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103D CONGRESS
1ST SESSION

H. R. 2695

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to require the inclusion of women and minorities in clinical investigations of new drugs, biological products, and medical devices.

IN THE HOUSE OF REPRESENTATIVES

JULY 21, 1993

Mrs. SCHROEDER (for herself and Ms. SNOWE) 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 and the Public Health Service Act to require the inclusion of women and minorities in clinical investigations of new drugs, biological products, and medical devices.

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 ''Pharmaceutical Testing Fairness Act''.

SEC. 2. NEW DRUG CLINICAL INVESTIGATIONS.

Section 505(b) of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

''(4)(A) Clinical investigations submitted as part of an application in accordance with paragraph (1)(A) shall include women and members of minority groups as subjects of such investigations unless the inclusion of women and minority groups is inappropriate with respect to the drug under investigation or is otherwise inappropriate under such guidelines as the Secretary shall by rule establish in accordance with subparagraph (B).

''(B) The guidelines of the Secretary respecting the inclusion of women and members of minority groups in clinical investigations—

''(i) shall provide that the costs of such inclusion is not a permissible consideration in determining whether such inclusion is inappropriate,

''(ii) shall provide that women or minority groups are not required to be included if women or minority groups will not be using the drug under investigation, and

''(iii) may provide that such inclusion is not required if there is substantial scientific data demonstrating that there is no significant difference between the effects that the variables to be studied in the investigation have on women or members of minority groups, respectively, and on the other individuals who would serve as subjects in the investigation

in the event that the inclusion of women and members of minority groups was not required.

''(C) Phase three clinical investigations which are submitted as part of an application in accordance with paragraph (1)(A) shall be designed so that there is a valid analysis of whether the drug under investigation affects women or members of minority groups differently than other users of the drug. If the Secretary determines that it would be appropriate for other phases of such investigations to be so designed, such other phases shall be so designed.''.

SEC. 3. DEVICE CLINICAL INVESTIGATIONS.

Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

''(3)(A) Clinical investigations submitted as part of an application in accordance with paragraph (1) shall include women and members of minority groups as subjects of such investigations unless the inclusion of women and minority groups is inappropriate with respect to the device under investigation or is otherwise inappropriate under such guidelines as the Secretary shall by rule establish in accordance with subparagraph (B).

''(B) The guidelines of the Secretary respecting the inclusion of women and members of minority groups in clinical investigations—

''(i) shall provide that the costs of such inclusion is not a permissible consideration in determining whether such inclusion is inappropriate,

''(ii) shall provide that women or minority groups are not required to be included if women or minority groups will not be using the device under investigation, and

''(iii) may provide that such inclusion is not required if there is substantial scientific data demonstrating that there is no significant difference between the effects that the variables to be studied in the investigation have on women or members of minority groups, respectively, and on the other individuals who would serve as subjects in the investigation in the event that the inclusion of women and members of minority groups was not required.

''(C)(i) Clinical investigations designated by the Secretary under clause (ii) which are submitted as part of an application in accordance with paragraph (1) shall be designed so that there is a valid analysis of whether the device under investigation affects women or members of minority groups differently than other users of the device.

''(ii) The Secretary shall designate which of the clinical investigations submitted as part of an application under paragraph (1) shall be subject to the requirement of clause (i).''.

SEC. 5. BIOLOGICAL PRODUCTS CLINICAL INVESTIGATIONS.

Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by adding at the end the following:

''(3)(A) Clinical investigations submitted as part of an application in accordance with paragraph (1) shall include women and members of minority groups as subjects of such investigations unless the inclusion of women and minority groups is inappropriate with respect to the biological product under investigation or is otherwise inappropriate under such guidelines as the Secretary shall by rule establish in accordance with subparagraph (B).

''(B) The guidelines of the Secretary respecting the inclusion of women and members of minority groups in clinical investigations—

''(i) shall provide that the costs of such inclusion is not a permissible consideration in determining whether such inclusion is inappropriate,

''(ii) shall provide that women or minority groups are not required to be included if women or

minority groups will not be using the biological product under investigation, and

''(iii) may provide that such inclusion is not required if there is substantial scientific data demonstrating that there is no significant difference between the effects that the variables to be studied in the investigation have on women or members of minority groups, respectively, and on the other individuals who would serve as subjects in the investigation in the event that the inclusion of women and members of minority groups was not required.

''(C)(i) Clinical investigations designated by the Secretary under clause (ii) which are submitted as part of an application in accordance with paragraph (1) shall be designed so that there is a valid analysis of whether the device under investigation affects women or members of minority groups differently than other users of the device.

''(ii) The Secretary shall designate which of the clinical investigations submitted as part of an application under paragraph (1) shall be subject to the requirement of clause (i).''.

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