

August 8, 2022

VIA EMAIL AND FED EX

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Re: *Violation of EUAs in HHS' "We Can Do This" Promotional Video*

Dear Secretary Becerra and Assistant Secretary Lovenheim:

On behalf of Informed Consent Action Network ("ICAN"), we write regarding the Department of Health and Human Services' June 23, 2022 "We Can Do This" promotional video titled, "Promise: COVID-19 Vaccines."¹ Because the promotional material fails to meet the required conditions as prescribed by the Emergency Use Authorizations ("EUA") for both Moderna's and Pfizer's COVID-19 vaccines, we request its immediate correction or removal.

¹ <https://www.youtube.com/watch?v=z8H7FHMP3Kk>.



The promotional video, which consists of a string of emotionally evocative scenes of parents interacting with their babies and toddlers, announces that there is now “one more way” for parents to “keep th[eir] promise” of keeping their children “safe”: COVID-19 vaccines, which, it says, are now available for all children 6 months and older. As you are surely aware, both Pfizer’s COVID-19 vaccine for children 6 months through 4 years of age, and Moderna’s COVID-19 vaccine for children 6 months to 5 years of age, are available pursuant only to their respective EUAs. The promotional video is in violation of both Pfizer’s and Moderna’s EUAs since it fails to meet the following required condition of the EUAs:


All descriptive printed matter, advertising, and promotional material relating to the use of the [company’s] 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 ... 6 months through 4 [or 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

² Pfizer’s EUA: <https://www.fda.gov/media/150386/download> p. 25 (emphasis added); Moderna’s EUA: <https://www.fda.gov/media/144636/download> pp. 24-25 (emphasis added).

ICAN requests that the promotional video either be corrected to meet the condition or immediately removed and looks forward to your prompt response.

Very truly yours,

A handwritten signature in black ink, appearing to read "E. Brehm". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

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