



ANNIEAPPLESEEDPROJECT



JACOBS INSTITUTE
OF WOMEN'S HEALTH

NATIONAL CENTER FOR HEALTH RESEARCH
The voice for prevention, treatment, and policy



June 5, 2014

The Honorable Jim Cooper
1536 Longworth HOB
Washington, DC 20515

Re: Members of the Patient, Consumer, and Public Health Coalition strongly support the *Research for All Act of 2014*.

Dear Congressman Cooper,

As members of the Patient, Consumer, and Public Health Coalition, we strongly support the *Research for All Act*. It would require the FDA to develop policies to ensure that clinical trials for medical products granted expedited approval are sufficient in design and size to determine the safety and effectiveness for men and women, using subgroup analysis. The Act also increases the study of female animals, tissues, and cells in basic research conducted or supported by NIH.

This legislation is needed because most medical research used as the basis of FDA approval decisions focuses on men. For example, although cardiovascular disease is the leading killer of women and men, only one-third of subjects in clinical trials are female. Even when studies do include women, 70% fail to report outcomes by sex. Insufficient inclusion in clinical trials,

failure to conduct appropriate subgroup analysis, and lack of publically available information puts women at risk when they use FDA-approved diagnostics and treatments. As an example, the unique way women metabolize drugs was not considered when the dosage for Ambien sleeping pills was determined. As a result, the recommended dosage was approximately twice as high for women as it should have been. It took many years before the FDA finally corrected the label to reflect different dosages for men and women.

Expedited pathways are designed to make important new drugs readily available; it is essential that the companies utilizing these pathways ensure that their products are safe and effective for women as well as men.

Men will also benefit by requiring clinical trials to report outcomes by sex. Low-dose aspirin has different preventive effects in women and men; there is now evidence that a diabetes drug may lower a women's risk of heart failure but increase men's risk; and some common blood pressure and antibiotic medications may be less effective for men. These potential problems are not identified if men and women are analyzed together rather than separately.

Thank you for sponsoring this legislation. The *Research for All Act* will improve health outcomes for women and men by more precisely ensuring the proper indication and dosage.

American Medical Student Association
American Medical Women's Association
Annie Appleseed Project
Breast Cancer Action
Connecticut Center for Patient Safety
Consumers United for Evidence-based Healthcare (CUE)
Jacobs Institute of Women's Health
National Center for Health Research
National Physicians Alliance
National Women's Health Network
Our Bodies Ourselves
Ovarian Cancer Alliance of San Diego
The TMJ Association
Center for Science and Democracy at the Union of Concerned Scientists
WoodyMatters
WomenHeart

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or pb@center4research.org