

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 1032**

OFFERED BY M_{rs.} Capps

Strike all after the enacting clause and insert the following:

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. REPORT BY GOVERNMENT ACCOUNTABILITY OF-
6 FICE.**

7 (a) IN GENERAL.—The Comptroller General of the
8 United States shall conduct a study investigating the ex-
9 tent to which sponsors of clinical studies of investigational
10 drugs, biologics, and devices and sponsors of applications
11 for approval or licensure of new drugs, biologics, and de-
12 vices comply with Food and Drug Administration require-
13 ments and follow guidance for presentation of clinical
14 study safety and effectiveness data by sex, age, and racial
15 subgroups.

16 (b) REPORT BY GAO.—

17 (1) SUBMISSION.—Not later than 12 months
18 after the date of the enactment of this Act, the

1 Comptroller General shall complete the study under
2 subsection (a) and submit to the Committee on En-
3 ergy and Commerce of the House of Representatives
4 and the Committee on Health, Education, Labor,
5 and Pensions of the Senate a report on the results
6 of such study.

7 (2) CONTENTS.—The report required by para-
8 graph (1) shall include each of the following:

9 (A) A description of the extent to which
10 the Food and Drug Administration assists
11 sponsors in complying with the requirements
12 and following the guidance referred to in sub-
13 section (a).

14 (B) A description of the effectiveness of
15 the Food and Drug Administration's enforce-
16 ment of compliance with such requirements.

17 (C) An analysis of the extent to which fe-
18 males, racial and ethnic minorities, and adults
19 of all ages are adequately represented in Food
20 and Drug Administration-approved clinical
21 studies (at all phases) so that product safety
22 and effectiveness data can be evaluated by gen-
23 der, age, and racial subgroup.

24 (D) An analysis of the extent to which a
25 summary of product safety and effectiveness

1 data disaggregated by sex, age, and racial sub-
2 group is readily available to the public in a
3 timely manner by means of the product label or
4 the Food and Drug Administration’s Website.

5 (E) Appropriate recommendations for—

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

8 or

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

11 (c) REPORT BY HHS.—Not later than 6 months
12 after the submission by the Comptroller General of the
13 report required under subsection (b), the Secretary of
14 Health and Human Services shall submit to the Com-
15 mittee on Energy and Commerce of the House of Rep-
16 resentatives and the Committee on Health, Education,
17 Labor, and Pensions of the Senate a response to that re-
18 port, including a corrective action plan as needed to re-
19 spond to the recommendations in that report.

20 (d) DEFINITIONS.—In this section:

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

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

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

7 **SEC. 3. REPORTING ON QUALITY OF AND ACCESS TO CARE**
8 **FOR WOMEN WITH CARDIOVASCULAR DIS-**
9 **EASES.**

10 Part P of title III of the Public Health Service Act
11 (42 U.S.C. 280g et seq.) is amended by adding at the end
12 the following:

13 **“SEC. 399V-5. REPORTING ON QUALITY OF AND ACCESS TO**
14 **CARE FOR WOMEN WITH CARDIOVASCULAR**
15 **DISEASES.**

16 “Not later than September 30, 2013, and annually
17 thereafter, the Secretary of Health and Human Services
18 shall prepare and submit to the Congress a report on the
19 quality of and access to care for women with heart disease,
20 stroke, and other cardiovascular diseases. The report shall
21 contain recommendations for eliminating disparities in,
22 and improving the treatment of, heart disease, stroke, and
23 other cardiovascular diseases in women.”.

1 **SEC. 4. EXTENSION OF WISEWOMAN PROGRAM.**

2 Section 1509 of the Public Health Service Act (42
3 U.S.C. 300n-4a) is amended—

4 (1) in subsection (a)—

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

7 (B) in the matter preceding paragraph (1),
8 by striking “may make grants” and all that fol-
9 lows through “purpose” and inserting the fol-
10 lowing: “may make grants to such States for
11 the purpose”; and

12 (2) in subsection (d)(1), by striking “there are
13 authorized” and all that follows through the period
14 and inserting “there are authorized to be appro-
15 priated \$23,000,000 for fiscal year 2012,
16 \$25,300,000 for fiscal year 2013, \$27,800,000 for
17 fiscal year 2014, \$30,800,000 for fiscal year 2015,
18 and \$34,000,000 for fiscal year 2016.”.

