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VIA EMAIL AND FEDEX

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

Dear Dr. Walensky:

We write on behalf of Informed Consent Action Network regarding the CDC's claim that "COVID-19 vaccines are safe and effective" since this claim conflicts with the findings of the FDA.

The FDA, in granting emergency use authorization pursuant to 21 U.S.C. § 360bbb-3(c)(2) for the three COVID-19 vaccines sold by Pfizer, Moderna, and Janssen, concluded that:

Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, **it is reasonable to believe** that [] COVID-19 Vaccine **may be effective**. Additionally, it is **reasonable to conclude**, based on the totality of the scientific evidence available, that **the known and potential benefits** of [] COVID-19 Vaccine **outweigh the known and potential risks** of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older.

<https://www.fda.gov/media/144412/download>; <https://www.fda.gov/media/144636/download>; and <https://www.fda.gov/media/146303/download> (emphasis added).

Contrary to the CDC's statements that "COVID-19 vaccines are safe and effective" (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>), the FDA has not found nor stated that the vaccines are "safe and effective." Rather, since it has not yet been proven that they are safe and effective, a standard required for licensure, the FDA has never made this statement and would not make this statement until licensed. Instead, as quoted above, the FDA has only concluded thus far that "it is reasonable to believe" they "may be effective" and that with regard to safety, only that at present it appears "the known and potential benefits ... outweigh the known and potential risks."

The FDA's core function is to determine whether a product is safe and effective, and only after making this finding, to grant it licensure. That determination has not yet occurred. It is improper and outside of the CDC's statutory mandate to usurp the FDA's core function and make this determination for an unlicensed product.

As you are well aware, health authorities across the country take their cue from the CDC. It is therefore imperative that the CDC share only accurate, scientific data about the COVID-19 vaccines.

Please advise that the CDC has modified its claim that "COVID-19 vaccines are safe and effective" to be in accord with the FDA's findings to date and that the CDC will otherwise cease stating that the COVID-19 vaccine products are "safe and effective" until the FDA has reached this conclusion.

Kind Regards,

A handwritten signature in blue ink, appearing to be 'ASB', written in a cursive style.

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.