Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT

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

July 14, 2021

Dr. Janet Woodcock
Acting Commissioner, U.S. Food and Drug Administration
M.D. 5630 Fishers Lane Rm. 1061
Rockville, MD 20852
Janet.woodcock@fda.hhs.gov

Ms. Lorrie H. McNeill
Director, Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Mailstop HFM-40
Bldg. WO71, Rm. 4120
Silver Spring, MD 20993
Lorrie.mcneill@fda.hhs.gov

Dear Dr. Woodcock and Ms. McNeill,

Thank you for your June 18, 2021 response to ICAN's March 3, 2021 letter referencing FDA Docket No. FDA-2020-P-1601. ICAN is pleased that the FDA agrees with the importance of a placebo control group within a clinical trial and with continuing that group even after issuance of an emergency use authorization ("EUA'). It also understands that the FDA cannot force participants to *not* get an EUA product. But what the FDA certainly could have done, and should have insisted upon, is that the companies granted EUA for their COVID-19 vaccines not actively encourage the placebo recipients in their COVID-19 trials to get the vaccine.

Pfizer sent a letter to placebo participants on December 14, 2020, 3 days after receiving EUA, saying: "Healthcare workers will be the first to receive the vaccine (if placebo group). The vaccine will be offered to all other participants (non-healthcare workers) during Visit 4/Month 6…We hope to vaccinate all healthcare participants Wednesday and Thursday of this week."

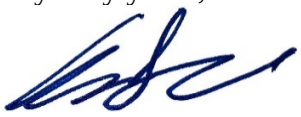
Moderna sent a letter as early as November 23, 2020 stating: "Our intention is to ensure that all participants ultimately have the option of receiving the vaccine." On December 14, 2020, 4 days prior to receiving EUA, a Moderna follow-up letter stated: "If you would like to know whether you have received the mRNA-1273 vaccine or placebo, then you will be offered the opportunity to be unblinded…If you find out that you received the placebo, we plan to offer you the opportunity to receive the mRNA-1273 vaccine and to continue to be followed in the study. We hope to start offering the vaccine within approximately 1-2 weeks after EUA is granted for mRNA-1273."

J&J reportedly sent an email to its trial participants in March 2021, days after receiving EUA, stating: "Once the upcoming protocol amendment is approved, we will be able to unblind

all of our research subjects, and we will be offering the investigational vaccine to subjects who were randomly assigned to the placebo group."

The obvious purpose of these letters and other communications to trial participants was to encourage their placebo recipients to get the vaccine. The worst part is that, despite this open defiance of the FDA's wishes and what is best to protect the American public and assure the safety and efficacy of the clinical trials, as far as we can tell, the FDA has done nothing to punish the companies for this open rebellion against the FDA's guidance. This should not stand. The FDA should, at the least, not reward these companies for defying it by still licensing any of these vaccines based on a mere 6 months' worth of data. It should demand at least two years' worth of data, especially because of the lack of placebo groups, before even considering granting licensure.

Very truly yours,



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