

200 Park Avenue, 17th Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

June 21, 2022

VIA EMAIL AND FED EX

Rochelle Walensky
Director, CDC
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30329
Aux7@cdc.gov

Re: *Rochelle Walensky Tweet of June 18, 2022 – False Claims Regarding Pediatric COVID-19 Vaccines and Lack of Required EUA Disclaimer*

Dear Director Walensky:

On behalf of the Informed Consent Action Network (“ICAN”), we write regarding your June 18, 2022 tweet posted on the @CDCDirector Twitter account.¹



¹See <https://twitter.com/CDCDirector/status/1538244130651906050>.

Because this tweet contains misinformation about the safety and effectiveness of COVID-19 vaccines, and because it lacks the disclaimer required by the Food and Drug Administration’s (“FDA”) Emergency Use Authorization (“EUA”) for Pfizer’s COVID-19 vaccine, we request its immediate removal.

In the video within the tweet, you state: “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.” (Emphasis added). You also state: “We have taken another important step together on our fight against COVID-19 by making **safe and effective** vaccines available for our little ones.” (Emphasis added). As you are surely aware, the mRNA vaccines for children ages 6 months through 15 years of age are in use pursuant to EUA. In issuing the EUAs, the FDA has **not** made a finding that the vaccines are “safe and effective.” Instead, the FDA has determined only that “it is reasonable to believe that [each vaccine] **may be effective**” and that “it is reasonable to conclude, based on the totality of scientific evidence available, that **the known and potential benefits** of [each vaccine] **outweigh the known and potential risks** of the vaccine.”² Therefore, it is highly misleading to parents and healthcare providers for the Director of the CDC to state – two times – that these vaccines have been determined to be “safe and effective.” That is the legal standard required for licensure³ and that standard has not been met for pediatric COVID-19 vaccinations.

In addition, the tweet is in violation of both the Pfizer and Moderna EUAs, since the tweet failed to include the required disclaimer. As provided in the EUA for each:

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 either in individuals 12 years of age and older, or in individuals 5 through 11 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

² <https://www.fda.gov/media/144636/download> p. 3 (emphasis added) and <https://www.fda.gov/media/150386/download> p. 4 (emphasis added).

³ See 42 U.S.C. § 262.

FD&C Act unless the declaration is terminated or authorization revoked sooner.⁴

Because the tweet is “descriptive printed matter,” which both advertises and promotes Pfizer’s EUA COVID-19 vaccine, it is required to contain this disclaimer.

ICAN requests that you immediately remove this misleading tweet and looks forward to your prompt response.

Very truly yours,



Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

cc: Commissioner Robert Califf – commissioner@fda.hhs.gov
Peter Marks – peter.marks@fda.hhs.gov

⁴ See <https://www.fda.gov/media/150386/download> p. 25 (emphasis added); see also <https://www.fda.gov/media/144636/download> p. 18 (emphasis added).