

103^D CONGRESS
1ST SESSION

H. R. 2694

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to require special testing for drugs and biological products used by women.

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 special testing for drugs and biological products used by women.

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 Inter-
5 actions Safety Act”.

6 **SEC. 2. 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) Clinical investigations to be submitted as part
2 of an application in accordance with paragraph (1)(A)
3 shall include investigations of the possible interaction of
4 the drug with relevant female or male hormones or related
5 substances unless there is substantial evidence that there
6 are no significant interactions between the drug under in-
7 vestigation and such substances or the inclusion of such
8 investigations is otherwise inappropriate under guidelines
9 established by the Secretary by rule.”.

10 **SEC. 3. BIOLOGICAL PRODUCTS CLINICAL INVESTIGA-**
11 **TIONS.**

12 Section 351(c) of the Public Health Service Act (42
13 U.S.C. 262(c)) is amended by adding at the end the fol-
14 lowing:

15 “(3) Clinical investigations submitted as part of an
16 application for a biological product in accordance with
17 paragraph (1) shall include investigations of the possible
18 interaction of the biological product with relevant female
19 or male hormones or related substances unless there is
20 substantial evidence that there are no significant inter-
21 actions between the biological product under investigation
22 and such substances or the inclusion of such investigations
23 is otherwise inappropriate under guidelines established by
24 the Secretary by rule.”.

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