

October 24, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the undersigned organizations, representing the Coalition to Advance Maternal Therapeutics (CAMT) and supporting organizations, we are writing to urge you to implement the recommendations of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) as soon as possible. As you know, the PRGLAC report was transmitted to you in September 2018, and under the 21st Century Cures Act (P.L. 114-255), requires you to consider and update regulations and guidance as appropriate and applicable regarding the inclusion of pregnant women and lactating women in clinical research not later than two years after the date of enactment of the legislation.

CAMT is comprised of a dozen organizations whose members and supporters believe strongly that every woman and family should have the information necessary to make empowered, informed, science-based decisions about pregnancy and childbearing. To that end, we are dedicated to ensuring that our government facilitates the generation of data about the safety and effectiveness of medications taken by pregnant and nursing mothers.

Over the past 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. As directed by P.L. 114-255, PRGLAC, convened by the Eunice Kennedy Shriver *National Institute of Child Health and Human Development* (NICHD) held a series of incredibly productive and engaging meetings, culminating in the recommendations sent to your office last month.

This report is a testament to the collaborative and inclusive PRGLAC process. We believe that by implementing the recommendations of the PRGLAC Task Force, more pregnant and lactating women will be included in clinical research, therefore advancing our scientific knowledge and understanding and furthering the health and wellbeing of women and their children.

We also know that more work needs to be done. As such, we strongly support the prioritization of PRGLAC Task Force Recommendation 14, which states the Secretary may use the authority granted under the law to extend the Task Force for another two years.

We stand ready to continue to work with you and the PRGLAC Task Force to support a cultural shift that will emphasize the importance and public health significance of building a knowledge base to inform medical decision-makingⁱ for pregnant and lactating women.

Should you have any questions, please contact Katie Schubert with the Society for Maternal-Fetal Medicine at kschubert@smfm.org or (202) 517-6122.

Sincerely,

Academy of Breastfeeding Medicine*

American Academy of Allergy, Asthma & Immunology*

American Academy of Pediatrics *+

American College of Nurse Midwives*

American College of Obstetricians and Gynecologists *+

Association of Congenital Diaphragmatic Hernia Research, Awareness and Support

Association of Maternal & Child Health Programs*

Association of Women's Obstetrics and Neonatal Nurses*

Elizabeth Glaser Pediatric AIDS Foundation

Endocrine Society

Expecting Health, Genetic Alliance*

International Maternal Pediatric Adolescent AIDS Clinical Trials Network

March of Dimes *+

National Association of Nurse Practitioners in Women's Health*

National Women's Health Network

Preeclampsia Foundation

PreemieWorld, LLC

Society for Maternal-Fetal Medicine *+

Society for Obstetric Anesthesia and Perinatology*

Teratology Society

Treatment Action Group*

Tuberculosis and Pregnancy Research Working Group

Vaccines and Medications in Pregnancy Surveillance System*

*denotes CAMT member

+ denotes CAMT Steering Committee member

Task Force on Research Specific to Pregnant Women and Lactating Women Recommendations

1. Include and integrate pregnant women and lactating women in the clinical research agenda
2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women
3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics
4. Remove regulatory barriers to research in pregnant women
5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women
6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women
7. Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the National Institute of Health (NIH) Best Pharmaceuticals for Children Act (BPCA) as a model
8. Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are or may become pregnant and by lactating women
9. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research
10. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women
11. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women
12. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women
13. Optimize registries for pregnancy and lactation
14. The Department of Health and Human Services Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019
15. Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research

¹Eunice Kennedy Shriver *National Institute of Child Health and Human Development*. (September 2018). *TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN Report to Secretary, Health and Human Services Congress*. Available at: https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf