

September 8, 2020

Submitted electronically via <http://www.regulations.gov>.

Lowell Schiller, JD
Principal Associate Commissioner for Policy
Food and Drug Administration
Silver Spring, MD 20993

Kaveeta Vasisht, MD
Associate Commissioner for Office of Women's Health
Food and Drug Administration
Silver Spring, MD 20993

RE: Request for Comments: Office of Women's Health Strategic Priorities (Docket ID: FDA-2020-N-1391)

Dear Mr. Schiller and Dr. Vasisht,

The undersigned members of the Coalition to Advance Maternal Therapeutics (CAMT) applaud the critical work of the Office of Women's Health (OWH) and thank you for the opportunity to provide input on OWH's new strategic priorities. Throughout its 26-year history, OWH has made significant strides in advancing women's health through its bold mission. Members of CAMT encourage OWH to build upon that success by including promoting the inclusion of pregnant women and lactating women in clinical trials as a primary strategic priority. Doing so will help eliminate ongoing and unacceptable data gaps that force pregnant women and lactating women and their clinicians to make difficult decisions regarding continuing or initiating therapies.

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 breastfeeding. 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. Our goal is aligned with OWH's mission to "promote the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials."

Each year in the United States, six million women become pregnant,ⁱ nearly four million give birth,ⁱⁱ and more than three million initiate breastfeeding.ⁱⁱⁱ We know that nearly 90 percent of US women will give birth during their lifetime.^{iv} Many women are becoming pregnant later in life, and more women are beginning pregnancy with a pre-existing condition that often requires medication to treat.^v The data clearly indicate that there is a critical need for information on the safety and effectiveness of prescription drugs, therapeutics, and vaccines for this population. More than 90 percent of pregnant women report taking a medication during pregnancy.^{vi} However, there is very little research to determine the safety, efficacy, and appropriate dosing for pregnant women and lactating women. A review of data from ClinicalTrials.gov by the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) shows that only 1 percent of trials mention the word pregnancy or pregnant and only 0.5 percent mention breastfeeding or lactation.^{vii} The dearth of quality clinical trial data forces women to choose whether to initiate or continue taking a medication with little or no clinical evidence

on the impact to her health or the health of her baby. Further, she and her medical provider have scant evidence to inform appropriate dosing.

The ongoing COVID-19 pandemic clearly demonstrates that pregnant women and lactating women continue to be disregarded in clinical trial design, despite the fact that COVID-19 may cause severe illness in pregnant women.^{viii} A recent study found that 65 percent of COVID-19 therapeutic clinical trials excluded pregnant persons, and only 48 actively recruiting or completed drug trials report inclusion of this population.^{ix} Pregnant women and lactating women are currently excluded from all ongoing vaccine trials.^x This hinders the ability of clinicians to treat pregnant women with COVID-19 and precludes more than 6 million Americans from participating in future mass immunization campaign, putting their health, as well as the health of their infants and the public, at risk.

To reverse past and ongoing exclusion of pregnant women and lactating women from clinical trials, OWH must prioritize leading efforts at the Food and Drug Administration to transition the existing research paradigm to one of inclusion. This will take a concerted effort across OWH's program areas: research and development, outreach and communications, and medical initiatives and scientific engagement. Further, OWH must continue to bring its considerable expertise to ongoing intra-agency efforts to advance this goal. Fortunately, in 2018, PRGLAC released its Report to Congress that included 15 detailed recommendations to promote the inclusion of pregnant and lactating women in clinical trials.^{xi} CAMT anticipates that PRGLAC will soon release its implementation plan for those recommendations. Both the 2018 recommendations and the forthcoming implementation plan will provide a blueprint for relevant federal agencies seeking to advance maternal therapeutics. CAMT suggests that by continuing its active engagement with PRGLAC and identifying opportunities to execute PRGLAC's recommendations and the relevant steps included in the forthcoming implementation plan, OWH could significantly advance the proposed strategic priority of promoting the inclusion of pregnant women and lactating women in clinical trials.

Again, CAMT appreciates the opportunity to comment and we urge you to include promoting the inclusion of pregnant women and lactating women in clinical trials as a primary strategic priority. Doing so will meet a critical unmet need and improve the health of women. Please direct questions to Rebecca Abbott, Director of Government Relations, Society for Maternal-Fetal Medicine (rabbott@smfm.org).

Sincerely,
2020 Mom

Academy of Breastfeeding Medicine

American Academy of Allergy, Asthma & Immunology, facilitator of the Vaccines and Medications in Pregnancy Surveillance Study (VAMPSS)

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

Association of Women's Health, Obstetric and Neonatal Nurses

Elizabeth Glaser Pediatric AIDS Foundation

Endocrine Society

Expecting Health

International Community of Women Living with HIV Eastern Africa

Johns Hopkins University

March of Dimes
National Association of Nurse Practitioners in Women's Health
Society for Maternal-Fetal Medicine
Society for Women's Health Research
Stellenbosch University
Treatment Action Group (TAG)
United States Breastfeeding Committee (USBC)
WomenHeart: The National Coalition for Women with Heart Disease

ⁱ Curtin S, Abma J, Ventura S, Henshaw S. Pregnancy rates for U.S. women continue to drop. NCHS data brief, no 136. National Center for Health Statistics. 2013. Available at: <https://www.cdc.gov/nchs/data/databriefs/db136.pdf>

ⁱⁱ Centers for Disease Control and Prevention. Births and Natality. Accessed September 1, 2020. Available at: <https://www.cdc.gov/nchs/fastats/births.htm>

ⁱⁱⁱ Centers for Disease Control and Prevention. Breastfeeding Report Card: United States, 2020. Accessed September 1, 2020. Available at: <https://www.cdc.gov/breastfeeding/data/reportcard.htm>

^{iv} Livingston, G. They're Waiting Longer, but U.S. Women Today More Likely to Have Children Than a Decade Ago. Pew Research Center. January 18, 2018. Available at: <https://www.pewsocialtrends.org/2018/01/18/theyre-waiting-longer-but-u-s-women-today-more-likely-to-have-children-than-a-decade-ago/>

^v Blue Cross Blue Shield Association. Trends in Pregnancy and Childbirth Complications in the U.S. June 17, 2020. Available at: <https://www.bcbs.com/the-health-of-america/reports/trends-in-pregnancy-and-childbirth-complications-in-the-us>

^{vi} Mitchell A, Gilboa S, Werler M, Kelley K, Louik C, Hernandez-Diaz S. Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008. American Journal of Obstetrics & Gynecology. July 2011. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3793635/>

^{vii} Task Force on Research Specific to Pregnant Women And Lactating Women. Report to Secretary, Health and Human Services and Congress. September 2018. Available at: https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf

^{viii} Ellington S, Strid P, Tong V, et al. Characteristics of Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–June 7, 2020. Morbidity and Mortality Weekly Report. June 26, 2020. Available at: <https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a1.htm>

^{ix} Pastick K, Nicol M, Smyth E, Zash R, Boulware D, Rajasingham R, McDonald E. A Systematic Review of Treatment and Outcomes of Pregnant Women with COVID-19 – A Call for Clinical Trials. Open Forum Infectious Diseases. August 13, 2020. Available at: <https://doi.org/10.1093/ofid/ofaa350>

^x Steenhuysen, J. Large U.S. COVID-19 vaccine trials will exclude pregnant women for now. July 31, 2020. Reuters. Available at: <https://www.reuters.com/article/us-health-coronavirus-vaccines-pregnancy/large-u-s-covid-19-vaccine-trials-will-exclude-pregnant-women-for-now-idUSKCN24W1NZ>

^{xi} Task Force on Research Specific to Pregnant Women And Lactating Women. Report to Secretary, Health and Human Services and Congress. September 2018. Available at: https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf