

107TH CONGRESS
1ST SESSION

H. R. 2783

To amend the Federal Food, Drug, and Cosmetic Act to provide for research on whether drugs approved under such Act for human use affect women differently than men, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2001

Mrs. MALONEY of New York 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 research on whether drugs approved under such Act for human use affect women differently than men, 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 “Women’s Health Drug

5 Studies Act”.

1 **SEC. 2. WOMEN'S-HEALTH STUDIES OF DRUGS.**

2 Chapter V of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 351 et seq.) is amended by inserting after
4 section 505A the following section:

5 **"SEC. 505B. WOMEN'S-HEALTH STUDIES OF DRUGS.**

6 "(a) IN GENERAL.—In the case of drugs for which
7 applications under section 505(b)(1) are pending, and in
8 the case of drugs for which applications under such section
9 have been approved, the Secretary may by order require
10 that the sponsors or holders of the applications involved
11 conduct or support research to obtain information on
12 whether the drugs affect females differently than males.

13 "(b) DESIGN OF STUDIES.—In providing for a study
14 of a drug under subsection (a), the Secretary shall require
15 that the study be designed and carried out in a manner
16 sufficient to provide for a valid analysis (through one or
17 more clinical investigations, as determined by the Sec-
18 retary) of whether the drug affects females differently
19 than males, taking into account biomedical and behavioral
20 factors.".

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