SOCIETY FOR WOMEN'S HEALTH RESEARCH FISCAL YEAR 2025 OUTSIDE WITNESS TESTIMONY:

PREPARED FOR HOUSE APPROPRIATIONS COMMITTEE SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES

Name: Lindsey Miltenberger, MA

Title: Chief Advocacy Officer, Society for Women's Health Research

The Society for Women's Health Research (SWHR)—a more than 30-year-old national nonprofit dedicated to advancing women's health through science, policy, and education while promoting research on sex differences to optimize women's health—is pleased to submit testimony for fiscal year (FY) 2025 addressing the National Institutes of Health (NIH), the NIH Office of Research on Women's Health (ORWH), and the NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

Given the momentum surrounding the White House Initiative on Women's Health Research, there has been no better time to show our nation's commitment to women's health research and the federal entities that support it. While progress has been made in women's health research, as evidenced by the White House's initiative announcement, the decades of women's exclusion from scientific research has left our nation playing "catch up" to make up for years of lost knowledge. SWHR urges Congress to ensure that women's health across the lifespan is prioritized in FY 2025 funding legislation by supporting NIH, ORWH, NICHD, and our nation's other federal research entities. Specifically, SWHR requests that in FY 2025 appropriators provide at least \$51.303 billion for the NIH base budget; at least \$153.9 million for the ORWH, reflecting the President's FY 2025 budget request; and \$1.891 billion for the NICHD.

NIH: Hailed by former Senator Arlen Specter as the "crown jewel of the federal government," the NIH is the premier medical research agency in the United States and the largest source of funding for biomedical and behavioral research in the world. The NIH plays an integral role in fostering discoveries and innovative research that promote the health, safety, and well-being of Americans; training and supporting the next generation of researchers to ensure a diverse, strong research pipeline to continue scientific progress; and expanding the scientific and medical knowledge base.

Ensuring NIH's continued vitality is necessary for driving women's health forward. Across the NIH, researchers conduct and support basic, clinical, and translational research on diseases and conditions that differently, disproportionately, or solely impact women across the lifespan—from menopause to Alzheimer's disease to heart disease and more.

As shared above, SWHR urges Congress to provide a program level of at least \$51.303 billion for the NIH, a \$3.579 billion (or 7.5%) increase over the comparable FY 2024 funding level. This request, which is supported across the public health and scientific research communities, would allow NIH's base budget to keep pace with the biomedical research and development price index (BRDPI) and allow for meaningful 5% growth.

In addition to this request, SWHR also supports renewed and increased investments in the newly established Advanced Research Projects Agency for Health (ARPA-H) and in the Office of Autoimmune Disease Research (OADR), housed within ORWH. Each of these entities hold tremendous promise for scientific advancement and for ensuring equity in health outcomes. However, as these entities build out their respective portfolios and pursue efforts to drive research advancements, SWHR believes that—for them to reach their greatest potential—funding for both ARPA-H and OADR should supplement, rather than supplant, the foundational investment in NIH.

Lastly with respect to the NIH, SWHR requests that appropriators include the following report language requests:

Women's Health Data Initiative. – The Committee supports greater investment in research on conditions unique to or that occur predominantly in women or manifest themselves differently in women than in men. To better coordinate and integrate additional investments in women's health research across NIH, the Committee believes that a data use community that will facilitate the systematic collection and sharing of clinical and research data in women's health is crucial to advance this research and provides \$50 million for the NIH to begin standing up this resource.

ARPA-H in Women's Health.—The Committee was glad to see ARPA-H's announcement about the Sprint for Women's Health, the \$100 million commitment in response to the White House Initiative for Women's Health Research to fund transformative research and development in women's health. The Committee allocates another \$100 million in fiscal year 2025 for ARPA-H to continue this important work to address women's health and accelerate and scale tools, products, and platforms to improve women's health outcomes.

ORWH: ORWH's role in prioritizing and integrating research across the federal government—as part of the White House Initiative and beyond—is vital. ORWH serves as a key partner for NIH's Institutes and Centers, ensuring that sex and gender are considered in research; in setting research priorities; and in leading core programs, such as the Specialized Centers of Research Excellence (SCORE) and the Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Initiative.

SWHR supports the President's budget request of \$153.9 million—a doubling of funding—for the ORWH in FY 2025 to support new and existing initiatives that emphasize women's health research. SWHR's report language request pertaining to ORWH is as follows:

ORWH.—The Committee recommends \$153.9 million in base funding for the Office of Research on Women's Health. The role of the Office to improve the health of all populations by ensuring women's health research and research on sex and gender influences in health and disease are included within the NIH scientific framework is critical for achieving equity in women's health across the lifespan. Particularly in light of the White House Initiative on Women's Health Research, Congress is committed to

prioritizing this research portfolio and ensuring the Office has the resources it needs to help fulfill its mission.

NICHD: The NICHD, founded to investigate human development throughout the life process, also provides an important home for women's health research in areas across reproductive sciences and maternal health, including infertility, pregnancy, and menopause. The Institute's research portfolio is critical for addressing pressing public health issues, such as pregnancy outcomes; gynecological health issues, such as uterine fibroids and endometriosis; and the environmental, behavioral, and social factors that shape women's health.

Among NICHD's contributions to women's health research is its work with respect to pregnant and lactating individuals, who are often excluded from clinical trials, leaving these women and their health care providers to make health care decisions without sufficient data. Although studies suggest that 90% of pregnant women take at least one prescription or over-the-counter medication during their pregnancy, ¹ 70% of FDA-approved medications have no human pregnancy data, and 98% have insufficient data to determine risk to the infant.²

Among NICHD's efforts to support these populations is the Maternal and Pediatric PRecisioN in Therapeutics (MPRINT) Hub, which serves as a national resource for expertise in maternal and pediatric therapeutics to conduct and foster therapeutics-focused research in obstetrics, lactation, and pediatrics, while enhancing inclusion of people with disabilities. The Hub was established to aggregate, present, and expand the available knowledge, tools, and expertise in maternal and pediatric therapeutics to the broader research, regulatory science, and drug development communities and has the potential to generate novel tools and approaches to advance and accelerate research in maternal and pediatric therapeutics.

SWHR calls on Congress to provide at least \$1.891 billion for NICHD in FY 2025 so the Institute can work to fulfill its mission and supports the following report language requests of the Coalition to Advance Maternal Therapeutics (CAMT), of which SWHR is a founding member:

Priority Research for Pregnant and Lactating Women. — The Committee remains concerned about the lack of pregnant and lactating women in clinical research. Women with chronic health conditions lack access to appropriate treatments during pregnancy, putting both them and their infants at risk. Despite, 90 percent of women taking at least one medication during pregnancy, only 5 percent of medications have data on the impact of the medications during pregnancy. The Committee provides \$2,000,000 for the Director to conduct priority research projects on existing medications, and therapeutics prescribed to pregnant and lactating women. The Secretary shall give preference to research applications demonstrating the following as it relates to pregnant and lactating women: an unmet medical need or gap in treatment, severity and prevalence of a specific disease or condition, and cost and availability of treatment or alternate treatments. The Committee requests an update in the fiscal year 2026 Congressional Budget Justification

¹ Ke, A. B., Greupink, R., & Abduljalil, K. (2018). Drug dosing in pregnant women: Challenges and opportunities in using physiologically based pharmacokinetic modeling and simulations. CPT: Pharmacometrics & CPT: Pharmacometric

on the amount of money obligated to priority research projects for pregnant and lactating women, a description of each project and rationale for prioritization, institutes at the NIH that can contribute to this research, and the existing medications and therapeutics that will be prioritized for study. (PRGLAC Recommendation #8)

Pregnant and Lactating Women in Clinical Trials Public Awareness Campaign. - The Committee provides \$1,000,000 for public awareness campaign to educate maternal and child health providers, patients, and their families on opportunities to enroll pregnant and lactating women into clinical trials and registries following the recommendations of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The campaign shall include information on registries and clinical trials that enroll pregnant and lactating women, how patients can enroll, and address common questions for clinicians and patients. The public awareness campaign shall have a public-facing website where providers and patients can access information from the public awareness campaign and registries and clinical trials that enroll pregnant and lactating women. In designing the public awareness campaign, the Secretary shall consult with outside organizations with subject matter expertise in pregnant women, lactating women, and infants. No later than 180 days after enactment of this Act, the Secretary shall provide the Committee with a report on the public awareness campaign and the public website including information to be included as part of the public awareness campaign, the launch date of the campaign and website, and outside organizations that have been engaged as part of the campaign. (PRGLAC Recommendation #5)

Pregnant Women and Lactating Women Advisory Committee. – The Committee provides \$200,000 for the Advisory Committee to continue activities within the 2020 Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) Implementation Plan. The Committee directs the agency to provide an update in the fiscal year 2026 Congressional Budget Justification on progress and federal activities undertaken to implement the PRGLAC recommendations and recommendations for further implementation of all PRGLAC recommendations, including policy needs and resources. (PRGLAC Recommendation #15)

SWHR appreciates the opportunity to submit this testimony and thanks the Subcommittee for considering these requests. We look forward to working with you to ensure the highest possible support for federal research agencies in FY 2025. If you have questions or need any additional information, please contact SWHR Chief Advocacy Officer Lindsey Miltenberger at lindsey@swhr.org.