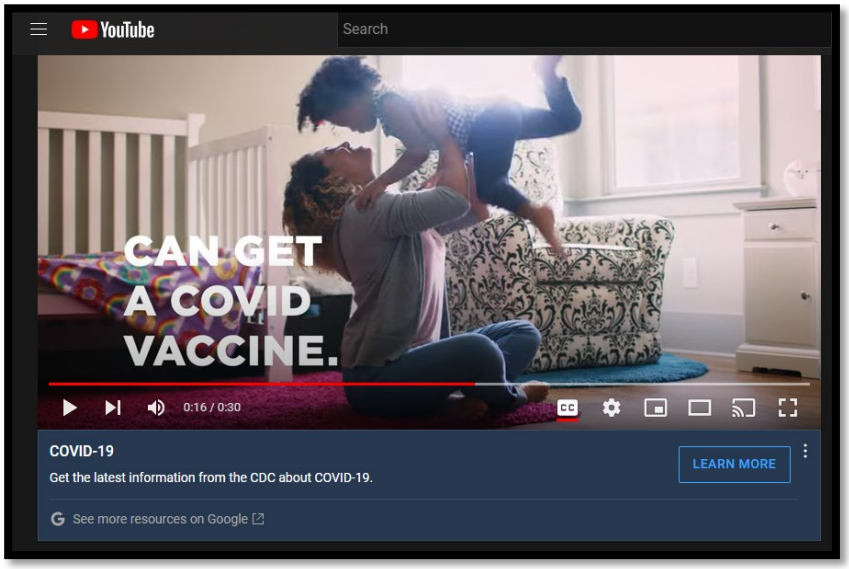
12. The CDC's Director's tweet is "descriptive printed matter, advertising, and promotional material" because it promotes COVID-19 vaccination for children. The mRNA vaccines for children ages 6 months through 12 years of age are in use pursuant to EUAs. Therefore, the tweet violates the Pfizer and Moderna EUAs as it failed to include the language

[7] *See* https://twitter.com/CDCDirector/status/1538244130651906050.

required by the EUA Advertising Conditions. And despite Petitioner advising the CDC, FDA, and HHS of this violation, none has addressed this blatant violation of the FDA's EUAs.[8]

13. In another example, on June 23, 2022, HHS launched a series of ad campaigns promoting the COVID-19 vaccines for infants and children.[9]





[8] https://www.icandecide.org/wp-content/uploads/2022/08/CDC-Director-Letter-re-mRNA-Tweet_2022_06_21.pdf; https://www.icandecide.org/wp-content/uploads/2022/08/HHS-Letter-re-mRNA-Tweet_2022_05_27-1.pdf; https://www.icandecide.org/wp-content/uploads/2022/08/Follow-Up-re-Ltr-to-HHS-re-mRNA-Tweet_2022_06_06-w-Attachment.pdf; https://www.icandecide.org/wp-content/uploads/2022/08/HHS-Letter-re-EUA-Violations-2022-08-08.pdf; https://www.icandecide.org/wp-content/uploads/2022/08/Final-Petition-and-Cover-Letter.pdf.

[9] https://www.youtube.com/watch?v=oQcuKfVYT_k.

14. Underneath each video, HHS states that "[n]othing matters more than keeping them safe. If your child is 6 months old and older, you can now help protect them from severe COVID illness by getting them a COVID vaccine."[10]

15. As you know, the mRNA vaccines for children ages 6 months through 12 years of age are in use pursuant to EUA. This HHS video is "descriptive printed matter, advertising, and promotional material" and violates both Pfizer's and Moderna's EUAs because it fails to include the language required by the conditions of those EUAs.

16. The above are just two of many examples of federal and state health agencies ignoring the EUA-required conditions. The following is a sampling of additional examples of EUA violations by numerous stakeholders:

- **a.** A February 26, 2021 Blue Cross and Blue Shield of Illinois email titled, "Important information about COVID-19 vaccines," inaccurately claims that "the Food and Drug Administration (FDA) has **approved** COVID-19 vaccines for use." The email also fails to comply with the EUA Advertising Conditions. *See* Exhibit A.
- **b.** A May 14, 2021 Kaiser Permanente email titled, "COVID-19 vaccine updates," inaccurately claims that the "Food and Drug Administration has **approved** use of the Pfizer vaccine for people 12 to 15…all the available vaccines are **proven to be safe, effective**, and lifesaving." The email also fails to comply with the EUA Advertising Conditions. *See* Exhibit B.
- **c.** A March 11, 2021 State of New Jersey webpage inaccurately claimed that "COVID-19 vaccines are **safe, effective**, and will help protect you from getting COVID-19…the known and potential benefits of **approved** vaccines outweigh the known and potential harms of becoming infected with COVID-19." The web page also failed to comply with the EUA Advertising Conditions. *See* Exhibit C.
- **d.** A March 25, 2021 TRICARE email titled, "COVID-19 Vaccine – Important Information from TRICARE," inaccurately claims that "these vaccines are safe and effective" and discuss "the three **approved** COVID-19 vaccines." The email also fails to comply with the EUA Advertising Conditions. *See* Exhibit D.
- **e.** A January 12, 2021 MDVIP ("a national network of primary care doctors") web page titled, "What You Need to Know About the Coronavirus or COVID-19," inaccurately claims that "two vaccines have been **approved** by the Food and Drug Administration." The web page also fails to comply with the EUA Advertising Conditions. *See* Exhibit E.
- **f.** A March 30, 2021 Harris County Public Health Facebook page posted about the Johnson & Johnson COVID-19 vaccine, inaccurately claiming it "is **approved** for use in people ages 18 and older." The post further stated: "All COVID-19 vaccines that are currently **approved** for use in the US **are effective**…" The Facebook post also fails to comply with the EUA Advertising Conditions. *See* Exhibit F.

At the time of all of the above promotions, none of the COVID-19 vaccines were FDA approved, despite every promotion claiming as much, and all lacked the language required by the EUA

[10] *Id*.

Advertising Conditions. Therefore, all of the promotions were in violation of the EUAs. This extremely widespread problem started with the issuance of the first EUA and continues to date. One would be hard-pressed to find any promotion of these EUA products that actually does contain the language required by the conditions of the EUAs. The FDA's continued inaction regarding this matter is an implied approval of widespread, ongoing conduct that violates federal law.

17. On March 24, 2021, Petitioner filed a Petition, Docket No. FDA-2021-P-0337, requesting that the FDA enforce, *inter alia*, the EUA Advertising Conditions. To date, the FDA has failed to provide a substantive response or, more importantly, to enforce this condition. At this stage, the best course of action is for the FDA to amend the EUAs to remove the EUA Advertising Condition since the FDA plainly does not intend to enforce this condition.

18. The public interest weighs strongly in favor of the requested relief because the FDA's failure to enforce the EUAs' "Conditions of Authorization" sows doubt in the American consumer slated to receive these EUA products and sows distrust in the FDA as an agency that does not enforce its own conditions. Removing the condition from the EUAs will also alleviate the agency's burden of oversight and enforcement of the required conditions and will end the current detrimental precedent being set: to wit, that even federal health authorities can violate an EUA and there will be no enforcement action taken and no consequences. The condition at issue has been rendered moot by the FDA's inaction.

C. ENVIRONMENTAL IMPACT

19. The undersigned hereby states that the relief requested in this petition will have no environmental impact, and therefore, an environmental assessment is not required under 21 C.F.R. §§ 25.30 and 25.31.

D. ECONOMIC IMPACT

20. Economic impact information will be submitted upon request of the Commissioner.

E. CERTIFICATION

21. The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

22. The Petitioner, therefore, respectfully urges that this request be granted forthwith.

Respectfully submitted,

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