

June 5, 2012

Dear Member of Congress:

We are writing in support of Section 908 of the Senate's version of the Food and Drug Administration (FDA) Safety and Innovation Act (S. 3187), which would require the FDA to report on the availability of new drug and device safety and efficacy data by sex, age, and racial and ethnic subgroups. As you work to reconcile differences between the House and Senate legislation, we strongly urge you to include this provision in the final FDA User Fee bill.

Numerous studies have found that subgroup-specific data about how new drugs and devices perform in women, minorities, and older Americans still is not publicly available to patients, clinicians, and researchers on a consistent and reliable basis. Sex-specific research results can and have yielded important differences in the way drugs and devices work in women and men. For example, the drug digoxin used to treat patients with heart failure is associated with an increased risk of death among women but not men. A next-generation ventricular assist device, used in heart failure patients, was associated with a higher rate of stroke in women versus men.

Having these types of results for women and other subpopulations is necessary for informed patient and provider decision-making. Yet, although progress has been made in the last two decades, there are still significant gaps in the analysis of research data to look for subgroup differences, and the availability of subgroup-specific safety and efficacy data to patients and their health care providers. These gaps caused the Institute of Medicine to conclude in its 2010 report, *Women's Health Research: Progress, Pitfalls, and Promise*, that:

“There also has been inadequate enforcement of requirements that representative numbers of women be included in clinical trials and that results in women be reported. ...a lack of reporting on sex and gender differences has hindered identification of potentially important sex-differences and slowed progress in women's health research and its translation to clinical practice.”

Section 908 would require the FDA to publicly report within one year on the extent to which clinical trial participation and safety and efficacy data reported by sex, age, race, and ethnicity is included in applications for FDA approval of new drugs and medical devices. The FDA is subsequently required to publish an action plan that includes recommendations for improving the availability of helpful information to patients, healthcare providers, and researchers. This language builds on a provision of the HEART for Women Act, bipartisan legislation that was passed by the House by voice vote in September 2010. In addition to making this important information available to healthcare professionals and their patients, it would highlight areas where the participation of women and other subpopulations in clinical trials is lacking.

This provision would help to close the knowledge gap that is contributing to substantial inequities in health care for women and for minorities. Again, we hope you will take a step towards ending this inequity by including Section 908 in the final FDA User Fee legislation. Thank you for your consideration.

Sincerely,

American Association of Colleges of Pharmacy
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Obstetricians and Gynecologists
American Heart Association/American Stroke Association
American Medical Women's Association
American Social Health Association
American Society of Echocardiography
American Thoracic Society
Asian & Pacific Islander American Health Forum
Association of Black Cardiologists, Inc.
Association of State and Territorial Health Officials
Association of Women's Health, Obstetric and Neonatal Nurses
Black Women's Health Imperative
Business and Professional Women's Foundation
California Latinas for Reproductive Justice (CLRJ)
Coalition of Labor Union Women–Metro-Detroit Chapter
Delta Kappa Gamma Society International
Disability Policy Consortium
Florida Heart Research Institute
Friends of Cancer Research
Hypertrophic Cardiomyopathy Association (HCMA)
Jacobs Institute of Women's Health
Lung Cancer Alliance
NAACP
National Association of Nurse Practitioners in Women's Health (NPWH)
National Black Nurses Association
National Council of Jewish Women
National Council of Women's Organizations
National Forum for Heart Disease and Stroke Prevention
National Hispanic Medical Association
National Partnership for Women & Families
National Patient Advocate Foundation
National Research Center for Women & Families
National Women's Health Network
National Women's Law Center
National Stroke Association
OWL-The Voice of Midlife and Older Women
Preventive Cardiovascular Nurses Association
Public Citizen
Reproductive Health Technologies Project
Society for Women's Health Research
Sudden Arrhythmia Death Syndromes (SADS) Foundation

Sudden Cardiac Arrest Association
Summit Health Institute for Research and Education, Inc.
WomenHeart: The National Coalition for Women and Heart Disease
Women's Research and Education Institute
Woodymatters