111TH CONGRESS
1ST SESSION

S. 422

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 SENATE OF THE UNITED STATES

FEBRUARY 12, 2009

Ms. STABENOW (for herself, Ms. MURKOWSKI, Mrs. FEINSTEIN, Ms. COLLINS, Mrs. LINCOLN, Mr. CHAMBLISS, Ms. MIKULSKI, Mr. COCHRAN, Ms. LANDRIEU, Mrs. BOXER, Mrs. SHAHEEN, Mr. CARDIN, Mr. KERRY, Mr. WHITEHOUSE, Mr. AKAKA, Mr. SANDERS, Mr. INOUYE, Mr. BEGICH, Mr. CASEY, Mr. MENENDEZ, Mr. BAYH, Mr. CARPER, Mr. WYDEN, and Mr. CONRAD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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

(a) DRUGS.—

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

(A) in paragraph (1), in the second sentence—

(i) by striking ''drug, and (G)'' and inserting ''drug; (G)''; and

(ii) by inserting before the period the following: ''; and (H) the information required under paragraph (7)''; and

(B) by adding at the end the following:

''(7)(A) With respect to clinical data in an application under this subsection, the Secretary may deny such an application if the application fails to meet the requirements of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the sections referred to in subparagraph (A) to require that an application under this subsection include any clinical data possessed by the applicant that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.

''(C) Promptly after approving an application under this subsection, the Secretary shall, through an Internet

site of the Department of Health and Human Services, make available to the public the information submitted to the Secretary pursuant to subparagraphs (A) and (B), subject to sections 301(j) and 520(h)(4) of this Act, subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the 'Freedom of Information Act'), and other provisions of law that relate to trade secrets or confidential commercial information.

''(D) The Secretary shall develop guidance for staff of the Food and Drug Administration to ensure that applications under this subsection are adequately reviewed to determine whether the applications include the information required pursuant to subparagraphs (A) and (B).''.

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

(A) in paragraph (2), by striking ''Subject to paragraph (3),'' and inserting ''Subject to paragraphs (3) and (5),'' ; and

(B) by adding at the end the following:

''(5)(A) The Secretary may place a clinical hold (as described in paragraph (3)) on an investigation if the sponsor of the investigation fails to meet the requirements of section 312.33(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the section referred to in subparagraph (A) to require that reports under such section include any clinical data possessed by the sponsor of the investigation that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.''.

(b) BIOLOGICS LICENSE APPLICATIONS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(k) The provisions of section 505(b)(7) of the Federal Food, Drug, and Cosmetic Act (relating to clinical data submission) apply with respect to an application under subsection (a) of this section to the same extent and in the same manner as such provisions apply with respect to an application under section 505(b) of such Act.''.

(c) DEVICES.—

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

(A) in subsection (c)(1)—

(i) in subparagraph (G)—

(I) by moving the margin 2 ems to the left; and

(II) by striking ''and'' after the semicolon at the end;

(ii) by redesignating subparagraph (H) as subparagraph (I); and

(iii) by inserting after subparagraph (G) the following subparagraph:

''(H) the information required under subsection (d)(7); and''; and

(B) in subsection (d), by adding at the end the following paragraph:

''(7) To the extent consistent with the regulation of devices, the provisions of section 505(b)(7) (relating to clinical data submission) apply with respect to an application for premarket approval of a device under subsection (c) of this section to the same extent and in the same manner as such provisions apply with respect to an application for premarket approval of a drug under section 505(b).''.

(2) INVESTIGATIONAL DEVICES.—Section 520(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(2)) is amended by adding at the end the following subparagraph:

''(D) To the extent consistent with the regulation of devices, the provisions of section 505(i)(5) (relating to individual study information) apply with respect to an application for an exemption pursuant to subparagraph (A) of this paragraph to the same extent and in the same manner

as such provisions apply with respect to an application for an exemption under section 505(i).''.

(d) RULES OF CONSTRUCTION.—This Act and the amendments made by this Act may not be construed—

(1) as establishing new requirements under the Federal Food, Drug, and Cosmetic Act relating to the design of clinical investigations that were not otherwise in effect on the day before the date of the enactment of this Act; or

(2) as having any effect on the authority of the Secretary of Health and Human Services to enforce regulations under the Federal Food, Drug, and Cosmetic Act that are not expressly referenced in this Act or the amendments made by this Act.

(e) APPLICATION.—This section and the amendments made by this section apply only with respect to applications received under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360e) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date of the enactment of this Act.

SEC. 3. 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. 4. 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: '', and 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, 2011, 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 dis-

ease, 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. 5. 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. 6. EXTENSION OF WISEWOMAN PROGRAM.

Section 1509 of the Public Health Service Act (42 U.S.C. 300n–4a) is amended—

(1) in subsection (a)—

(A) by striking the heading and inserting ''IN GENERAL.—''; and

(B) in the matter preceding paragraph (1), by striking ''may make grants'' and all that follows through ''purpose'' and inserting the following: ''may make grants to such States for the purpose''; and

(2) in subsection (d)(1), by striking ''there are authorized'' and all that follows through the period and inserting ''there are authorized to be appropriated $70,000,000 for fiscal year 2010, $73,500,000 for fiscal year 2011, $77,000,000 for fiscal year 2012, $81,000,000 for fiscal year 2013, and $85,000,000 for fiscal year 2014.''.

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