ENDOCRINE SOCIETY
Hormone Science to Health

October 24, 2015

Senator Lamar Alexander
Chairman
United States Senate
Committee on Health, Education, Labor & Pensions
428 Dirksen Office Building
Washington, D.C. 20510

Senator Patty Murray
Ranking Member
United States Senate
Committee on Health, Education, Labor & Pensions
428 Dirksen Office Building
Washington, D.C. 20510

Dear Chairman Alexander and Senator Murray,

The Endocrine Society strongly supports the efforts by the Senate Committee on Health, Education, Labor, and Pensions (HELP) to improve patients' access to safe and effective medical products in a timely manner through the Innovations for Healthier Americans Initiative.

One critical area that needs to be examined is the healthcare disparities between men and women that are perpetuated because of the way medical research is currently conducted in the United States. The Endocrine Society's members include researchers dedicated to understanding the roles of hormones in fundamental biology and human health, and we recognize the importance of considering sex as a critical biological variable at all phases of biomedical research, from basic science through clinical application. Therefore, we urge the Committee to consider the inclusion of components of the Research for All Act of 2015 in the legislative text of the Innovations initiative.

The Research for All Act codifies new NIH policies to examine sex differences in basic research. Biomedical research has historically utilized male research subjects disproportionately, creating a significant gap in knowledge regarding the extent to which disease processes and underlying physiology are influenced by biological sex. This exclusion of females in pre-clinical basic research has resulted in treatments that sometimes are less effective or less safe for women. It is important to recognize that data reported in the scientific literature is uniformly biased toward male-only studies, even in clinical studies in which female inclusion has been mandated since 1993[1].

The NIH has recognized this gap and announced policies intended to balance the study of males and females in preclinical research. We are pleased the NIH has taken steps toward achieving equity in biomedical research, yet significant questions remain on how effectively this will be implemented throughout the Institutes. Therefore, we believe codification through legislation is necessary and will demonstrate Congressional support for this critical change.

[1] Sex-based biomedical research policy needs an implementation plan.Woodruff TK, Green S, Paller A, Schlosser BJ, Spring B, Castle M, Stock MC, Carnethon MR, Clark CT, Gerard E, Turek FW, Wisner KL, Wakschlag LS, Kibbe MR, Mendelson MA, Simon MA, Hansen NM, Kenton K, Garcia PM, Zee P, Ramsey-Goldman R, Sutton SH, Van Horn L. Womens Health (Lond Engl). 2015 Jul;11(4):449-52.

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The Research for All Act provisions regarding the FDA provide a second point in the drug and device pipeline that would have an immediate and important impact. It directs the FDA to ensure that the design and size of clinical trials for products granted expedited approval under any program within section 506 of the Federal Food, Drug and Cosmetic Act, are sufficient to determine the safety and effectiveness of such products for both men and women. The Agency has signaled it is currently moving in that direction for studies in general, but the voluntary, unenforced efforts have had a limited impact thus far. Including this provision in the law is necessary to ensure that important new medications are tested to determine if they are safe and effective for women and men. We note, however, that we would recommend strengthening this provision so that all clinical trials submitted in support of new drug and device approvals, and not just those submitted for expedited approval, would be required to be safe and effective for both sexes.

We believe it is important to include the provisions in the Research for All Act to update Government Accountability Office (GAO) reports on women and minorities inclusion in medical research at the NIH and FDA. GAO reviews on these topics have not been updated in over a decade, and this information is imperative to ensuring federal agencies include representative groups in medical research that guide treatment decisions. GAO reports should ascertain the extent to which agencies have examined not only the inclusion of female subjects, but, importantly, whether those studies properly examine sex as an independent variable. Enabling such analysis could reveal whether interventions affect women and men differently.

Thank you for your leadership in support of the Innovations initiative. We would like to continue to work with you on incorporating the Research for All Act into this effort to help ensure a healthier future for all Americans.

Sincerely,

Lisa N. Fish MD

Lisa Fish, MD
President
Endocrine Society