

September 14, 2021

VIA ELECTRONIC TRANSMISSION

Janine Austin Clayton, M.D., FARVO
Office of Research on Women's Health
6707 Democracy Boulevard, Suite 400
Bethesda, MD 20817

RE: Request for Information: Inviting Comments to Inform the Women's Health Consensus Conference (WHCC)

Dear Dr. Clayton,

The Endocrine Society appreciates this opportunity to comment on the Request for Information (RFI) regarding the upcoming the Women's Health Consensus Conference (WHCC). Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. The Society's membership of over 18,000 includes experts in all research and clinical aspects of hormone health, including specific research areas linked to maternal morbidity and mortality, chronic conditions affecting women, and hormonally influenced cancers—three areas included in the RFI.

We are grateful for the National Institutes of Health's (NIH) Office of Research on Women's Health's (ORWH) continued commitment to women's health research and appreciate the need to identify research gaps and clinical pitfalls in the three specific research domains highlighted in the RFI. We note several chronic endocrine disorders are highly prevalent among reproductive age women, including polycystic ovarian syndrome (PCOS), endometriosis, and leiomyomas. Such conditions impact fertility, quality of life, pregnancy outcomes and maternal morbidity and mortality. Moreover, hormonal changes that occur in aging women have key implications for cardiovascular, bone, and metabolic health. **As an overarching recommendation, we urge the conference to consider how gaps in our understanding of endocrine science and hormonal signaling contribute to the issues under discussion at the conference.**

We also want to call attention to the fact that a fundamental understanding of endocrine disorders and progress in therapies and outcomes in young women have been hampered by the systemic exclusion of reproductive age and pregnant and lactating women from clinical trials. Exclusion of pregnant and lactating women from research has led to major gaps in women's health. Expanding our understanding of how women react to interventions including vaccines, therapeutics, and devices will benefit all women. The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), established in



the 21st Century Cures Act, released a report in 2018 with recommendations to advance inclusion of pregnant and lactating women in clinical research. Furthermore, the Task Force released its Report Implementation Plan in August of 2020 to respond to various concerns on how to integrate pregnant and lactating women into research. **We encourage ORWH to consider how discussions among participants could help identify opportunities to advance the implementation of PRGLAC recommendations in the context of the specific topics featured at the conference.**

Thank you for your consideration. If we can be of further assistance, please contact Grace Kranstover, Manager of Government Delegations & Grassroots Advocacy, at gkranstover@endocrine.org.

Sincerely,

Carol Wysham, MD
President, Endocrine Society