

November 10, 2022

VIA EMAIL AND FED EX

Robert Califf, MD
Commissioner at FDA
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
commissioner@fda.hhs.gov

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

Victoria Wright, MPH,
Deputy Director, Division of
Reproductive Health
National Center for Chronic
Disease Prevention and Health
Promotion at CDC
Mailstop F-80 Room 2239
4770 Buford Highway NE
Atlanta, GA 30341-3717
Vdc4@cdc.gov

Re: *Reproductive harms and COVID-19 Vaccines*

Dear Commissioner Califf, Director Walensky, and Deputy Director Wright:

On behalf of Informed Consent Action Network (“ICAN”), we write regarding COVID-19 vaccines and their impact on reproduction.

In its COVID-19 vaccine clinical trial, Pfizer implemented strict protocols concerning reproduction in its human participants. Specifically, “during the intervention period and for at least 28 days after the last dose” male participants were required to:

- **Refrain from donating sperm.**

PLUS either:

- **Be abstinent from heterosexual intercourse** with a female of childbearing potential as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent.

OR

- Must agree to **use a male condom** when engaging in any activity that allows for passage of ejaculate to another person.
- **In addition to male condom use, a highly effective method of contraception** may be considered in WOCBP partners of male

participants (refer to the list of highly effective methods below in Section 10.4.4).¹

Pfizer explained that these requirements applied during the intervention period [receipt of the vaccine] and for at least 28 days after the last dose of study intervention, as that time period “corresponds to **the time needed to eliminate reproductive safety risk of the study intervention(s).**”²

Likewise, females who were pregnant or breastfeeding were ineligible to participate in the trial and all other females were only eligible to participate in the study if one of the following conditions applied:

- Is not a WOCBP [woman of childbearing potential].

OR

- Is a WOCBP and **using an acceptable contraceptive method** as described below during the intervention period (for a minimum of 28 days after the last dose of study intervention). The investigator should evaluate the effectiveness of the contraceptive method.³

Pfizer plainly had a reason for implementing these eligibility requirements for its trial (to eliminate reproductive safety risk), which resulted in the COVID-19 vaccine not being studied as to its effects on reproduction or on breastfeeding babies.⁴ It is highly concerning that Pfizer did not study potential reproductive issues given that its own study conducted prior to the clinical trial showed that the lipids and mRNA from the COVID-19 vaccine remain in the testes for at least up to 48 hours with increasing concentration levels at 25 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 24 hours, and 48 hours post-vaccination.⁵

In light of this, ICAN requests an explanation as to why these same instructions and conditions concerning reproduction were not part of the use instructions when the vaccines were offered to the American public. Instead, both the FDA and CDC both strongly promote that *everyone* 6 months and older receive a COVID-19 vaccines as soon as he or she is eligible – including pre-pubescent children, women of childbearing potential, pregnant women, breastfeeding women, and men and women who are sexually active. There were no instructions given to Americans to abstain from intercourse post-vaccination to “eliminate reproductive safety risk of the” vaccine. An explanation is warranted.

¹ https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf at 132 (emphasis added).

² *Id.* (emphasis added).

³ *Id.* at 132-133.

⁴ The one developmental toxicity study performed in female rats is inadequate.

⁵ See https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf#page=3 at 24.

Moreover, post-marketing studies show:

- Pregnancy and menstrual abnormalities⁶
- Impairment of semen concentration and total motile count⁷
- Increased incidence of spontaneous abortion⁸

These post-marketing studies, among myriad others, reflect that there exists a real-world concern about adverse effects of COVID-19 vaccines on reproduction generally – a concern that Pfizer appeared to understand when its trial was being conducted yet did not adequately assess. The FDA’s role is to demand adequate testing on new vaccines and to be transparent about benefits and risks. This has not occurred.

ICAN requests that you provide the following:

1. An explanation as to why the conditions concerning reproduction that were part of Pfizer’s trial were not part of the use instructions when the vaccines were offered to the American public;
2. While it is no substitute for clinical trial data, please provide any and all studies that led the FDA and CDC to conclude that the vaccine would not adversely affect reproductive health when authorizing, licensing, and recommending Pfizer’s COVID-19 vaccine to all Americans ages 6 months and older; and
3. Any other relevant studies that have been conducted or are being conducted by Pfizer, federal health agencies, or any third parties that are looking at these reproductive issues and that have not been made public.

ICAN looks forward to your prompt response to this alarming concern.

Very truly yours,



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

⁶ Thorp, J.A.; Rogers, C.; Deskevich, M.P.; Tankersley, S.; Benavides, A.; Redshaw, M.D.; McCullough, P.A. COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function. Preprints 2022, 2022090430 (doi: 10.20944/preprints202209.0430.v1) available at <https://www.preprints.org/manuscript/202209.0430/v1>; see also <https://pubmed.ncbi.nlm.nih.gov/34991109/> (demonstrating change in menstrual cycles length); <https://bmjmedicine.bmj.com/content/1/1/e000297> (confirming link between COVID-19 vaccination and increase in menstrual cycle length).

⁷ Gat, I, Kedem, A, Dviri, M, et al. Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors. *Andrology*. 2022; 10: 1016– 1022. <https://doi.org/10.1111/andr.13209> available at <https://onlinelibrary.wiley.com/doi/epdf/10.1111/andr.13209>.

⁸ https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_2bd97450072f4364a65e5cf1d7384dd4.pdf.