



March 1, 2021

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:

The undersigned members of the Coalition to Advance Maternal Therapeutics (CAMT) thanks the Advisory Committee on Immunization Practices' (ACIP) for its unprecedented efforts to respond to the ongoing COVID-19 pandemic and appreciates the opportunity to submit public comments as you consider recommendations for the use of the Janssen Biotech Inc. COVID-19 vaccine. We appreciate that the Committee has respected patient autonomy and the unique needs of pregnant and lactating people during past deliberations and not excluded them from ACIP interim recommendations for the use of the Pfizer-BioNtech mRNA and Moderna, Inc. COVID-19 vaccines. We urge you to make similar recommendations for the Janssen Biotech Inc. COVID-19 vaccine if these populations are included in a forthcoming Emergency Use Authorization from the Food and Drug Administration.

CAMT was launched in 2014 with the goal of better understanding the safety and efficacy of prescription drugs, therapeutics, and vaccines used during pregnancy and lactation. The coalition and its member organizations are committed to raising awareness among policy makers and industry about the need to include pregnant and lactating women in clinical trials, where appropriate, to close gaps in knowledge and ultimately improve the health of women and their families. CAMT is committed to protecting the health of pregnant and lactating people through research, not from it.

Recent data has demonstrated that pregnant people are more likely to have severe COVID-19 disease, including an increased risk of ICU admission, mechanical ventilation, extracorporeal membrane oxygenation (ECMO), and death compared to non-pregnant peopleⁱ. Further, mothers with COVID-19 are at an increased risk of preterm birth.ⁱⁱ We also know that pregnant and lactating people comprise a significant number of individuals in priority groups that are currently eligible or will soon be eligible for vaccination. In addition to the estimated 330,000 pregnant health care workers, many essential workers are women of reproductive age, including a disproportionate number of people of color who already face increased risk for complications from COVID-19 illness because of health system inequitiesⁱⁱⁱ. For example, seventy-six percent of teachers, a critical subset of essential workers, are women, and many of them are of reproductive age^{iv}. Unnecessarily prohibiting pregnant and lactating people from accessing vaccinations puts their health, as well as the health of their families and the public, at risk. In general, our organizations recommend that COVID-19 vaccines be made available to pregnant and lactating people who choose to be vaccinated. This enables pregnant and lactating people to make

autonomous decisions regarding receipt of the vaccine. Pregnant and lactating individuals can discuss the potential benefits and unknown risks with their clinicians when appropriate and desired. Given the clear evidence of the dangers of COVID-19 in pregnancy, and the importance of patient autonomy, our organizations urge ACIP to continue to include pregnant and lactating individuals in your recommendations and provide guidance to allow them to make their own decisions regarding COVID-19 vaccination.

CAMT thanks you again for your work during this unprecedented time and your consideration of the needs of pregnant and lactating people. Our organizations stand ready to work with you to ensure that COVID-19 vaccines are equitably, safely, and quickly administered to bring this pandemic to an end.

Please direct questions to Elizabeth Karan at ekaran@artemispolicygroup.com.

Coalition to Advance Maternal Therapeutics

Academy of Breastfeeding Medicine
American Association of Colleges of Pharmacy
American College of Nurse-Midwives
American College of Obstetricians and Gynecologists
Association of Maternal & Child Health Programs
Elizabeth Glaser Pediatric AIDS Foundation
Endocrine Society
Expecting Health
March of Dimes
Maternal Mental Health Leadership Alliance
Mom Congress
National Association of Nurse Practitioners in Women's Health
Organization of Teratology Information Specialists
Preeclampsia Foundation
Society for Birth Defects Research and Prevention
Society for Maternal-Fetal Medicine
Society for Women's Health Research
The American Academy of Allergy, Asthma, & Immunology, with and on behalf of the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS)

ⁱ Zambrano LD, Ellington S, Strid P, et al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1641–1647. DOI: <http://dx.doi.org/10.15585/mmwr.mm6944e3>.

ⁱⁱ Dr. Megan Wallace presentation at October 30, 2020 Advisory Committee on Immunization Practice meeting. Slides available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Wallace.pdf>.

ⁱⁱⁱ Associated Press (2020). Pandemic's front-line work falls on women, minorities. CBS News. Accessed at: <https://www.cbsnews.com/news/fontline-work-women-minorities-pandemic/>

^{iv} National Center on Education Statistics. Characteristics of Public School Teachers. Last updated May 2020. Available at:

[https://nces.ed.gov/programs/coe/indicator_clr.asp#:~:text=See%20Digest%20of%20Education%20Statistics,school%20level%20\(36%20percent\)](https://nces.ed.gov/programs/coe/indicator_clr.asp#:~:text=See%20Digest%20of%20Education%20Statistics,school%20level%20(36%20percent).).