111TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
111–639

HEART DISEASE EDUCATION, ANALYSIS RESEARCH, AND TREATMENT FOR WOMEN ACT

SEPTEMBER 28, 2010.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 1032]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1032) 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, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

89–006

AMENDMENT

The amendments are as follows:
Strike all after the enacting clause and insert the following:

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 following: "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.

PURPOSE AND SUMMARY

H.R. 1032, the "Heart Disease Education, Analysis, Research, and Treatment for Women Act" or "HEART for Women Act", was introduced on February 12, 2009, by Rep. Lois Capps (D–CA) and referred to the Committee on Energy and Commerce.

The goal of H.R. 1032 is to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women. H.R. 1032 extends the Centers for Disease Control and Prevention (CDC) WISEWOMAN program and contains other provisions addressing the quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases.

BACKGROUND AND NEED FOR LEGISLATION

Heart disease is the number one killer of women in the United States today. H.R. 1032 is designed to support efforts to improve prevention and treatment of heart disease within this population by strengthening data collection efforts and extending and expanding the WISEWOMAN program. Administered by the CDC, this program provides important preventive services to uninsured and underinsured women who may be at risk for heart disease.

COMMITTEE CONSIDERATION

H.R. 1032, the "Heart Disease Education, Analysis, Research, and Treatment for Women Act", was introduced by Mrs. Capps of California on February 12, 2009, and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on February 13, 2009. On September 15, 2010, the Subcommittee held a legislative hearing on the bill. The Subcommittee met in open markup session to consider H.R. 1032 on September 16, 2010. An amendment in the nature of a substitute (manager's amendment) by Mrs. Capps was adopted by a voice vote. Subsequently, H.R. 1032 was favorably forwarded to the full Committee, amended, by a voice vote.

On September 23, 2010, the Committee on Energy and Commerce met in open markup session and considered H.R. 1032 as approved by the Subcommittee. There were no amendments offered in full Committee and subsequently the Committee ordered H.R. 1032

favorably reported to the House, as amended by the Subcommittee on Health, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. A motion by Mr. Waxman ordering H.R. 1032 reported to the House, as amended, was approved by a voice vote. There were no record votes taken during consideration of this bill.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause (2)(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portions of this report, including the finding that the WISEWOMAN program provides important preventive services to uninsured and underinsured women who may be at risk for heart disease.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1032 would result in no new budget authority, entitlement authority, or tax expenditures or revenues.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal of extending the WISEWOMAN program.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional authority for H.R. 1032 is provided under article I, section 8, clauses 3 and 18 of the Constitution of the United States.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 1032 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

FEDERAL ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation does not establish or authorize the establishment of an advisory committee within the definition of 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch where the bill relates to terms and conditions of employment or access to public services and accommodations. H.R. 1032 contains no such provisions.

FEDERAL MANDATES STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act of 1974 (as amended by section 101(a)(2) of the Unfunded Mandates Reform Act, Public Law 104–4) requires a statement on whether the provisions of the report include unfunded mandates. In compliance with this requirement the Committee adopts as its own the analysis of federal mandates prepared by the Director of the Congressional Budget Office regarding H.R. 1032.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate of H.R. 1032 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 1032 from the Director of Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 27, 2010.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1032, the Heart Disease Education, Analysis Research, and Treatment for Women Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Ellen Werble and Stephanie Cameron.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 1032—Heart Disease Education, Analysis Research, and Treatment for Women Act

Summary: H.R. 1032 would amend the Public Health Service Act to improve the prevention and treatment of cardiovascular disease in women. H.R. 1032 would extend the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program administered by the Centers for Disease Control and Preven-

tion (CDC) through fiscal year 2016. In addition, the bill would require several reports from federal agencies and a study by the Government Accountability Office (GAO) on the extent to which sponsors of clinical studies adhere to requirements and guidelines for the presentation of clinical study safety and effectiveness data by sex, age, and racial subgroups.

CBO estimates that implementing H.R. 1032 would cost less than $500,000 in 2011 and $82 million over the 2011–2015 period. Enacting H.R. 1032 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 1032 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1032 is shown in the following table. The costs of this legislation fall primarily within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2011	2012	2013	2014	2015	2011–2015
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	*	23	25	28	31	107
Estimated Outlays	*	9	20	25	28	82

Note: * = less than $500,000.

Basis of estimate: For this estimate, CBO assumes that H.R. 1032 will be enacted near the beginning of fiscal year 2011, that the necessary amounts will be appropriated each year, and that outlays will follow historical patterns for similar activities of the Department of Health and Human Services. CBO estimates that implementing H.R. 1032 would cost less than $500,000 in 2011 and $82 million over the 2011–2015 period.

The WISEWOMAN program provides chronic disease screening and educational services to low-income women between the ages of 40 and 64. H.R. 1032 would authorize the appropriation of $107 million over the 2012–2015 period and an additional $34 million for fiscal year 2016 to the CDC to extend the WISEWOMAN program. Assuming the appropriation of the specified amounts, CBO estimates that provision would cost $82 million over the 2012–2015 period and an additional $57 million after 2015. In addition, H.R. 1032 would require several reports from federal agencies on quality and access to care for women with cardiovascular disease and from the GAO on adherence to requirements and guidelines for the presentation of data in clinical studies. CBO estimates that these provisions would cost less than $500,000 over the 2011–2015 period.

Pay-As-You-Go considerations: None.

Estimated impact on state, local, and tribal governments: H.R. 1032 contains no intergovernmental mandates as defined in UMRA. Grant funds authorized in the bill would benefit states that provide blood pressure and cholesterol screening and education services to women.

Estimated impact on the private sector: This bill contains no private-sector mandates as defined in UMRA.

Estimate prepared by: Federal costs: Stephanie Cameron and Ellen Werble; Impact on state, local, and tribal governments: Lisa Ramirez-Branum; Impact on the private sector: Jimmy Jin.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the Act may be cited as the "Heart Disease Education, Analysis Research, and Treatment for Women Act" or the "HEART for Women Act".

Section 2. Report by the Government Accountability Office

Section 2 requires the Government Accountability Office (GAO) to conduct a review of the effectiveness of the Food and Drug Administration (FDA) in enforcing regulations that require sponsors of applications for approval of certain FDA-regulated products to stratify the data submitted in support of such applications by gender. This section also requires HHS to respond to the GAO report, including a corrective action plan as needed to respond to the recommendations in the report.

Section 3. Reporting on quality of and access to care for women with cardiovascular disease

Section 3 amends the Public Health Service Act to require HHS to submit an annual report to Congress on the quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases.

Section 4. Extension of WISEWOMAN program

Section 4 extends the CDC WISEWOMAN program for an additional five fiscal years and authorizes the following sums in each such year: $23 million for FY2012; $25.3 million for FY2013; $27.8 million for FY2014; $30.8 million for FY2015; and $34 million for FY2016.

EXPLANATION OF AMENDMENTS

During the Subcommittee on Health markup of H.R. 1032, Mrs. Capps of California offered an amendment in the nature of a substitute (manager's amendment), which was adopted by a voice vote. The substance of the substitute amendment is reflected in the section-by-section analysis contained in this report.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART P—ADDITIONAL PROGRAMS

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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.

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TITLE XV—PREVENTIVE HEALTH MEASURES WITH RESPECT TO BREAST AND CERVICAL CANCERS

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SEC. 1509. SUPPLEMENTAL GRANTS FOR ADDITIONAL PREVENTIVE HEALTH SERVICES.

(a) **[**DEMONSTRATION PROJECTS**]** *IN GENERAL*.—In the case of States receiving grants under section 1501, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, **[**may make grants to not more than 3 such States to carry out demonstration projects for the purpose**]** *may make grants to such States for the purpose* of—

(1) * * *

* * * * * * *

(d) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), for the purpose of carrying out this section, **[**there are authorized to be appropriated $3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.**]** *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.*

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