December 10, 2024

VIA EMAIL AND FEDEX

Members, Vaccines and Related Biological
Products Advisory Committee
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71
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Re: *Upcoming December 12, 2024, VRBPAC Committee Meeting – Considerations for Respiratory Syncytial Virus Vaccine Safety in Pediatric Populations*

Dear VRBPAC Members:

We write on behalf of our client, Informed Consent Action Network ("**ICAN**"), regarding VRBPAC's upcoming December 12, 2024 meeting, wherein vaccine safety considerations regarding Respiratory Syncytial Virus ("**RSV**") vaccines in pediatric populations will be discussed. We urge you to pay particular attention to the phase 3 clinical trial data on pediatric and maternal RSV vaccine candidates that were recently presented at the October 23, 2024 Advisory Committee for Immunization Practices ("**ACIP**") meeting.

As you are most certainly aware, Merck's new pediatric RSV vaccine candidate, Clesrovimab (MK-1654), is currently undergoing phase 3 clinical trials. During October's ACIP meeting, Dr. Anushua Sinha of Merck presented data from a study of approximately 3,600 healthy infants, as well as a study of approximately 900 infants with underlying medical conditions.[1] In the healthy infant study, there were 7 infant deaths in the vaccinated cohort and 3 in the placebo group. In the study of infants with underlying conditions, there were 8 infant deaths in the vaccinated group compared to just 4 infant deaths in the placebo group. Incredibly, adverse events were only solicited for 5 days. Despite the fact that there were *double the number of infant deaths in the vaccinated groups in both studies*, not one ACIP member expressed any safety concerns. Astonishingly, Merck nevertheless concluded that Clesrovimab's safety profile was "generally comparable to placebo."[2] VRBPAC must not make the same dangerous mistake. It is VRBPAC's obligation to investigate and address the glaringly obvious safety issues with this vaccine before it is recommended to any individual—most especially American children.

Relatedly, during ACIP's October meeting, Dr. Malini DeSilva of Health Partners Institute presented Vaccine Safety Datalink data on Pfizer's maternal RSV vaccine candidate, RSVpreF

[1] *See generally* https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/02-RSV-Mat-Peds-Sinha-508.pdf.

[2] https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/02-RSV-Mat-Peds-Sinha-508.pdf at 12.

(Abrysvo).[3] Dr. DeSilva mentions that GSK was forced to halt its trial of a similar vaccine because of the undeniable imbalance in preterm births in the vaccinated group compared to the placebo group, and that Pfizer's clinical trial also showed an imbalance.[4] Most premature births occurred beyond 30 days after vaccination. However, the new data for Abrysvo that Dr. DeSilva presented showed that the risk of preterm and SGA birth was similar among the vaccinated and placebo groups in women who received the experimental vaccine at 32-36 weeks gestation. Dr. DeSilva confidently stated that the RSV vaccine "is not associated with increased risk for preterm birth or SGA at birth."[5] What is concerning about the data Dr. DeSilva presented is that it does not show the distribution of gestational age at birth for the babies in the analysis. Since we know that the premature births were occurring more than 30 days after vaccination, it would be critical to know if the vaccine was causing early births at 37- or 38-weeks' gestation. While that age is not considered preterm, it still carries an increased – and potentially unjustifiable – risk for an adverse outcome.[6]

As detailed above, a closer review of the safety data for both Clesrovimab and Abrysvo is critical to protecting the safety of unborn children and infants. At a minimum, any public messaging regarding this vaccine **must** include the warning that pregnant women should not receive these vaccines prior to 32 weeks gestation or else they risk harming their babies. VRBPAC must unequivocally consider, address, and debate the above points at its December 2024 meeting before even considering a vote on recommending these vaccine candidates to pregnant women and infants. Failure to do so will only further erode the public's highly diminished level of trust and confidence.

Very truly yours,
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[3] https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/03-RSV-Mat-Peds-DeSilva-508.pdf.

[4] https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/03-RSV-Mat-Peds-DeSilva-508.pdf at 5.

[5] https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/03-RSV-Mat-Peds-DeSilva-508.pdf at 13.

[6] https://pmc.ncbi.nlm.nih.gov/articles/PMC9314589/.