Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER

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

March 23, 2022

VIA EMAIL
Members, Vaccines and Related Biological Products Advisory Committee
Food and Drug Administration
VRBPAC@hhs.fda.gov

Re: March 3, 2022 meeting, recommendations on the selection of strains to be included in the influenza virus vaccines for the 2022-2023 influenza season

We write on behalf of the Informed Consent Action Network ("**ICAN**") to bring to your attention several concerns in connection with your meeting on March 3, 2022 during which you discussed and recommended strains for use in the influenza vaccines for the upcoming flu season.

As you know, VRBPAC met a year ago – on March 5, 2021 – to recommended four strains to include in influenza vaccines for the 2021-2022 flu season. The evidence subsequently presented by Captain Lisa Grohskopf at the ACIP meeting February 23, 2022 and at the VRBPAC meeting March 3, 2022 showed that your plan did not work. Evidence from the 7 sites that participate in the U.S. Flu Vaccine Effectiveness Network showed that the influenza vaccine that you recommended is only **8% effective** against influenza A and **14% effective** against influenza A/H3N2.[1] The 95% confidence intervals included the **possibility of negative efficacy** against both of those strains.

What is more, evidence presented by Captain Grohskopf from "an influenza outbreak at a large university campus" during October-November 2021 showed that the vaccine effectiveness was zero.[2] Paul Offit attempted to save the narrative by asking if perhaps the vaccine prevented hospitalizations? Captain Grohskopf answered, "no data on that."

The complete failure of your recommendations from the year before should prompt critical questions and a re-examination of the committee's whole approach before moving forward this year. Instead, however, the committee repeated the exact same failed steps from the year before (one-size-fits-all recommendations from the World Health Organization, rubber stamped by VRBPAC). It is alarming to see scientific experts doing the same thing over and over again and expecting a different result. The American people deserve better.

[1] https://www.fda.gov/media/156627/download slide 13 at p. 12.

[2] https://www.fda.gov/media/156627/download at p. 9.

Vaccines that are less than 50% effective should not be recommended, period. If these flu vaccines were coming before the FDA for the first time as novel vaccines (instead of being grandfathered in, year after year, despite changing formulations) they would not be approved. Based on the data presented at the VRBPAC meeting, the FDA/VRBPAC and CDC/ACIP have a duty of care to remove approval and recommendation for this product.

Relatedly, it is troubling that Dr. Wentworth seemingly does not understand some of the statistics he is discussing regarding vaccine efficacy. During the recent meeting, Dr. Wentworth stated that, "There is no such thing as negative VE. That negative number does not mean that the vaccine causes more flu." That is simply not the case. There is a large body of literature on original antigenic sin and antibody-dependent enhancement that shows that some vaccines do indeed lead to more cases and worse outcomes than not vaccinating at all.[3] ICAN asks that VRBPAC members challenge him on this point and raise these important issues of original antigenic sin and antibody-dependent enhancement.

Further, the absence of any discussion regarding adverse events over the course of the four-hour meeting recommending a vaccine is concerning. It is impossible to assess the tradeoff between risks and benefits from a product without discussing adverse events.

In her presentation to ACIP on February 23, Sinead Morris noted that 80% of people who receive the flu vaccine receive the "enhanced" formulation (enhanced in this case refers to "high dose, adjuvanted, and recombinant flu vaccines").[4] The enhanced formulations come with a safety profile that must be factored into any risk benefit calculations. For example, FLUAD and FLUAD Quadrivalent are adjuvanted with MF59, an "oil-in-water emulsion of squalene oil."[5] Squalene has been linked with a wide range of adverse effects including autoimmunity.[6] Any discussion of the use of enhanced flu vaccines must incorporate valid real-world estimates of the increased rate of adverse events. Anyone who is considering receiving these injections must be presented with accurate information about risks and benefits or informed consent is impossible.

To be clear, influenza is a concern. But there is little to no evidence from the VRBPAC meeting that your response to the flu offers any improvement over doing nothing at all. Indeed, given the historic low efficacy and high rate of adverse events, the recommendations of VRBPAC will likely leave patients worse off which is a violation of your duty of care.

Assuring that no shortcuts are taken in reaching your conclusion, including assuring complete data and careful analysis, is critical because, as you know, many institutions convert your recommendations into rights-crushing and informed consent-eliminating mandates.

---

[3] See e.g. Anup Vatti et al. "Original antigenic sin: a comprehensive review." *Journal of autoimmunity* 83 (2017): 12-21. https://doi.org/10.1016/j.jaut.2017.04.008

[4] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-23-24/03-influenza-morris-508.pdf at p. 2.

[5] https://www.cdc.gov/flu/prevent/adjuvant.htm

[6] See e.g. Yehuda Shoenfeld, Nancy Agmon-Levin, and Lucija Tomljenovic (Editors), *Vaccines and Autoimmunity*. (2015). https://www.amazon.com/Vaccines-Autoimmunity-Yehuda-Shoenfeld/dp/1118663438.

Unfortunately, it appears that VRBPAC continues to stick with a failed strategy in spite of the abundant evidence that it should change course. ICAN looks forward to your response to the concerns we have raised.

Very truly yours

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

Cc: Peter Marks, Peter.Marks@fda.hhs.gov
Janet Woodcock, Janet.Woodcock@fda.hhs.gov