

113TH CONGRESS
2^D SESSION

H. R. 4879

To amend the Federal Food, Drug, and Cosmetic Act to provide for expedited review of drugs and biological products to provide safer or more effective treatment for males or females, to amend the Public Health Service Act to enhance the consideration of sex differences in basic and clinical research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 17, 2014

Mr. COOPER (for himself and Mrs. LUMMIS) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for expedited review of drugs and biological products to provide safer or more effective treatment for males or females, to amend the Public Health Service Act to enhance the consideration of sex differences in basic and clinical research, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Research for All Act
5 of 2014”.

1 **SEC. 2. SUFFICIENCY OF DESIGN AND SIZE OF CLINICAL**
2 **TRIALS DURING EXPEDITED REVIEW.**

3 The Secretary of Health and Human Services, acting
4 through the Commissioner of Food and Drugs, shall re-
5 view and develop policies, as appropriate, to ensure that
6 the design and size of clinical trials for products granted
7 expedited approval pursuant to section 506 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 356) are suffi-
9 cient to determine the safety and effectiveness of such
10 products for men and women using subgroup analysis.

11 **SEC. 3. EXPEDITED REVIEW OF DRUGS AND BIOLOGICAL**
12 **PRODUCTS TO PROVIDE SAFER OR MORE EF-**
13 **FECTIVE TREATMENT FOR MALES OR FE-**
14 **MALES.**

15 (a) IN GENERAL.—Section 506 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 356) is amended by
17 adding at the end the following:

18 “(g) EXPEDITED REVIEW OF DRUGS AND BIOLOGI-
19 CAL PRODUCTS TO PROVIDE SAFER OR MORE EFFECTIVE
20 TREATMENT FOR MALES OR FEMALES.—

21 “(1) ELIGIBLE PRODUCT.—The Secretary shall,
22 at the request of the sponsor of a new drug, facili-
23 tate the development and expedite the review of such
24 drug if the drug—

25 “(A) is intended—

26 “(i) to avoid serious adverse events; or

1 “(ii) to treat a serious or life-threat-
2 ening disease or condition;

3 “(B) whether alone or in combination with
4 one or more other drugs or biological products,
5 is intended for safer or more effective treatment
6 for men or women than a currently available
7 product approved to treat the general popu-
8 lation or the other sex; and

9 “(C) is supported by results of clinical
10 trials that include and separately examine out-
11 comes for both men and women.

12 “(2) DESIGNATION.—At the request of the
13 sponsor of an eligible product described in para-
14 graph (1), the Secretary shall designate the drug as
15 an expedited product to provide safer or more effec-
16 tive treatment for males or females.

17 “(3) EARLY AND FREQUENT COMMUNICA-
18 TION.—The Secretary shall, with respect to each ex-
19 pedited product designated under this subsection,
20 provide early and frequent communication and re-
21 view of incomplete applications to the same extent
22 and in the same manner as is provided under sub-
23 sections (b) and (d).

24 “(4) RULE OF CONSTRUCTION.—Nothing in
25 this subsection shall be construed—

1 “(A) to lessen or otherwise alter the stand-
2 ard of safety and effectiveness required for the
3 approval or licensing of drugs or biological
4 products under section 505 of this Act or sec-
5 tion 351 of the Public Health Service Act; or

6 “(B) to authorize application of the provi-
7 sions of subsection (c) (relating to the use of
8 surrogate endpoints) to expedited products des-
9 ignated under this subsection.”.

10 (b) **TECHNICAL CORRECTIONS.**—Subsection (f) of
11 section 506 of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 356) (relating to awareness efforts), as des-
13 ignated by section 902(a) of Public Law 112–144, is
14 amended—

15 (1) in paragraph (1), by striking “and and”
16 and inserting “and”; and

17 (2) by moving such subsection (f) so that it fol-
18 lows subsection (e) of such section 506.

19 **SEC. 4. RESEARCH ON SEX DIFFERENCES.**

20 (a) **INCLUSION IN NIH RESEARCH.**—

21 (1) **IN GENERAL.**—Section 492B of the Public
22 Health Service Act (42 U.S.C. 289a–2) is amend-
23 ed—

1 (A) by redesignating subsections (b)
2 through (g) as subsections (e) through (h), re-
3 spectively; and

4 (B) by inserting after subsection (a) the
5 following:

6 “(b) INCLUSION OF SEX DIFFERENCES IN BASIC RE-
7 SEARCH.—

8 “(1) APPLICABILITY TO BASIC RESEARCH.—

9 “(A) IN GENERAL.—The Director of NIH
10 shall determine when it is appropriate for
11 projects of basic research involving cells, tissues
12 or animals to include both male and female
13 cells, tissues, or animals.

14 “(B) DEADLINE FOR INITIAL DETERMINA-
15 TION; UPDATES.—The Director of NIH—

16 “(i) shall make the initial determina-
17 tions required by subparagraph (A) not
18 later than one year after the date of enact-
19 ment of the Research for All Act of 2014;
20 and

21 “(ii) may subsequently update or re-
22 vise such determinations as the Director
23 determines appropriate.

1 “(C) CONSULTATION.—In making the ini-
2 tial determinations required by subparagraph
3 (A), the Director of NIH—

4 “(i) shall consult with the Office of
5 Research on Women’s Health, the Institute
6 of Medicine, the Office of Laboratory Ani-
7 mal Welfare, and appropriate members of
8 the scientific and academic communities;
9 and

10 “(ii) may conduct outreach and edu-
11 cational initiatives within the scientific and
12 academic communities on the influence of
13 sex as a variable in basic research in order
14 to develop a consensus within such commu-
15 nities on when it is appropriate for projects
16 of basic research involving cells, tissues or
17 animals to include both male and female
18 cells, tissues, or animals.

19 “(2) INCLUSION.—Beginning on the date that
20 is 1 year after the date of enactment of the Re-
21 search for All Act of 2014, in conducting or sup-
22 porting basic research in accordance with paragraph
23 (1), the Director of NIH shall, subject to paragraph
24 (3), ensure that—

1 “(A) in the case of research on cells or tis-
2 sues—

3 “(i) cells or tissues, as applicable, are
4 derived from both male and female orga-
5 nisms in each project of such research; and

6 “(ii) the results are disaggregated ac-
7 cording to whether the cells or tissues are
8 derived from male or female organisms;
9 and

10 “(B) in the case of animal research—

11 “(i) both male and female animals are
12 included as subjects in each project of such
13 research; and

14 “(ii) the results are disaggregated ac-
15 cording to whether the subjects are male
16 or female.

17 “(3) EXCEPTION.—Paragraph (2) shall not
18 apply to a project of basic research if the Director
19 of NIH determines that the inclusion of cells or tis-
20 sues derived from both male and female organisms,
21 or the inclusion of both male and female animals as
22 subjects, as applicable, is inappropriate in the case
23 of such project.”.

1 (2) DESIGN OF RESEARCH.—Subsection (d) of
2 section 492B of the Public Health Service Act (42
3 U.S.C. 289a–2), as redesignated, is amended—

4 (A) by striking “(d)” and all that follows
5 through “In the case” and inserting the fol-
6 lowing:

7 “(d) DESIGN OF RESEARCH.—

8 “(1) CLINICAL TRIALS.—In the case”; and

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

10 “(2) BASIC RESEARCH.—In the case of basic
11 research in which cells or tissues derived from both
12 male and female organisms will be included in ac-
13 cordance with subsection (b)(2)(A) or both male and
14 female animals will be included as subjects in ac-
15 cordance with subsection (b)(2)(B), the Director of
16 NIH shall ensure that sex differences are examined
17 and analyzed, as appropriate.”.

18 (3) UPDATING GUIDELINES FOR CLINICAL AND
19 BASIC RESEARCH.—Section 492B(f)(1) of the Public
20 Health Service Act (42 U.S.C. 289a–2), as redesi-
21 gnated, is amended to read as follows:

22 “(1) DATE CERTAIN; UPDATE.—The guidelines
23 required in subsection (e) regarding the require-
24 ments of this section for clinical and basic research
25 shall—

1 “(A) be updated and published in the Fed-
2 eral Register not later than 1 year after the
3 date of enactment of the Research for All Act
4 of 2014;

5 “(B) reflect the growing understanding
6 that sex differences matter;

7 “(C) ensure better enforcement of the re-
8 quirements of this section by the personnel of
9 the agencies of the National Institutes of
10 Health responsible for reviewing grant pro-
11 posals; and

12 “(D) include guidance on when research
13 strongly supports or strongly negates the con-
14 clusion that there is a significant difference in
15 how the variables being studied affect women or
16 members of minority groups, as the case may
17 be, relative to how such variables affect other
18 subjects in the research.”.

19 (4) APPLICABILITY.—Section 492B(f)(2) of the
20 Public Health Service Act (42 U.S.C. 289a–2), as
21 redesignated, is amended by adding at the end the
22 following: “For fiscal year 2016 and subsequent fis-
23 cal years, the Director of NIH may not approve any
24 proposal of basic research to be conducted or sup-
25 ported by any agency of the National Institutes of

1 Health unless the proposal specifies the manner in
2 which the research will comply with this section.”.

3 (5) CONFORMING CHANGES.—Section 492B of
4 the Public Health Service Act (42 U.S.C. 289a–2)
5 is amended—

6 (A) in the heading of subsection (a), by
7 striking “REQUIREMENT OF INCLUSION” and
8 inserting “INCLUSION IN CLINICAL RE-
9 SEARCH”;

10 (B) in subsection (a)(1), by striking “sub-
11 section (b)” and inserting “subsection (c)”;

12 (C) in subsection (e)(1)(A), as redesign-
13 ated, by striking “subsection (b)” and insert-
14 ing “subsection (c)”;

15 (D) in subsection (e)(1)(B), as redesign-
16 ated, by striking “subsection (c)” and insert-
17 ing “subsection (d)”;

18 (E) in subsection (e)(2), as redesignated,
19 by striking “subsection (b)” and inserting “sub-
20 section (c)”.

21 (b) BIENNIAL REPORTS OF DIRECTOR OF NIH.—
22 Subparagraph (C) of section 403(a)(4) of the Public
23 Health Service Act (42 U.S.C. 283(a)(4)) is amended—

24 (1) by redesignating clause (vi) as clause (vii);
25 and

1 (2) by inserting after clause (v) the following:

2 “(vi) Basic research, including a
3 breakdown of the sex of organisms from
4 which cells and tissues are derived, a
5 breakdown of the sex of animal subjects,
6 and such other information as may be nec-
7 essary to demonstrate compliance with sec-
8 tion 492B (regarding sex differences in
9 basic research).”.

10 (c) SPECIAL CENTERS OF RESEARCH ON SEX DIF-
11 FERENCES.—Part H of title IV of the Public Health Serv-
12 ice Act is amended by inserting after section 492B of such
13 Act (42 U.S.C. 289a–2) the following:

14 **“SEC. 492C. SPECIAL CENTERS OF RESEARCH ON SEX DIF-
15 FERENCES.**

16 “The Secretary may award grants or other support
17 to entities for the continued operation and expansion of
18 Special Centers of Research on Sex Differences.”.

19 (d) RULE OF CONSTRUCTION.—Nothing in this Act
20 or the amendments made by this Act shall be construed
21 to lessen any standard or requirement set forth in part
22 1, 2, or 3 of subchapter A of chapter I of title 9, Code
23 of Federal Regulations.

1 **SEC. 5. GAO REPORTS.**

2 Not later than 1 year after the date of enactment
3 of the Research for All Act of 2014, the Comptroller Gen-
4 eral of the United States shall—

5 (1) submit to the Congress updated versions of
6 the reports of the Government Accountability Office
7 entitled “Women’s Health: NIH Has Increased Its
8 Efforts To Include Women in Research” (published
9 in May 2000; GAO/HEHS–00–96) and “Women’s
10 Health: Women Sufficiently Represented in New
11 Drug Testing, But FDA Oversight Needs Improve-
12 ment” (published in July 2001; GAO–01–754); and

13 (2) in such updated reports—

14 (A) examine the inclusion of women, fe-
15 male animals, and female-derived cells and tis-
16 sues in federally funded research over the past
17 decade;

18 (B) examine how Federal agencies report
19 and analyze subgroup information and translate
20 any differences to the medical community and
21 patients;

22 (C) determine whether the quality of care
23 which women receive is being negatively im-
24 pacted by inclusion rates in basic and clinical
25 research; and

1 (D) address current efforts within National
2 Institutes of Health and other government
3 agencies to encourage the sharing of research
4 data on sex differences and evaluate mecha-
5 nisms to improve such sharing, including a pub-
6 licly accessible online system that will conform
7 with policies protecting commercial, proprietary,
8 or private information.

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