



Comments from the Coalition to Advance Maternal Therapeutics August 2019 PRGLAC Meeting

Hello, my name is Johanna Gray and I am a federal policy advisor to the Coalition to Advance Maternal Therapeutics (CAMT). CAMT sincerely appreciates the opportunity to provide public comments to PRGLAC this morning.

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 these medications is as transparent and comprehensive as possible.

For more than four years, we have been working together to raise awareness about research gaps in therapeutics for pregnant and lactating women, and the need for inclusion of pregnant and lactating women in clinical trials where appropriate to close those gaps. We are strong supporters of the work that PRGLAC has taken over the last few years and appreciate your thoughtful consideration regarding maternal and infant health.

We are glad that PRGLAC is now beginning the second phase of its work to develop a strategy to implement the 15 recommendations included in its initial report. We agree with the need to shift our culture to protecting women *from* research to protecting them *through* research and are eager to hear the discussion over the next two days about how we can achieve that goal.

The PRGLAC Task Force is also vital because it ensures public participation in its work. The Task Force's open meetings like this facilitate expert participation and solicit feedback from all relevant stakeholders. Many of our organizations nominated individuals to participate in the Working Groups and appreciate your inclusion of our experts more directly, as well. Without this collaborative and transparent process, it will be difficult to develop effective implementation strategies for the recommendations.

Continuing PRGLAC's work and implementing its recommendations is critical to ensuring 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, other federal officials, industry partners and other stakeholders to achieve these goals. We encourage you to see us as partners as the Working Groups consider which stakeholders can assist with implementing various recommendations. Thank you for the opportunity to provide these comments.



Coalition to Advance Maternal Therapeutics

COALITION TO ADVANCE MATERNAL THERAPEUTICS MEMBER ORGANIZATIONS

- Academy of Breastfeeding Medicine
- American Academy of Pediatrics *
- American Academy of Allergy, Asthma & Immunology's Vaccines and Medications in Pregnancy Surveillance System
- American College of Nurse-Midwives
- American Association of Colleges of Pharmacy
- 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 *
- National Association of Nurse Practitioners in Women's Health
- National Coalition for Maternal Mental Health
- North American Society for Psychosocial Obstetrics & Gynecology
- Society for Obstetric Anesthesia and Perinatology
- Society for Maternal-Fetal Medicine*
- Society for Women's Health Research
- Treatment Action Group
- United States Breastfeeding Committee
- WomenHeart

*Denotes Steering Committee Members