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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) Heart disease, stroke, and other cardiovascular diseases are the leading cause of death among women.

(2) Despite being the number 1 killer, only 13 percent of women are aware that cardiovascular diseases, including heart disease and stroke, are their greatest health risk.

(3) Many minority women, including African American, Hispanic, Native American, and some Asian American women, are at a higher risk of death from heart disease, stroke, and other cardiovascular diseases, but they are less likely to know of this risk.

(4) There is a pervasive lack of awareness among healthcare providers that cardiovascular disease is the leading killer of women.

(5) Women are less likely than men to receive certain treatments for cardiovascular diseases, perhaps due to lack of awareness and the presence of different symptoms in women than in men.

(6) Women tend to experience later onset of heart disease than men, and therefore more often suffer from multiple conditions that mask symptoms of heart disease and complicate treatment.

(7) Certain diagnostic tests for cardiovascular disease may be less accurate in women than in men.

(8) Drug effectiveness and metabolism differ in women and men, impacting successful treatment of cardiovascular disease.

(9) In addition, stroke kills 2.3 times as many females as does breast cancer. Nearly 61 percent of stroke-related deaths occur in females. Studies have found differences in the effects, diagnosis, and treatment of stroke depending on the sex of the patient. For instance—

(A) stroke severity is greater in women than in men;

(B) women often receive fewer diagnostic tests and intervention procedures than men; and

(C) strokes present treatment issues unique to women.

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

(a) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(6)(A) Notwithstanding any other provision of this Act, the applicant shall include in any submission to the

Secretary pursuant to this subsection, to the extent appropriate, information stratified by sex, race, and ethnicity, including any differences in safety and effectiveness.

''(B) The Secretary shall withhold approval of an application if the applicant fails to submit the required information described in subparagraph (A).

''(C) The Secretary shall develop standards to ensure that submissions to the Secretary pursuant to this subsection are adequately reviewed to determine whether such submissions include the information required under subparagraph (A).

''(D) Upon the approval under this subsection of an application for a drug, the Secretary shall report to the scientific community and make available to the public, in a timely manner, data regarding such drug stratified by sex, race, and ethnicity.''.

(b) INVESTIGATIONAL NEW DRUG APPLICATIONS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended—

(1) in paragraph (2), by inserting ''and paragraph (5)'' after ''Subject to paragraph (3)''; and

(2) by adding at the end the following:

''(5)(A) Notwithstanding any other provision of this Act, the manufacturer or sponsor of an investigation of a new drug shall include in any submission to the Sec-

retary pursuant to this subsection on the clinical investigation of the new drug and to the extent appropriate, information stratified by sex, race, and ethnicity, including any differences in safety and effectiveness.

''(B) The Secretary shall place a clinical hold (as described in paragraph (3)) on an investigation if the manufacturer or sponsor of the investigation fails to submit the required information described in subparagraph (A).

''(C) The Secretary shall develop standards that ensure that submissions to the Secretary pursuant to this subsection on clinical investigations of new drugs are adequately reviewed to determine whether such submissions include the information required under this paragraph.''.

(c) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)(A), by inserting before the period at the end the following: '', subject to paragraph (10)'';

(2) in paragraph (3)(A), by adding at the end the following: ''The Secretary shall require such individuals who review such applications to ensure that such applications include the information on sex, race, and ethnicity data required under paragraph (10).'';

(3) in paragraph (4)—

(A) in subparagraph (J), by striking ''or'' after the semicolon;

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

(C) by adding at the end the following:

''(L) the application does not include appropriate information stratified by sex, race, and ethnicity, as required under paragraph (10).''; and

(4) by adding at the end the following:

''(10)(A) Notwithstanding any other provision of this Act, a person shall include in any submission to the Secretary pursuant to this subsection appropriate drug information stratified by sex, race, and ethnicity, including any differences in safety and effectiveness.

''(B) The Secretary shall develop standards that ensure that submissions to the Secretary pursuant to this subsection are adequately reviewed to determine whether such submissions include the information required under this paragraph.

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

a timely manner, data regarding such drug stratified by sex, race, and ethnicity.''.

(d) PREMARKET APPROVALS.—Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is amended—

(1) in subsection (c)—

(A) in paragraph (1)—

(i) in subparagraph (F), by striking ''and'' at the end;

(ii) in subparagraph (G), by striking the period and inserting ''; and''; and

(iii) by adding at the end the following:

''(H) information regarding the device, to the extent appropriate, stratified by sex, race, and ethnicity, including differences in safety and effectiveness.''; and

(B) by adding at the end the following:

''(5) The Secretary shall develop standards that ensure that submissions to the Secretary pursuant to this subsection are adequately reviewed to determine whether such submissions include the information required under paragraph (1)(H).''; and

(2) in subsection (d)—

(A) in paragraph (2)—

(i) in subparagraph (D), by striking ''or'' at the end;

(ii) in subparagraph (E), by striking the period and inserting ''; or''; and

(iii) by inserting after subparagraph (E), the following:

''(F) the application does not contain, as appropriate, the information required in subsection (c)(1)(H).''; and

(B) by adding at the end the following:

''(7) Upon the approval of an application under this section, the Secretary shall report to the scientific community and make available to the public, in a timely manner, data regarding such device stratified by sex, race, and ethnicity.''.

(e) INVESTIGATIONAL DEVICE EXEMPTIONS.—Section 520(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is amended—

(1) in subparagraph (B), by adding at the end the following:

''(iv) A requirement that any application include information regarding the device, to the extent appropriate, stratified by sex, race, and ethnicity, including differences in safety and effectiveness.''; and

(2) by adding at the end the following:

''(D) The Secretary shall develop standards that ensure that submissions to the Secretary pursuant to this subsection are adequately reviewed to determine whether such submissions include the information required under subparagraph (B)(iv).''.

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

''(D)(i) Notwithstanding any other provision of this Act, the applicant shall include in any application to the Secretary pursuant to this section appropriate information regarding the subject biological product stratified by sex, race, and ethnicity, including differences in safety and effectiveness.

''(ii) The Secretary shall develop standards that ensure that submissions to the Secretary pursuant to this section are adequately reviewed to determine whether such submissions include the information required under clause (i).

''(iii) Upon the approval of an application under this subsection, the Secretary shall report to the scientific community and make available to the public, in a timely manner, data regarding such biological product stratified by sex, race, and ethnicity.''.

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

SEC. 4. REPORTING AND ANALYSIS OF PATIENT SAFETY DATA.

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

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

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

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

(1) in subsection (b)(1)(B), by inserting before the semicolon the following: ", including quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases"; and

(2) in subsection (c), by adding at the end the following:

"(4) ANNUAL REPORT ON WOMEN AND HEART DISEASE.—Not later than September 30, 2007, and annually thereafter, the Secretary, acting through the Director, shall prepare and submit to Congress a report concerning the findings related to the quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases. The report shall contain recommendations for eliminating disparities in, and improving the treatment of, heart disease, stroke, and other cardiovascular diseases in women.".

SEC. 6. EDUCATIONAL CAMPAIGNS.

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

diseases in women. The Secretary may carry out this subsection through contracts with public and private nonprofit entities.

(b) HEALTHCARE PROFESSIONAL EDUCATIONAL CAMPAIGN.—The Secretary, acting through the Bureau of Health Professions of the Health Resources and Services Administration, shall conduct an education and awareness campaign for physicians and other healthcare professionals relating to the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women. The Bureau of Health Professions may carry out this subsection through contracts with public and private nonprofit entities.

SEC. 7. EXTENSION OF WISEWOMAN.

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

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