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December 9, 2020

*Submitted electronically via regulations.gov.*

Hana El Sahly, MD  
Chair  
Vaccines and Related Biological Products Advisory Committee  
US Food and Drug Administration  
Silver Spring, MD 20993

RE: Docket No. FDA-2020-N-1898; Vaccines and Related Biological Products Advisory Committee; US Food and Drug Administration

Dear Dr. Sahly,

On behalf of the Society for Maternal-Fetal Medicine (SMFM), which represents more than 5,000 members dedicated to optimizing the health of high-risk pregnant women and their babies, I thank you for the opportunity to submit public comments as you consider Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine. Your committee’s commitment to carefully reviewing data and developing recommendations centered in equity are essential to inspiring vaccine confidence and ending the COVID-19 pandemic. As you deliberate tomorrow, SMFM encourages you to carefully consider the unique needs of both pregnant and lactating individuals.

On October 30, the Advisory Committee on Immunization Practice received a presentation that included the latest data from the Centers for Disease Control and Prevention (CDC) on the epidemiology of COVID-19 in pregnant women. The presentation confirmed that pregnant women with COVID-19 have a higher relative risk of intensive care unit admission, mechanical ventilation, extracorporeal membrane oxygenation (ECMO), and death compared to non-pregnant women. Further, newborns born to mothers with COVID-19 are at an increased risk of preterm birth. Additionally, the presentation highlighted that 330,000 healthcare personnel are expected to be pregnant or recently postpartum when new COVID-19 vaccines become available. Given that pregnant women are at increased risk for severe COVID-19 and that a significant number of pregnant or lactating women are healthcare personnel, which will be prioritized for vaccination in phase 1a, it is important that this Committee not exclude individuals who are pregnant and those who are lactating from receiving the Pfizer-BioNTech COVID-19 vaccine.



On December 1, SMFM released a statement to educate our members about forthcoming COVID-19 vaccines and help them counsel their patients.<sup>1</sup> The statement notes that, “SMFM strongly recommends that pregnant women have access to COVID-19 vaccines in all phases of future vaccine campaigns, and that she and her healthcare professional engage in shared decision-making regarding her receipt of the vaccine. Counseling should balance available data on vaccine safety, risks to pregnant women from SARS-CoV-2 infection, and a woman’s individual risk for infection and severe disease. As data emerge, counseling will likely shift, as some vaccines may be more suitable for pregnant women.” Further, the statement explicitly recommends “that healthcare workers, who are considered prioritized for vaccination, be offered the vaccine if pregnant.” The statement also provides details on presumed vaccine safety for mRNA vaccines, data that is essential to inform shared decision-making.

In the absence of safety data on pregnancy and lactation from the vaccine sponsor, SMFM strongly encourages the Committee to permit the use of the Pfizer-BioNTech COVID-19 vaccine by pregnant or lactating individuals. A woman’s decision to receive the vaccine should be made in consultation with her healthcare provider. Further, we are pleased to see that the vaccine sponsor plans to maintain a pregnancy registry and look forward to collaborating to ensure robust data collection. A permissive recommendation for these two populations is especially important as there are many pregnant and lactating women in phase 1 priority populations. Failure to incorporate these populations in recommendations has the potential to limit access to vaccines for pregnant and postpartum women.

SMFM thanks you again for your work during this unprecedented time. Our members stand ready to work with you to ensure that COVID-19 vaccines are quickly administered to the patients we serve and bring this pandemic to an end. Please direct questions to Rebecca Abbott, Director of Government Relations ([rabbott@smfm.org](mailto:rabbott@smfm.org)).

Sincerely,



Judette Louis, MD, MPH  
President

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<sup>1</sup> Society for Maternal Fetal-Medicine. Society for Maternal-Fetal Medicine (SMFM) Statement: SARS-CoV-2 Vaccination in Pregnancy. December 1, 2020. Available at: [https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM\\_Vaccine\\_Statement\\_12-1-20\\_\(final\).pdf](https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM_Vaccine_Statement_12-1-20_(final).pdf).

