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December 1, 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-2020-0121, 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 women 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. As you continue your work, SMFM encourages you to carefully consider the unique needs of both pregnant and lactating individuals and incorporate these populations in forthcoming recommendations.

On October 30, ACIP received an update from Megan Wallace, DrPH, MPH, BS, on the epidemiology of COVID-19 in pregnant women. During her presentation, Dr. Wallace shared the latest Centers for Disease Control and Prevention (CDC) data confirming 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. Dr. Wallace also 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 of 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, ACIP's recommendations must include guidance on immunizing pregnant and lactating populations to guarantee access to vaccine for these populations.

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 include pregnant and postpartum individuals in your recommendations and provide guidance to patients and health care providers using the best available evidence. This 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, as well as forcing them and their clinicians to make decisions regarding the receipt of vaccine without the benefit of ACIP guidance.

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,



Judette Louis, MD, MPH
President

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).

