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114TH CONGRESS
1ST SESSION

H. R. 2101

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

APRIL 29, 2015

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Research for All Act of 2015''.

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

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and develop policies, as appropriate, to ensure that the design and size of clinical trials for products granted expedited approval pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) are sufficient to determine the safety and effectiveness of such products for men and women using subgroup analysis.

SEC. 3. EXPEDITED REVIEW OF DRUGS AND BIOLOGICAL PRODUCTS TO PROVIDE SAFER OR MORE EFFECTIVE TREATMENT FOR MALES OR FEMALES.

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

''(g) EXPEDITED REVIEW OF DRUGS AND BIOLOGICAL PRODUCTS TO PROVIDE SAFER OR MORE EFFECTIVE TREATMENT FOR MALES OR FEMALES.—

''(1) ELIGIBLE PRODUCT.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if the drug—

''(A) is intended—

''(i) to avoid serious adverse events; or

"(ii) to treat a serious or life-threatening disease or condition;

"(B) whether alone or in combination with one or more other drugs or biological products, is intended for safer or more effective treatment for men or women than a currently available product approved to treat the general population or the other sex; and

"(C) is supported by results of clinical trials that include and separately examine outcomes for both men and women.

"(2) DESIGNATION.—At the request of the sponsor of an eligible product described in paragraph (1), the Secretary shall designate the drug as an expedited product to provide safer or more effective treatment for males or females.

"(3) EARLY AND FREQUENT COMMUNICATION.—The Secretary shall, with respect to each expedited product designated under this subsection, provide early and frequent communication and review of incomplete applications to the same extent and in the same manner as is provided under subsections (b) and (d).

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

''(A) to lessen or otherwise alter the standard of safety and effectiveness required for the approval or licensing of drugs or biological products under section 505 of this Act or section 351 of the Public Health Service Act; or

''(B) to authorize application of the provisions of subsection (c) (relating to the use of surrogate endpoints) to expedited products designated under this subsection.''.

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

(1) in paragraph (1), by striking ''and and'' and inserting ''and''; and

(2) by moving such subsection (f) so that it follows subsection (e) of such section 506.

SEC. 4. RESEARCH ON SEX DIFFERENCES.

(a) INCLUSION IN NIH RESEARCH.—

(1) IN GENERAL.—Section 492B of the Public Health Service Act (42 U.S.C. 289a–2) is amended—

(A) by redesignating subsections (b) through (g) as subsections (c) through (h), respectively; and

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

''(b) INCLUSION OF SEX DIFFERENCES IN BASIC RESEARCH.—

''(1) APPLICABILITY TO BASIC RESEARCH.—

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

''(B) DEADLINE FOR INITIAL DETERMINATION; UPDATES.—The Director of NIH—

''(i) shall make the initial determinations required by subparagraph (A) not later than one year after the date of enactment of the Research for All Act of 2015; and

''(ii) may subsequently update or revise such determinations as the Director determines appropriate.

"(C) CONSULTATION.—In making the initial determinations required by subparagraph (A), the Director of NIH—

"(i) shall consult with the Office of Research on Women's Health, the Institute of Medicine, the Office of Laboratory Animal Welfare, and appropriate members of the scientific and academic communities; and

"(ii) may conduct outreach and educational initiatives within the scientific and academic communities on the influence of sex as a variable in basic research in order to develop a consensus within such communities on when it is appropriate for projects of basic research involving cells, tissues or animals to include both male and female cells, tissues, or animals.

"(2) INCLUSION.—Beginning on the date that is 1 year after the date of enactment of the Research for All Act of 2015, in conducting or supporting basic research in accordance with paragraph (1), the Director of NIH shall, subject to paragraph (3), ensure that—

''(A) in the case of research on cells or tissues—

''(i) cells or tissues, as applicable, are derived from both male and female organisms in each project of such research; and

''(ii) the results are disaggregated according to whether the cells or tissues are derived from male or female organisms; and

''(B) in the case of animal research—

''(i) both male and female animals are included as subjects in each project of such research; and

''(ii) the results are disaggregated according to whether the subjects are male or female.

''(3) EXCEPTION.—Paragraph (2) shall not apply to a project of basic research if the Director of NIH determines that the inclusion of cells or tissues derived from both male and female organisms, or the inclusion of both male and female animals as subjects, as applicable, is inappropriate in the case of such project.''.

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

(A) by striking ''(d)'' and all that follows through ''In the case'' and inserting the following:

''(d) DESIGN OF RESEARCH.—

''(1) CLINICAL TRIALS.—In the case''; and

(B) by adding at the end the following:

''(2) BASIC RESEARCH.—In the case of basic research in which cells or tissues derived from both male and female organisms will be included in accordance with subsection (b)(2)(A) or both male and female animals will be included as subjects in accordance with subsection (b)(2)(B), the Director of NIH shall ensure that sex differences are examined and analyzed, as appropriate.''.

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

''(1) DATE CERTAIN; UPDATE.—The guidelines required in subsection (e) regarding the requirements of this section for clinical and basic research shall—

''(A) be updated and published in the Federal Register not later than 1 year after the date of enactment of the Research for All Act of 2015;

''(B) reflect the growing understanding that sex differences matter;

''(C) ensure better enforcement of the requirements of this section by the personnel of the agencies of the National Institutes of Health responsible for reviewing grant proposals; and

''(D) include guidance on when research strongly supports or strongly negates the conclusion that there is a significant difference in how the variables being studied affect women or members of minority groups, as the case may be, relative to how such variables affect other subjects in the research.''.

(4) APPLICABILITY.—Section 492B(f)(2) of the Public Health Service Act (42 U.S.C. 289a–2), as redesignated, is amended by adding at the end the following: ''For fiscal year 2017 and subsequent fiscal years, the Director of NIH may not approve any proposal of basic research to be conducted or supported by any agency of the National Institutes of

Health unless the proposal specifies the manner in which the research will comply with this section.''.

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

(A) in the heading of subsection (a), by striking ''REQUIREMENT OF INCLUSION'' and inserting ''INCLUSION IN CLINICAL RESEARCH'';

(B) in subsection (a)(1), by striking ''subsection (b)'' and inserting ''subsection (c)'';

(C) in subsection (e)(1)(A), as redesignated, by striking ''subsection (b)'' and inserting ''subsection (c)'';

(D) in subsection (e)(1)(B), as redesignated, by striking ''subsection (c)'' and inserting ''subsection (d)''; and

(E) in subsection (e)(2), as redesignated, by striking ''subsection (b)'' and inserting ''subsection (c)''.

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

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

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

''(vi) Basic research, including a breakdown of the sex of organisms from which cells and tissues are derived, a breakdown of the sex of animal subjects, and such other information as may be necessary to demonstrate compliance with section 492B (regarding sex differences in basic research).''.

(c) SPECIAL CENTERS OF RESEARCH ON SEX DIFFERENCES.—Part H of title IV of the Public Health Service Act is amended by inserting after section 492B of such Act (42 U.S.C. 289a–2) the following:

''SEC. 492C. SPECIAL CENTERS OF RESEARCH ON SEX DIFFERENCES.

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

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

SEC. 5. GAO REPORTS.

Not later than 1 year after the date of enactment of the Research for All Act of 2015, the Comptroller General of the United States shall—

(1) submit to the Congress updated versions of the reports of the Government Accountability Office entitled ''Women's Health: NIH Has Increased Its Efforts To Include Women in Research'' (published in May 2000; GAO/HEHS–00–96) and ''Women's Health: Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement'' (published in July 2001; GAO–01–754); and

(2) in such updated reports—

(A) examine the inclusion of women, female animals, and female-derived cells and tissues in federally funded research over the past decade;

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

(C) determine whether the quality of care which women receive is being negatively impacted by inclusion rates in basic and clinical research; and

(D) address current efforts within National Institutes of Health and other government agencies to encourage the sharing of research data on sex differences and evaluate mechanisms to improve such sharing, including a publicly accessible online system that will conform with policies protecting commercial, proprietary, or private information.

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