## 112TH CONGRESS 1ST SESSION

## H. R. 3526

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, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 30, 2011

Mrs. Capps introduced the following bill; which was referred to the Committee on Energy and Commerce

## 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, and for other purposes.

- 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 Web site
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 such re-
- 8 port, including a corrective action plan as needed to re-
- 9 spond to the recommendations in such 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
- Health of the Food and Drug Administration shall
- submit to the Committee on Energy and Commerce
- of the House of Representatives and the Committee
- on Health, Education, Labor, and Pensions of the
- 18 Senate, a report that includes each of the elements
- described in subparagraphs (A) through (E) of sub-
- section (b)(2), with respect to women's health; and
- 21 (2) the Director of the Office of Minority
- Health of the Food and Drug Administration shall
- submit to such Committees a report that includes
- 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 of Health and Human Services
22	shall prepare and submit to the Congress a report on the
23	quality of and access to care for women with heart disease,
24	stroke, and other cardiovascular diseases. The report shall
25	contain recommendations for eliminating disparities in.

1	and improving the treatment of, heart disease, stroke, and
2	other cardiovascular diseases in women.".
3	SEC. 4. 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";
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."; and
21	(3) by adding at the end the following new sub-
22	section:
23	"(e) Study.—
24	"(1) The Secretary shall (directly or through
25	grants or contracts) conduct a study of the impact

of the Patient Protection and Affordable Care Act on the preventive health services, referrals, and follow-up services described in subsection (a).

"(2) Not later than 18 months after the date of enactment of this subsection, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the results of the study under paragraph (1) and recommendations for improving the provision of preventive health services, referrals, and follow-up services described in paragraph (1) to women eligible for such services under grants funded under this section.".

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