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July 24, 2019

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

Re: The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) and Administration's Executive Order on Evaluating and Improving the Utility of Federal Advisory Committees

Dear Secretary Azar:

The Society for Women's Health Research (SWHR) supports the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), established by the [21st Century Cures Act \(P.L. 114-255\)](#) in 2016, but we are concerned about its future status after the Administration's recent [Executive Order on Evaluating and Improving the Utility of Federal Advisory Committees](#).

SWHR, an education and advocacy nonprofit dedicated to promoting research on biological differences in disease and improving women's health through science, policy, and education, strongly supports the inclusion and study of pregnant and lactating women in clinical trials.

The lack of evidence available for clinical decision-making during pregnancy and lactation is an important public health issue that must continue to be addressed.

Each year, more than 6 million pregnancies occur¹ and nearly 4 million women give birth.² Of these 4 million new mothers, more than 80% will breastfeed.³ Further, more than 90% of pregnant women and about 50% of lactating women will take one or more medications during these periods.⁴ These women take medications for a wide range of pregnancy and non-pregnancy-related conditions, including hypertension, postpartum depression, nausea and vomiting, seizure

disorders, type 1 and type 2 diabetes mellitus, endocrine disorders, and more.⁵

Despite these profound statistics, there is a dearth of data on safe and effective therapies for pregnant and lactating women. Fueled by the practice of excluding of women who are pregnant or breastfeeding from clinical research, these gaps in knowledge threaten the health and well-being of pregnant and breastfeeding women. Pregnancy and lactation do not give women immunity to sicknesses and conditions that require treatment, so these women are often forced to make health care decisions without proper data or information to support a treatment's safety and efficacy.⁶

The ongoing work of PRGLAC is essential to address and reform the paucity of human data available to inform pregnant and lactating women.

PRGLAC was given the task of advising the Secretary of Health and Human Services (HHS) about the knowledge and research gaps on therapies for pregnant and lactating women. At the end of its first two-year charter in September 2018, the Task Force released a report with 15 recommendations for expanding knowledge about safe, functional therapies for pregnant and breastfeeding women.⁷ SWHR commends PRGLAC's work in developing these recommendations and thanks HHS for extending the Task Force's charter an additional two years so PRGLAC can develop strategies to implement its recommendations, as sanctioned by P.L. 1140255.

The continued authorization of PRGLAC is necessary for the implementation of these recommendations as part of HHS' statutory responsibility to update guidance and regulations that address the knowledge and research gaps for pregnant and lactating women. Additionally, PRGLAC's existence is essential because the Task Force's public meetings attract stakeholders and experts from different disciplines, making implementation of the recommendations an interdisciplinary and transparent procedure.

SWHR urges HHS to preserve PRGLAC's standing as a Federal Advisory Committee.

The Administration's *Executive Order on Evaluating and Improving the Utility of Federal Advisory Committees* will require you to eliminate at least one-third of the Federal Advisory Committees advising your department. We urge you to consider the aforementioned evidence of PRGLAC's important work and maintain this Task Force so it may continue to develop implementation strategies that support its recommendations.

PRGLAC's work is essential to advancing the participation of pregnant and lactating women in clinical trials and, as a result, shrinking the research and knowledge gaps on safe and effective therapies for these women. The continuation of the PRGLAC Task Force is vital to the future health and well-being of millions of pregnant and lactating women in the United States. SWHR looks forward to working with you and the PRGLAC Task Force to ensure appropriate steps are taken to advance and protect the health of pregnant and lactating women.

Thank you for your consideration of the above comments. If you have questions, please contact me or Sarah Wells Kocsis, Vice President of Public Policy, at 202.496.5003 or swellskocsis@swhr.org.

Sincerely,



Amy Miller, PhD
President and Chief Executive Officer
Society for Women's Health Research

¹ Curtin et al. Pregnancy Rates for U.S. Women Continue to Drop. NCHS Data Brief, no. 136. National Center for Health Statistics: Hyattsville, MD, 2013.

² Martin et al. Births: Final Data for 2015. National Vital Statistics Report; vol 66, no 1. National Center for Health Statistics: Hyattsville, MD, 2017.

³ Breastfeeding report card. Centers for Disease Control and Prevention: United States, 2018.

⁴ Report to Secretary, Health and Human Services. Task Force on Research Specific to Pregnant Women and Lactating Women: United States, 2018.

⁵ Ibid.

⁶ Clemow et al. *Therapeutic Innovation & Regulatory Science*: 2015. doi 10.1177/2168479015572373.

⁷ Report to Secretary, Health and Human Services. Task Force on Research Specific to Pregnant Women and Lactating Women: United States, 2018.