Society for Maternal-Fetal Medicine

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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-2021-N-0173; 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 people and their babies, we thank you for the opportunity to submit public comments as you consider Emergency Use Authorization (EUA) of the Janssen Biotech Inc. 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.

SMFM appreciates the careful consideration VRBPAC members have paid to the unique needs of pregnant and lactating people during deliberations, and we are pleased that both pregnant and lactating individuals were not excluded from the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) for the use of the Pfizer-BioNtech and Moderna, Inc., COVID-19 mRNA vaccines. FDA's decision, supported by this Committee's recommendation, will ensure that these populations are able to weigh the risks and benefits of vaccination, often in consultation with their clinicians, and then decide the best course of action for themselves. SMFM encourages VRBPAC to make a similar recommendation for the COVID-19 Vaccine from Janssen Biotech Inc.

Including pregnant and lactating people in the authorizations for COVID-19 vaccines is especially important given the increased risk posed to pregnant individuals by COVID-19 infection. On October 30, the Advisory Committee on Immunization Practice (ACIP) 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 people. The presentation confirmed that pregnant patients 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 patients. 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 currently pregnant or recently postpartum, and that number will be even greater as vaccines are offered to essential workers and other priority populations in phase 1 and beyond. Given that pregnant people are at increased risk for severe COVID-19 and that a significant number of pregnant or lactating people are included in populations prioritized for vaccination, this Committee should not exclude individuals who are pregnant and those who are lactating from receiving the Janssen Biotech Inc. 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.[i] 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 vaccine safety for both mRNA and viral vector vaccines, data that is essential to inform shared decision-making.

SMFM strongly encourages the Committee to permit the use of the Janssen Biotech Inc. COVID-19 vaccine by pregnant or lactating individuals. These individuals should be allowed to make a decision regarding the receipt of vaccine after weighing unknown potential risks and known benefits in in consultation with their healthcare provider. A permissive recommendation for these two populations is especially important because many states are moving to vaccinate individuals in phase 1c, which includes pregnant people due to their increased risk of severe illness. Failure to incorporate these populations in recommendations has the potential to limit access to vaccines for pregnant and postpartum people.

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).

Sincerely,

William Grobman, MD, MBA
President

Christina J. Wurster, MBA, CAE
Chief Executive Officer

[i] 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.