

110TH CONGRESS
2D SESSION

H. R. 1014

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 26 (legislative day, SEPTEMBER 17), 2008

Received

AN ACT

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Heart Disease Edu-
3 cation, Analysis Research, and Treatment for Women
4 Act” or the “HEART for Women Act”.

5 **SEC. 2. REPORTING OF DATA IN APPLICATIONS FOR**
6 **DRUGS, BIOLOGICS, AND DEVICES.**

7 (a) DRUGS.—

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

11 (A) in paragraph (1), in the second sen-
12 tence—

13 (i) by striking “drug, and (G)” and
14 inserting “drug; (G)”; and

15 (ii) by inserting before the period the
16 following: “; and (H) the information re-
17 quired under paragraph (7)”; and

18 (B) by adding at the end the following:

19 “(7)(A) With respect to clinical data in an application
20 under this subsection, the Secretary may deny such an ap-
21 plication if the application fails to meet the requirements
22 of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title
23 21, Code of Federal Regulations.

24 “(B) The Secretary shall modify the sections referred
25 to in subparagraph (A) to require that an application
26 under this subsection include any clinical data possessed

1 by the applicant that relates to the safety or effectiveness
2 of the drug involved by gender, age, and racial subgroup.

3 “(C) Promptly after approving an application under
4 this subsection, the Secretary shall, through an Internet
5 site of the Department of Health and Human Services,
6 make available to the public the information submitted to
7 the Secretary pursuant to subparagraphs (A) and (B),
8 subject to sections 301(j) and 520(h)(4) of this Act, sub-
9 section (b)(4) of section 552 of title 5, United States Code
10 (commonly referred to as the ‘Freedom of Information
11 Act’), and other provisions of law that relate to trade se-
12 crets or confidential commercial information.

13 “(D) The Secretary shall develop guidance for staff
14 of the Food and Drug Administration to ensure that appli-
15 cations under this subsection are adequately reviewed to
16 determine whether the applications include the informa-
17 tion required pursuant to subparagraphs (A) and (B).”.

18 (2) INVESTIGATIONAL NEW DRUG APPLICA-
19 TIONS.—Section 505(i) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 355(i)) is amended—

21 (A) in paragraph (2), by striking “Subject
22 to paragraph (3),” and inserting “Subject to
23 paragraphs (3) and (5),” ; and

24 (B) by adding at the end the following:

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

6 “(B) The Secretary shall modify the section referred
7 to in subparagraph (A) to require that reports under such
8 section include any clinical data possessed by the sponsor
9 of the investigation that relates to the safety or effective-
10 ness of the drug involved by gender, age, and racial sub-
11 group.”.

12 (b) BIOLOGICS LICENSE APPLICATIONS.—Section
13 351 of the Public Health Service Act (42 U.S.C. 262) is
14 amended by adding at the end the following:

15 “(k) The provisions of section 505(b)(7) of the Fed-
16 eral Food, Drug, and Cosmetic Act (relating to clinical
17 data submission) apply with respect to an application
18 under subsection (a) of this section to the same extent
19 and in the same manner as such provisions apply with re-
20 spect to an application under section 505(b) of such Act.”.

21 (c) DEVICES.—

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

25 (A) in subsection (c)(1)—

1 (i) in subparagraph (G)—
2 (I) by moving the margin 2 ems
3 to the left; and
4 (II) by striking “and” after the
5 semicolon at the end;
6 (ii) by redesignating subparagraph
7 (H) as subparagraph (I); and
8 (iii) by inserting after subparagraph
9 (G) the following subparagraph:
10 “(H) the information required under subsection
11 (d)(7); and”;
12 (B) in subsection (d), by adding at the end
13 the following paragraph:
14 “(7) To the extent consistent with the regulation of
15 devices, the provisions of section 505(b)(7) (relating to
16 clinical data submission) apply with respect to an applica-
17 tion for premarket approval of a device under subsection
18 (c) of this section to the same extent and in the same man-
19 ner as such provisions apply with respect to an application
20 for premarket approval of a drug under section 505(b).”.

1 “(D) To the extent consistent with the regulation of
2 devices, the provisions of section 505(i)(5) (relating to in-
3 dividual study information) apply with respect to an appli-
4 cation for an exemption pursuant to subparagraph (A) of
5 this paragraph to the same extent and in the same manner
6 as such provisions apply with respect to an application for
7 an exemption under section 505(i).”.

8 (d) RULES OF CONSTRUCTION.—This Act and the
9 amendments made by this Act may not be construed—
10 (1) as establishing new requirements under the
11 Federal Food, Drug, and Cosmetic Act relating to
12 the design of clinical investigations that were not
13 otherwise in effect on the day before the date of the
14 enactment of this Act; or
15 (2) as having any effect on the authority of the
16 Secretary of Health and Human Services to enforce
17 regulations under the Federal Food, Drug, and Cos-
18 metic Act that are not expressly referenced in this
19 Act or the amendments made by this Act.

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

1 **SEC. 3. REPORTING AND ANALYSIS OF PATIENT SAFETY**2 **DATA.**

3 (a) DATA STANDARDS.—Section 923(b) of the Public
4 Health Service Act (42 U.S.C. 299b–23(b)) is amended
5 by adding at the end the following: “The Secretary shall
6 provide that all nonidentifiable patient safety work prod-
7 uct reported to and among the network of patient safety
8 databases be stratified by sex.”.

9 (b) USE OF INFORMATION.—Section 923(c) of the
10 Public Health Service Act (42 U.S.C. 299b–23(c)) is
11 amended by adding at the end the following: “Such anal-
12 yses take into account data that specifically relates to
13 women and any disparities between treatment and the
14 quality of care between males and females.”.

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

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

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

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

25 “(4) ANNUAL REPORT ON WOMEN AND HEART
26 DISEASE.—Not later than September 30, 2009, and

1 annually thereafter, the Secretary, acting through
2 the Director, shall prepare and submit to Congress
3 a report concerning the findings related to the qual-
4 ity of and access to care for women with heart dis-
5 ease, stroke, and other cardiovascular diseases. The
6 report shall contain recommendations for eliminating
7 disparities in, and improving the treatment of, heart
8 disease, stroke, and other cardiovascular diseases in
9 women.”.

10 **SEC. 5. EDUCATIONAL CAMPAIGNS.**

11 (a) **DISTRIBUTION OF EDUCATIONAL MATERIAL.**—
12 The Secretary of Health and Human Services (referred
13 to in this section as the “Secretary”) shall develop and
14 distribute to females who are age 65 or older, physicians,
15 and other appropriate healthcare professionals, edu-
16 cational materials relating to the prevention, diagnosis,
17 and treatment of heart disease, stroke, and cardiovascular
18 diseases in women. The Secretary may carry out this sub-
19 section through contracts with public and private non-
20 profit entities.

21 (b) **HEALTHCARE PROFESSIONAL EDUCATIONAL**
22 **CAMPAIGN.**—The Secretary, acting through the Bureau of
23 Health Professions of the Health Resources and Services
24 Administration, shall conduct an education and awareness
25 campaign for physicians and other healthcare profes-

1 sionals relating to the prevention, diagnosis, and treat-
2 ment of heart disease, stroke, and other cardiovascular
3 diseases in women. The Bureau of Health Professions may
4 carry out this subsection through contracts with public
5 and private nonprofit entities.

6 **SEC. 6. EXTENSION OF WISEWOMAN PROGRAM.**

7 Section 1509 of the Public Health Service Act (42
8 U.S.C. 300n–4a) is amended—

9 (1) in subsection (a)—

10 (A) by striking the heading and inserting
11 “IN GENERAL.—”; and

12 (B) in the matter preceding paragraph (1),
13 by striking “may make grants” and all that fol-
14 lows through “purpose” and inserting the fol-
15 lowing: “may make grants to such States for
16 the purpose”; and

17 (2) in subsection (d)(1), by striking “there are
18 authorized” and all that follows through the period
19 and inserting “there are authorized to be appro-
20 priated \$37,000,000 for fiscal year 2009,
21 \$38,850,000 for fiscal year 2010, \$40,792,500 for

1 fiscal year 2011, \$42,832,000 for fiscal year 2012,
2 and \$44,974,000 for fiscal year 2013.”.

Passed the House of Representatives September 25,
2008.

Attest: LORRAINE C. MILLER,
Clerk.