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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

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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.

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) IN GENERAL.—The Comptroller General of the United States shall conduct a study investigating the extent to which sponsors of clinical studies of investigational drugs, biologics, and devices and sponsors of applications for approval or licensure of new drugs, biologics, and devices comply with Food and Drug Administration requirements and follow guidance for presentation of clinical study safety and effectiveness data by sex, age, and racial subgroups.

(b) REPORT BY GAO.—

(1) SUBMISSION.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the results of such study.

(2) CONTENTS.—The report required by paragraph (1) shall include each of the following:

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

and following the guidance referred to in subsection (a).

(B) A description of the effectiveness of the Food and Drug Administration's enforcement of compliance with such requirements.

(C) An analysis of the extent to which females, racial and ethnic minorities, and adults of all ages are adequately represented in Food and Drug Administration-approved clinical studies (at all phases) so that product safety and effectiveness data can be evaluated by gender, age, and racial subgroup.

(D) An analysis of the extent to which a summary of product safety and effectiveness data disaggregated by sex, age, and racial subgroup is readily available to the public in a timely manner by means of the product label or the Food and Drug Administration's Web site.

(E) Appropriate recommendations for—

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

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

(c) REPORT BY HHS.—Not later than 6 months after the submission by the Comptroller General of the report required under subsection (b), the Secretary of Health and Human Services 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 Senate a response to such report, including a corrective action plan as needed to respond to the recommendations in such report.

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

(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 Senate, a report that includes each of the elements described in subparagraphs (A) through (E) of subsection (b)(2), with respect to women's health; and

(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 health.

(e) DEFINITIONS.—In this section:

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

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

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

SEC. 3. REPORTING ON QUALITY OF AND ACCESS TO CARE FOR WOMEN WITH CARDIOVASCULAR DISEASES.

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

''SEC. 399V–6. REPORTING ON QUALITY OF AND ACCESS TO CARE FOR WOMEN WITH CARDIOVASCULAR DISEASES.

''Not later than September 30, 2014, and annually thereafter, the Secretary of Health and Human Services shall prepare and submit to the Congress a report on the quality of and access to care for women with heart disease, 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. 4. 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'';

(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 $23,000,000 for fiscal year 2012, $25,300,000 for fiscal year 2013, $27,800,000 for fiscal year 2014, $30,800,000 for fiscal year 2015, and $34,000,000 for fiscal year 2016.''; and

(3) by adding at the end the following new subsection:

''(e) STUDY.—

''(1) The Secretary shall (directly or through 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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