

AMENDMENTS TO H.R. 1014
OFFERED BY MRS. CAPPS

Strike section 2 and redesignate sections 3 through 7 as sections 2 through 6, respectively.

Beginning at page 3, line 19, strike section 2, as so redesignated, and insert the following:

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

3 (a) DRUGS.—

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

7 (A) in paragraph (1), in the second sen-
8 tence—

9 (i) by striking “drug, and (G)” and
10 inserting “drug; (G)”; and

11 (ii) by inserting before the period the
12 following: “; and (H) the information re-
13 quired under paragraph (6)”; and

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

15 “(6)(A) With respect to clinical data in an application
16 under this subsection, the Secretary may deny such an ap-

1 plication if the application fails to meet the requirements
2 of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title
3 21, Code of Federal Regulations.

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

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

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

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

4 (A) in paragraph (2), by striking “Subject
5 to paragraph (3),” and inserting “Subject to
6 paragraphs (3) and (5),” ; and

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

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

13 “(B) The Secretary shall modify the section referred
14 to in subparagraph (A) to require that reports under such
15 section include any clinical data possessed by the sponsor
16 of the investigation that relates to the safety or effective-
17 ness of the drug involved by gender, age, and racial sub-
18 group.”.

19 (b) BIOLOGICS LICENSE APPLICATIONS.—Section
20 351 of the Public Health Service Act (42 U.S.C. 262) is
21 amended by adding at the end the following:

22 “(k) The provisions of section 505(b)(6) of the Fed-
23 eral Food, Drug, and Cosmetic Act (relating to clinical
24 data submission) apply with respect to an application
25 under subsection (a) of this section to the same extent

1 and in the same manner as such provisions apply with re-
2 spect to an application under section 505(b) of such Act.”.

3 (c) DEVICES.—

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

7 (A) in subsection (c)(1)—

8 (i) in subparagraph (G)—

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

11 (II) by striking “and” after the
12 semicolon at the end;

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

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

17 “(H) the information required under subsection
18 (d)(7); and”;

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

21 “(7) To the extent consistent with the regulation of
22 devices, the provisions of section 505(b)(6) (relating to
23 clinical data submission) apply with respect to an applica-
24 tion for premarket approval of a device under subsection
25 (c) of this section to the same extent and in the same man-

1 ner as such provisions apply with respect to an application
2 for premarket approval of a drug under section 505(b).”.

3 (2) INVESTIGATIONAL DEVICES.—Section
4 520(g)(2) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 360j(g)) is amended by adding at
6 the end the following subparagraph:

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

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

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

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

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

Page 11, line 8, strike “September 30, 2007” and
insert “September 30, 2009”.

Beginning at page 12, line 14, strike section 6, as
so redesignated, and insert the following:

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

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

10 (1) in subsection (a)—

11 (A) by striking the heading and inserting
12 “IN GENERAL”; and

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

18 (2) in subsection (d)(1), by striking “there are
19 authorized” and all that follows through the period
20 and inserting “there are authorized to be appro-

1 priated \$37,000,000 for fiscal year 2009,
2 \$38,850,000 for fiscal year 2010, \$40,792,500 for
3 fiscal year 2011, \$42,832,000 for fiscal year 2012,
4 and \$44,974,000 for fiscal year 2013.”.

