

110TH CONGRESS
1ST SESSION

S. 573

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 13, 2007

Ms. STABENOW (for herself, Ms. MURKOWSKI, Ms. COLLINS, Ms. SNOWE, Mr. AKAKA, Mr. COCHRAN, and Mr. MENENDEZ) 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 and Research, and Treatment for Women
6 Act” or the “HEART for Women Act”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Heart disease, stroke, and other cardio-
4 vascular diseases are the leading cause of death
5 among women.

6 (2) Despite being the number 1 killer, only 13
7 percent of women are aware that cardiovascular dis-
8 eases, including heart disease and stroke, are their
9 greatest health risk.

10 (3) Many minority women, including African
11 American, Hispanic, Native American, and some
12 Asian American women, are at a higher risk of
13 death from heart disease, stroke, and other cardio-
14 vascular diseases, but they are less likely to know of
15 this risk.

16 (4) There is a pervasive lack of awareness
17 among healthcare providers that cardiovascular dis-
18 ease is the leading killer of women.

19 (5) Women are less likely than men to receive
20 certain treatments for cardiovascular diseases, per-
21 haps due to lack of awareness and the presence of
22 different symptoms in women than in men.

23 (6) Women tend to experience later onset of
24 heart disease than men, and therefore more often
25 suffer from multiple conditions that mask symptoms
26 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 (c)—

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.

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