Union Calendar No. 379

111TH CONGRESS
2D SESSION

H. R. 1032

[Report No. 111–639]

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 HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2009

Mrs. CAPPS (for herself, Mrs. BONO MACK, Mr. ABERCROMBIE, Mr. BACA, Ms. BALDWIN, Ms. BEAN, Ms. BERKLEY, Mr. BERMAN, Mrs. BIGGERT, Mr. BISHOP of New York, Ms. BORDALLO, Mr. BOUCHER, Ms. CORRINE BROWN of Florida, Ms. GINNY BROWN-WAITE of Florida, Mr. BURTON of Indiana, Mrs. CAPITO, Mr. CARSON of Indiana, Ms. CASTOR of Florida, Mrs. CHRISTENSEN, Mr. CUMMINGS, Mrs. DAVIS of California, Ms. DEGETTE, Ms. DELAURO, Mr. LINCOLN DIAZ-BALART of Florida, Ms. EDWARDS of Maryland, Mrs. EMERSON, Mr. ENGEL, Ms. ESHOO, Mr. FORTENBERRY, Mr. FRANK of Massachusetts, Mr. GERLACH, Ms. GIFFORDS, Mr. GONZALEZ, Mr. GORDON of Tennessee, Ms. GRANGER, Mr. GRAVES, Mr. AL GREEN of Texas, Mr. GENE GREEN of Texas, Mr. GRIJALVA, Ms. HARMAN, Mr. HINCHEY, Ms. HIRONO, Mr. HOLT, Mr. ISRAEL, Mr. ISSA, Ms. JACKSON-LEE of Texas, Ms. KAPTUR, Mr. KILDEE, Ms. KILPATRICK of Michigan, Ms. LEE of California, Mr. LEVIN, Mr. LIPINSKI, Mr. LOBIONDO, Ms. ZOE LOFGREN of California, Mrs. LOWEY, Mrs. MALONEY, Mr. MARKEY of Massachusetts, Mr. MARSHALL, Ms. MATSUI, Ms. MCCOLLUM, Mr. MCDERMOTT, Mr. MCGOVERN, Mr. MCHUGH, Mr. MOORE of Kansas, Ms. MOORE of Wisconsin, Mr. NADLER of New York, Mrs. NAPOLITANO, Ms. NORTON, Mr. OBERSTAR, Mr. OLVER, Mr. PASCRELL, Ms. PINGREE of Maine, Mr. PLATTS, Mr. RADANOVICH, Mr. REYES, Mr. ROGERS of Alabama, Ms. ROS-LEHTINEN, Ms. ROYBAL-ALLARD, Ms. SCHAKOWSKY, Mrs. SCHMIDT, Ms. SCHWARTZ, Mr. SERRANO, Mr. SESTAK, Ms. SHEA-PORTER, Mr. SIRES, Ms. SLAUGHTER, Mr. SMITH of New Jersey, Mr. STARK, Ms. SUTTON, Mrs. TAUSCHER, Mr. TAYLOR, Mr. TIERNEY, Ms. TSONGAS, Mr. VAN HOLLEN, Mr. WALZ, Ms. WASSERMAN SCHULTZ, Mr. WHITFIELD, Ms. WOOLSEY, Mr. WU, Mr. MICHAUD, Mr. PRICE of North Carolina, and

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

SEPTEMBER 28, 2010

Additional sponsors: Mr. SCALISE, Mr. PASTOR of Arizona, Ms. LORETTA SANCHEZ of California, Mrs. MYRICK, Mrs. MCMORRIS RODGERS, Mr. KENNEDY, Mr. WEINER, Mr. ALEXANDER, Mr. FILNER, Mr. BISHOP of Georgia, Mr. JOHNSON of Georgia, Mr. MURTHA, Mr. ROTHMAN of New Jersey, Mr. SPACE, Mrs. MCCARTHY of New York, Mr. HALL of New York, Mr. GUTIERREZ, Ms. KILROY, Ms. KOSMAS, Mr. KIRK, Mr. ARCURI, Mr. JACKSON of Illinois, Ms. TITUS, Mr. LYNCH, Mr. KANJORSKI, Mr. STUPAK, Ms. WATERS, Mr. SNYDER, Mr. CALVERT, Ms. LINDA T. SÁNCHEZ of California, Mr. COURTNEY, Mr. MCCOTTER, Mr. JONES, Ms. FALLIN, Ms. RICHARDSON, Mr. FRELINGHUYSEN, Mr. CARTER, Mr. PETERSON, Mr. LANCE, Mrs. KIRKPATRICK of Arizona, Mr. BARTLETT, Mr. PATRICK J. MURPHY of Pennsylvania, Ms. JENKINS, Mr. CAO, Mr. MORAN of Virginia, Mr. BOSWELL, Mr. PAULSEN, Mr. PETRI, Mr. KISSELL, Mr. YOUNG of Alaska, Mr. ELLISON, Mr. HARPER, Mr. ELLSWORTH, Mr. BUTTERFIELD, Mr. MCCARTHY of California, Ms. HERSETH SANDLIN, Mr. MILLER of North Carolina, Mr. ROSS, Ms. SPEIER, Mr. RODRIGUEZ, Mr. LEWIS of Georgia, Mr. RAHALL, Mr. TIAHRT, Mr. WITTMAN, Mr. MELANCON, and Mr. COHEN

SEPTEMBER 28, 2010

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on February 12, 2009]

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.

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. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

(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 Website.

(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 that report, including a corrective action plan as needed to respond to the recommendations in that report.

(d) 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–5. REPORTING ON QUALITY OF AND ACCESS TO CARE FOR WOMEN WITH CARDIOVASCULAR DISEASES.

"Not later than September 30, 2013, 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 fol-

lowing: ''may make grants to such States for the purpose''; and

(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.''.

Amend the title so as to read: ''A bill to amend the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.''.

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