On behalf of the Coalition to Advance Maternal Therapeutics (CAMT), I am here providing comments broadly on the topic of research specific to pregnant and breastfeeding women, as well as on the communication piece.

CAMT is comprised of a dozen organizations who care very deeply about the inclusion of pregnant and breastfeeding women in research, and dedicated to ensuring safe and effective information about medications taken during this time are improved and transparent.

Overall, CAMT hopes that PRGLAC will proceed with a presumption of inclusion in research. This shift in perspective would go a long way to ensure inclusion in research. As part of this, animal models must include pregnant females, and the consent for research involving a pregnant woman and fetus should only require *the mother's consent*, to better align with the current one-parent consent requirement for pediatric research.

Beyond this, we encourage HHS, through NIH, to prioritize disease states in which there is a significant need for data about medications used during pregnancy and lactation. Currently, we know women take prescription medications while pregnant and breastfeeding. Anecdotally, we know that women are prescribed medication that we think are safe and are effective, but we could be doing better, and women deserve better. A prioritized list of disease states would be great first step for further research.

The release of final pregnancy exposure registry guidance by FDA would assist with communicating risks and benefits to patients and providers, but more needs to be done to make this information transparent and easily available.

We support the creation of an education and awareness campaign surrounding both mediations in pregnancy and lactation as well as surrounding research in pregnancy and lactation. Such a campaign must be geared toward both consumers and health care professionals.

Finally, NIH needs additional funding that would allow truly prioritizing research involving pregnant women across Institutes, but also to expand current research related to pregnancy and lactation generally.

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.