

Janine Clayton, MD
Director, Office of Research on Women's Health
6707 Democracy Boulevard
Bethesda, MD 20817

September 12, 2017

Dear Dr. Clayton,

The Endocrine Society appreciates the opportunity to make recommendations to the National Institutes of Health (NIH) Strategic Plan for Women's Health Research for the period 2018 to 2022. 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. Today, our membership of over 17,000 includes clinical, translational, and basic scientists, as well as clinicians in practice. Our members include researchers dedicated to basic and clinical research in support of women's health, and practitioners dedicated to women's health issues. We appreciate the importance of a strategic plan that captures the most recent research advances and emerging opportunities. In our comments, we identify areas of scientific opportunity, cross-cutting themes, and specific recommendations for the existing goals.

Areas of Scientific Opportunity

Research in the past decade has advanced our understanding of sex and gender differences, and there are emerging opportunities in many fields, in both basic and clinical research, to better understand sex as a biological variable and the influence of hormones in diseases and disorders. Specific areas of recent scientific advances and emerging scientific opportunity include:

- Sex differences and the influence of sex hormones in neuronal degeneration, psychiatric disorders and mood.
- Sex hormone influences on the immune response, both in the context of cancer treatment and autoimmune disease.
- Sex specific differences in drug metabolism; specifically, to identify gaps in knowledge and inform drug dosing differences.
- Sex differences in diabetes and reproductive health.
- Endocrine counseling and metabolic supervision of transgender individuals.
- Development and utilization of new prevention strategies for breast cancer.
- Research on contraception, including development, efficacy, and utilization.
- Research to evaluate the decision-making surrounding, and use of, bioidentical hormone therapies, especially for postmenopausal women.



- Science at the interface of convergent research disciplines, such as oncology and reproductive health (oncofertility), cardiovascular effects of polycystic ovarian syndrome, diabetes and reproductive health, and obstetrics and endocrinology.

Cross-Cutting Themes

In addition to the specific areas identified above, there are cross-cutting themes and approaches that should be supported in the strategic plan in response to new scientific knowledge and discoveries. Research priorities are needed to advance the application of basic and clinical research findings; objectives should be updated to reflect the need to enhance the ability of new tools, resources, and data to achieve clinical impact e.g., in clinical practice guidelines. We also support the need articulated in the strategic plan to advance the study of health disparities. We urge ORWH to explicitly include pediatric and geriatric populations in goals and objectives throughout the plan. For example, studies devoted to both typical and abnormal growth and development in pediatric populations should be explicitly supported. Moreover, there are pressing clinical challenges and research questions for transgender populations, such as the safety of continued use of hormone therapy in transgender women throughout aging.

We strongly support the Specialized Centers for the Study of Sex Differences to conduct sex differences research in specific areas. As the new NIH policy to consider sex as a biological variable in research continues to be implemented, we anticipate that researchers will be well-served by integration of the specialized centers with other institutional research activities. An expanded role for the centers, similar to the Clinical and Translational Science Awards, or the Specialized Programs of Research Excellence (SPORE) would be extremely helpful to ensure that researchers across disciplines are engaged and able to investigate sex-specific effects in their research programs.

Recommendations in the Context of Existing Goals

Goal 1: The science of endocrine-disrupting chemicals (EDCs) has advanced rapidly in recent years. We appreciate the recognition of the importance of hormone-mimicking environmental agents in the existing strategic plan; however, environmental EDCs can also include chemicals that block normal hormone action. **We recommend that the first sentence of Objective 1.7 be adjusted to read “Investigate the actions of steroid hormones and environmental agents that interfere with normal hormone function...”** in order to be consistent with the updated World Health Organization’s definition of EDCs. Recent research also implicates EDCs in a wide variety of diseases and sex-specific adverse health consequences including reproductive disorders beyond the illustrative examples provided. **We also recommend that the last sentence in Objective 1.7 be**



adjusted to broadly include diseases and general adverse health and developmental effects, in addition to sex-specific diseases.

Goal 3: Advances in developmental biology have increased our understanding of how the environment influences development, for example through exposures to EDCs (see Goal 1.) **We recommend adding the word “environment” to Objective 3.1** to ensure that these findings are captured. Another research area that should be included in this goal is lactation. **We therefore recommend that Objective 3.3 should be adjusted by adding the words “and lactating” after “pregnant.”**

Goal 6: As we learn more about the challenges facing women in research and the educational needs of researchers throughout their careers, new solutions to help build a well-trained, diverse, and vigorous women’s health research workforce should be identified and pursued. For example, mentoring and educational efforts need to be tuned to match the needs of scientists and clinicians at all educational and career stages, from grade school through a career as an established researcher or clinician. Researchers will have different needs at different career stages, and mentors will need to have different expertise to assist, for example, an undergraduate seeking a career in science or an early stage investigator seeking tenure. Also, to further advance the science of women’s health research, educational programs need to recognize the study of women’s health and sex differences prior to advanced professional training. To further advance Goal 6, we recommend:

- **Expanding Objective 6.2 to recognize the need to have appropriate mentors not only in training programs, but throughout a career as an established investigator.**
- **Include educational objectives and curricula prior to professional training in Objective 6.5.**
- **Adding a new objective, or adjusting Objective 6.4 to include advancing opportunities to facilitate the reentry of women into science careers, for example through new funding mechanisms.**

Conclusion

Research findings consistent with the goals in the Strategic Plan for Women’s Health Research have advanced our knowledge of sex differences and created opportunities to further improve the health of women. Moreover, progress towards the goals of the strategic plan will increase understanding of the unique health challenges facing women and how this increased knowledge of sex differences will improve the health of all citizens. The Endocrine Society stands ready to partner with the Office of Research in Women’s Health in support of the strategic plan, in general and specifically as articulated in Goal 4 and Objective 5.3. Our members can advance the goals of the plan not only through their research leadership, but also through our international reach and



high-impact programs. For example, please see the Society's webpage at <https://www.endocrine.org/topics/female-reproductive-endocrinology> and the Society's Hormone Health Network's women's health page at www.hormone.org. Thank you for considering the Endocrine Society's comments. If we can be of any further assistance, please contact Joe Laakso, Associate Director of Science Policy at jlaakso@endocrine.org or 202.971.3632.

Sincerely,

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Endocrine Society Research Affairs Core Committee
Chair, Basic Research Subcommittee

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