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VIA EMAIL AND DOCKET NO. CDC 2022-0051 April 19, 2022

Rochelle Walensky
Director, CDC
Aux7@cdc.gov

Members, Advisory Committee for
Immunization Practices
acip@cdc.gov

Re: *April 20, 2022 ACIP Meeting: "Discussion on COVID-19 vaccine booster doses"*

Dear Dr. Walensky and ACIP Members:

We write on behalf of our client, Informed Consent Action Network ("**ICAN**"), in advance of the ACIP meeting scheduled to discuss Covid-19 vaccine booster doses. We would like to bring to your attention several concerns in connection with a vote to recommend same.

A large body of literature shows that pharmaceutical companies design clinical trials in their favor by asking the wrong questions.[1] ICAN has observed a similar pattern with the CDC and ACIP which often get the wrong answers because they ask the wrong questions. As we will explain below, "how many and for whom do we recommend boosters" is the wrong question.

There is a lack of adequate data to evaluate the efficacy of, and therefore to conduct a proper risk/benefit analysis of, Covid-19 vaccine booster doses. First, it was recently revealed that the CDC has collected yet withheld large portions of data relevant to Covid-19 and, importantly, "the performance of vaccines and boosters, particularly in younger adults, is the most glaring omissions in data that CDC has made public."[2] It is unclear whether ACIP members will be privy to this data prior to voting on any vaccine booster recommendations.

Second, interpreting data that *has* been disclosed raises concerns as much of this data relies on measures of antibody response. As numerous members of VRBPAC recently pointed out at their April 6, 2022 meeting, and a large body of literature in vaccinology underscores, antibody response does not necessary tell one if a vaccine will work.[3] In fact, B and T cells may be more important but the vaccine manufacturers, FDA, and CDC do not have sufficient data on B and T

[1] Richard Smith, (2005). Medical journals are an extension of the marketing arm of pharmaceutical companies. *PLoS Medicine*, 2(5), 364–366 available at https://doi.org/10.1371/journal.pmed.0020138.

[2] https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html.

[3] *See* https://www.youtube.com/watch?v=x8rq247E80I&t=31027s starting at 3:32:09 (Dr. Rubin stated: "We don't really have the great, very specific, level of antibody that correlates highly with protection…It's hard to know where [among antibody levels] …protection is occurring…We know what kind of antibody response can be generated, we just don't know if it works." The response to his concern is that this "is a reasonable criticism.").

cell response (or if they do have that data, it has not been publicly released).

Despite this lack of data, the FDA recently authorized additional booster shots for individuals 50 years of age or older and certain immunocompromised individuals. Some of the data relied upon by the FDA to do so was immunogenicity data from an ongoing, non-randomized study in healthcare workers at one location in Israel. In this study, healthcare workers who had received a first booster were administered a second booster dose. Only 154 individuals received a Pfizer booster and only 120 individuals received a Moderna booster. Increases in neutralizing antibody levels against the virus were observed two weeks after the second booster. First, this is a non-randomized study. Second, it is underpowered. Third, it is unclear how long the increase in antibodies will last beyond two weeks.

Additionally, there is the question of whether these results even translate to real-world efficacy. At the April 6, 2022 VRBPAC meeting, Dr. Eric Rubin stated, "We know what kind of antibody response can be generated, we just don't know if it works."[4] While ICAN appreciated Dr. Rubin's candor, what he has described is a stopping condition. If you do not know if the vaccine works, you should not proceed. Said differently, you cannot proceed with a recommendation for boosters unless the FDA can clearly determine correlates of protection, which would require properly powered and administered clinical trials using real world health outcomes. Short of that, arbitrary increases in short-lasting antibodies are not enough to support a recommendation.

During an April 6, 2022 VRBPAC discussion concerning the future of Covid-19 vaccine authorizations or approvals, Dr. Cody Meissner posed the following valid and important questions which went unanswered during the meeting:

"At what point will we say that the vaccine is not working well enough?"

"Why are we seeing so many variants?"

"Why do we see mutations in SAR-CoV-2 that are greater than in influenza?"

Answering these questions is essential and, yet again, ICAN has no confidence that CDC or anyone on ACIP will likewise raise them or answer them. ICAN believes that the answer to the first question is, "Now." We now know that the vaccines do not stop infection and transmission. We also know that any protective effect they do offer quickly wanes. Yet ACIP will soon vote on whether to recommend continued doses of these vaccines, expecting, somehow, different results.

What Dr. Meissner appears to be getting at with his second and third questions is whether Covid-19 vaccines are accelerating the evolution of the virus in ways that increase the likelihood of viral escape. Other experts have theorized that we may soon be facing highly infectious and highly virulent variants in vacinees as a result of the very vaccines which ACIP considers recommending additional doses of.[5] The fact that the FDA is unable to answer these essential

[4] *See* https://youtu.be/x8rq247E80I?t=12762 from 3:32:42 to 3:32:42.

[5] *See* https://uploads-ssl.webflow.com/616004c52e87ed08692f5692/6244c3b09ad5701f3ec17765_GVB_s%2B

questions, after 564 million doses of this product have already been injected into Americans, is astonishing,[6] and is certainly reason enough for ACIP and the CDC to withhold a recommendation for additional booster shots.

ICAN should not have to point any of this out. If the CDC and ACIP were doing their jobs and upholding foundational scientific principles, these issues would have been addressed and resolved in the interests of the American public prior to the April 20 meeting. The scientific evidence does not support recommending Covid-19 vaccine booster recommendations.

Therefore, ICAN strongly encourage the CDC and ACIP to engage with these foregoing critiques prior to and during its upcoming meeting.

Regards,

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

analysis%2Bof%2BC-19%2Bevolutionary%2Bdynamics.pdf.

[6] *See* https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.