

October 2, 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 undersigned organizations strongly support the Senate Committee on Health, Education, Labor, and Pensions (HELP) Committee's efforts 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 healthcare disparities that exist between men and women due to the way medical research is conducted in the United States. We urge the Committee to consider the inclusion of components of the Research for All Act of 2015 within the legislative text of the Innovations initiative.

The Research for All Act codifies the new NIH policies aimed at examining sex differences in basic research at the NIH. 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. The lack of inclusion of females in pre-clinical basic research has resulted in treatments that sometimes are less effective or less safe in women. The NIH has recognized this gap and announced policies to balance the study of males and females in preclinical research. With this announcement, the NIH has begun to take steps towards achieving equity in biomedical research, yet significant questions remain on how well this will be implemented throughout the Agency. Therefore, codification through legislation is necessary and will demonstrate Congressional support for this critical change.

The Research for All Act's provisions regarding the FDA would have an even more immediate and important impact. The Research for All Act 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 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. Although the Research for All Act includes that provision only for expedited drugs, ideally, that provision would apply to all clinical trials submitted in support of new drug and device approvals.

Additionally, the Research for All Act provides for increased communication with the Agency and rolling review of applications for new drugs and biologics to ensure that new drugs will be

safe and effective for both men and women. Further, the Research for All Act includes provisions to update Government Accountability Office (GAO) reports on women and minority inclusion in medical research at the NIH and FDA. The GAO is due to release a report on inclusion at the NIH in the coming month; however, reports on these topics at the FDA have not been updated in over a decade and this information is imperative to ensuring our federal health and research agencies are including representative groups in medical research that guide treatment decisions.

Thank you for your leadership in support medical and health services research and its commitment to the health of the nation. We look forward to continuing to work with you to build a healthier future for all Americans.

Sincerely,

American College of Radiation Oncology
American Heart Association
American Medical Women's Association
Association of American Medical Colleges
Breast Cancer Action
Center for Science and Democracy at the Union of Concerned Scientists
Colon Cancer Alliance
Hadassah, The Women's Zionist Organization of America, Inc.
Jacobs Institute for Women's Health
MANA, A National Latina Organization
National Center for Health Research
National Consumers League
National Hispanic Medical Association
National Women's Health Network
Our Bodies Ourselves
OWL – The Voice of Women 40+
Reproductive Health Technologies Project
The Society for Maternal-Fetal Medicine
The Society for Women's Health Research
WomenHeart

cc:

Senator Michael B. Enzi
Senator Richard Burr
Senator Johnny Isakson
Senator Rand Paul
Senator Susan Collins
Senator Lisa Murkowski
Senator Mark Kirk
Senator Tim Scott
Senator Orrin Hatch
Senator Pat Roberts
Senator Bill Cassidy, M.D.

Senator Barbara Mikulski
Senator Bernie Sanders
Senator Robert P. Casey, Jr
Senator Al Franken
Senator Michael F. Bennet
Senator Sheldon Whitehouse
Senator Tammy Baldwin
Senator Christopher S. Murphy