



February 25, 2021

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
Request for Comments

Dear Dr. Sahly;

The undersigned members of the Coalition to Advance Maternal Therapeutics (CAMT) thank members of the Vaccines and Related Biological Products Advisory Committee for their unprecedented efforts to respond to the ongoing COVID-19 pandemic and appreciate the opportunity to submit public comments as you assess an Emergency Use Authorization (EUA) of the Janssen Biotech Inc. COVID-19 vaccine. We appreciate that the Committee has respected patient autonomy by not recommending that pregnant and lactating people be denied access to previously reviewed COVID-19 vaccines, allowing individuals in these populations to make decisions about whether to receive a vaccine based on their own assessment of risk and benefit. We urge you to follow suit for the Janssen Biotech Inc. COVID-19 vaccine and recommend permitting the use of this vaccine by pregnant and lactating people.

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 the Committee to allow pregnant and lactating individuals 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 College of Nurse-Midwives
American College of Obstetricians and Gynecologists
Association of Maternal & Child Health Programs
Elizabeth Glaser Pediatric AIDS Foundation
Endocrine Society
March of Dimes
Maternal Mental Health Leadership Alliance
Mom Congress
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).).