

103^D 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

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.

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 “Pharmaceutical Test-
5 ing Fairness Act”.

6 **SEC. 2. NEW DRUG CLINICAL INVESTIGATIONS.**

7 Section 505(b) of the Federal Food, Drug, and Cos-
8 metic Act is amended by adding at the end the following:

1 “(4)(A) Clinical investigations submitted as part of
2 an application in accordance with paragraph (1)(A) shall
3 include women and members of minority groups as sub-
4 jects of such investigations unless the inclusion of women
5 and minority groups is inappropriate with respect to the
6 drug under investigation or is otherwise inappropriate
7 under such guidelines as the Secretary shall by rule estab-
8 lish in accordance with subparagraph (B).

9 “(B) The guidelines of the Secretary respecting the
10 inclusion of women and members of minority groups in
11 clinical investigations—

12 “(i) shall provide that the costs of such inclu-
13 sion is not a permissible consideration in determin-
14 ing whether such inclusion is inappropriate,

15 “(ii) shall provide that women or minority
16 groups are not required to be included if women or
17 minority groups will not be using the drug under in-
18 vestigation, and

19 “(iii) may provide that such inclusion is not re-
20 quired if there is substantial scientific data dem-
21 onstrating that there is no significant difference be-
22 tween the effects that the variables to be studied in
23 the investigation have on women or members of mi-
24 nority groups, respectively, and on the other individ-
25 uals who would serve as subjects in the investigation

1 in the event that the inclusion of women and mem-
2 bers of minority groups was not required.

3 “(C) Phase three clinical investigations which are
4 submitted as part of an application in accordance with
5 paragraph (1)(A) shall be designed so that there is a valid
6 analysis of whether the drug under investigation affects
7 women or members of minority groups differently than
8 other users of the drug. If the Secretary determines that
9 it would be appropriate for other phases of such investiga-
10 tions to be so designed, such other phases shall be so de-
11 signed.”.

12 **SEC. 3. DEVICE CLINICAL INVESTIGATIONS.**

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

16 “(3)(A) Clinical investigations submitted as part of
17 an application in accordance with paragraph (1) shall in-
18 clude women and members of minority groups as subjects
19 of such investigations unless the inclusion of women and
20 minority groups is inappropriate with respect to the device
21 under investigation or is otherwise inappropriate under
22 such guidelines as the Secretary shall by rule establish in
23 accordance with subparagraph (B).

1 “(B) The guidelines of the Secretary respecting the
2 inclusion of women and members of minority groups in
3 clinical investigations—

4 “(i) shall provide that the costs of such inclu-
5 sion is not a permissible consideration in determin-
6 ing whether such inclusion is inappropriate,

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

11 “(iii) may provide that such inclusion is not re-
12 quired if there is substantial scientific data dem-
13 onstrating that there is no significant difference be-
14 tween the effects that the variables to be studied in
15 the investigation have on women or members of mi-
16 nority groups, respectively, and on the other individ-
17 uals who would serve as subjects in the investigation
18 in the event that the inclusion of women and mem-
19 bers of minority groups was not required.

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

1 “(ii) The Secretary shall designate which of the clini-
2 cal investigations submitted as part of an application
3 under paragraph (1) shall be subject to the requirement
4 of clause (i).”.

5 **SEC. 5. BIOLOGICAL PRODUCTS CLINICAL INVESTIGA-**
6 **TIONS.**

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

10 “(3)(A) Clinical investigations submitted as part of
11 an application in accordance with paragraph (1) shall in-
12 clude women and members of minority groups as subjects
13 of such investigations unless the inclusion of women and
14 minority groups is inappropriate with respect to the bio-
15 logical product under investigation or is otherwise inap-
16 propriate under such guidelines as the Secretary shall by
17 rule establish in accordance with subparagraph (B).

18 “(B) The guidelines of the Secretary respecting the
19 inclusion of women and members of minority groups in
20 clinical investigations—

21 “(i) shall provide that the costs of such inclu-
22 sion is not a permissible consideration in determin-
23 ing whether such inclusion is inappropriate,

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

1 minority groups will not be using the biological prod-
2 uct under investigation, and

3 “(iii) may provide that such inclusion is not re-
4 quired if there is substantial scientific data dem-
5 onstrating that there is no significant difference be-
6 tween the effects that the variables to be studied in
7 the investigation have on women or members of mi-
8 nority groups, respectively, and on the other individ-
9 uals who would serve as subjects in the investigation
10 in the event that the inclusion of women and mem-
11 bers of minority groups was not required.

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

18 “(ii) The Secretary shall designate which of the clini-
19 cal investigations submitted as part of an application
20 under paragraph (1) shall be subject to the requirement
21 of clause (i).”.

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