

March 18, 2020

Dr. Francis Collins
Director
National Institutes of Health
10 Center Drive
Bethesda, MD 20892

Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: COVID-19 and Pregnant Women and Lactating Women

Dear Drs. Collins and Hahn,

The undersigned members of the Coalition to Advance Maternal Therapeutics (CAMT) write today to urge you to ensure that pregnant women and lactating women are included in all research for the development of vaccines and therapeutics related to COVID-19. CAMT is comprised of more than twenty organizations who care deeply about the inclusion of pregnant women and lactating women in research and are dedicated to ensuring that medications taken during this time are safe and effective and that the information about them is as transparent and comprehensive as possible.

For more than five years, our organizations have worked together to raise awareness about research gaps in therapeutics for pregnant women and lactating women and the need for inclusion of these women in clinical trials where appropriate to close those gaps. There remain significant gaps in understanding the effects of COVID-19 on pregnant women and lactating women and their infants, and there are few recommendations specific to these women regarding this virus. Based on research from previous coronaviruses, such as SARS-coV and MERS-coV, there is reason to believe that pregnant women may be particularly vulnerable relative to the general population.

Accordingly, we urge you to ensure that pregnant women and lactating women are included in any clinical research related to vaccines and treatments for COVID-19. We are disappointed that pregnant women and breastfeeding women are explicitly excluded from the Adaptive COVID-19 Treatment Trial currently underway at NIH. Rather than excluding pregnant and lactating women from research, we urge your agencies to use their authorities to incentivize and ensure the development of vaccines and treatments suitable for this population by investing in early non-clinical studies to provide for the eventual enrollment of these women in late-stage clinical trials. We also ask that you proactively remove any other barriers and work with sponsors and researchers to ensure that pregnant women and lactating women are included in this critical research.

We also urge you to consult with the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The task force is in the process of developing a report outlining how to implement the 15 recommendations included in its September 2018 report to the Secretary of Health and Human Services. Its experts can provide critical guidance on how to address the unique needs of pregnant

women and lactating women. Most importantly, CAMT agrees with PRGLAC that there needs to be a cultural shift to protect women *through* research rather than protecting them *from* research.

The COVID-19 situation is evolving rapidly, and we appreciate all you are doing to protect Americans from this pandemic. We seek to ensure that pregnant women and lactating women are likewise protected and know that the best way to achieve this goal is to ensure their inclusion in research.

Sincerely,

American Academy of Pediatrics
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 at Genetic Alliance
Marce of North America
March of Dimes
Maternal Mental Health Leadership Alliance
National Association of Nurse Practitioners in Women's Health
Organization of Teratology Information Specialists
Society for Birth Defects Research and Prevention
Society for Maternal-Fetal Medicine
Society for Women's Health Research
Treatment Action Group
United States Breastfeeding Committee
WomenHeart: The National Coalition for Women with Heart Disease

Cc: Dr. Diana Bianchi, Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development and Chair, Task Force on Research Specific to Pregnant Women and Lactating Women

Lisa Kaeser, JD, Executive Secretary, Task Force on Research Specific to Pregnant Women and Lactating Women