

The Coalition to Advance Maternal Therapeutics (CAMT), appreciates this opportunity to provide public comments on the PRGLAC task force's recommendations to the Secretary.

CAMT is comprised of a dozen organizations who care deeply about the inclusion of pregnant and breastfeeding women in research and are dedicated to ensuring medications taken during this time are safe and effective and the information about these medications is transparent and comprehensive. We are supportive of the work that PRGLAC has taken on over the last year, and appreciate the amount of thoughtful consideration the task force has engaged in with regards to maternal and infant health.

CAMT requests that the task force make further recommendations in several areas of need: Workforce; Infrastructure; Data; Opportunities; Regulation; and Education. Within each of these areas of focus, our concern is rooted in the belief that there should be a presumption of inclusion in research for pregnant and lactating women. With this shift in perspective, the research community, industry, health care providers and consumers will be better able to work together to close the gaps in knowledge and research on safe and effective therapies for this population.

CAMT first recommends that PRGLAC extend its work for another year to further implement and examine additional issues related to research in pregnancy and lactation.

We continue to urge HHS, through NIH, to prioritize disease states in which there is a significant need for data about medications used during pregnancy and lactation. Inclusion of pregnant and lactating women in clinical trials is necessary to provide the best evidence-based care for women and research in pregnant women requires thoughtful study design. Currently, we know 7 in 10 women take prescription medications while pregnant and breastfeeding.¹ More data is needed related to what conditions women use medications for during pregnancy and while breastfeeding. A prioritized list of disease states would be a great first step for further research.

Additional efforts are also needed to ensure that research is designed to include representation of all potentially affected individuals, including those in diverse and underserved populations who often are not fully represented in current study designs. Underserved women are typically in need of more health services because of high rates of chronic conditions and unmet reproductive health care needs. PRGLAC should take the necessary steps to address obstacles to participation that may be experienced disproportionately by underserved women, such as the lack of child care during time spent as a research participant.

Workforce. Specific to workforce, we urge PRGLAC to support investments in development and training of investigators with obstetrical, lactation and pharmacology expertise.

Infrastructure. On the topic of infrastructure, we continue to advocate for supplemental, prioritized funding for research in pregnancy and lactation.

Data. Regarding data, CAMT supports the PRGLAC determination that there is insufficient available data related to medications in pregnancy and lactation. We support recommendations that would require research studies to have plans for incident pregnancies so that outcomes could be captured, to leverage

¹ Mitchell AA, Gilboa SM, Werler MM, et al. Medication Use During Pregnancy, With Particular Focus on Prescription Drugs: 1976-2008. *American journal of obstetrics and gynecology*. 2011;205(1): 51.e1-51.e8. doi:10.1016/j.ajog.2011.02.029.

existing registries to capture data, and to create a plan to allow data sharing among this population for further study.

Opportunities. CAMT also supports recommendations that would improve opportunities to encourage innovative trial designs, and that provide robust ways in which to collect data from existing and new models of study.

Regulation. We appreciated the ongoing PRGLAC discussions around the implications of potential regulatory or policy fixes. CAMT continues to support the need for a regulatory framework that ensures investigators can begin with a presumption of inclusion when evaluating the use of medication in pregnant and lactating women. It will be important to consider that there may be separate pathways for medications that are currently being used in pregnancy and lactation versus those that are in development or slated for future development.

Education. Finally, CAMT supports recommendations that would highlight the importance of education and advocacy efforts around research on therapies in pregnancy and lactation. We urge PRGLAC to support the development of public-facing information to help the public understand the new package insert format for pharmaceuticals, the meaning of the data described on the new pregnancy and lactation label, and clinical trial opportunities and inclusion in research.

Thank you for the opportunity to provide these comments. We look forward to continuing to support the work of PRGLAC and improving the health and wellbeing of women and their children.