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THE HEART DISEASE EDUCATION, ANALYSIS RESEARCH, AND TREATMENT FOR WOMEN ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

H.R. 1014

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H.R. 1014, THE HEART DISEASE EDUCATION, ANALYSIS RESEARCH, AND TREATMENT FOR WOMEN ACT

TUESDAY, MAY 1, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:08 a.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone (chairman) presiding.

Members present: Representatives Capps, Schakowsky, Solis, Hooley, Deal, Murphy, Burgess, Barton, and Blackburn.

Staff present: William Garner, Bobby Clark, John Ford, Jesse Levine, Melissa Sidman, Carrie Annand, Lauren Bloomberg, Lyn Walker, Chad Grant, Ryan Long, and Katherine Martin.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Today we have a hearing on H.R. 1014, the Heart Disease Education, Analysis Research, and Treatment for Women Act. I recognize myself initially for an opening statement.

I first of all should thank the sponsor of the bill, the gentlewoman from California, Lois Capps. She has been a leader on so many healthcare issues. I often think of the nursing aspect because you talk to me about it so often but also on women's issues in general. It is no surprise that she has introduced this bill that is the subject of our hearing today. It is about coronary heart disease which occurs of course when the arteries that supply blood to the heart muscle become hardened and narrowed due to a buildup of plaque on the arteries in the walls. As plaque continues to build up in the arteries, blood flow to the heart is reduced, which can lead to a heart attack. There is a common misperception that exists today that heart disease is a man's disease, but this simply is not true. In reality, heart disease has a deadly impact on both men and women. In fact, I think most people would be surprised to learn that heart disease is the No. 1 killer of women in the United States followed by cancer and stroke. One in four American women die from heart disease each year, while one in 30 by contrast dies of breast cancer.

There are a number of risk factors that might lead a person to develop heart disease including cigarette smoking, high blood pres-

sure, high blood cholesterol, overweight, physical inactivity, and diabetes. Research shows that more than 95 percent of those who die from heart disease have at least one of these major risk factors. But many of the risk factors are within our control. We have the ability to decrease our chance of developing heart disease through diet, exercise, and medication therapy.

Education is obviously the key. Knowing what the risk factors are and how to change them is crucial to decreasing your chance of suffering from heart disease, and that is why this bill is so important. Under Mrs. Capps' legislation, a new program would be authorized to educate health care professionals and older women about unique aspects of care in the prevention, diagnosis, and treatment of women with heart disease. But these risk factors don't tell the whole story. The interaction between age and sex also plays a significant role in developing heart disease. Starting around age 50, women are at increased risk of developing heart disease. For those women, ensuring access to screening services is vital to survival. Without a way to receive an appropriate screening test, many women who suffer from heart disease will go undetected and be unable to receive proper treatment. Needless to say, those who are uninsured are disproportionately impacted by heart disease because of their inability to access screening services and follow-up treatment. And even when there are no barriers to accessing care, determining the most appropriate treatment is crucial.

The final component of Mrs. Capps' bill deals with treatment service and encourages better research into the most effective treatments for women who suffer from heart disease. Although coronary heart disease causes more than 250,000 deaths in women each year, much of the research and clinical trials in the last 20 years on CHD has either excluded women entirely or included only limited numbers of women. That is incredible to me that those are the facts.

This bill would change that by improving the availability of gender-specific information on drugs and devices designed to treat heart disease and the risk factors that lead to it.

Again, I want to thank Mrs. Capps for all her efforts in this area and for leading the charge in so many women's health issues. As a husband and father of two girls, I know how important it is that we tackle this issue. I want to thank you, Lois, really for all that you do.

I would now recognize our ranking member, Mr. Deal.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman. I got him beat. As the husband and father of three girls, I am certainly interested in hearing what we have to say today about educating women about the dangers of heart disease and cardiovascular disease and learning about the risks it imposes.

Many women, of course, consider the cancers, breast cancer in particular, as being the primary focus and say, "well, heart disease is a problem relegated to men" but as it has been pointed out, it is the leading cause of deaths among women. And in fact, while

nearly 450,000 died of coronary heart disease in 2004, nearly 220,000 of those were in fact women.

Another portion of the bill that we will be looking at is the provisions that take steps to ensure that drug, device, and biological product applications submitted to the FDA include safety and efficacy data broken down by sex, race, and ethnicity. This information certainly has a useful role to play as doctors and patients determine the best course of treatment, and I support providing the FDA with these statistics. However, I think the committee should look very closely at the legislation to ensure that those provisions do not prevent or delay needed medications from reaching patients, and I am glad and we are given the opportunity today to evaluate those portions of the bill as well.

I look forward to the testimony of the witnesses and thank them for being here today and hope that as we address the issue of heart disease among women and the role of the FDA in this effort that we will have the opportunity to have other testimony from people such as you, and we thank you for your presence today.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Deal. And now I recognize the sponsor, the gentlewoman from California.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. Thank you, Chairman Pallone. I appreciate very much that you are holding this hearing today. I think it is appropriate timing that we are having this hearing just before Mother's Day. What greater gift could this Congress give to mothers and daughters this holiday than the tools to combat the No. 1 health crisis for women in the United States? I am so proud to have introduced H.R. 1014 in the House with Congresswoman Barbara Cubin and to work with our colleagues in the Senate, Senators Stabenow and Murkowski on companion legislation that they have introduced.

Unfortunately, Congresswoman Cubin has been detained in Casper, Wyoming, due to a family health situation; but I want to thank her and her staff for her commitment to this bill. As many of our colleagues know, Congresswoman Cubin is a heart disease survivor herself, and I am happy to share that this legislation is on the Women's Caucus priority list for the 110th Congress boasting the co-sponsorship of over 50 women members in the House and all 16 women Senators. We felt it was necessary to introduce this legislation because of the substantial knowledge gaps that exist in diagnosing and treating heart disease in women.

Heart disease kills more women than the next five causes of death combined. Most Americans don't know this, and unfortunately, many health professionals don't know this either. Though awareness has been increasing, we simply must do more to improve our Nation's ability to fight heart disease. H.R. 1014 would accomplish this in three main ways: one, by initiating awareness campaigns about cardiovascular disease for women and also health professionals; second, requiring that healthcare data be reported to the Federal Government and that it be stratified by gender, race, and ethnicity; and third, expanding the CDC's WISEWOMAN pro-

gram which provides screenings to low-income women from 14 States currently to all 50 States.

Today I am so happy to welcome two terrific witnesses to testify on this subject. County Supervisor, Janet Wolf, from my district in Santa Barbara, will discuss her own experiences stemming from a heart attack at age 50. Supervisor Wolf has been a leader on a number of important health issues in my district, and I am very proud to have her here today. Dr. Sue Bennett, whose full credentials are way too long to list, is a cardiologist and a spokeswoman for the American Heart Association. She has dedicated herself to improving the treatment of heart disease in women and was instrumental in the writing of this legislation.

As the subcommittee will hear from these two witnesses, too many women are unaware of the symptoms of heart disease as they manifest themselves differently in women than in men. And when women present these symptoms to a health professional, they too often go unrecognized.

I am very excited to discuss this issue further with our colleagues today, and I am sure that we are going to learn valuable information that I hope we will all share with the women in our lives. Thank you.

Mr. Chairman, I yield back.

Mr. PALLONE. Thank you. Dr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman, and I will be pretty brief this morning. These are both very worthwhile bills. I think our witness from the American Heart Association sums it up best with the phrase an alarming lack of awareness in her testimony, and if there was one constructive criticism I might make to you to this bill dealing with heart disease is making section VI a more robust section as far as getting the information out to healthcare providers because the awareness seems to come in ways that are not direct pipelines from the NIH; and that has been one of my disappointments up here is learning about all the good things that go on at the NIH and realize that for 25 years in clinical practice I was barely aware of the NIH's existence and I don't think that was just inattentiveness on my part. I think it is more widespread than that.

And the other reason this bill is worthy of support is Texas is not one of the States that is colored in, and that is a shame; and we ought to expand the program to at least include Texas, and if some other States are looped in as a byproduct of that, then I guess that is ultimately a good thing.

H.R. 20 which I have co-sponsored with subcommittee Chairman Rush for the last two Congresses is also a good bill. I would make the same comments about that as far as disseminating the information. The legislative language is good and it is sound, but the research doesn't deliver on the promise if we don't get the information and the tools into the hands of the clinicians; and largely that is the primary care physician, the family practice doctor, the pediatrician, and the OB/GYN who are going to be on the front lines of

making the diagnosis and at least initiating the cascade of treatment.

Thank you, Mr. Chairman, for bringing these two bills up. I look forward to some lively interchange today, and I will yield back.

Mr. PALLONE. Thank you, Doctor, and I believe that concludes our opening statements. Any other statements will be accepted for the record at this time as well as the text of H.R. 1014.

[The prepared statements of Members and H.R. 1014 follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, thank you for holding this important hearing on H.R. 1014, the HEART for Women Act.

Heart disease, stroke, and other cardiovascular diseases are the leading cause of death among women. Despite being the No. 1 killer, only 13 percent of women are aware that cardiovascular diseases are their greatest health risk. Cardiovascular diseases disproportionately affect minority women, and statistics show that unfortunately, these populations are less likely to know of their risk.

During 2004 in California, nearly 128 women died every day from cardiovascular diseases, making them the No. 1 killer of women in the State. Stroke accounted for 10,049 female deaths in California that same year, ranking as the No. 3 cause of female deaths in the State.

Heart disease, stroke and other cardiovascular diseases are preventable and treatable when women are aware of their risk factors and are appropriately screened by health care professionals.

Under H.R. 1014, the highly successful WISEWOMAN heart disease and stroke prevention screening program would be expanded from 14 States to all 50. This CDC-funded programs helps women with little or no health insurance gain access to screening and lifestyle interventions that can reduce their risk for heart disease, stroke, and other chronic diseases.

The bill also authorizes grants to educate healthcare professionals about the prevalence and unique aspects of care for women in the prevention and treatment of cardiovascular diseases. It also authorizes Medicare to conduct an educational awareness campaign for older women about the risks of heart disease and stroke.

H.R. 1014 has been endorsed by has been endorsed by the American Heart Association/American Stroke Association, the American College of Cardiology, and the American College of Obstetricians and Gynecologists (ACOG).

I'm proud to be a cosponsor of the bill, and want to thank Rep. Lois Capps for sponsoring this very important legislation which will go a long way toward preventing unnecessary illness and death.

I look forward to hearing from our witnesses today and I urge my colleagues to support this bill.

PREPARED STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Chairman, thank you for holding this hearing on H.R.1014, the Heart Disease Education, Analysis Research, and Treatment for Women Act. Often times we move forward on legislation that is well-intended but fails to fully examine the policy ramifications of the substance of the legislation. I hope that today's hearing will provide us with a better understanding of the goals of H.R. 1014 and what effects the legislative text will have on the programs at the Centers for Disease Control and the Food and Drug Administration.

The legislation has several notable goals including raising awareness among women and their health care providers regarding the prevention and treatment of cardiovascular diseases, calling for gender and race-specific information for clinicians and researchers, and improving screening for low-income women at risk for heart disease and stroke. Additionally, the legislation would authorize the expansion of the Centers for Disease Control's WISEWOMAN program.

As several of you know, I recently suffered a heart attack and thanks to a wonderful team of medical personnel and the research that has gone into heart disease, I have made a full recovery. I undoubtedly understand the need for research and treatment of heart disease.

However, some of the provisions of the bill relating to the Food and Drug Administration may be well intentioned, but may not provide a significant public health

benefit. As I understand much of the information required to be reported under the bill for New Drug applications is already being given to the agency. Additionally, the provisions related to Abbreviated New Drug Applications and Investigational New Drugs would not improve the safety of these products but could needlessly delay the approval of generic drugs and disrupt the development of clinical trials for investigational drugs.

Thank you again Mr. Chairman for holding this hearing. I hope we can work together to examine the ways in which we can improve the legislation before us today.

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WYOMING

Heart disease, stroke and other cardiovascular diseases are the leading causes of death in Wyoming. Nationwide, these diseases claim the lives of over 480,000 American women annually. To give perspective to that number, it amounts to the death of one American woman every minute. Though long perceived as a "man's disease," more women than men die from heart disease annually. The lives of American women may depend on correcting that faulty perception.

That is why I joined Representative Lois Capps in introducing H.R. 1014, the bipartisan, bicameral Heart Disease Education, Analysis, Research, and Treatment for Women Act, or HEART for Women Act. Representative Capps has demonstrated tremendous commitment and leadership on this issue. I am proud to partner with her on H.R. 1014, not just as a colleague and friend, but as a heart attack survivor myself.

Unfortunately, there is a startling lack of understanding about the threat of heart disease among women. A recent survey conducted by the American Heart Association found that only 21 percent of women believed heart disease to be the greatest threat to their health. Many women are also unaware of heart disease risk factors and symptoms, which tend to be more subtle than those manifested in men.

Even worse, the same survey revealed that less than 10 percent of primary care physicians recognize that heart disease kills more women than men each year, a fact that has been established since 1984. If doctors fail to realize women are at risk, they are less likely to refer them for the necessary screening and treatment. Even after a diagnosis, treatment options may not be as effective for women as men. Women are also less likely than men to receive certain diagnostic testing and treatment, such as angioplasties and stents.

H.R. 1014 takes a three-prong approach to reducing the death rate in women from cardiovascular disease. The legislation will raise awareness about cardiovascular disease among both women and the healthcare providers they rely on. It accomplishes this through grants for provider education regarding the prevalence and unique aspects of care for women in the prevention and treatment of cardiovascular diseases. It also authorizes the Medicare program to conduct an educational awareness campaign for older women about their risk for cardiovascular disease.

To improve the quality of healthcare data already being collected by the federal government, H.R. 1014 requires stratification by sex, race and ethnicity. This includes pharmaceutical and medical device approval data, medical errors data, hospital quality data, and quality improvement data. This information will assist clinicians and researchers as they seek to determine best practices relating to screening, diagnosis, and treatment for women with cardiovascular disease.

Finally, the legislation authorizes the expansion to all 50 States of the WISEWOMAN program administered by the Centers for Disease Control and Prevention. The program provides heart disease and stroke prevention screening, such as tests for high blood pressure and high cholesterol, to low-income uninsured and underinsured women. Fourteen states currently benefit from the program. My home state of Wyoming is not one of them. Expanding WISEWOMEN nationwide would give women in Wyoming the number one tool in fighting any disease—early detection.

I am very grateful that our panelists have joined us today to share their own personal experiences with cardiovascular disease. I am hopeful their testimony will help this committee realize the gravity of this issue and the need to take up and pass the HEART for Women Act for the health of our Nation's women.

PREPARED STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

I would like to thank the chairman for holding this hearing today and welcome our witnesses. Heart disease is ranked as the No. 1 killer of women in the United

States and the No. 3 killer of women in my home State of Tennessee. Heart disease and stroke accounted for nearly 36 percent of all female deaths in Tennessee in 2003. Further, heart disease alone is the leading cause of death in Tennessee, accounting for 8,052 female deaths in 2003.

As we all know, Congress determines funding for the National Heart, Lung, and Blood Institute for medical research on heart disease, as well as funding for heart disease prevention and education programs. Last year, Congress provided almost $3 billion to the National Heart, Lung, and Blood Institute and almost $45 million for cardiovascular prevention and health promotion. Other federal laws and regulations promote cardiovascular health by discouraging smoking, promoting physical exercise and nutrition education, and establish food labeling requirements.

As a cosponsor of H.R. 1014, I appreciate the intent of the HEART for Women Act to increase the focus on cardiovascular disease in women. I would hope that this legislation will further enhance our knowledge and research, and not be duplicative of existing programs. I also hope that personal responsibility and maintenance will play a role in reducing the number of cardiovascular-related deaths. It is imperative that a balance exist between the bureaucratic role and personal responsibility when addressing this very serious health issue.

I look forward to hearing testimony from today's witnesses. Thank you Mr. Chairman and I yield back the balance of my time.

REMARKS FOR THE SUBCOMMITTEE ON HEALTH ON H.R. 1014, "DISEASE EDUCATION, ANALYSIS RESEARCH AND TREATMENT FOR WOMEN ACT."

CONGRESSMAN EDOLPHUS "ED" TOWNS

MAY 1, 2006

THANK YOU, MR. CHAIRMAN, FOR BRINGING THIS CRITICAL LEGISLATION BEFORE THE SUBCOMMITTEE. RESEARCH ON WOMEN'S HEALTH IN GENERAL HAS UNFORTUNATELY TAKEN A BACKSEAT UNTIL VERY RECENTLY IN U.S. MEDICAL SCHOOLS AND MEDICAL RESEARCH FACILITIES, PARTICULARLY RESEARCH INCLUDING MINORITY WOMEN. THE HEART FOR WOMEN ACT INTRODUCED BY CONGRESSWOMEN CAPPS AND CUBIN IS AN IMPORTANT PART OF IMPROVING THE DIAGNOSIS AND TREATMENT OF HEART DISEASE IN WOMEN. THIS IS AN IMPORTANT PART OF ACHIEVING PARITY FOR HEALTH RESEARCH IN OUR COUNTRY AND I STRONG SUPPORT THIS EFFORT AS WE MOVE FORWARD.

HEART DISEASE IS THE NUMBER ONE KILLER OF WOMEN IN THE UNITED STATES. MORE THAN ONE-THIRD OF ALL DEATHS AMONG U.S. WOMEN ARE DUE TO HEART DISEASE, WHICH USUALLY OCCURS ABOUT 10 YEARS LATER IN LIFE IN WOMEN THAN IN MEN.

UNFORTUNATELY, WOMEN OF COLOR HAVE HIGHER RATES OF HIGH BLOOD PRESSURE, TEND TO DEVELOP IT AT AN EARLIER AGE AND ARE LESS LIKELY THAN WHITE WOMEN TO RECEIVE TREATMENT. WHILE HEART DISEASE IS MORE LIKELY FOUND IN BLACK WOMEN, THEY ARE LESS LIKELY THAN OTHER WOMEN OR MEN TO HAVE ACCESS TO LIFESAVING THERAPIES FOR HEART ATTACKS.

THE REQUIREMENT THAT THE FOOD AND DRUG ADMINISTRATION REPORT DATA BY GENDER AND RACE WHEN APPROVING A DRUG DEVICE OR BIOLOGIC PRODUCT IS AN IMPORTANT STEP IN

DETERMINING THE MEDICAL EFFECT OF A WIDE RANGE OF PRODUCTS AND DRUGS SPECIFIC TO WOMEN, MINORITY WOMEN AND MINORITIES IN GENERAL. IN ADDITION, I SUPPORT THE EDUCATIONAL OUTREACH PROVISIONS OF THIS BILL TO INFORM THESE POPULATIONS ABOUT THE IMPACT OF CARDIOVASCULAR DISEASE AND THE STEPS NEEDED FOR PREVENTION.

THANK YOU AGAIN, MR. CHAIRMAN FOR BRINGING THIS BILL BEFORE THE SUBCOMMITTEE TODAY.

I

110TH CONGRESS
1ST SESSION

H. R. 1014

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2007

Mrs. CAPPS (for herself and Mrs. CUBIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the Heart Disease Education, Analysis Research, and Treatment for Women Act or the "HEART for Women Act".

SEC. 2. FINDINGS.

Congress makes the following findings:

1 (1) Heart disease, stroke, and other cardio-
2 vascular diseases are the leading cause of death
3 among women.
4 (2) Despite being the number 1 killer, only 13
5 percent of women are aware that cardiovascular dis-
6 eases, including heart disease and stroke, are their
7 greatest health risk.
8 (3) Many minority women, including African
9 American, Hispanic, Native American, and some
10 Asian American women, are at a higher risk of
11 death from heart disease, stroke, and other cardio-
12 vascular diseases, but they are less likely to know of
13 this risk.
14 (4) There is a pervasive lack of awareness
15 among healthcare providers that cardiovascular dis-
16 ease is the leading killer of women.
17 (5) Women are less likely than men to receive
18 certain treatments for cardiovascular diseases, per-
19 haps due to lack of awareness and the presence of
20 different symptoms in women than in men.
21 (6) Women tend to experience later onset of
22 heart disease than men, and therefore more often
23 suffer from multiple conditions that mask symptoms
24 of heart disease and complicate treatment.

1 (7) Certain diagnostic tests for cardiovascular
2 disease may be less accurate in women than in men.
3 (8) Drug effectiveness and metabolism differ in
4 women and men, impacting successful treatment of
5 cardiovascular disease.
6 (9) In addition, stroke kills 2.3 times as many
7 females as does breast cancer. Nearly 61 percent of
8 stroke-related deaths occur in females. Studies have
9 found differences in the effects, diagnosis, and treat-
10 ment of stroke depending on the sex of the patient.
11 For instance—
12 (A) stroke severity is greater in women
13 than in men;
14 (B) women often receive fewer diagnostic
15 tests and intervention procedures than men;
16 and
17 (C) strokes present treatment issues
18 unique to women.

19 **SEC. 3. REPORTING OF DATA IN APPLICATIONS FOR**
20 **DRUGS, BIOLOGICS, AND DEVICES.**

21 (a) NEW DRUG APPLICATIONS.—Section 505(b) of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(b)) is amended by adding at the end the following:
24 "(6)(A) Notwithstanding any other provision of this
25 Act, the applicant shall include in any submission to the

1 Secretary pursuant to this subsection, to the extent appro-
2 priate, information stratified by sex, race, and ethnicity,
3 including any differences in safety and effectiveness.
4 "(B) The Secretary shall withhold approval of an ap-
5 plication if the applicant fails to submit the required infor-
6 mation described in subparagraph (A).
7 "(C) The Secretary shall develop standards to ensure
8 that submissions to the Secretary pursuant to this sub-
9 section are adequately reviewed to determine whether such
10 submissions include the information required under sub-
11 paragraph (A).
12 "(D) Upon the approval under this subsection of an
13 application for a drug, the Secretary shall report to the
14 scientific community and make available to the public, in
15 a timely manner, data regarding such drug stratified by
16 sex, race, and ethnicity.".
17 (b) INVESTIGATIONAL NEW DRUG APPLICATIONS.—
18 Section 505(i) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 355(i)) is amended—
20 (1) in paragraph (2), by inserting "and para-
21 graph (5)" after "Subject to paragraph (3)"; and
22 (2) by adding at the end the following:
23 "(5)(A) Notwithstanding any other provision of this
24 Act, the manufacturer or sponsor of an investigation of
25 a new drug shall include in any submission to the Sec-

1 retary pursuant to this subsection on the clinical investiga-
2 tion of the new drug and to the extent appropriate, infor-
3 mation stratified by sex, race, and ethnicity, including any
4 differences in safety and effectiveness.

5 "(B) The Secretary shall place a clinical hold (as de-
6 scribed in paragraph (3)) on an investigation if the manu-
7 facturer or sponsor of the investigation fails to submit the
8 required information described in subparagraph (A).

9 "(C) The Secretary shall develop standards that en-
10 sure that submissions to the Secretary pursuant to this
11 subsection on clinical investigations of new drugs are ade-
12 quately reviewed to determine whether such submissions
13 include the information required under this paragraph.".

14 (c) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
15 tion 505(j) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 355(j)) is amended—

17 (1) in paragraph (2)(A), by inserting before the
18 period at the end the following: ", subject to para-
19 graph (10)";

20 (2) in paragraph (3)(A), by adding at the end
21 the following: "The Secretary shall require such in-
22 dividuals who review such applications to ensure
23 that such applications include the information on
24 sex, race, and ethnicity data required under para-
25 graph (10).";

1 (3) in paragraph (4)—

2 (A) in subparagraph (J), by striking "or"
3 after the semicolon;

4 (B) in subparagraph (K), by striking the
5 period at the end and inserting "; or"; and

6 (C) by adding at the end the following:

7 "(L) the application does not include ap-
8 propriate information stratified by sex, race,
9 and ethnicity, as required under paragraph
10 (10)."; and

11 (4) by adding at the end the following:

12 "(10)(A) Notwithstanding any other provision of this
13 Act, a person shall include in any submission to the Sec-
14 retary pursuant to this subsection appropriate drug infor-
15 mation stratified by sex, race, and ethnicity, including any
16 differences in safety and effectiveness.

17 "(B) The Secretary shall develop standards that en-
18 sure that submissions to the Secretary pursuant to this
19 subsection are adequately reviewed to determine whether
20 such submissions include the information required under
21 this paragraph.

22 "(C) Upon the approval under this subsection of an
23 application for a drug, the Secretary shall report to the
24 scientific community and make available to the public, in

1 a timely manner, data regarding such drug stratified by
2 sex, race, and ethnicity.".
3 (d) PREMARKET APPROVALS.—Section 515 of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)
5 is amended—
6 (1) in subsection (e)—
7 (A) in paragraph (1)—
8 (i) in subparagraph (F), by striking
9 "and" at the end;
10 (ii) in subparagraph (G), by striking
11 the period and inserting "; and"; and
12 (iii) by adding at the end the fol-
13 lowing:
14 "(H) information regarding the device, to the
15 extent appropriate, stratified by sex, race, and eth-
16 nicity, including differences in safety and effective-
17 ness."; and
18 (B) by adding at the end the following:
19 "(5) The Secretary shall develop standards that en-
20 sure that submissions to the Secretary pursuant to this
21 subsection are adequately reviewed to determine whether
22 such submissions include the information required under
23 paragraph (1)(H)."; and
24 (2) in subsection (d)—
25 (A) in paragraph (2)—

1 (i) in subparagraph (D), by striking
2 "or" at the end;
3 (ii) in subparagraph (E), by striking
4 the period and inserting "; or"; and
5 (iii) by inserting after subparagraph
6 (E), the following:
7 "(F) the application does not contain, as appro-
8 priate, the information required in subsection
9 (c)(1)(H)."; and
10 (B) by adding at the end the following:
11 "(7) Upon the approval of an application under this
12 section, the Secretary shall report to the scientific commu-
13 nity and make available to the public, in a timely manner,
14 data regarding such device stratified by sex, race, and eth-
15 nicity.".
16 (e) INVESTIGATIONAL DEVICE EXEMPTIONS.—Sec-
17 tion 520(g)(2) of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 360j(g)) is amended—
19 (1) in subparagraph (B), by adding at the end
20 the following:
21 "(iv) A requirement that any application in-
22 clude information regarding the device, to the extent
23 appropriate, stratified by sex, race, and ethnicity, in-
24 cluding differences in safety and effectiveness."; and
25 (2) by adding at the end the following:

1 "(D) The Secretary shall develop standards that en-
2 sure that submissions to the Secretary pursuant to this
3 subsection are adequately reviewed to determine whether
4 such submissions include the information required under
5 subparagraph (B)(iv).".

6 (f) BIOLOGICAL PRODUCT LICENSES.—Section
7 351(a)(2) of the Public Health Service Act (42 U.S.C.
8 262) is amended by adding at the end the following:

9 "(D)(i) Notwithstanding any other provision of this
10 Act, the applicant shall include in any application to the
11 Secretary pursuant to this section appropriate information
12 regarding the subject biological product stratified by sex,
13 race, and ethnicity, including differences in safety and ef-
14 fectiveness.

15 "(ii) The Secretary shall develop standards that en-
16 sure that submissions to the Secretary pursuant to this
17 section are adequately reviewed to determine whether such
18 submissions include the information required under clause
19 (i).

20 "(iii) Upon the approval of an application under this
21 subsection, the Secretary shall report to the scientific com-
22 munity and make available to the public, in a timely man-
23 ner, data regarding such biological product stratified by
24 sex, race, and ethnicity.".

1 (g) GAO STUDY.—Not later than 2 years after the
2 date of enactment of this section, the Comptroller General
3 of the United States shall study the drug approval proc-
4 esses of the Food and Drug Administration to ensure that
5 the Food and Drug Administration is complying with the
6 amendments made by this section.

7 **SEC. 4. REPORTING AND ANALYSIS OF PATIENT SAFETY**
8 **DATA.**

9 (a) DATA STANDARDS.—Section 923(b) of the Public
10 Health Service Act (42 U.S.C. 299b–23(b)) is amended
11 by adding at the end the following: "The Secretary shall
12 provide that all nonidentifiable patient safety work prod-
13 uct reported to and among the network of patient safety
14 databases be stratified by sex.".

15 (b) USE OF INFORMATION.—Section 923(c) of the
16 Public Health Service Act (42 U.S.C. 299b–23(c)) is
17 amended by adding at the end the following: "Such anal-
18 yses take into account data that specifically relates to
19 women and any disparities between treatment and the
20 quality of care between males and females.".

21 **SEC. 5. QUALITY OF CARE REPORTS BY THE AGENCY FOR**
22 **HEALTHCARE RESEARCH AND QUALITY.**

23 Section 903 of the Public Health Service Act (42
24 U.S.C. 299a–1) is amended—

1 (1) in subsection (b)(1)(B), by inserting before
2 the semicolon the following: ", including quality of
3 and access to care for women with heart disease,
4 stroke, and other cardiovascular diseases"; and
5 (2) in subsection (c), by adding at the end the
6 following:
7 "(4) ANNUAL REPORT ON WOMEN AND HEART
8 DISEASE.—Not later than September 30, 2007, and
9 annually thereafter, the Secretary, acting through
10 the Director, shall prepare and submit to Congress
11 a report concerning the findings related to the qual-
12 ity of and access to care for women with heart dis-
13 ease, stroke, and other cardiovascular diseases. The
14 report shall contain recommendations for eliminating
15 disparities in, and improving the treatment of, heart
16 disease, stroke, and other cardiovascular diseases in
17 women.".

18 **SEC. 6. EDUCATIONAL CAMPAIGNS.**

19 (a) DISTRIBUTION OF EDUCATIONAL MATERIAL.—
20 The Secretary of Health and Human Services (referred
21 to in this section as the "Secretary") shall develop and
22 distribute to females who are age 65 or older, physicians,
23 and other appropriate healthcare professionals, edu-
24 cational materials relating to the prevention, diagnosis,
25 and treatment of heart disease, stroke, and cardiovascular

1 diseases in women. The Secretary may carry out this sub-
2 section through contracts with public and private non-
3 profit entities.

4 (b) HEALTHCARE PROFESSIONAL EDUCATIONAL
5 CAMPAIGN.—The Secretary, acting through the Bureau of
6 Health Professions of the Health Resources and Services
7 Administration, shall conduct an education and awareness
8 campaign for physicians and other healthcare profes-
9 sionals relating to the prevention, diagnosis, and treat-
10 ment of heart disease, stroke, and other cardiovascular
11 diseases in women. The Bureau of Health Professions may
12 carry out this subsection through contracts with public
13 and private nonprofit entities.

14 **SEC. 7. EXTENSION OF WISEWOMAN.**

15 There are authorized to be appropriated such sums
16 as may be necessary for each fiscal year to enable the Di-
17 rector of the Centers for Disease Control and Prevention
18 to implement Well-Integrated Screening and Evaluation
19 for Women Across the Nation (WISEWOMAN) program
20 projects in all States and territories, which may include
21 projects among Indian tribes.

○

Mr. PALLONE. I will turn to our two witnesses. First of all, thank you for being here today, and let me introduce first, Dr. Susan Bennett who is clinical director of the Women's Heart Program at George Washington University Hospital, and next to her is Ms. Janet Wolf who is the second district supervisor for the county of Santa Barbara in Santa Barbara, CA. Thank you both for being here today.

We have 5-minute opening statements. They become part of the hearing record, but each of you may, in the discretion of the committee, submit additional brief or statements in writing for including in the record. And I will start now by recognizing Dr. Bennett. Thank you again.

STATEMENT OF SUSAN K. BENNETT, M.D., CLINICAL DIRECTOR, WOMEN'S HEART PROGRAM, THE GEORGE WASHINGTON UNIVERSITY HOSPITAL, WASHINGTON, DC

Dr. BENNETT. Well, thank you, Congressman Pallone. It is a pleasure to be here, and Representative Capps, thank you for sponsoring this bill.

My name is Susan Bennett, and I am a practicing cardiologist; and I think first and foremost, I am one of the doctors in the trenches. I see patients 5 days a week, and I see men and women. About 70 percent of my practice is women, and that is primarily what I do. I am a clinical assistant professor of medicine 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 president of the Association of Women's Heart Programs and I also serve on the Advisory Board of Women Heart which is the national coalition for women with heat disease.

On behalf of the American Heart Association, or AHA, and its more than 22 million volunteers and supporters, I appreciate the opportunity to testify today on H.R. 1014 known as the HEART for Women Act. We wish to thank this House Committee on Energy and Commerce, Subcommittee on Health, for holding today's hearing on this Act which we strongly support along with many other non-profit health organizations.

Heart disease, stroke, and other forms of cardiovascular diseases are the No. 1 killer of American women, claiming more than 460,000 lives each year or about a death a minute. That is more female lives than the next five causes of death combined, including deaths from lung and breast cancer. An estimated 42 million women, about one in three, are living with the chronic affects of heart disease, stroke, or some other form of cardiovascular disease.

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 of cardiovascular disease, or CVD. During that time we have made good progress in reducing CVD mortality for men but the same cannot be said for women. Although mortality rates have gone down for women, the decline is not nearly as steep as it is for men.

The HEART for Women Act is intended to help close that gap by focusing on three strategies to improve diagnosis, treatment, and prevention of heart disease and stroke in women. Part of the prob-

lem is that there is not enough women nor their physicians who recognize heart disease as a serious health threat that it truly is. Efforts like the AHA's Go Red for Women movement and the NHLDI's Heart Truth campaign have helped to increase awareness among women about their risk of heart disease, but much more work remains.

The latest American Heart Association survey tracking women's awareness of heart disease found that 43 percent of women are still not aware that heart disease is the leading cause of death for women. Women of color are even significantly less likely to know this important fact despite being at greater risk for cardiovascular disease.

Even more alarming especially to me is the pervasive lack of awareness about women and heart disease among physicians. According to an American Heart Association sponsored survey published in 2005, fewer than one in five physicians surveyed recognized that more women than men die of heart disease than other cardiovascular disease each year. Astoundingly, only 8 percent of primary care physicians knew this basic fact.

Healthcare professionals treat what they perceive to be a problem; and partially as a result of the above statistics, we see that women are often treated less aggressively. For instance, women are more likely to die within a year of their first heart attack, but are less likely to be referred for diagnostic testing ahead of time that could have caught the disease early in the preventive phase. And according to the Agency for Health Care 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 Health Resources and Services Administration 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 forms of CVD.

The bill also authorizes the Secretary of Health and Human Services to develop and distribute educational materials to women 65 years and older to educate them about a woman's risk for heart attacks and strokes, risk factors, and symptoms.

Another problem that I struggle with every day in my practice is the lack of information available to us about the safety and efficacy of heart and stroke treatments for women. When a new therapy comes on the market, one of the first things I want to know is how does it work in women compared to men, and all too often that information is simply 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 from womb to tomb. Researchers are learning that sex differences play an increasingly important role in prevention, diagnosis, and treatment. For instance, we have learned from the National Heart, Lung, and Blood Institute funded WISE

study that coronary artery disease may manifest itself differently in women than in men which suggest that treatment testing regimens that work in men may not work as well in women.

Diagnostic tests, prescription drugs, and medical devices may work differently in women than men. These differences are likely due to a variety of reasons. The presence of the excess chromosome which is in all cells may change the pharmacology of the drug and cells certainly change——

Mr. PALLONE. Dr. Bennett, I would just ask you to summarize because we are over by about 30 seconds.

Dr. BENNETT. There are several drugs that I can talk to you about in regard to differences and their response to women, and certainly the WISEWOMAN program needs to be expanded to all 50 States, and I can talk to you later if you need to know any information about the effectiveness.

So in summary, for me as a practicing clinician, it is absolutely important for this Act to be passed so I can take care of women better. Thank you.

[The prepared statement of Dr. Bennett follows:]

[AHA LETTERHEAD]

American Heart Association

Statement for the Hearing Record

Susan K. Bennett, M.D.
Volunteer and Professional Member, American Heart Association
Clinical Assistant Professor of Medicine and Director of the Women's Heart Program, George Washington University Medical Center
President, Association of Women's Heart Programs

Submitted to:
The U.S. House of Representatives Committee on Energy and Commerce
Subcommittee on Health

Hearing on H.R. 1014, the Heart disease Education, Analysis and Research, and Treatment for Women Act (HEART for Women Act)
May 1, 2007

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.

Mr. PALLONE. Thank you, Doctor. Ms. Wolf.

STATEMENT OF JANET WOLF, SANTA BARBARA COUNTY SUPERVISOR, SANTA BARBARA, CA

Ms. WOLF. Thank you very much, Mr. Chairman, and members of the committee. I want to thank you for holding this hearing and in particular I want to thank my beloved Congresswoman, Lois Capps who is highly respected in our district, and it is truly an honor to be here and to be asked to come here and to tell my story. I am not a physician, so the story I have to tell you is about my personal experience, and I also just want to point out that my husband is here with me. I have three daughters as well. This has been an incredible experience for me and my entire family and friends and relatives, and so it is an honor to be able to tell you my story as well in the hope that it will help and educate other women and husbands.

On December 7, 2004, I suffered a massive heart attack. I had a 100 percent occluded left anterior descending artery. I was 50 years old and considered myself to be very healthy and incredibly blessed. I had a wonderful family and great friends. I ran a successful business. I had just finished serving 11 years as a school board member. I played on a roller hockey team, and I exercised fairly regularly at the gym. I am 5'4″ and at the time of my heart attack I weighed 155 pounds. I was told that I carried it very well. I had annual medical exams which included EKG's, blood work, mammograms, and I even had a colonoscopy. I felt that I had covered all of my bases.

My experience began on a Friday evening when after going out to dinner with friends, I experienced extremely painful heartburn which felt as if a hole was burning in my esophagus. When I returned home, I took over-the-counter heartburn medication. As the weekend progressed, the heartburn sensation continued intermittently.

By Monday morning, the pain was worse and I noticed that it became more intense after slight exertion. I became concerned that it was more than just heartburn and that it might be cardiac related. I called my internist and I told him that I thought I was either having a heart attack or a very bad case of heartburn. He listened to my symptoms and prescribed medication over the phone for heartburn. I rushed to the pharmacy to get the prescription filled and took the first pill before leaving the pharmacy.

I went to bed that evening and woke up at 2:00 in the morning with what I thought was continued horrible heartburn. Because I couldn't get back to sleep, I went on the Internet to find out what I could do to ease my discomfort. By 4:00 in the morning, the pain was even more severe and I went back to the Internet. This time I went to WebMD and I compared the symptoms of heartburn with a heart attack. At that time it didn't appear that I had any of the symptoms of a heart attack. And then at 5 o'clock I started to feel clammy, a feeling that was described as a heart attack symptom. I decided to wake up my husband. He soon realized as my pain was getting worse and I was hanging over our kitchen counter that we should go to the hospital.

When we arrived at the ER and after what seemed like eternity, which actually was about 15 minutes, I had an EKG and was immediately told I was having angina.

After having a chest X-ray and finding out that I was also experiencing congestive heart failure, they told me that indeed I had and was having a massive heart attack. The doctors immediately performed an angioplasty and inserted a medicated stent in my artery. Approximately 2 weeks later I began cardiac rehab at the hospital three times a week and completed it after 8 weeks.

Since my heart attack, I have modified my lifestyle. I currently work out at the local gym about five times a week. I stopped drinking coffee and I have altered my eating habits by adopting a version of the Mediterranean diet, and I have cut my portions of food in half. I have lost 25 pounds that the hospital dietician recommended that I lose.

Many people have experienced a degree of confusion as to how it was me who had a heart attack. The answer to that question remains somewhat elusive, but I am told that in my case, heredity played a big factor. My father at the age of 52 had coronary bypass surgery and at the age of 65 he had a heart attack and additional coronary bypass surgery.

As for my current health status, my cardiologist states that my laboratory results are superb and my exercise, weight control, and medication program are paying huge dividends. I consider myself very lucky to have received the excellent medical care that I did, but in retrospect I wish I had a greater understanding of my own risk factors so that I could have been more proactive.

I am very hopeful that the HEART for Women Act will increase the educational and medical knowledge to a greater number of women who might otherwise not be aware of their risks of heart disease and how to prevent it. The Heart Act will also result in an important education and awareness campaign for physicians and other healthcare professionals about the prevention, diagnosis, and treatment of cardiovascular disease in women. I urge your committee to support the passage of this bill, and I thank you for the opportunity to testify before you today. Thank you.

[The prepared statement of Ms. Wolf follows:]

Statement for the Hearing Record

Janet Wolf
Second District Supervisor
Santa Barbara County Board of Supervisors

Submitted to:
The U.S. House of Representatives Committee
on Energy and Commerce
Subcommittee on Health

Hearing on H.R. 1014, the Heart Disease Education, Analysis and Research, and Treatment for Women Act
(HEART for Women Act)
May 1 2007

On December 7, 2004, I suffered a massive heart attack (100% occluded LAD). I was 50 years old and considered myself very healthy and incredibly blessed. I had a wonderful family and great friends, ran a successful business, had just finished serving 11 years as a school board member, played on a roller hockey team and exercised fairly regularly at the gym. I am 5'4" and at the time of my heart attack I weighed 155 pounds. I was told that I carried "it very well". I had annual medical exams, which included EKG's, blood work and mammograms and I even had a colonoscopy. I felt that I had covered all of my bases.

My experience began on a Friday evening, when after going out to dinner with friends; I experienced extremely painful heartburn which felt like a hole was burning in my esophagus. When I returned home, I took over-the-counter heartburn medication. As the weekend progressed, the heartburn sensation continued intermittently.

By Monday morning, the pain was worse and I noticed that it became more intense after slight exertion. I became concerned that it was more than just heartburn and that it might be cardiac related. I called my internist and I told him that I "was either having a heart attack or a very bad case of heartburn". He listened to my symptoms and prescribed medication for the heartburn. I rushed to the pharmacy to get the prescription filled and took the first pill before leaving the pharmacy.

I went to bed, then woke up at 2:00 in the morning with what I thought was continued horrible heartburn. Because I could not get back to sleep I went on the internet to find out what I could do to ease my discomfort. By 4:00AM the pain was worse and I went back to the internet. This time I went to Web MD and compared the symptoms of heartburn with a heart attack. At that time it didn't appear as if I had any of the symptoms of a heart attack. Then at 5:00AM I started to feel "clammy', a feeling that was described as a heart attack symptom. I decided to wake up my husband. He soon realized, as my pain was getting worse and I was hanging over our kitchen counter, that we should go to the hospital. We arrived at the ER and after what seemed like eternity (probably 15 minutes) I had an EKG and was immediately told that I was having angina.

After having a chest X-ray and finding out that I was also experiencing congestive heart failure, they told me I had indeed had a heart attack. The doctors immediately performed an angioplasty and inserted a medicated stent in my artery.

Approximately 2 weeks later, I began a cardiac rehabilitation program at the hospital three times a week and completed it after 8 weeks.

Since my heart attack, I have modified my lifestyle. I currently work out at my local gym at least 5 times a week. I stopped drinking coffee and I have altered my eating habits by adopting a version of the Mediterranean diet, and I have cut my portions of food in half. I have lost 25 pounds that the hospital dietician recommended I loose.

Many people have expressed a degree of confusion as to how it was me who had a heart attack. The answer to that question remains somewhat elusive, but I am told that in my case, heredity played a big factor. My father, at the age of 52 had coronary bypass surgery and at the age of 65 he had a heart attack and another bypass surgery.
As for my current health status, my cardiologist stated my laboratory results are "superb" and my "exercise, weight control and medication program is paying huge dividends".

I consider myself very lucky to have received the excellent medical care that I did but in retrospect I wish I had a greater understanding of my own risk factors so that I could have been more proactive.

I'm hopeful that the HEART for Women Act will increase the educational and medical knowledge to a greater number of women who might otherwise not be aware of their risks of heart disease and how to prevent it.

The HEART Act will also result in an important education and awareness campaign for physicians and other healthcare professionals about the prevention, diagnosis and treatment of cardiovascular disease in women. I urge your committee to support the passage of this Bill.

Thank you for the opportunity to testify before you today.

Mr. PALLONE. Thank you, Ms. Wolf, and that concludes our opening statements. We are going to have some questions, and I will start by asking some questions myself.

I just wanted to ask Ms. Wolf, I know that this bill is primarily education oriented, and I guess the conclusion I can come to from your statement is because you were relatively young and in good health that you just didn't think that you had a problem and that is one of the reasons that you didn't go to the hospital so quickly. In other words you say you have lost a lot of weight, you talk about the Mediterranean diet, all this. I think many of us just don't think that we have to worry about it if we are in relatively good health. I mean, was that a factor? I mean, is part of the purpose here to educate people that even though they may think that they are in pretty good shape they are not?

Ms. WOLF. I think, yes. When I was in the hospital and I think most of us know what we need to do to lead a healthier lifestyle, and sometimes we don't because we feel like we are kind of sliding along and we are doing OK. Just like I said, I was very active but I knew I needed to lose weight. I also knew that my diet was not what it should be, although my cholesterol level was fairly low. It was 170. But I also knew that I had these risk factors related to my family, but I never took any proactive measures. For me it was just a little too hard to lose 20 pounds. But I will tell you, a motivating factor is having a heart attack. And one of my messages to people is to not wait until you have a heart attack, that there are certain things you can do. And it takes time. I knew and wanted to lose weight, but I wanted to lose it in a week. It took me a long time to lose the weight, and I think that's also a message that needs to get out to people is that eating healthier, eating better, eating smarter, and also making time to exercise is very important. And so while I may have appeared healthy, certain things can happen; and I think at this point I would do everything I can to make sure that I have a healthier lifestyle.

Mr. PALLONE. Sure. Now, you said you were 50 at the time, but the bill is I guess mainly targeted for women aged 65 and older; so I guess I would ask Dr. Bennett, what is the reason for that targeted audience of over 65? I mean, why not target women age 64 and younger, Ms. Wolf being a good example?

Dr. BENNETT. Well, certainly the Act has several components to it. I think the over 65 was the Medicare portion of the Act. The FDA certainly is a big part of that, and getting data to understand how heart disease functions in women who are age 50 is very important. It turns out that family history, especially for women, is a huge risk factor. It increases risk by about 1.7 fold, so there are some things potentially that could have been done ahead of time. And when we look at women who have heart attacks in their 50's, they do far worse than men who are the same age; and we don't really know why. Research, in looking at the FDA research especially, in that age group, men versus women, is going to be very important to gain a better understanding of what medical treatments might make people better off.

Mr. PALLONE. OK. You started to talk about the WISEWOMAN program, Dr. Bennett, that has been a big factor in providing these pre-cardiovascular disease screenings for low-income, uninsured

women. You want to talk about how this bill would expand it? Apparently now it is in 14 States and this bill would expand it to 50 States. I know you were starting to talk about that maybe when I cut you off, so why don't you tell us why it is important or what you see with this expansion.

Dr. BENNETT. The WISEWOMAN program really targets those women that are underinsured or not insured at all, and that turns out to be a very high risk factor group. In fact, when they screened women in the existing 14 States, they found that almost 75 percent had some risk factors that needed attention. And it really makes a difference. Not only is it saying, hey, you are at risk, it actually provides a venue for them to get some training in regards to smoking cessation which is critical, looking at weight loss, exercise, medical management of blood pressure; and it really does make a difference. Cardiovascular risk in women who participated in these programs for a year declined anywhere between 5½ to 8.3 percent, and smoking rates, which as you know, are very tough to get people to quit smoking, smoking rates decreased about 5.9 to 10 percent. So that parlays out into a huge benefit, and that of course should be expanded to all 50 States because at-risk women are of course in all 50 States.

Mr. PALLONE. OK. And then the last thing I wanted to ask the doctor about, what was the rationale for including an increased data collection requirement for abbreviated new drug applications. Doesn't that add a regulatory burden on the abbreviated new drug applications?

Dr. BENNETT. I think the burden is nothing compared to the burden that women are suffering right now from lack of information. The data that is collected for research studies, and I am very familiar with industry-related studies, they always collect gender. So it is there. It is just a matter of getting it tabulated. And even more importantly, once it is tabulated and put in the new application, whether abbreviated or not, the FDA reviewers really need to include that as an important issue because once the FDA reviewers collate their data and it goes to panel, if it is missed at some point in the line there, it is not going to be an important item that is discussed. And there are treatments no doubt that respond the same in men and women, and that is great, we should know about that. But I think we can't assume that drug is going to pharmacologically be the same as in men and women. We have a very strong blood thinner call glycoprotein inhibitors that is used if you came in with a heart attack or near heart attack, and we know that it is great for men. It really is very effective and should be used. For women, sometimes the data is a little more equivocal as far as benefit, and we know that it causes a lot more bleeding. And of course, we would like to know, how do I deal with that when I have a woman who is coming in with a heart attack? How can I better administer that drug to decrease the side-effects and maximize the benefit?

Mr. PALLONE. All right. Thank you. Thank you both. Mr. Deal.

Mr. DEAL. Thank you, Mr. Chairman. I certainly agree on the education side of it. I failed to say that while I have three daughters, I also have four granddaughters, the oldest of whom is in first grade. On the education side of it, one of the things that I am con-

cerned about is that childhood obesity, which of course is leading to more childhood diabetes and then ultimately to heart disease as they become older, so the education component certainly I think needs to spread all of the age groups and include both sexes, of course.

One of the areas of concern that I have is the part that relates to the FDA. Dr. Bennett, let me ask you just a couple of questions about that. There are two parts of the bill, one that deals with new drug applications and another one that deals with investigational new drug applications. Both of course require that information be stratified by sex, race, and ethnicity. Now, the information I have is that the current Code of Federal Regulations requires that already. Am I incorrect and if I am not incorrect, are you simply saying by this bill they are not doing what the Code of Federal Regulations requires currently?

Dr. BENNETT. No, you are correct that there are regulations that state that the data needs to be collated on that basis and reported on that basis. The problem is it is just not done, and it doesn't come out in the final review. In about a third of the cases, the trial participants' sex was unknown which seems astounding since——

Mr. DEAL. That is getting to be more and more a problem now.

Dr. BENNETT. It is pretty easy to defer them, and most of us are pretty good at it.

Mr. DEAL. Ethnicity is a problem, too, obviously.

Dr. BENNETT. Ethnicity is a problem, too. When ethnicity is determined and collated for trials, it is the participants' self-declared ethnicity which is pretty much across the board, how we collect that particular set of data.

Mr. DEAL. So you are simply saying there needs to be more attention paid to what is already the current requirement of making sure that it is enforced in terms of breaking it down in all of these various categories, is that what you are saying?

Dr. BENNETT. In the HA's conversations with the Office of Women's Health at the FDA, we really felt that having an across-the-board methodology of approaching this and having a set way that all this information needed to be collected and tabulated by the reviewers was essential and unifying that and making that mandatory and having a little more teeth in it with the statutory law was really the best solution to this.

This data is really essential, and I don't think anybody—it is a difficult position for me to be in when I see a woman in the ER and I just don't know if the drugs I am going to give are as safe and effective as I know they are for men.

Mr. DEAL. OK. The question that Mr. Pallone asked with regard to the abbreviated new drug applications, I just generally think those as generic drugs; and we are all trying to make sure that we get generics on the market and to the consumers' hands because of the cost factors that make them more available to constituents. But as I read the bill, it requires that they go through a new set of providing safety and efficacy of their product instead of being able to rely on the patented holder of the product, which is the way generics currently operate. That seems to me is going to place a time and cost burden on generics and will prevent many of them from getting to the market as soon as we had hoped that they

would and as they do now under the current system. Do you see that as a potential problem?

Dr. BENNETT. Yes, I am personally not that familiar with the abbreviated portion of it and the regulations that the FDA has to go through, generics versus non-generics. I mean, I certainly agree that generics are a big benefit for women in particular because they often are not covered by insurance, and we want that to be offered. And I would say that in general, stratifying results by gender is a pretty easy thing to do mechanically. It is one little statistical run and one hit of the computer. So if it truly is not that burdensome, having that information available is important.

Mr. DEAL. But if they can do that for the approved drug, then the biologic should be able to piggy-back on that, wouldn't you think, if it has already been done?

Dr. BENNETT. It sounds reasonable.

Mr. DEAL. That is the way we get them to the market quicker, obviously. Finally, Dr. Bennett, do you have any examples of adverse effects of drugs currently on the market as it relates to heart-related problems that have had adverse effects on women?

Dr. BENNETT. There is a medication called digoxin which is widely available in treatment of heart failure and is quite commonly used. In 1997, that was really the first prospective randomized clinical trial showing that digoxin was helpful in heart failure patients across the board, men and women, and decreased hospitalizations. Five years later in 2002, a post-hack analysis or an analysis of the data looking at gender was published raising the issue that digoxin was not as helpful in women as in men; and in fact, it may be harmful and may have led to more mortality in women. That could be explained by higher serum levels, but that kind of information would have been extremely helpful to a physician's daily practice in the treatment of heart failure. And my concern is why did it take 5 years later to come out, and I think starting with the FDA and having that information available before it is released to the general public to at least start that dialogue of how can we maybe treat women better remains essential.

Mr. DEAL. Thank you.

Mr. PALLONE. Thank you. Mrs. Capps.

Mrs. CAPPS. Thank you. Ms. Wolf, I think it is important that you mentioned what happened when you first called your primary care physician. I think we were all hanging on your words at that moment. And he, as we might have guessed, prescribed you medication for heartburn. I understand this is a very common misdiagnosis of heart disease in women, and I wondered if you ever had the chance to discuss this with this primary provider afterward or do you think he or she would have benefited by being exposed to an awareness campaign earlier?

Ms. WOLF. Thank you. He did come to the hospital the first night when I was there, and that was the last time I had seen him. I chose to, because of everything that had happened, I chose to change doctors. There is this sense, I think we grow up with this appropriate sense that we trust our doctors. And so when I called and got the information from him, I trusted him as though he had the right answer for me. And I have subsequently come to feel that had my husband called and said the same thing, that I am experi-

encing chest pains, I think I may be having a heart attack or maybe indigestion, that—I would think that most physicians would say because my husband, being a man, would say either come into my office and let me evaluate you or go directly to the ER. And that didn't happen. And I think that one of the reasons that I think this is so valuable is to make physicians aware that this is certainly a possibility and a likely possibility and they shouldn't just tell women, which I have heard that it is anxiety or it is heartburn. At least give us the direction to take care of ourselves. And I think one of the reasons it is the No. 1 killer of women is because we don't have time, and I was lucky and fortunate to get to the hospital on time. And I was told even with that, I should have called an ambulance because time was of the essence. And so it is critically important that physicians have an understanding of what the potential of risks are for women. And I also think that women bear the responsibility, too, to be a little bit more proactive and to understand when our—I knew that something was wrong. After having three children, I know what labor is like; and having a heart attack was pretty close to that, if not more so. So I should have listened to my body as well and taken initiative on my own.

Mrs. CAPPS. Let me follow up without interrupting you because you are Supervisor Janet Wolf, as well. You have a responsibility for the county of Santa Barbara, and you know how many people don't have the wherewithal or the resources that you had to follow up, to get on the Internet, and do all the things that you did, even though it was late. Do you want to comment briefly? I want to ask Dr. Bennett a quick question, too, but what does it feel like to have gone through what you have gone through knowing how many women in the county that you serve don't even have what you have to get themselves treated.

Ms. WOLF. Right. Well, it is not a great feeling, and I think it goes back to Mr. Deal's question about education. After my heart attack—and I didn't know this, that it is the No. 1 killer of women. I went to a Heart Association meeting and found that out. I subsequently went through training through Women Heart which is a program that trains women to become spokespeople to go back to their community and talk about their personal stories. And having gone through that program, it has given me an opportunity to talk to different groups of people, from churches, synagogues, I have gone into high schools, just any group that will listen to me, I talk to them about my experience. And so that is a little piece of what I do. And of course, healthcare in our community and our society is not what I believe it should be; so I am trying to do my part to educate as many women as possible. And again, going to Mr. Deal with the question about obesity in children, when you have a healthy mom, it kind of flows to the children; and I think that is so important. If I didn't die from having a heart attack, I almost died seeing my kids in my hospital room because it was very sad. And I think as a woman, as a mother, and as a politician, as a school board member, we know how important it is to take care of our children. It is just not that tough. We just need to be educated and work on it a little bit more.

Mrs. CAPPS. I will have to save my questions.

Mr. PALLONE. Thank you. Dr. Burgess is recognized.

Mr. BURGESS. Thanks, Mr. Chairman. Let us stay on the concept of making sure that physicians and practitioners are aware. I will just share with you an experience I had where I almost by serendipity came across the symptom of unrelenting fatigue as perhaps warranting further investigation as to the possibility of underlying heart disease, and I think I came across that in something as mundane as the Reader's Digest, and then when confronted with the patient within the next couple of weeks who presented with such symptoms, she thought I was nuts for making her go see the cardiologist. And she went from the treadmill to the cath lab to the operating room in the space of an afternoon, but it would have been fairly easy to just check the box, yes, fatigue, 50 years old, what else is going on in your life. So it is not always easy to come to those conclusions, and sometimes I recognize my practice, it was better to be lucky than good.

On the educational initiatives, Dr. Bennett, what are some of the paths we should take to improve the provider education; and let me just ask specifically, what are you doing at George Washington to get the information into the hands of the people on the front lines?

Dr. BENNETT. It is interesting that you ask. The Association of Women's Heart Programs is actually taking this on nationally, and we have decided that our first target audience is going to be those first-line physicians, the OB/GYN's, the primary care physicians, the nurse practitioners and PA's who work in those organizations. And we did a very in-depth audit of about 40 thought leaders across the country, and we basically got back information that, as you know, primary care physicians are just overwhelmed with patients, overwhelmed with time constraints. And basically they thought, hey, this is a difficult area, the research is somewhat murky at times. We basically just want to know the three things that we need to keep in our minds when that door closes and we are talking with the woman behind that door. And we want to know when do we need to refer her to a cardiologist, when should we initiate blood pressure and cholesterol treatment. So having those standards of care from what is derived from the American Heart Association, the American College of Cardiology Guidelines, making those guidelines livable, breathable, and usable I think is one of the key pieces that we can do for those first-line providers. And then the usual, continuing medical education and motivation.

Mr. BURGESS. Do you key in on what questions should be asked during the history, during the interview?

Dr. BENNETT. We are actually going to be holding a summit on June 28 in regard to that and starting that dialog about how that process should be done, how best to reach those primary care physicians. It might be a simple checklist. We don't have a mammogram equivalent in cardiovascular disease——

Mr. BURGESS. That is what I was going to ask you.

Ms. BENNETT. Yes.

Mr. BURGESS. C-reactive protein or are there any other screening tests quite there yet?

Dr. BENNETT. I wish we were there, but it still boils down to Framingham risk score which we think is the best global approach, and we all do it in our heads as physicians. We kind of, hey, you don't look like you got heart disease, your blood pressure is not

that high. But it turns out we do a pretty bad job of that, and gender is one of those things that sort of knocks down the risk in our minds unfortunately. So maybe it is just as simple a thing as screening form that physicians need to do and that extra work needs to be recognized.

Mr. BURGESS. Ms. Wolf, let me just ask you, did you seek a second opinion for WebMD. Did you fire WebMD also?

Ms. WOLF. Well, actually, it was through WebMD that I was actually able to have the symptoms of heartburn next to the symptoms of heart attack. No, I didn't fire them. I think that they in some ways saved my life because the symptom of being clammy was on the heart attack side and——

Mr. BURGESS. But in fairness you did not share that information with your internist because that information developed later in the course of the disease?

Ms. WOLF. That is true, but what I did share with my physician was what I was feeling. And because I had had Rolaids or whatever it was at home, I had had heartburn in the past. But when I called him and said—I used the word heart attack. I said, something is going wrong. I said, like I said, I am either having a heart attack or really bad heartburn.

Mr. BURGESS. Yes, I can't quarrel if the wrong decision was made.

Ms. WOLF. Well, I do know again——

Mr. BURGESS. I used to instruct my nurses in labor and delivery, never give me an option in the middle of the night because if it is an option to go back to sleep, that is what I am going to take. Just tell me, you need to come to the hospital, and I will figure out the reason why when I get here.

Let me just ask you, too, in retrospect, were there other milder symptoms you could share with this panel that you may have encountered earlier that in retrospect could have been a harbinger of something more serious just around the corner?

Ms. WOLF. No.

Mr. BURGESS. So there was absolutely symptom-free days up until the bad heartburn or the bad cardiac pain started?

Ms. WOLF. Right. Yes, it basically started on that Friday. Otherwise, I would never have known. This was in November, in the summer we went to Greece and I remember climbing the Acropolis and I said, it is a good thing it didn't happen then. And back then I felt fine. So it can just happen like that.

Mr. BURGESS. Thank you.

Mr. PALLONE. Thank you, Doctor. The gentlewoman from Illinois.

Ms. SCHAKOWSKY. Thank you. I thank the witnesses, and I also thank Congresswoman Capps. Before women came to the United States Congress, the clinical trials that were done on heart disease were only done on men; and some of the differences that have since emerged were never found. And so I think it is another example of why it is very important to have everyone at the table so that these kinds of gender differences are recognized and attended to. And I thank our witnesses very much for pointing that out.

I wanted to ask Dr. Bennett, while more women die of heart attacks than men, is cardiovascular disease also more common or is it just that we are not treated appropriately for it?

Dr. BENNETT. More women than men die of cardiovascular disease so including heart attacks and strokes and other forms of cardiovascular disease, and they have done so since 1984.

Ms. SCHAKOWSKY. We die more from it but is that because it is not recognized, we are not treated, or that we have it more than men?

Dr. BENNETT. It is multi-factorial, no doubt, as to why women are dying more so than men. I think it has to do with——

Ms. SCHAKOWSKY. Is it more common in women? Is the disease more common in women?

Dr. BENNETT. It depends on what age group you are talking about. Based on the NHAIN survey, which is a national survey, when women get in their 50's and 60's, the prevalence of the disease so those living with disease is about the same. And that is different than about 10 years ago where the prevalence started to become equal when women were more in their 70's. So it appears that more women are living with cardiovascular disease.

Ms. SCHAKOWSKY. I see. I wanted to ask the question actually that Mrs. Capps was unable to ask because of time. The question was for Dr. Bennett to follow up on a statement you made regarding the fact that more than one-third of the time information about demographic data isn't being provided to the FDA and clinicians. And I was wondering if you could elaborate on that and tell us how you think this legislation could help improve on that statistic.

Dr. BENNETT. I think it is critical, and I think there is enough differences between men and women from a biologic standpoint, from a societal standpoint, from a stress and anxiety standpoint that all plays into how well we take our medicines, do our doctors give them to us early enough, that we just can't assume that the next drug *X* works equally well in men as in women. We can't necessarily say the same thing as far as race and ethnicity.

So going on that premise, which I think for me is true, we need that data to make that determination; and you mentioned earlier that women weren't allowed in cardiovascular trials a while ago. It has certainly changed. In NIH sponsored trials, women represented about 38 percent of trial participants. Most of the information that I use in daily practice comes out of industry-sponsored trials as far as new medications. And in those trials, women represent about 25 percent. And what happens when you only have 25 percent of the population studied, when you go to look at statistics, those statistics are often weakened. So they don't achieve statistical significance. So it may trend toward a positive effect in women. It may be helpful in women, but we don't definitively, we can't statistically say that it is effective in women. And we have been living with that for a while. I think what this FDA portion of the act does is allows us to at least see what is going on. In a recent trial that looked at over 600 studies done fairly recently in major medical journal, cardiovascular trials, only 24 percent of those studies reported results by gender. We knew how many women were in the trial, but when it came to prevents heart attacks, men versus women, that data was not listed in 75 percent of the trials.

Ms. SCHAKOWSKY. And what was the proportion of women to men in those trials?

Dr. BENNETT. Approximately 25 percent, sometimes a little more, sometimes a little less.

Ms. SCHAKOWSKY. Now, what is the justification for that?

Dr. BENNETT. Well, I don't know if there is a justification. It is what it is. Having done trials——

Ms. SCHAKOWSKY. Well, it doesn't have to always be.

Dr. BENNETT. No, it doesn't. I am aware of one trial that was a government-sponsored trial called the BEST trial. That was a heart failure trial, and it was mainly based in the VA. And of course, they had to get more women in those trials. And one of the things they did to more heavily recruit women was to pay the investigators a higher reimbursement for enrolling women, and that seemed to be fairly effective. Other barriers to enrolling women is that I don't have the time, I got to take care of my husband, I don't have the time, I have to take care my kids, I don't have transportation. And sometimes it is a little bit of I am concerned. I don't want to expose myself to risk or my husband says I shouldn't do this because there is some risk in the study. I think that is changing as sort of the our bodies, ourselves generation grows up to the point where we are enrolling in trials ourselves and I think we are willing to take those risks because we know that it is a benefit to everyone.

Ms. SCHAKOWSKY. But in essence though what you are saying is that often it is the fault of the women themselves, that there aren't more women in trials, and that may be true; but is there not a need for more increased effort to make sure that it is more balanced than just a quarter of those that are in these trials are women?

Dr. BENNETT. I certainly wouldn't place all the reasoning on the women themselves. There have been several NIH symposia and conferences about how to recruit more women. In Women's Health Initiative they did a great job recruiting women. So I think a lot of this just needs to be propagated and discussed more about; and certainly there is always an analysis that needs to be done in people who decide, hey, I don't want to participate in this trial. I think there is a wealth of information in that in determining why and how we can correct that.

Ms. SCHAKOWSKY. That seems to me a major point. I hope that particularly women in the profession will work on that.

Mr. PALLONE. Thanks. I recognize our ranking member, Mr. Barton.

Mr. BARTON. Thank you. Mr. Chairman, I would be happy to yield a minute of my time to the gentle lady from Illinois if she still has a question. I support this Act. Obviously, as somebody who has had a heart attack I am very sensitive to doing things to help prevent others having heart attacks. My only concern is the reporting requirements, require reporting by ethnicity. And I am not sure that that might not cause more problems than it solves. So my question to you, Dr. Bennett, I certainly understand the need to report by gender but why do we need to report by ethnicity?

Dr. BENNETT. I would say the first reason is that that is where America is right now, and if we are going to be releasing a drug to the general population, we should release it to or we should know how it performs in what I am typically going to be seeing in

the emergency room. All ethnicity data is typically self-reported data. There are certainly examples even in the cardiovascular literature where African-Americans, Asian-Americans respond differently to medications as far as the pharmacology and serum levels. So there may be some important biologic understanding of that. There was just a drug that the FDA approved for African-Americans for heart failure that was an old drug combination of more than 10 years ago that on a post-hack analysis many years later, lo and behold it looked like these old-fashioned drug combinations were very helpful in African-Americans. So I think from a clinician, when I sit across the table from a patient, I am trying to tailor therapy to that patient; and I use every bit of information I possibly can to try to maximize my effective treatment for that patient.

Mr. BARTON. What is the difference to reporting by race and reporting by ethnicity because as I understand it this legislation requires both, although it gives some discretion to the Secretary?

Dr. BENNETT. I couldn't tell you the strict definitional differences between the two. I don't know.

Mr. BARTON. And if we are going to require that, would you support putting in a safeguard that the person requesting the information can't be accused of a civil rights violation for requesting it?

Dr. BENNETT. I think on the basis that it is self-reported data, so the individual who is participating in the trial doesn't want to discuss that information, there should certainly be a box saying unavailable data.

Mr. BARTON. OK. That is all my questions, Mr. Chairman. I support the legislation. I just hope we can work in a bipartisan basis to fine tune it to prevent unanticipated problems.

Mr. PALLONE. I appreciate that. Thank you. I recognize Ms. Solis.

Ms. SOLIS. Thank you, Mr. Chairman. I apologize for coming in late. I also want to commend Congresswoman Capps for introducing this legislation. We have been talking about disparities for the last week. We were celebrating National Minority Health Month, and something that we talk about often with the tri-caucus, Congressional Hispanic Caucus, Congressional Black Caucus, and the Congressional Asian Pacific American Caucus, is healthcare disparities. When the question is asked, how do we deal with those communities of color, oftentimes we don't have adequate information. How can you prevent and detect diseases when you don't have access to information? As I understand it we do see higher incidence of heart disease in the African-American and Latino population, especially Mexican-American. Thirty four point four percent of Mexican-American women, have cardiovascular disease while Anglo women have 32 percent and African-American have 45 percent. It is very important that we move in a direction where we can actually collect the data and do a better analysis and outreach, particularly to those communities that have different cultural barriers. Language is also a barrier, not just for Latinos, but for Asian communities, Asian-Pacific Islanders, and other immigrant groups that may not understand what the difference is between having, for example, problems with heartburn over time and telling your doctor that and him just prescribing Zantac and knowing later that you

may have ended up developing a cancer which has happened so often in our community.

There is a provision in the bill that I am particularly interested in hearing more about. That is the Centers for Disease Control Prevention Program , the WISEWOMAN Well-Integrated Screening Evaluation across the Nation. I understand there are projects in 14 States. This bill would carry it to 50, and I would like for you to elaborate on why we need to expand the program.

Dr. BENNETT. The women that the WISEWOMAN program targets are those that are underinsured, uninsured, and often those are the women with the highest risk factor profiles, so really, the women that would stand most to benefit from early intervention and prevention. We know that if we are able to get all our health ducks in a row or control all those risk factors that lead to cardiovascular disease, we can reduce the burden of death, disability, need for bypass surgery and angioplasty in over 82 percent; and this is the perfect population to target. The WISEWOMAN program combines screening and education. The education has an impact in smoking cessation and reducing overall cardiovascular risk in a very vulnerable population. And I really appreciate your comments in regards to the cultural competency because there is nothing that will tear down a physician/patient relationship than not listening and understanding. Communication and ability to convey the importance of testing, the importance of weight loss and exercise, the importance of taking your medications all breaks down if you don't find that common bond in communication.

Ms. SOLIS. Last week we had a special orders hour on healthcare disparities, and we had a discussion about tobacco and the high incidence of young Latinos picking up that habit and that fact that we are seeing a larger number of our pre-teens smoke, so I am wondering if programs like this can also reach down and work even with some of the young women who are already starting with these bad habits. Many of those cases are going to affect us later on. For Latinos, our nutritional values may be a little different because of cultural differences. Early detection is equally important as being aware of how to balance your diet and if you know, maybe you could speak on that.

Dr. BENNETT. There are certainly some of my colleagues who have accrued a bit of cynicism across their years for practicing medicine, for all us adults it is too late for us. We don't listen and that going after primordial prevention or prevention in pre-teens and teens is where we are most likely to get our bang for our public healthcare buck. There is nothing that would replace early education; and being the mother of two sons that are 10 and 13, when I have to shush my 10-year-old from saying, boy, that man is smoking over there. Isn't that horrible? I know that the education is working.

Mr. PALLONE. Thank you. Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman. I thank both of you for being here, and I am sorry I was running late as well. But I just wanted to ask a couple of questions with regard to this because I am a psychologist by training and I think back when I was in graduate school how little information was emerging back in those olden days about gender issues and race issues, ethnicity, age. I

still think we are far, far behind where we need to be in understanding age issues, true, but let me just ask, Doctor, in terms of your knowledge that has emerged over the years, the significance of what we are learning in terms of what gender has taught us about clear biological differences and its impact upon medical issues, and I would also add, too, that if you could comment on some of those things, if we have some other knowledge on things like ethnicity and age as well to that sort of complicates or at least makes it that we can be more specific in our treatment. Can you comment on those issues?

Dr. BENNETT. Certainly age is one of those risk factors that increases the complexity of treatment. Oftentimes drug levels get fairly high in somebody whose renal function is not as good, kidney function is not as good, and then ensues complications. There is almost always more concomitant disease of high cholesterol, diabetes, there may be lung disease and liver disease. That always complicates the medical therapy. And there are also significant barriers to exercise and weight loss when it comes to our older patients. I think it is interesting that you mention the psychological aspects of it because I think that that really has a tremendous impact on cardiovascular disease for both men and women. We know that anxiety and depression puts people at increased risk for cardiovascular disease. If somebody develops anxiety and depression after a diagnosis of heart disease, their outcome is worse. So it is very mixed together as far as its negative effects. We know that women are more depressed after bypass surgery than men. We know that women are less likely to be referred to cardiac rehab, and that may involve some depression and anxiety. I would have to say in my practice that one of my most common referrals is to licensed clinical social workers to help deal with the issues of weight loss that are often tangled up in stress and anxiety and depression.

Mr. MURPHY. In fact, to elaborate on what you are saying, I believe that some of the numbers are that persons who have anxiety and depressive disorders, it doubles some of the risks for other problems such as heart disease; and I believe once they have a diagnosis of heart disease, it doubles the cost of their healthcare if these things are not dealt with. Along those lines, do you see some differences as well with regard to not only the present psychological issues but if you add this to a large spreadsheet would also affect gender issues as well? You mentioned a couple, but then add the other element of age as well. You are saying not only the risk for heart disease with age goes on but also some of the other risks for some of the psychological issues that exacerbate that?

Dr. BENNETT. Well, certainly there is higher rates of depression, whether it is reactive depression or more serious depression after a diagnosis of heart disease and stroke. Women tend to be more debilitated after a stroke, so it is certainly possible, although I don't know that there is higher rates of depression after a stroke. I think that a lot of this is not as well-clarified and as known as we would like it to. Also, response to medications. There has been some recent studies that look at certain drugs that could be used to treat depression safely after heart disease has been diagnosed, and to my knowledge I don't know of a significant look into age relation to

that, as far as response to treatment or gender relationship to that treatment.

Mr. MURPHY. I think I have seen some other studies that talk about response to medication that some of the errors are sometimes made in prescribing as people assume that you give the same dose to a 17-year-old as to a 70-year-old, and that is not the case. Similarly that we have medication issues where the same medication dosage or type may have different responses to women as to men would you say?

Dr. BENNETT. In regard to treatment of depression and anxiety or cardiovascular disease?

Mr. MURPHY. Cardiovascular disease.

Dr. BENNETT. Certainly there has been with the glycoprotein inhibitors as a good example. That is an intravenous drug we give just around the time of an acute coronary syndrome or heart attack, and we know that that leads to higher bleeding complications in women. There is no doubt about it. That has been shown across many, many studies with that class of drugs. There is also the question raised as to whether they have the same effectiveness. Some of those studies actually pointed out that perhaps rates of mortality, morbidity were increased with use of those drugs. The data is mixed. That sort of thing needs a big discussion. I have to say in my cardiology community, we are not discussing that as heavily as I think we should.

Mr. MURPHY. Let me close with this thought, too, because passed recently out of here is the Genetic Information Act which prohibits employers and others from discriminating on the basis of genetic information. One of the things that will come from this as we develop more knowledge of gender differences, age differences, racial ethnicity issues, I think it helps us better to read patients and target diagnosis and treatment to the individual. One of the things we have to make sure is we do not use any of that as a basis for discriminating against people and saying because this group is more risk, we won't hire them. So I am hoping what comes out of all this legislation is some research that tells us how to better treat patients, how to open doors and not close doors to them; but I thank you for your testimony today.

Mr. PALLONE. Thank you. Ms. Hooley.

Ms. HOOLEY. Thank you, Mr. Chairman. And again, I too apologize. I had another hearing before this. I have just a few question, and I would like to ask Dr. Bennett. The bill requires a clinical hold to be placed on manufacturers when they fail to submit sex-specific data. From your perspective, do you believe the clinical hold is an appropriate tool to ensure compliance with the bill's statutory requirements?

Dr. BENNETT. Right now the FDA has that ability to do that anyway at their own discretion. Gender data is a very-easily collectible piece of data, and having personally run trials for industry on many occasions, it is one of the first pieces of demographic data that you collect. So the data is there, and I think it is just very easy to transmit. Personally, I don't think that imposes a great burden considering all the bits of data they have to transfer to the FDA anyway.

Ms. HOOLEY. The larger question that was a follow-up question from Ms. Schakowsky is how do we ensure that we have women in the clinical trials?

Dr. BENNETT. By talking about it is certainly one, impressing upon women before they may be asked to be in a trial that this is an important issue for them that we will never know unless they make a really big sacrifice of being in a trial and it often is a sacrifice because there is often a risk. They may not get the drug they want, they may end up getting the drug they didn't want. I think encouraging the investigators to create an environment that would be better able for women to participate in trials would be essential. With the Women's Health Initiative, I know people were very creative organizing van pools and the like to make sure that women could come for their visits and go back to their home. So we just need to think a little bit outside the box.

Ms. HOOLEY. I firmly believe in the importance of educating women and providers about strokes, about heart attacks. What information do you have on the effectiveness of such educational efforts? I mean, have they worked? Have we really penetrated into the greater population?

Dr. BENNETT. The National Heart, Lung, and Blood Heart Truth campaign has been going on for now 5 years, and we looked at awareness levels of do you recognize the red dress symbol, do you know that heart disease is the No. 1 killer, and it has definitely gone off. As that has gone off and achieved levels of greater than 50 percent in the general population, we have data that shows that those women are going in and getting their issues addressed as far as cholesterol and blood pressure. So women are taking steps based on this information. What I would have to say from the medical community's standpoint, we don't get the red dress campaign. We need a red coat campaign or something because the medical community in general is less aware about some basic facts of women and cardiovascular disease, for instance, that more American women have died of heart disease than stroke. Only 8 percent of primary care physicians knew that. We did a recent survey of 1,000 Americans, 500 men and 500 women; and 22 percent of American men knew that heart disease killed more women than men. So the red dress campaign works, and it really motivates women to change. And not only does it reach women, but it reaches the men that love those women.

Ms. HOOLEY. What is it, do women and men have different symptoms for a heart attack?

Dr. BENNETT. They can. Sort of the classic symptoms of an elephant on my chest, tremendous pressure, tightness, heaviness, it doesn't have to be pain, are fairly common for both men and women. Women can have more shortness of breath. Dr. Burgess mentioned that he had a patient with unrelenting fatigue. That can be a symptom in women. Pain between the shoulder blades is a little more characteristic for women. The bottom line is that women are often embarrassed to come to the emergency room if it is just a case of indigestion, and I think far better to be in the ER with a bad case of indigestion, be sent home with a clean bill of health, than to wait too many hours and perhaps lose heart tissue that could be never be regained again.

Ms. HOOLEY. Thank you. Again, I just think we have to be relentless in our campaign to educate not only our doctors but both men and women about the disease. Thank you.

Mr. PALLONE. Thank you. Mrs. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman, and thank you to our witnesses, and thank you for your patience while we run out and meet school groups and jump back in. Ms. Wolf, I want to thank you for coming in, for sharing your story as openly as you do. I am certain that you are a great advocate for the Heart Association and for the programs that they have in place and being someone who, in my private life before coming to Congress, I have been on the boards for heart and lung and cancer and arthritis and children's hospital and all of these things. My husband laughingly says sometimes that we have a disease ball of the month going on at our house as we work to raise funds for this.

Dr. Bennett, just a couple of kind of little wrap-up points that I want to make. We have talked a lot about the data that you gather, and I thought you might want to provide some kind of a framework around this. Many times in my role as a volunteer, we would talk about data collection when we were working on a program with a grant at Vanderbilt or St. Jude's or somewhere. People would be fearful if they were going to be transparent in the system with that data being collected, and it may be an insurance company or an employer would find out more than they wanted them to know. Would you like to explain the anonymity that is allowed to individuals when they participate in trials or when their data is collected and used for ongoing research? You want just maybe 30 seconds or a minute on that?

Dr. BENNETT. There are some pretty big firewalls that are put up and that are mandated. The data is delinked as far as identifying demographic information. When we collect information in something called a case report form, that information is delinked with that person. There can't be any tracing back. So when the industry comes in to review the CRF's or when the FDA reviews the CRF's, there is no identifying information on them.

Mrs. BLACKBURN. OK. So women who are participating or in some way know that data is being held and used, they can have the confidence that they are helping to find an answer to the problems and that they are not exposing themselves to the system?

Dr. BENNETT. That is correct.

Mrs. BLACKBURN. Thank you so much for that. Now, a couple of other things. As I mentioned, working on the volunteer side and then coming to the public sector side, or the not-for-profit side and then the public sector side, grants are always so very important to us; and when we look at the prevention and treatment and education, can you give me an idea of when you are looking at grant dollars, what percentage are you pulling from the public sector and what percentage is coming from the private sector on the research work that is done?

Dr. BENNETT. I would estimate at least from a clinical trial standpoint that Federal dollars and government dollars that actually funnel into how we practice medicine on a daily basis represent maybe a fifth to two-fifths of what we utilize in treating patients. A vast majority of the information that we know and under-

stand and incorporate in our practice comes through the industry side, and as you know with cardiovascular disease it is a very fast river of new information with new medications, with new ways to use those medications, and a vast majority of that does come through the private sector.

Mrs. BLACKBURN. So the private sector really is leading the way and then the public sector is supplementing that in this arena.

FDA. As we look at the programs, on cardiovascular education and prevention, and we have talked a good bit about heredity, exercise, weight control. The times that I have been here, educating children has been mentioned looks like five or six different times. Do we have anything there that is being done to address educating children on health heart programs, on obesity, on a wellness lifestyle? One of the things that amazes me, my children are out of high school, have been out of high school for a long time now, but when you go in and visit middle school and high school, all of your life skills classes have been eliminated. Many of your physical education classes have been eliminated, and I know that some of our not-for-profits are trying to do teacher training curriculums and help fill that void and put some of that back in. But we have talked about the FDA and their participation. What are they coordinating in the education realm, and are they backing it up enough to get to those children to start that education early enough that bad habits are not formed?

Dr. BENNETT. I am not at all sure what educational programs the FDA has for the community. I know the CDC certainly has the WISEWOMEN program. I am personally just not aware of all the other programs that they have for teens and preteens and elementary school children. I am sure there are. I know the American Heart Association does Jump rope for Heart and Hoops for Heart which at least gets it on their radar screen, and I know that Congress has worked fairly extensively on lunch programs and things like that.

Mrs. BLACKBURN. I think we are all painfully aware of Jump rope for Heart right now. My 7-year-old niece tried to have me participate. It was entertaining.

Thank you. My time has expired. I appreciate you all. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. That concludes all questions, and I just want to thank both of our witnesses again. This is a very important hearing and of course thank Mrs. Capps as well for sponsoring the bill. I just would remind members that you may submit additional questions for the record to be answered by the witnesses, so you may get additional questions in writing. We should get those within the next 10 days, but expect that you may get those additional questions.

But thank you again. I know we have another hearing at 12:00 so we are going to take a half-an-hour break here. And without objection, this meeting of the subcommittee is adjourned. Thank you.

[Whereupon, at 11:30 a.m., the subcommittee was adjourned, subject to the call of the Chair.]