

112TH CONGRESS
1ST SESSION

S. 438

To amend the Public Health Service Act to improve women’s health by prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

IN THE SENATE OF THE UNITED STATES

MARCH 2, 2011

Ms. STABENOW (for herself, Ms. MURKOWSKI, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to improve women’s health by 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) IN GENERAL.—The Comptroller General of the
4 United States shall conduct a study investigating the ex-
5 tent to which sponsors of clinical studies of investigational
6 drugs, biologics, and devices and sponsors of applications
7 for approval or licensure of new drugs, biologics, and de-
8 vices comply with Food and Drug Administration require-
9 ments and follow guidance for presentation of clinical
10 study safety and effectiveness data by sex, age, and racial
11 subgroups.

12 (b) REPORT BY GAO.—

13 (1) SUBMISSION.—Not later than 12 months
14 after the date of the enactment of this Act, the
15 Comptroller General shall complete the study under
16 subsection (a) and submit to the Committee on En-
17 ergy and Commerce of the House of Representatives
18 and the Committee on Health, Education, Labor,
19 and Pensions of the Senate a report on the results
20 of such study.

21 (2) CONTENTS.—The report required by para-
22 graph (1) shall include each of the following:

23 (A) A description of the extent to which
24 the Food and Drug Administration assists
25 sponsors in complying with the requirements

1 and following the guidance referred to in sub-
2 section (a).

3 (B) A description of the effectiveness of
4 the Food and Drug Administration's enforce-
5 ment of compliance with such requirements.

6 (C) An analysis of the extent to which fe-
7 males, racial and ethnic minorities, and adults
8 of all ages are adequately represented in Food
9 and Drug Administration-approved clinical
10 studies (at all phases) so that product safety
11 and effectiveness data can be evaluated by gen-
12 der, age, and racial subgroup.

13 (D) An analysis of the extent to which a
14 summary of product safety and effectiveness
15 data disaggregated by sex, age, and racial sub-
16 group is readily available to the public in a
17 timely manner by means of the product label or
18 the Food and Drug Administration's Website.

19 (E) Appropriate recommendations for—

20 (i) modifications to the requirements
21 and guidance referred to in subsection (a);
22 or

23 (ii) oversight by the Food and Drug
24 Administration of such requirements.

1 (c) REPORT BY HHS.—Not later than 6 months
2 after the submission by the Comptroller General of the
3 report required under subsection (b), the Secretary of
4 Health and Human Services shall submit to the Com-
5 mittee on Energy and Commerce of the House of Rep-
6 resentatives and the Committee on Health, Education,
7 Labor, and Pensions of the Senate a response to that re-
8 port, including a corrective action plan as needed to re-
9 spond to the recommendations in that report.

10 (d) BIENNIAL REPORTS BY THE FOOD AND DRUG
11 ADMINISTRATION.—Not later than 2 years after the date
12 of enactment of this Act, and every 2 years thereafter—

13 (1) the Director of the Office of Women’s
14 Health of the Food and Drug Administration shall
15 submit to the Committee on Energy and Commerce
16 of the House of Representatives and the Committee
17 on Health, Education, Labor, and Pensions of the
18 Senate, a report that includes each of the elements
19 described in subparagraphs (A) through (E) of sub-
20 section (b)(2), with respect to women’s health; and

21 (2) the Director of the Office of Minority
22 Health of the Food and Drug Administration shall
23 submit to such Committees a report that includes
24 each of such elements, with respect to minority
25 health.

1 (e) DEFINITIONS.—In this section:

2 (1) The term “biologic” has the meaning given
3 to the term “biological product” in section 351(i) of
4 the Public Health Service Act (42 U.S.C. 262(i)).

5 (2) The term “device” has the meaning given to
6 such term in section 201(h) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 321(h)).

8 (3) The term “drug” has the meaning given to
9 such term in section 201(g) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 321(g)).

11 **SEC. 3. REPORTING ON QUALITY OF AND ACCESS TO CARE**
12 **FOR WOMEN WITH CARDIOVASCULAR DIS-**
13 **EASES.**

14 Part P of title III of the Public Health Service Act
15 (42 U.S.C. 280g et seq.) is amended by adding at the end
16 the following:

17 **“SEC. 399V–6. REPORTING ON QUALITY OF AND ACCESS TO**
18 **CARE FOR WOMEN WITH CARDIOVASCULAR**
19 **DISEASES.**

20 “Not later than September 30, 2014, and annually
21 thereafter, the Secretary shall prepare and submit to the
22 Congress a report on the quality of and access to care
23 for women with heart disease, stroke, and other cardio-
24 vascular diseases. The report shall contain recommenda-
25 tions for eliminating disparities in, and improving the

1 treatment of, heart disease, stroke, and other cardio-
 2 vascular diseases in women.”.

3 **SEC. 4. EXTENSION OF WISEWOMAN PROGRAM.**

4 (a) IN GENERAL.—Section 1509 of the Public Health
 5 Service Act (42 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 \$23,000,000 for fiscal year 2012,
 18 \$25,300,000 for fiscal year 2013, \$27,800,000 for
 19 fiscal year 2014, \$30,800,000 for fiscal year 2015,
 20 and \$34,000,000 for fiscal year 2016.”.

21 (b) STUDY.—

22 (1) IN GENERAL.—The Secretary of Health and
 23 Human Services shall (directly or through grants or
 24 contracts) conduct a study of the impact of the Pa-
 25 tient Protection and Affordable Care Act (Public

1 Law 111–148) on the preventive health services, re-
2 ferrals, and follow-up services authorized under sec-
3 tion 1509 of the Public Health Service Act (42
4 U.S.C. 300n–4a), as amended by this section.

5 (2) REPORT.—Not later than 18 months after
6 the date of enactment of this Act, the Secretary of
7 Health and Human Services shall complete the
8 study required by paragraph (1) and submit a report
9 to the Committee on Energy and Commerce of the
10 House of Representatives and to the Committee on
11 Health, Education, Labor, and Pensions of the Sen-
12 ate containing the results of the study and rec-
13 ommendations for improving the provision of serv-
14 ices to eligible women authorized under such section
15 1509.

