January 24, 2025

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
Silver Spring, MD 20993-0002
VRBPAC@fda.hhs.gov
CBERVRBPAC@fda.hhs.gov

Re: *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 December 12, 2024 meeting, at which vaccine safety considerations for Respiratory Syncytial Virus ("**RSV**") vaccines in pediatric populations were discussed.

Given the acknowledged connection between Moderna's mRNA vaccine and vaccine-associated enhanced respiratory disease ("**VAERD**"), we are relieved that the clinical trial has been halted. However, we find it deeply concerning that VRBPAC appears undeterred in its support for clinical trials of live-attenuated RSV vaccines and monoclonal antibodies for infants, despite committee members' admission that there is a crucial lack of knowledge when it comes to the infant immune response to RSV.

During the meeting's discussion on safety guidelines for the clinical trials of RSV vaccines for infants, Committee Chair Hana El Sahly, MD stated, "It seems that the moment you get into the unexposed infants, the predictive value of all these steps goes down. So, it remains that these infants, these seronegative infants have no animal model that predicts their response to a degree, nor do their older seropositive counterparts predict their response either. That is a conundrum."[1] Subsequently, NIH's Adam Berger, PhD stated, "I'd like to see … a better evidence base about what's actually happening in response to natural disease so we can understand the vaccine-induced immunology."[2] Finally, CDC's Captain Sarah Meyer, MD, MPH, stated, "[W]e are talking about a safety signal and we don't really understand the mechanism why. So, for me, it makes it very difficult to comment… without really understanding what we think may have happened here or why the safeguards we put in place didn't necessarily predict severe outcomes."[3] In light of this

[1] https://www.fda.gov/media/184700/download at 119.

[2] *Id*. at 136.

[3] *Id.* at 144.

clear and admitted gap in vital data, we strongly urge you to recommend halting the participation of *any* infants younger than 6 months in RSV vaccine clinical trials until a clearer understanding of the young infant immune system is obtained.

In addition, we once again ask that you dig deeper on the safety data for the monoclonal antibody Clesrovimab and the maternal vaccine Abrysvo, as we highlighted in our December 10, 2024 letter to you. Specifically, we encourage you to closely review the data that showed double the number of infant deaths among the treatment groups for both Clesrovimab studies,[4] as well as the data showing an undeniable imbalance in preterm births occurring among pregnant women who received Abrysvo.[5] VBRPAC must satisfactorily address this gravely serious issue before it considers recommending the approval of *any* RSV product for infants.

Beyond the troubling clinical trial data and the gaps in data for seronegative infants, the lack of currently available data on infant RSV-related deaths in the United States is highly concerning. The most recent study available cites only 96 annual infant RSV-related deaths.[6] Significantly, this data has not been updated since 2018, which was well before any licensed RSV preventatives were available. Given the recent uncertainty surrounding whether RSV products prevent or exacerbate illness in infants, it is critical that VRBPAC obtain thorough, updated RSV mortality statistics as soon as possible; as VRBPAC should be well aware, it is impossible to conduct an accurate benefit-risk profile for any vaccine without first having accurate and up-to-date data on the disease that the vaccine is intended to prevent.

We look forward to seeing the above issues promptly addressed at your next meeting.

Very truly yours,

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[4] https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/02-RSV-Mat-Peds-Sinha-508.pdf at 11 and 16.

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

[6] https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2789446.