

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. INOUE, 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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Heart Disease Edu-
5 cation, Analysis Research, and Treatment for Women
6 Act” or the “HEART for Women Act”.

1 **SEC. 2. REPORTING OF DATA IN APPLICATIONS FOR**
 2 **DRUGS, BIOLOGICS, AND DEVICES.**

3 (a) DRUGS.—

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

7 (A) in paragraph (1), in the second sen-
 8 tence—

9 (i) by striking “drug, and (G)” and
 10 inserting “drug; (G)”; and

11 (ii) by inserting before the period the
 12 following: “; and (H) the information re-
 13 quired under paragraph (7)”; and

14 (B) by adding at the end the following:

15 “(7)(A) With respect to clinical data in an application
 16 under this subsection, the Secretary may deny such an ap-
 17 plication if the application fails to meet the requirements
 18 of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title
 19 21, Code of Federal Regulations.

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

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

1 site of the Department of Health and Human Services,
 2 make available to the public the information submitted to
 3 the Secretary pursuant to subparagraphs (A) and (B),
 4 subject to sections 301(j) and 520(h)(4) of this Act, sub-
 5 section (b)(4) of section 552 of title 5, United States Code
 6 (commonly referred to as the ‘Freedom of Information
 7 Act’), and other provisions of law that relate to trade se-
 8 crets or confidential commercial information.

9 “(D) The Secretary shall develop guidance for staff
 10 of the Food and Drug Administration to ensure that appli-
 11 cations under this subsection are adequately reviewed to
 12 determine whether the applications include the informa-
 13 tion required pursuant to subparagraphs (A) and (B).”.

14 (2) INVESTIGATIONAL NEW DRUG APPLICA-
 15 TIONS.—Section 505(i) of the Federal Food, Drug,
 16 and Cosmetic Act (21 U.S.C. 355(i)) is amended—

17 (A) in paragraph (2), by striking “Subject
 18 to paragraph (3),” and inserting “Subject to
 19 paragraphs (3) and (5),” ; and

20 (B) by adding at the end the following:

21 “(5)(A) The Secretary may place a clinical hold (as
 22 described in paragraph (3)) on an investigation if the
 23 sponsor of the investigation fails to meet the requirements
 24 of section 312.33(a) of title 21, Code of Federal Regula-
 25 tions.

1 “(B) The Secretary shall modify the section referred
 2 to in subparagraph (A) to require that reports under such
 3 section include any clinical data possessed by the sponsor
 4 of the investigation that relates to the safety or effective-
 5 ness of the drug involved by gender, age, and racial sub-
 6 group.”.

7 (b) BIOLOGICS LICENSE APPLICATIONS.—Section
 8 351 of the Public Health Service Act (42 U.S.C. 262) is
 9 amended by adding at the end the following:

10 “(k) The provisions of section 505(b)(7) of the Fed-
 11 eral Food, Drug, and Cosmetic Act (relating to clinical
 12 data submission) apply with respect to an application
 13 under subsection (a) of this section to the same extent
 14 and in the same manner as such provisions apply with re-
 15 spect to an application under section 505(b) of such Act.”.

16 (c) DEVICES.—

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

20 (A) in subsection (c)(1)—

21 (i) in subparagraph (G)—

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

24 (II) by striking “and” after the
 25 semicolon at the end;

1 (ii) by redesignating subparagraph

2 (H) as subparagraph (I); and

3 (iii) by inserting after subparagraph

4 (G) the following subparagraph:

5 “(H) the information required under subsection

6 (d)(7); and”; and

7 (B) in subsection (d), by adding at the end

8 the following paragraph:

9 “(7) To the extent consistent with the regulation of
10 devices, the provisions of section 505(b)(7) (relating to
11 clinical data submission) apply with respect to an applica-
12 tion for premarket approval of a device under subsection
13 (c) of this section to the same extent and in the same man-
14 ner as such provisions apply with respect to an application
15 for premarket approval of a drug under section 505(b).”.

16 (2) INVESTIGATIONAL DEVICES.—Section
17 520(g)(2) of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 360j(g)(2)) is amended by adding at
19 the end the following subparagraph:

20 “(D) To the extent consistent with the regulation of
21 devices, the provisions of section 505(i)(5) (relating to in-
22 dividual study information) apply with respect to an appli-
23 cation for an exemption pursuant to subparagraph (A) of
24 this paragraph to the same extent and in the same manner

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

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

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

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

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

21 **SEC. 3. REPORTING AND ANALYSIS OF PATIENT SAFETY**
22 **DATA.**

23 (a) DATA STANDARDS.—Section 923(b) of the Public
24 Health Service Act (42 U.S.C. 299b–23(b)) is amended
25 by adding at the end the following: “The Secretary shall

1 provide that all nonidentifiable patient safety work prod-
 2 uct reported to and among the network of patient safety
 3 databases be stratified by sex.”.

4 (b) USE OF INFORMATION.—Section 923(c) of the
 5 Public Health Service Act (42 U.S.C. 299b–23(c)) is
 6 amended by adding at the end the following: “Such anal-
 7 yses take into account data that specifically relates to
 8 women and any disparities between treatment and the
 9 quality of care between males and females.”.

10 **SEC. 4. QUALITY OF CARE REPORTS BY THE AGENCY FOR**
 11 **HEALTHCARE RESEARCH AND QUALITY.**

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

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

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

20 “(4) ANNUAL REPORT ON WOMEN AND HEART
 21 DISEASE.—Not later than September 30, 2011, and
 22 annually thereafter, the Secretary, acting through
 23 the Director, shall prepare and submit to Congress
 24 a report concerning the findings related to the qual-
 25 ity of and access to care for women with heart dis-

1 ease, stroke, and other cardiovascular diseases. The
 2 report shall contain recommendations for eliminating
 3 disparities in, and improving the treatment of, heart
 4 disease, stroke, and other cardiovascular diseases in
 5 women.”.

6 **SEC. 5. EDUCATIONAL CAMPAIGNS.**

7 (a) DISTRIBUTION OF EDUCATIONAL MATERIAL.—
 8 The Secretary of Health and Human Services (referred
 9 to in this section as the “Secretary”) shall develop and
 10 distribute to females who are age 65 or older, physicians,
 11 and other appropriate healthcare professionals, edu-
 12 cational materials relating to the prevention, diagnosis,
 13 and treatment of heart disease, stroke, and cardiovascular
 14 diseases in women. The Secretary may carry out this sub-
 15 section through contracts with public and private non-
 16 profit entities.

17 (b) HEALTHCARE PROFESSIONAL EDUCATIONAL
 18 CAMPAIGN.—The Secretary, acting through the Bureau of
 19 Health Professions of the Health Resources and Services
 20 Administration, shall conduct an education and awareness
 21 campaign for physicians and other healthcare profes-
 22 sionals relating to the prevention, diagnosis, and treat-
 23 ment of heart disease, stroke, and other cardiovascular
 24 diseases in women. The Bureau of Health Professions may

1 carry out this subsection through contracts with public
 2 and private nonprofit entities.

3 **SEC. 6. EXTENSION OF WISEWOMAN PROGRAM.**

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

6 (1) in subsection (a)—

7 (A) by striking the heading and inserting
 8 “IN GENERAL.—”; and

9 (B) in the matter preceding paragraph (1),
 10 by striking “may make grants” and all that fol-
 11 lows through “purpose” and inserting the fol-
 12 lowing: “may make grants to such States for
 13 the purpose”; and

14 (2) in subsection (d)(1), by striking “there are
 15 authorized” and all that follows through the period
 16 and inserting “there are authorized to be appro-
 17 priated \$70,000,000 for fiscal year 2010,
 18 \$73,500,000 for fiscal year 2011, \$77,000,000 for
 19 fiscal year 2012, \$81,000,000 for fiscal year 2013,
 20 and \$85,000,000 for fiscal year 2014.”.

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