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February 25, 2020

Submitted electronically via regulations.gov.

José R. Romero, MD, FAAP
Chair
Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
Atlanta, GA 30329

Re: Docket No. CDC-2021-0021, Notice of meeting and request for comment, Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Department of Health and Human Services

Dear Dr. Romero,

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, thank you for the opportunity to submit public comments regarding the Advisory Committee on Immunization Practices' (ACIP) important work to develop recommendations to guide the administration and distribution of forthcoming SARS-CoV-2 vaccines (COVID-19 vaccines). Your committee's commitment to carefully reviewing data as it becomes available and developing evidence-based recommendations centered in equity are essential to inspiring vaccine confidence and ending the COVID-19 pandemic.

SMFM appreciates the careful consideration ACIP 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 ACIP interim recommendations for the use of the Pfizer-BioNtech mRNA and Moderna, Inc., COVID-19 vaccines. ACIP's decision will help 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 ACIP to make a similar recommendation for the COVID-19 vaccine from Janssen Biotech Inc. if these populations are included in a forthcoming Emergency Use Authorization from the Food and Drug Administration.

Including pregnant and lactating people in ACIP's recommendations is especially important given the increased risk posed to pregnant individuals by COVID-19 infection. On October 30, ACIP received an update from Megan Wallace, DrPH, MPH, BS, on the epidemiology of COVID-19 in pregnant people. During her presentation, Dr. Wallace shared the latest Centers for Disease Control and Prevention data confirming 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. Dr. Wallace also highlighted that there are approximately 330,000 healthcare personnel that are pregnant or recently postpartum at any given point in time, and the number of pregnant and postpartum individuals will be even greater as vaccines are offered to essential workers and other priority populations in phase 1. Given that pregnant people are at increased risk of severe COVID-19 and that a significant number of pregnant or lactating people are included in populations prioritized for vaccination, ACIP's recommendations must continue to include guidance on immunizing pregnant and lactating populations to guarantee access to vaccine.

On December 1, SMFM released a statement to educate our members about forthcoming COVID-19 vaccines and help them counsel their patients.¹ 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 ACIP to continue to include pregnant and postpartum individuals in your recommendations and provide guidance to patients and health care providers using the best available evidence. This will guarantee access to vaccine for these populations and support them and their clinicians to make the best decisions regarding the receipt of vaccine based on individual circumstances.

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

¹ 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).

