

Comments from the Coalition to Advance Maternal Therapeutics February 2020 PRGLAC Meeting

The Coalition to Advance Maternal Therapeutics sincerely appreciates the opportunity to provide public comments to the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). CAMT is comprised of more than twenty organizations (membership list below) who care deeply about the inclusion of pregnant and breastfeeding 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, we have been working 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. We are strong supporters of the work that PRGLAC has done over the last few years and we agree a shift in our culture is needed to protect women *through* research rather than protecting them *from* research.

We are eager to hear more about the work of PRGLAC Working Groups to develop strategies to implement the 15 recommendations included in its initial report. We also want to again thank PRGLAC for always providing for public participation in its work. The Task Force's open meetings facilitate expert participation and solicit feedback from all relevant stakeholders. Many of our organizations nominated individuals that have been participating in the Working Groups and we appreciate your inclusion of our experts more directly, as well. A collaborative and transparent process is necessary to develop effective implementation strategies for the recommendations.

While some of the issues are very challenging, we believe that successful implementation of PRGLAC's recommendations is critical to achieving our mutual goals of increasing the number of pregnant and lactating women included in clinical research, advancing our scientific knowledge and understanding of these populations, and furthering the health and wellbeing of women and their children. We look forward to continuing our work with the Task Force, Congress, other federal officials, industry partners and other stakeholders to implement PRGLAC's recommendations and achieve these goals.

COALITION TO ADVANCE MATERNAL THERAPEUTICS MEMBER ORGANIZATIONS

- 2020Mom
- Academy of Breastfeeding Medicine
- American Academy of Pediatrics *
- American Academy of Allergy, Asthma & Immunology's Vaccines and Medications in Pregnancy Surveillance System
- 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
- Epilepsy Foundation
- Genetic Alliance
- Marce Society of North America
- March of Dimes *
- Maternal Mental Health Leadership Alliance
- National Association of Nurse Practitioners in Women's Health
- North American Society for Psychosocial Obstetrics & Gynecology
- Preeclampsia Foundation
- Society for Birth Defects Research and Prevention
- Society for Maternal-Fetal Medicine*
- Society for Obstetric Anesthesia and Perinatology
- Society for Women's Health Research
- Treatment Action Group
- United States Breastfeeding Committee
- WomenHeart

*Denotes Steering Committee Members