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Experts in High-Risk Pregnancy Respond to the FDA's Decision to Offer the Newly Approved COVID-19 Vaccine to Pregnant and Lactating People

Healthcare Workers Among the First Expected to Be Impacted

December 11, 2020 - The Food and Drug Administration's Advisory Committee on Vaccines and Related Biological Products met on December 10, 2020 to consider the request for Emergency Use Authorization of a SARS-CoV-2 (COVID-19) vaccine from Pfizer. The Advisory Committee recommended, and the FDA Commissioner today agreed to <u>authorize the EUA</u>. The Society for Maternal-Fetal (SMFM) released the following statement in response.

"SMFM applauds the FDA's recent decision, which will allow pregnant and lactating people to access the COVID-19 vaccine. It is expected that this decision will impact pregnant and lactating healthcare workers beginning as early as next week. In addition to affording significant individual-level protections, keeping health care workers safe enables them to continue to provide medical care to those who are sick with COVID-19 or other illnesses.

An estimated 75% of healthcare workers are women and the Centers for Disease Control and Prevention estimates that 330,000 healthcare workers will be pregnant or will have recently given birth when COVID-19 vaccines become more widely available. Recent data have demonstrated that pregnant people are more likely to have severe COVID disease, including an increased risk of ICU admission and death.

In general, <u>SMFM strongly recommends that pregnant and lactating people have access to COVID-19 vaccines</u> and that they engage in a discussion about potential benefits and unknown risks together their with healthcare providers regarding receipt of the vaccine. As stated previously, counseling should balance the lack of data on vaccine safety for the fetus, risks to pregnant people from COVID-19 infection, and a person's individual risk for infection and severe disease.

SMFM acknowledges that data do not exist regarding COVID-19 vaccine safety in pregnant and lactating people, and has long advocated that pre-clinical studies be conducted and that these <u>populations be included in clinical trials</u>. As data emerge, counseling and clinical recommendations will likely shift, as some vaccines may be more suitable for pregnant women."

About SMFM

The Society for Maternal-Fetal Medicine (SMFM) is a non-profit, membership organization based in Washington, DC. With more than 5,000 physicians, scientists and women's health professionals around the world, the Society supports the clinical practice of maternal-fetal medicine by providing education, promoting research, and engaging in advocacy to optimize the health of high-risk pregnant women and their babies. SMFM hosts an annual scientific meeting in which new ideas and research related to high risk pregnancies are unveiled and discussed. For more information, visit SMFM.org.