110TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
110–874

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

SEPTEMBER 23, 2008.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 1014]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1014) 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 an amendment and recommend that the bill as amended do pass.

CONTENTS

69–006

AMENDMENT

The amendment is 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. REPORTING OF DATA IN APPLICATIONS FOR DRUGS, BIOLOGICS, AND DEVICES.

(a) DRUGS.—

(1) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended—

(A) in paragraph (1), in the second sentence—

(i) by striking "drug, and (G)" and inserting "drug; (G)"; and

(ii) by inserting before the period the following: "; and (H) the information required under paragraph (7)"; and

(B) by adding at the end the following:

"(7)(A) With respect to clinical data in an application under this subsection, the Secretary may deny such an application if the application fails to meet the requirements of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title 21, Code of Federal Regulations.

"(B) The Secretary shall modify the sections referred to in subparagraph (A) to require that an application under this subsection include any clinical data possessed by the applicant that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.

"(C) Promptly after approving an application under this subsection, the Secretary shall, through an Internet site of the Department of Health and Human Services, make available to the public the information submitted to the Secretary pursuant to subparagraphs (A) and (B), subject to sections 301(j) and 520(h)(4) of this Act, subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the 'Freedom of Information Act'), and other provisions of law that relate to trade secrets or confidential commercial information.

"(D) The Secretary shall develop guidance for staff of the Food and Drug Administration to ensure that applications under this subsection are adequately reviewed to determine whether the applications include the information required pursuant to subparagraphs (A) and (B).".

(2) INVESTIGATIONAL NEW DRUG APPLICATIONS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended—

(A) in paragraph (2), by striking "Subject to paragraph (3)," and inserting "Subject to paragraphs (3) and (5)," ; and

(B) by adding at the end the following:

"(5)(A) The Secretary may place a clinical hold (as described in paragraph (3)) on an investigation if the sponsor of the investigation fails to meet the requirements of section 312.33(a) of title 21, Code of Federal Regulations.

"(B) The Secretary shall modify the section referred to in subparagraph (A) to require that reports under such section include any clinical data possessed by the sponsor of the investigation that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.".

(b) BIOLOGICS LICENSE APPLICATIONS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(k) The provisions of section 505(b)(7) of the Federal Food, Drug, and Cosmetic Act (relating to clinical data submission) apply with respect to an application under subsection (a) of this section to the same extent and in the same manner as such provisions apply with respect to an application under section 505(b) of such Act.".

(c) DEVICES.—

(1) PREMARKET APPROVAL.—Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is amended—

(A) in subsection (c)(1)—

(i) in subparagraph (G)—

(I) by moving the margin 2 ems to the left; and

(II) by striking "and" after the semicolon at the end;

(ii) by redesignating subparagraph (H) as subparagraph (I); and

(iii) by inserting after subparagraph (G) the following subparagraph:

"(H) the information required under subsection (d)(7); and"; and

(B) in subsection (d), by adding at the end the following paragraph:

"(7) To the extent consistent with the regulation of devices, the provisions of section 505(b)(7) (relating to clinical data submission) apply with respect to an applica-

tion for premarket approval of a device under subsection (c) of this section to the same extent and in the same manner as such provisions apply with respect to an application for premarket approval of a drug under section 505(b).".

(2) INVESTIGATIONAL DEVICES.—Section 520(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(2)) is amended by adding at the end the following subparagraph:

"(D) To the extent consistent with the regulation of devices, the provisions of section 505(i)(5) (relating to individual study information) apply with respect to an application for an exemption pursuant to subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to an application for an exemption under section 505(i).".

(d) RULES OF CONSTRUCTION.—This Act and the amendments made by this Act may not be construed—

(1) as establishing new requirements under the Federal Food, Drug, and Cosmetic Act relating to the design of clinical investigations that were not otherwise in effect on the day before the date of the enactment of this Act; or

(2) as having any effect on the authority of the Secretary of Health and Human Services to enforce regulations under the Federal Food, Drug, and Cosmetic Act that are not expressly referenced in this Act or the amendments made by this Act.

(e) APPLICATION.—This section and the amendments made by this section apply only with respect to applications received under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360e) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date of the enactment of this Act.

SEC. 3. REPORTING AND ANALYSIS OF PATIENT SAFETY DATA.

(a) DATA STANDARDS.—Section 923(b) of the Public Health Service Act (42 U.S.C. 299b–23(b)) is amended by adding at the end the following: "The Secretary shall provide that all nonidentifiable patient safety work product reported to and among the network of patient safety databases be stratified by sex.".

(b) USE OF INFORMATION.—Section 923(c) of the Public Health Service Act (42 U.S.C. 299b–23(c)) is amended by adding at the end the following: "Such analyses take into account data that specifically relates to women and any disparities between treatment and the quality of care between males and females.".

SEC. 4. QUALITY OF CARE REPORTS BY THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.

Section 903 of the Public Health Service Act (42 U.S.C. 299a–1) is amended—

(1) in subsection (b)(1)(B), by inserting before the semicolon the following: ", including quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases"; and

(2) in subsection (c), by adding at the end the following:

"(4) ANNUAL REPORT ON WOMEN AND HEART DISEASE.—Not later than September 30, 2009, and annually thereafter, the Secretary, acting through the Director, shall prepare and submit to Congress a report concerning the findings related to 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. 5. EDUCATIONAL CAMPAIGNS.

(a) DISTRIBUTION OF EDUCATIONAL MATERIAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall develop and distribute to females who are age 65 or older, physicians, and other appropriate healthcare professionals, educational materials relating to the prevention, diagnosis, and treatment of heart disease, stroke, and cardiovascular diseases in women. The Secretary may carry out this subsection through contracts with public and private nonprofit entities.

(b) HEALTHCARE PROFESSIONAL EDUCATIONAL CAMPAIGN.—The Secretary, acting through the Bureau of Health Professions of the Health Resources and Services Administration, shall conduct an education and awareness campaign for physicians and other healthcare professionals relating to the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women. The Bureau of Health Professions may carry out this subsection through contracts with public and private nonprofit entities.

SEC. 6. 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 $37,000,000 for fiscal year 2009, $38,850,000 for fiscal year 2010, $40,792,500 for fiscal year 2011, $42,832,000 for fiscal year 2012, and $44,974,000 for fiscal year 2013.".

PURPOSE AND SUMMARY

The purpose of H.R. 1014, the Heart Disease Education, Analysis, Research, and Treatment for Women Act (or the HEART for Women Act), is to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

H.R. 1014 authorizes the Department of Health and Human Services (HHS) to educate health care professionals and older women about unique aspects of care in the prevention, diagnosis, and treatment of women with heart disease and stroke.

H.R. 1014 authorizes the Secretary to deny an application for approval or place a clinical hold on an investigation, as appropriate, of a new drug, investigational new drug, biologic, device, or investigational device, if the application fails to meet current reporting requirements concerning the stratification of data by gender, age, and race. The Secretary is then required to make this information publicly available.

H.R. 1014 requires the Secretary, acting through the Director of the Agency for Healthcare Research and Quality (AHRQ), to prepare and submit annual recommendations to Congress for eliminating disparities in, and improving the treatment of, heart disease in women.

H.R. 1014 authorizes the expansion of the program of the Centers for Disease Control and Prevention (CDC) known as the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program. This program, currently available in only 20 States, provides free cardiovascular disease screenings to low-income uninsured women.

BACKGROUND AND NEED FOR LEGISLATION

Heart disease and other forms of cardiovascular disease are the leading cause of death in the United States and a major cause of disability. More than 850,000 people die of cardiovascular disease in the United States annually, representing nearly 36 percent of all U.S. deaths. Cardiovascular disease is a broad term that includes several more specific groups of diseases of the heart, the blood vessel system within the heart, and stroke. Heart disease alone is the number one cause of death in the United States, and stroke alone is the third leading cause of death. The most common heart disease in the United States is coronary heart disease, which often appears as a heart attack.

Although heart disease is sometimes thought of as a "man's disease," one in three American women die of heart disease and other cardiovascular diseases, making it the leading cause of death for both women and men in the United States. Heart disease is the leading cause of death among women aged 65 years and older and

is the second and third leading cause of death among women aged 45 to 64 years and women aged 25 to 44 years, respectively.

Recent studies attribute these statistics in part to disparities in preventive care and treatment for cardiovascular disease between women and men. In particular, there is a pervasive lack of awareness among women about cardiovascular health and the risks of heart disease. Many minority women, including African American, Hispanic, Native American, and some sub-groups of Asian American women, have a greater prevalence of risk factors or are at a higher risk of death from heart disease, stroke, and other cardiovascular diseases, but they are less likely to be aware of this risk.

There is also a pervasive lack of awareness among health care providers that cardiovascular disease is the leading cause of death for women. For instance, a recent survey found that only about 8 percent of primary care physicians know that more women than men die each year from cardiovascular disease. Women are less likely than men to receive certain treatments for cardiovascular disease, perhaps due to lack of awareness and the differences in symptoms between women and men. For example, only about 33 percent of percutaneous coronary interventions, such as angioplasties and stent placements, are performed in women.

Additionally, women tend to present with cardiovascular disease at an older age than men, and therefore often suffer from multiple conditions that may mask the symptoms of heart attacks and complicate treatment. Certain diagnostic tests may be less accurate in women, such as electrocardiogram exercise stress tests. Additionally, drug effectiveness and metabolism differ between women and men, which affect the success of treatment.

Stroke kills 2.3 times as many women as breast cancer. Nearly 61 percent of stroke-related deaths occur in women. Although the evidence of disparities in stroke presentation and treatment is unclear, there are important sex differences in patients experiencing stroke. For instance, stroke severity is greater in women than in men. Women often receive fewer diagnostic tests and interventional procedures than men. Additionally, although 46,000 more women than men have a stroke each year, women receive only 39 percent of carotid endarterectomy procedures to prevent stroke; however, this may be due to higher perioperative risks for women.

There is no statutory requirement that women must be included in clinical trials, but the Food and Drug Administration (FDA) requires new drug applicants to submit data, stratified by sex, age group, and race, to the agency during the Investigational New Drug stage and as part of the New Drug Application. According to a 2001 Government Accountability Office report, however, new drug applicants routinely fail to comply with these mandatory reporting requirements and FDA frequently fails to enforce them. Consequently, treating physicians are often missing specific information about how drugs and medical devices perform in women or whether or not tests have been conducted for these products in women.

The CDC administers the WISEWOMAN program. WISEWOMAN began as a demonstration program authorized in 1993 by Congress. The program is available to low-income women aged 40 to 64 who are enrolled in the National Breast and Cervical Cancer Early Detection Program. WISEWOMAN successfully

screens low-income and uninsured women for heart disease, stroke, and other forms of cardiovascular disease through blood pressure and blood cholesterol testing. Up to this point, however, the available funding has limited the program to 21 projects in only 20 States.

HEARINGS

The Subcommittee on Health held a legislative hearing on H.R. 1014 on May 1, 2007. The Subcommittee heard from two witnesses: Susan K. Bennett, M.D., Clinical Director, Women's Heart Program, George Washington University Hospital, a national spokesperson for the American Heart Association; and, Ms. Janet Wolf, Supervisor, County of Santa Barbara, heart disease survivor.

COMMITTEE CONSIDERATION

On Wednesday, September 17, 2008, the full Committee met in open markup session and ordered H.R. 1014 favorably reported to the House, amended, 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 the record votes on the motion to report legislation and amendments thereto. No record votes were taken on amendments or in connection with ordering H.R. 1014 reported to the House. A motion by Mr. Dingell to order H.R. 1014 favorably reported to the House, amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Subcommittee on Health held a legislative hearing on H.R. 1014, and the oversight findings of the Committee regarding the bill are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objectives of H.R. 1014 are to improve the prevention, diagnosis, and treatment of women with cardiovascular disease through a multi-pronged strategy, including requiring the Food and Drug Administration to enforce reporting requirements regarding gender-specific data about new and investigational medicines and devices; raising awareness among older women and their health care providers; and improving cardiovascular disease screening for women.

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 will adopt as its own the estimate of budget authority and revenues regarding H.R. 1014 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 1014 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 1014 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Regarding clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, a cost estimate on H.R. 1014 by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available at the time of the filing of this report.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates regarding H.R. 1014 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act would be created by H.R. 1014.

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. 1014 is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian Tribes, and in the provisions of Article I, section 8, clause 1, that relate to expending funds to provide for the general welfare of the United States.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 1014 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1995.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title as the Heart Disease Education, Analysis, Research, and Treatment for Women Act or the HEART for Women Act.

Section 2. Reporting of data in applications for drugs, biologics, and devices

Section 2 grants the HHS Secretary the authority to deny New Drug Applications, Biologics Licensing Applications, and Premarket Approval applications for devices or to place a clinical hold on Investigational New Drugs or Investigational Device Exemptions that do not include safety or efficacy data reported by gender, age, and racial subgroup. FDA currently requires this information, and this provision reasserts the importance of collecting clinical trial information stratified by gender, age, and race.

Section 2 requires the HHS Secretary to make information about the safety and effectiveness of newly approved drugs, biologics, or devices available to the public through its Internet site, consistent with laws protecting trade secrets or commercially confidential information. The Secretary is also required to develop guidance for FDA staff to ensure that applications are adequately reviewed for safety and efficacy data reported by gender, age, and racial subgroup.

Section 2 clarifies that this Act neither establishes new requirements under the FFDCA relating to the design of clinical trials nor affects the authority of the HHS Secretary to enforce regulations under the FFDCA not expressly referenced in this Act. The requirements of this section apply only to applications received by the FDA on or after the date of enactment of this Act.

Section 3. Reporting and analysis of patient safety data

Section 3 requires that non-identifiable patient safety data reported by Patient Safety Organizations (PSOs) be stratified by sex and requires that PSOs analyze such data to identify any disparities in treatment and quality of care between males and females in issuing their findings.

Section 4. Quality of care reports by the Agency for Healthcare Research and Quality

Section 4 requires the Agency for Healthcare Research and Quality to submit an annual report to Congress no later than September 30, 2009, and annually thereafter on the quality of, and access to, care for women with heart disease, stroke, and other cardiovascular diseases. This annual report will make recommendations for eliminating disparities in, and improving the treatment of, heart disease, stroke, and other forms of cardiovascular disease in women.

Section 5. Educational campaigns

Section 5 requires the Secretary to develop and distribute to women who are 65 years or older, physicians, and other appropriate health care professionals educational materials related to the prevention, diagnosis, and treatment of cardiovascular diseases in women.

Section 5 also requires the Secretary, acting through the Bureau of Health Professions of the Health Resources and Services Administration, to conduct an education and awareness campaign for physicians and other health care professionals related to the prevention, diagnosis, and treatment of heart disease, stroke, and other forms of cardiovascular disease in women.

Section 6. Extension of WISEWOMAN Program

Section 6 makes all States, U.S. territories, and Indian Tribes eligible to receive grants from the CDC under the WISEWOMAN program. Section 6 authorizes $37,000,000 for fiscal year (FY) 2009, $38,850,000 for FY 2010, $40,792,500 for FY 2011, $42,832,000 for FY 2012, and $44,974,000 for FY 2013 to carry out this section.

The Committee has authorized increased funding for WISEWOMAN to allow the program to screen more low-income uninsured and underinsured women across the Nation. Heart disease, stroke, and other cardiovascular diseases are the leading killer of women in all 50 States. The Committee intends that the CDC use the increased resources authorized under this Act to fund WISEWOMAN programs in as many additional States as possible, subject to appropriations being made available. The Committee believes it is important to continue to monitor the effectiveness of this program.

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):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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NEW DRUGS

SEC. 505. (a) * * *

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such [drug, and (G)] *drug; (G)* any assessments required under section 505B*; and (H) the information required under paragraph (7)*. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably

be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If a application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

* * * * * * *

(7)(A) With respect to clinical data in an application under this subsection, the Secretary may deny such an application if the application fails to meet the requirements of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title 21, Code of Federal Regulations.

(B) The Secretary shall modify the sections referred to in subparagraph (A) to require that an application under this subsection include any clinical data possessed by the applicant that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.

(C) Promptly after approving an application under this subsection, the Secretary shall, through an Internet site of the Department of Health and Human Services, make available to the public the information submitted to the Secretary pursuant to subparagraphs (A) and (B), subject to sections 301(j) and 520(h)(4) of this Act, subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the "Freedom of Information Act"), and other provisions of law that relate to trade secrets or confidential commercial information.

(D) The Secretary shall develop guidance for staff of the Food and Drug Administration to ensure that applications under this subsection are adequately reviewed to determine whether the applications include the information required pursuant to subparagraphs (A) and (B).

* * * * * * *

(i)(1) * * *

(2) ⟦Subject to paragraph (3),⟧ *Subject to paragraphs (3) and (5),* a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) * * *

* * * * * * *

(5)(A) The Secretary may place a clinical hold (as described in paragraph (3)) on an investigation if the sponsor of the investigation fails to meet the requirements of section 312.33(a) of title 21, Code of Federal Regulations.

(B) The Secretary shall modify the section referred to in subparagraph (A) to require that reports under such section include any clinical data possessed by the sponsor of the investigation that re-

lates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.

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PREMARKET APPROVAL

SEC. 515. (a) * * *

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(c) APPLICATION FOR PREMARKET APPROVAL.—(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) * * *

* * * * * * *

(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application); **[**and**]**

(H) the information required under subsection (d)(7); and

[(H)**]** *(I)* such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

* * * * * * *

(d) ACTION ON AN APPLICATION FOR PREMARKET APPROVAL.—(1) * * *

* * * * * * *

(7) To the extent consistent with the regulation of devices, the provisions of section 505(b)(7) (relating to clinical data submission) apply with respect to an application for premarket approval of a device under subsection (c) of this section to the same extent and in the same manner as such provisions apply with respect to an application for premarket approval of a drug under section 505(b).

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GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

SEC. 520. (a) * * *

* * * * * * *

(g) EXEMPTION FOR DEVICES FOR INVESTIGATIONAL USE.—(1) * * *

(2)(A) * * *

* * * * * * *

(D) To the extent consistent with the regulation of devices, the provisions of section 505(i)(5) (relating to individual study information) apply with respect to an application for an exemption pursuant to subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to an application for an exemption under section 505(i).

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PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS

SEC. 351. (a) * * *

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(k) The provisions of section 505(b)(7) of the Federal Food, Drug, and Cosmetic Act (relating to clinical data submission) apply with respect to an application under subsection (a) of this section to the same extent and in the same manner as such provisions apply with respect to an application under section 505(b) of such Act.

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TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

PART A—ESTABLISHMENT AND GENERAL DUTIES

* * * * * * *

SEC. 903. RESEARCH ON HEALTH DISPARITIES.

(a) * * *

(b) RESEARCH AND DEMONSTRATION PROJECTS.—

(1) IN GENERAL.—In carrying out subsection (a), the Director shall conduct and support research and support demonstrations to—

(A) * * *

(B) identify and evaluate clinical and organizational strategies to improve the quality, outcomes, and access to care for health disparity populations, including minority health disparity populations*, including quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases*;

* * * * * * *

(c) QUALITY MEASUREMENT DEVELOPMENT.—

(1) * * *

* * * * * * *

(4) ANNUAL REPORT ON WOMEN AND HEART DISEASE.—Not later than September 30, 2009, and annually thereafter, the Secretary, acting through the Director, shall prepare and submit to Congress a report concerning the findings related to 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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PART C—PATIENT SAFETY IMPROVEMENT

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SEC. 923. NETWORK OF PATIENT SAFETY DATABASES.

(a) * * *

(b) DATA STANDARDS.—The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of nonidentifiable patient safety work product, including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act. *The Secretary shall provide that all nonidentifiable patient safety work product reported to and among the network of patient safety databases be stratified by sex.*

(c) USE OF INFORMATION.—Information reported to and among the network of patient safety databases under subsection (a) shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 913(b)(2). *Such analyses take into account data that specifically relates to women and any disparities between treatment and the quality of care between males and females.*

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

* * * * * * *

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 $37,000,000 for fiscal year 2009, $38,850,000 for fiscal year 2010, $40,792,500 for fiscal year 2011, $42,832,000 for fiscal year 2012, and $44,974,000 for fiscal year 2013.*

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