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Florence P. Haseltine, PhD, MD
Founder
Society for Women's Health Research
Alexandria, VA

Phyllis Greenberger, MSW
President and CEO
Society for Women's Health Research
Washington, D.C.

March 11, 2015

The Honorable Jim Cooper
United States House of Representatives
Washington, D.C. 20515

Dear Representative Cooper:

Last Congress, the Society for Women's Health Research (SWHR) endorsed the Research for All Act of 2014. This legislation had bipartisan support and represented a significant step forward in addressing the health inequities between men and women. We write to urge you to reintroduce this legislation, as critical issues remain that must be addressed in order to improve the efficiencies of biomedical research, and ultimately the health of American women and men.

SWHR is the thought leader in promoting research on biological differences in disease and is dedicated to transforming women's health through science advocacy, and education. For 25 years, SHWR has brought attention to diseases and conditions that affect women uniquely or differently and the impact that biological sex has on diseases and treatments.

In May 2014, Francis Collins, Director of the National Institutes of Health (NIH) co-authored a commentary with Dr. Janine Clayton, Director of the Office of Research on Women's Health (ORWH) at the NIH, announcing that the Agency would require applicants to report their plans for the balance of male and female cells and animals in preclinical studies in all future applications. The commentary stated that the new policy would be rolled out in phases beginning in October of 2014; yet to date, no further details have been provided from the Agency.

The Research for All Act would provide the necessary guidance and accountability to codify the development and full implementation of the new policies at NIH. NIH is considered the world leader in biomedical research and thus, when it implements policies that stress the importance of biological sex as a fundamental variable in research and requires analysis of data by sex as a part of grant progress reporting and published results, others in the scientific community will follow suit. This will revolutionize the way biomedical research is conducted in the United States.



As highlighted by the recent unveiling of the President's Precision Medicine Initiative, the future of medicine lies in targeting therapies to the appropriate patients. Science tells us that biological sex differences exist at every level of the human body and persist through the life span. Therefore, it is crucial that we know how our federal health and research agencies are doing in terms of inclusion of women and minorities in medical research. This research guides medical decision making, so it is imperative that the Government Accountability Office (GAO) update its reports on women and minority inclusion in medical research at the National Institutes of Health (NIH) and Food and Drug Administration (FDA), as required by the legislation. Much emphasis has been placed on inclusion of these groups in medical research, yet no reports have ultimately examined this issue in over a decade.

Additionally, the Research for All Act creates an expedited FDA review of drugs and biologics for male or female specific indications to treat a serious or life-threatening disease of condition, or is intended for safer or more effective treatment than a product that is currently on the market and is supported by results of clinical trials that include and separately examine outcomes for both men and women. This provides an incentive for industry to engage and be leaders in bringing therapies to market that work better in targeted populations. While SWHR believes that the research submitted to FDA for product approval should provide analysis by sex, race, and other important sub-demographics, this is a promising step to foster innovation and product development.

Thank you for your leadership in introducing the Research for All Act last Congress. We are hoping that you will reintroduce this legislation this year. We look forward to continuing to work with you to build a healthier future for all Americans.

Sincerely,

A handwritten signature in black ink that reads "Phyllis Greenberger".

Phyllis Greenberger, MSW
President and CEO
SWHR

A handwritten signature in black ink that reads "Martha Nolan".

Martha Nolan, JD
Vice President, Public Policy
SWHR

A handwritten signature in black ink that reads "Leslie Ritter".

Leslie Ritter, MA
Director, Government Affairs
SWHR