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June 6, 2022

VIA EMAIL

Xavier Becerra
HHS Office of the Secretary
Secretary, Health & Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201
c/o Sean McCluskie
sean.mccluskie@hhs.gov

Re: *Follow up re: HHS Tweet of April 23, 2022 – False Claims Regarding COVID-19 Vaccine Ingredients and Lack of EUA Disclaimer*

Dear Secretary Becerra:

We write to follow up on our May 27, 2022 letter attached hereto¹ regarding the April 23, 2022 tweet posted on the official HHS.gov Twitter account.² Once again, we ask that you address the inaccurate information contained in the tweet and its violation of Pfizer's EUA for failure to include the required disclaimer. We look forward to your prompt response.

Very truly yours,



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

Attachment

cc: Sara Lovenheim, Assistant Secretary for Public Affairs, Sarah.Lovenheim@hhs.gov
media@hhs.gov

¹ Attachment 1.

² https://twitter.com/hhsgov/status/1517896142226403329?s=21&t=VpWy_d9NQy3I3PJm3wN50Q.

Attachment 1

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May 27, 2022

VIA EMAIL

Xavier Becerra
HHS Office of the Secretary
Secretary, Health & Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201
c/o Sean McCluskie
sean.mccluskie@hhs.gov

Re: *HHS Tweet of April 23, 2022 – False Claims Regarding COVID-19 Vaccine Ingredients and Lack of EUA Disclaimer*

Dear Secretary Becerra:

We write to you on behalf of Informed Consent Action Network (“ICAN”) with regard to an April 23, 2022 tweet posted on the official HHS.gov Twitter account.¹



¹ https://twitter.com/hhsgov/status/1517896142226403329?s=21&t=VpWy_d9NQy3I3PJm3wN50Q.

Because this tweet contains misinformation about the ingredients in COVID-19 vaccines, and because it lacks the disclaimer required by Food and Drug Administration's ("FDA") Emergency Use Authorization ("EUA") for Pfizer's COVID-19 vaccine, we request its immediate removal.

The tweet begins by stating, "COVID vaccines for children are made up of ingredients that naturally occur inside of our bodies' cells." Underneath the text is a video of Dr. Amy Edwards, who claims that Pfizer's COVID-19 vaccine is made up of "messenger RNA, which is something that is naturally occurring inside of our cells, wrapped in fat, which is something that is naturally occurring inside of our cells." These are inaccurate and misleading statements.

The mRNA found in Pfizer's COVID-19 vaccines is not like the mRNA that naturally occurs in human cells. The mRNA in COVID-19 vaccines is synthetic. mRNA is made up of a chain of four bases: adenine, guanine, uracil and cytosine.² Uridine is a nucleoside consisting of uracil and D-ribose and a component of RNA.³ The mRNA used in COVID-19 vaccine swaps out the nucleoside Uridine and replaces it with a pseudouridine, a wholly foreign substance not naturally found inside human cells.⁴ Moreover, the "mRNA" in the vaccine has non-coding sections at the beginning and the end that are modified and optimized, and not found naturally in human cells.⁵

Additionally, the tweet and accompanying video clip insist that the lipid envelope, or fat, containing the mRNA is also just like naturally occurring fat found in the human body's cells. To the contrary, the "fat" found in COVID-19 vaccines is made up of lipid nanoparticles,⁶ which are not the same kind of fat that is naturally occurring in the human body. For instance, nano-lipid particles contain the ingredient polyethylene glycol (PEG-2000).⁷

Beyond that, Pfizer's mRNA vaccines, depending on the formulation, may contain other ingredients such as acids and stabilizers, including tromethamine and tromethamine hydrochloride, dibasic sodium phosphate dihydrate, and monobasic potassium phosphate. None of these are ingredients that "naturally occur inside of our bodies' cells."

Finally, the tweet is in violation of the Pfizer EUA, since the tweet failed to include the required disclaimer:

² See <https://www.ncbi.nlm.nih.gov/books/NBK558999/>.

³ See <https://pubchem.ncbi.nlm.nih.gov/compound/uridine>.

⁴ See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8071766/>.

⁵ See <https://berthub.eu/articles/11889.doc>

⁶ Specifically, it is made up of 4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol. <https://www.comirnaty.com/authorized-use?gclid=aw.ds> ("What are the ingredients in the vaccine?").

⁷ Cross, Ryan, *Without these lipid shells, there would be no mRNA vaccines for COVID-19*, Chem. & Engineering News (Mar. 6, 2021), <https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8>. Notably, this ingredient is known to cause anaphylaxis in some. See <https://aacijournal.biomedcentral.com/articles/10.1186/s13223-016-0172-7>.

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 FD&C Act unless the declaration is terminated or authorization revoked sooner.⁸

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.

⁸ See <https://www.fda.gov/media/150386/download> p. 21 (emphasis added).