

PUBLIC COMMENTS PRGLAC
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COALITION TO ADVANCE MATERNAL THERAPEUTICS
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I am Katie Schubert, Chief Advocacy Officer at the Society for Maternal-Fetal Medicine. I am providing comment today on behalf of the Coalition to Advance Maternal Therapeutics, an advocacy coalition whose steering committee includes the American Congress of Obstetricians and Gynecologists, American Academy of Pediatrics, March of Dimes, and SMFM. The Coalition's members represent organizations in the maternal and child health community, as well as organizations who care about the safety and efficacy of medications used in pregnancy and breastfeeding.

We began discussing this issue in 2013, when we realized that our members – healthcare providers and consumers – pregnant and lactating women – simply didn't know enough about the medications they were prescribing or being prescribed. This is largely in part because pregnant women are not only not included in clinical trials, but often are actively excluded. Women taking medications get pregnant and pregnant and lactating women take medications. We came together with the idea that more guidance and data are essential to improving the care and treatment of this population.

Speaking on behalf of CAMT - we believe that it is unethical to not include pregnant and lactating women in trials where it is appropriate. There are mechanisms in place already to do this – IRBs are equipped to consider the risks and make expert recommendations on trial design. We recognize that research in pregnancy and lactation is multi-faceted – that is, that to have the broader picture, the answers may include randomized controlled trials, prospective and retrospective studies, pregnancy exposure registries and the use of existing models such as LactMed and VAMPSS. We encourage PRGLAC to ensure that studies will be conducted and identify the areas of most importance and urgency to encourage such research.