

I'd like to thank the members of the Committee and program staff for the opportunity to speak to you about this important project and share the perspective of the Endocrine Society. My name is Monica Laronda and I am an Investigator at Lurie Children's Hospital of Chicago, I am also an Assistant Professor of Pediatrics and Obstetrics and Gynecology at Northwestern University Feinberg School of Medicine. Today, I am representing the Endocrine Society as a member of the Research Affairs Core Committee.

We are the world's oldest and largest organization devoted to research on hormones and the clinical practice of endocrinology. Our members include many NIH-funded scientists who are advancing women's health through research encompassing conditions that only affect women such as PCOS, fibroids, endometriosis, and menopause; and those that disproportionately impact or affect women differently such as thyroid disease, osteoporosis, diabetes, and infertility. Collectively, we are dedicated to improving women's health through the discovery and application of scientific advancements. Today, I will highlight several key themes that our members urge you to consider in your deliberations; additional suggestions will be shared with the Committee through the online form. In our comments, we define women's health as pertaining to individuals that identify as women, and/or have female reproductive organs, and/or produce or use gonadal hormones commonly associated with the female sex.

First, a definition of women's health should reflect the entire life-course. While the reproductive-age years are a critical component of women's health, peripubertal girls and postmenopausal women face unique health issues and disparities; advancing health and gender equity therefore requires the inclusion of girls and women of all ages in research. Because the relative levels of estrogen and other ovarian hormones change at different points in a woman's life, research strategies that include women at all life stages will improve outcomes and help us better understand the role of gonadal hormones in disease as well as healthy aging. In utero development is also critical, as maternal environmental exposures and other factors may influence health in ways that manifest throughout life.

Second, gender and biological sex are both essential components of women's health. We commend the NIH for establishing the SABV policy; however, structures, systems, and review processes should be strengthened to ensure that this policy is implemented in research as intended. For example, grant reviewers with expertise should be identified to provide useful evaluations and feedback to prospective grantees so that they are empowered to identify sex specific effects. When possible, NIH should require disaggregated, sex-specific analysis of male and female research participants at all levels of biological complexity.



Gender is also essential to defining women's health; clinical research should capture information about a person's biological sex and their self-reported gender to ensure that we can better conclude and understand how sex and gender are not interchangeable, how sex and gender may diverge under biological and social influences, and avoid a strictly binary approach to sex and gender health. We note that persistent structural gender biases in society may create challenges as the Committee considers funding recommendations. For instance, males are predominantly studied in neurotrauma research because it is a male dominated injury, but women may experience unreported or unrecognized mild or repetitive traumatic brain injury. Therefore, while we must be mindful of the leading causes of death in women, it may not be appropriate to rely on relative rates of injury or disease when making recommendations.

Third, more researchers should be encouraged to study women's health. We emphasize the importance of diversity, equity, and inclusion, including representation of women, across the biomedical research enterprise and at leadership levels. We note the success of cohort programs such as the Building Interdisciplinary Research Careers in Women's Health and the Women's Reproductive Health Research program in developing peer and mentor networks to advance the careers of underrepresented groups in research. The Committee should explore ways that NIH could expand these programs to encourage women's health research in more fields, especially where the Committee identifies gaps and opportunities.

Considering historical biases we note that it may be appropriate to reevaluate clinical targets and goals that were originally based on studies done predominantly in men. Replication studies in some fields may be required with more rigorous sex-specific analysis. We stress that all Institutes and Centers at NIH should work together to address all of these issues.

Thank you for considering our suggestions, we look forward to continuing to engage and support your work on this important project.