[AHA LETTERHEAD]

American Heart Association

Statement for the Hearing Record

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My name is Sue Bennett, and I am a practicing cardiologist, a Clinical Assistant Professor of Medicine in the Division of Cardiology and Director of the Women's Heart Program at George Washington University Medical Center. I am also a volunteer and national spokeswoman for the American Heart Association and Past-President of the Greater Washington Area American Heart Association.

On behalf of the American Heart Association and its more than 22 million volunteers and supporters, I am pleased to have the opportunity to testify today on H.R. 1014, the Heart disease Education, Analysis and Research, and Treatment for Women Act, known briefly as the HEART for Women Act. We wish to thank the House Committee on Energy and Commerce Subcommittee on Health for holding today's hearing on the HEART for Women Act, which we strongly support. We also want to thank Representatives Capps and Cubin for their leadership in introducing this important legislation.

Overview

Since 1924, the American Heart Association has dedicated itself to reducing disability and death from cardiovascular diseases, including stroke, through research, education and advocacy. Providing widespread access to effective, credible scientific information is vital to our mission. The American Heart Association and its American Stroke Association division actively participate in efforts to improve the delivery of cardiovascular health care by promulgating scientifically based standards and guidelines, sponsoring and overseeing clinical research, publishing peer-reviewed journals, and researching and developing programs to assist providers and patients. For example, the American Heart Association released new Guidelines for Preventing Cardiovascular Disease in Women earlier this year.

Heart disease, stroke and other forms of cardiovascular disease are the No. 1 killer of American women, claiming more than 460,000 lives each year or about a death a minute. To put this number into context, cardiovascular diseases (CVD) kill more female lives than the next five causes of death combined (all forms of cancer, chronic lower respiratory diseases, Alzheimer's, diabetes and accidents). When considered separately, stroke alone is the third leading cause of death of American women, and women accounted for 61 percent of all U.S. stroke deaths in 2004.

Many more women are living with the chronic effects of heart disease, stroke or some other form of CVD. An estimated 42 million females – about one in three – suffers from some form of cardiovascular disease, ranging from high blood pressure to heart attack, unstable angina, stroke, congenital vascular defects and congestive heart failure.

Unfortunately, despite the statistics cited above, too many of us – patients and health care providers alike – still tend to think of heart disease as a "man's disease." However, in 1984, women achieved equality and then surpassed men in one area where they don't want it, heart disease mortality. Every year since then, more women than men have died from CVD. During that time, we've made good progress in reducing CVD mortality for men but the same cannot be said for women.

The good news is that the National Institutes of Health reported earlier this year that the number of heart disease deaths in women declined by 17,000 in 2004. But despite this positive news, a significant disparity still exists in heart disease mortality between women and men. In fact, cardiovascular diseases still killed about 50,000 more women than men in 2004, even with the decline in female deaths. The HEART for Women Act is intended to help close that gap by focusing on three strategies to improve the diagnosis, treatment, and prevention of heart disease and stroke in women.

An Alarming Lack of Awareness

Part of the problem is that not enough women or their physicians recognize heart disease as the serious health threat that it is. Efforts like the American Heart Association's Go Red For Women movement and the National Heart, Lung, and Blood Institute's (NHLBI) Heart Truth campaign have helped to increase awareness among women about their risk of heart disease, but more work remains.

The latest American Heart Association survey tracking women's awareness of heart disease, published in February of 2007, found that 43 percent of women still are not aware that heart disease is the leading cause of death of women. Women of color are significantly less likely to know about heart disease as their leading killer, despite being at greater risk for CVD. For instance, only 38 percent of black women could identify heart disease as the leading cause of death, compared to 62 percent of white women, even though black women have a higher death rate from CVD. Additionally, only 21 percent of all women perceive heart disease to be their own greatest health problem. Women who don't perceive heart disease or stroke as a potential problem are less likely to take steps to reduce their risk.

Even more alarming is the pervasive lack of awareness about heart disease among physicians. According to an American Heart Association-sponsored survey published in 2005, fewer than 1 in 5 physicians surveyed recognized that more women than men die of heart disease and other cardiovascular diseases each year. Astoundingly, only 8 percent of primary care physicians knew this basic fact. Cardiologists did better on the survey but still only 17 percent of them knew heart disease kills more women each year.

As part of this same survey, physicians were also given 10 theoretical patient cases with information about age, sex, ethnicity and race, smoking status, cholesterol levels, blood pressure, body mass index, and personal and family history of heart disease or diabetes, and the physicians were asked to assess the patients' risk. The survey found that the physicians were more likely to find women to be at lower risk for coronary heart disease than men despite having similar Framingham risk scores.

Unfortunately, the same holds true in the real world. Health care professionals treat what they perceive to be a problem, and women are being treated less aggressively. For instance, women are more likely to die within a year of their first heart attack, but they are less likely to be referred to diagnostic testing that would be standard for men. Women are also less likely to receive coronary interventions, such as angioplasties and stents, as well as carotid endarterectomy procedures to prevent stroke. And according to the Agency for Healthcare

Research and Quality's 2006 "National Healthcare Disparities Report," female Medicare patients who suffer from a heart attack are less likely to receive the recommended care, compared to their male counterparts.

The HEART for Women Act would help to increase awareness among populations for which there are still gaps, particularly older women and healthcare professionals. For healthcare professionals, the bill authorizes the Bureau of Health Professions of the Health Resources and Services Administration (HRSA) to conduct an education campaign to increase professionals' understanding about the prevalence and unique aspects of care for women in the prevention and treatment of heart disease, stroke and other forms of CVD.

The bill also authorizes the Secretary of Health and Human Services to develop and distribute educational material to women 65 and older to educate them about women's risk for heart disease and stroke, risk factors for CVD, and the symptoms of CVD in women.

Better Information Needed about Treatment Options

Another problem that I struggle with every day in my practice is the lack of information available to physicians, researchers, and our patients about the safety and efficacy of CVD treatments for women. When a new therapy comes on the market, one of the first things I want to know is how it works in females, compared to males, and all too often that information simply is not available.

For far too long, we have simply assumed that if a new drug or medical device works for a man, then it must work for a woman. Thanks to reports such as the national Institute of Medicine's landmark 2001 report, *Does Sex Matter?*, we know that sex really does make a difference. Researchers are learning that sex differences play an increasingly important role in the prevention, diagnosis, and treatment of CVD. For instance, we have learned from the NHLBI-funded WISE study that coronary artery disease may manifest itself differently in women than in men, which suggests that the testing regimes that work in men may not work in women.

Diagnostic tests, prescription drugs, and medical devices may work differently in women than in men. We cannot assume that drugs and devices work the same in women as in men. Drugs that are beneficial for men may not only *not* be helpful to women, they may even be harmful to them. For example, a drug commonly used to treat patients with heart failure (digoxin) has been associated with an increased risk of death among women but not among men. Likewise, a group of drugs called IIb/IIIa inhibitors used to treat acute coronary syndromes have shown a significant benefit in men but appear to cause more bleeding problems in women that put them at increased risk for heart attack and even death.

The bottom line is that we still have more questions than answers when it comes to sex differences in CVD among women and men. Part of the reason for this is that women still are not widely enough represented in clinical trials. Women make up just 38 percent of subjects in NIH-funded CVD studies and even less of the subjects in industry-sponsored studies. And even when there are enough women included in a trial to better understand sex differences, this

information often is not reported. According to one recent review of 645 cardiovascular trials published in lead medical journals in 2004, only 24 percent reported sex-specific results.[1]

The HEART for Women Act would help to ensure that treating physicians know how drugs or medical devices perform in women or even whether tests have been conducted on these products in women. Applicants to the FDA for clinical trials, new drugs or biologics, or new medical devices would be statutorily required to include sex-specific data, when appropriate, and also to stratify the data by race and ethnicity. The FDA would also be required to develop standards for medical reviewers to ensure that individuals and FDA advisory committees reviewing these applications check for the inclusion of sex, race and ethnicity data.

This legislation does *not* mandate that women be included in clinical trials or that they be represented in certain numbers. Rather, the intent of this legislation is to shine additional light on the data that is available in the hope that it will help physicians make more informed treatment decisions and also spur researchers to seek a better understanding of sex differences.

We recognize that the FDA already has in place regulatory requirements for the reporting of a broad range of "demographic" data, including gender and racial subgroups. Unfortunately, however, more than one-third of the time this information is not being provided.[2]

More importantly, this data is often not available to physicians, researchers and the public in a meaningful way. Even when sex-specific information exists in a file at the FDA somewhere, it is often not readily available to researchers or the public, as it needs to be. There may not always be a difference in the way that treatments work between men and women. But when there is a difference, patients and their healthcare providers need and deserve to know this. And when there's not a difference doctors and patients should know that, too.

Disparities in Treatment

Finally, the HEART for Women Act would focus more attention and resources on the prevention of heart disease and stroke, especially among women at high risk for these diseases. We know that 82 percent of heart disease deaths in women are preventable if only patients controlled their risk factors and maintained healthy lifestyles – easier said than done, I recognize.

The good news is that there is a federally-funded program already in place that has been tremendously successful in helping low-income, disadvantaged women identify their risk and then live healthier lifestyles – the WISEWOMAN program (Well-Integrated Screening and Evaluation for Women Across the Nation). This program, funded through the Centers for Disease Control and Prevention, provides free heart disease and stroke screening to low-income, uninsured or underinsured women ages 40-64, and it has proven highly effective in reaching women most at-risk for CVD and therefore most in need of the WISEWOMAN screenings and

[1] Blauwet et al. Low rate of sex-specific result reporting in cardiovascular trials. *Mayo Clin Proc*. Feb 2007; 82 (2); 166-170.

[2] GAO-01-754, "Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement" (2001).

lifestyle interventions. In fact, nearly 3 out of 4 women screened through WISEWOMAN had at least one risk factor for CVD.

In the last six years in just 14 states, WISEWOMAN has screened over 50,000 women and identified more than 5,000 new cases of high blood pressure, nearly 6,000 new cases of high cholesterol, and nearly 1,000 new cases of high blood sugar.

WISEWOMAN goes beyond just screening to offer educational opportunities to eligible women to help them change their behavioral risk factors, such as by exercising more, eating healthier diets, and smoking cessation. WISEWOMAN programs offered women more than 135,000 lifestyle change sessions. Women who participate in these sessions have been more likely to quit smoking and make other healthy lifestyle choice – in fact, after 1 year of participation in WISEWOMAN, participants' CVD risk declined between 5.5 and 8.3 percent and smoking rates decreased between 5.9 and 10 percent.

The bad news is that the WISEWOMAN program is currently limited to 14 states because it still has demonstration program status. WISEWOMAN began as a demonstration program authorized by Congress in 1993. The program is available to low-income women aged 40 to 64 who are enrolled in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). Over its 12-year history, we feel that the program has more than demonstrated its value and sustainability. Cardiovascular diseases are the leading cause of death of women in all 50 states, and we believe each state should have a WISEWOMAN program. We feel strongly that the time for the expansion of WISEWOMAN to all 50 states is long overdue.

The HEART for Women Act would give the WISEWOMAN program permanent statutory authorization and make all states, territories, and Indian tribes eligible to receive funding. It would authorize "such sums as necessary" for this purpose.

Conclusions

In conclusion, on behalf of the millions of American Heart Association professionals, volunteers and donors, I sincerely thank the Subcommittee for its interest in women with cardiovascular disease. We are enthusiastic supporters of the HEART for Women Act and believe that this legislation is both cost-effective and necessary to improving the heart health of American women.

We look forward to working with the Subcommittee, Representatives Capps and Cubin, and the other organizations that have endorsed this bill to get it passed by the House of Representatives in this session of Congress. Thank you for your time. I would be pleased to answer any questions.