

103D CONGRESS  
1ST SESSION

# H. R. 695

To amend the Public Health Service Act to establish an Office of Research on Women's Health, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

JANUARY 27, 1993

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 Public Health Service Act to establish an Office of Research on Women's Health, 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 Re-  
5 search Act of 1993".

6 **SEC. 2. ESTABLISHMENT OF OFFICE OF RESEARCH ON**  
7 **WOMEN'S HEALTH.**

8 (a) IN GENERAL.—Title IV of the Public Health  
9 Service Act, as amended by section 2 of Public Law 101–  
10 613, is amended—

1           (1) by redesignating section 486 as section  
2           485A;

3           (2) by redesignating parts F through H as  
4           parts G through I, respectively; and

5           (3) by inserting after part E the following new  
6           part:

7           “PART F—RESEARCH ON WOMEN’S HEALTH

8           **“SEC. 486. OFFICE OF RESEARCH ON WOMEN’S HEALTH.**

9           “(a) ESTABLISHMENT.—There is established within  
10          the Office of the Director of NIH an office to be known  
11          as the Office of Research on Women’s Health (in this part  
12          referred to as the ‘Office’). The Office shall be headed by  
13          a director, who shall be appointed by the Director of NIH.

14          “(b) PURPOSE.—The Director of the Office shall—

15                 “(1) identify projects of research on women’s  
16                 health that should be conducted or supported by the  
17                 national research institutes;

18                 “(2) identify multidisciplinary research relating  
19                 to research on women’s health that should be so con-  
20                 ducted or supported;

21                 “(3) carry out paragraphs (1) and (2) with re-  
22                 spect to the aging process in women, with priority  
23                 given to menopause;

1           “(4) promote coordination and collaboration  
2 among entities conducting research identified under  
3 any of paragraphs (1) through (3);

4           “(5) encourage the conduct of such research by  
5 entities receiving funds from the national research  
6 institutes;

7           “(6) recommend an agenda for conducting and  
8 supporting such research;

9           “(7) promote the sufficient allocation of the re-  
10 sources of the national research institutes for con-  
11 ducting and supporting such research;

12           “(8) ensure that women are appropriately rep-  
13 resented as subjects in projects of clinical research  
14 conducted or supported by the national research in-  
15 stitutes; and

16           “(9) prepare the report required in section  
17 486B.

18           “(c) COORDINATING COMMITTEE.—

19           “(1) In carrying out subsection (b), the Direc-  
20 tor of the Office shall establish a committee to be  
21 known as the Coordinating Committee on Research  
22 on Women’s Health (hereafter in this subsection re-  
23 ferred to as the ‘Coordinating Committee’).

1           “(2) The Coordinating Committee shall be com-  
2           posed of the Directors of the national research insti-  
3           tutes (or the designees of the Directors).

4           “(3) The Director of the Office shall serve as  
5           the chair of the Coordinating Committee.

6           “(4) With respect to research on women’s  
7           health, the Coordinating Committee shall assist the  
8           Director of the Office in—

9                   “(A) identifying the need for such re-  
10                  search, and making an estimate each fiscal year  
11                  of the funds needed to adequately support the  
12                  research;

13                  “(B) identifying needs regarding the co-  
14                  ordination of research activities, including in-  
15                  tramural and extramural multidisciplinary ac-  
16                  tivities;

17                  “(C) supporting the development of meth-  
18                  odologies to determine the circumstances in  
19                  which obtaining data specific to women (includ-  
20                  ing data relating to the age of women and the  
21                  membership of women in ethnic or racial  
22                  groups) is an appropriate function of clinical  
23                  trials of treatments and therapies;

24                  “(D) supporting the development and ex-  
25                  pansion of clinical trials of treatments and

1 therapies for which obtaining such data has  
2 been determined to be an appropriate function;  
3 and

4 “(E) encouraging the national research in-  
5 stitutes to conduct and support such research,  
6 including such clinical trials.

7 “(d) ADVISORY COMMITTEE.—

8 “(1) In carrying out subsection (b), the Direc-  
9 tor of the Office shall establish an advisory commit-  
10 tee to be known as the Advisory Committee on Re-  
11 search on Women’s Health (hereafter in this sub-  
12 section referred to as the ‘Advisory Committee’).

13 “(2) The Advisory Committee shall be com-  
14 posed of no fewer than 12, and not more than 18  
15 individuals, who are not officers or employees of the  
16 Federal Government. The Director of the Office  
17 shall make appointments to the Advisory Committee  
18 from among physicians, practitioners, scientists, and  
19 other health professionals, whose clinical practice,  
20 research specialization, or professional expertise in-  
21 cludes a significant focus on research on women’s  
22 health. A majority of the members of the Advisory  
23 Committee shall be women.

24 “(3) The Director of the Office shall serve as  
25 the chair of the Advisory Committee.

1 “(4) The Advisory Committee shall—

2 “(A) advise the Director of the Office on  
3 appropriate research activities to be undertaken  
4 by the national research institutes with respect  
5 to—

6 “(i) research on women’s health;

7 “(ii) research on gender differences in  
8 clinical drug trials, including responses to  
9 pharmacological drugs;

10 “(iii) research on gender differences  
11 in disease etiology, course, and treatment;

12 “(iv) research on obstetrical and gyne-  
13 cological health conditions, diseases, and  
14 treatments; and

15 “(v) research on women’s health con-  
16 ditions which require a multidisciplinary  
17 approach;

18 “(B) report to the Director of the Office  
19 on such research;

20 “(C) provide recommendations to such Di-  
21 rector regarding activities of the Office (includ-  
22 ing recommendations on the development of the  
23 methodologies described in subsection (c)(4)(C)  
24 and recommendations on priorities in carrying

1 out research described in subparagraph (A));  
2 and

3 “(D) assist in monitoring compliance with  
4 section 486(b)(8) regarding the inclusion of  
5 women in clinical research.

6 “(5)(A) The Advisory Committee shall prepare  
7 a biennial report describing the activities of the  
8 Committee, including findings made by the Commit-  
9 tee regarding—

10 “(i) compliance with section 486(b)(8);

11 “(ii) the extent of expenditures made for  
12 research on women’s health by the agencies of  
13 the National Institutes of Health; and

14 “(iii) the level of funding needed for such  
15 research.

16 “(B) The report required in subparagraph (A)  
17 shall be submitted to the Director of NIH for inclu-  
18 sion in the report required in section 403.

19 “(e) REPRESENTATION OF WOMEN AMONG RE-  
20 SEARCHERS.—The Secretary, acting through the Assist-  
21 ant Secretary for Personnel and in collaboration with the  
22 Director of the Office, shall determine the extent to which  
23 women are represented among senior physicians and sci-  
24 entists of the national research institutes and among phy-  
25 sicians and scientists conducting research with funds pro-

1 vided by such institutes, and as appropriate, carry out ac-  
2 tivities to increase the extent of such representation.

3 “(f) DEFINITIONS.—For purposes of this part:

4 “(1) The term ‘women’s health conditions’, with  
5 respect to women of all age, ethnic, and racial  
6 groups, means all diseases, disorders, and conditions  
7 (including with respect to mental health)—

8 “(A) unique to, more serious, or more  
9 prevalent in women;

10 “(B) for which the factors of medical risk  
11 or types of medical intervention are different  
12 for women, or for which it is unknown whether  
13 such factors or types are different for women;  
14 or

15 “(C) with respect to which there has been  
16 insufficient clinical research involving women as  
17 subjects or insufficient clinical data on women.

18 “(2) The term ‘research on women’s health’  
19 means research on women’s health conditions, in-  
20 cluding research on preventing such conditions.

21 **“SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE**  
22 **ON RESEARCH ON WOMEN’S HEALTH.**

23 “(a) DATA SYSTEM.—

24 “(1) The Director of NIH, in consultation with  
25 the Director of the Office, shall establish a data sys-

1       tem for the collection, storage, analysis, retrieval,  
2       and dissemination of information regarding research  
3       on women’s health that is conducted or supported by  
4       the national research institutes. Information from  
5       the data system shall be available through informa-  
6       tion systems available to health care professionals  
7       and providers, researchers, and members of the  
8       public.

9           “(2) The data system established under para-  
10       graph (1) shall include a registry of clinical trials of  
11       experimental treatments that have been developed  
12       for research on women’s health. Such registry shall  
13       include information on subject eligibility criteria,  
14       sex, age, ethnicity or race, and the location of the  
15       trial site or sites. Principal investigators of such  
16       clinical trials shall provide this information to the  
17       registry within 30 days after it is available. Once a  
18       trial has been completed, the principal investigator  
19       shall provide the registry with information pertain-  
20       ing to the results, including potential toxicities or  
21       adverse effects associated with the experimental  
22       treatment or treatments evaluated.

23       “(b) CLEARINGHOUSE.—The Director of NIH, in  
24       consultation with the Director of the Office and with the  
25       National Library of Medicine, shall establish, maintain,

1 and operate a program to provide information on research  
2 and prevention activities of the national research institutes  
3 that relate to research on women's health.

4 **“SEC. 486B. BIENNIAL REPORT.**

5 “(a) IN GENERAL.—With respect to research on  
6 women's health, the Director of the Office shall, not later  
7 than February 1, 1994, and biennially thereafter, prepare  
8 a report—

9 “(1) describing and evaluating the progress  
10 made during the preceding 2 fiscal years in research  
11 and treatment conducted or supported by the Na-  
12 tional Institutes of Health;

13 “(2) describing and analyzing the professional  
14 status of women physicians and scientists of such  
15 Institutes, including the identification of problems  
16 and barriers regarding advancements;

17 “(3) summarizing and analyzing expenditures  
18 made by the agencies of such Institutes (and by  
19 such Office) during the preceding 2 fiscal years; and

20 “(4) making such recommendations for legisla-  
21 tive and administrative initiatives as the Director of  
22 the Office determines to be appropriate.

23 “(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR  
24 OF NIH.—The Director of the Office shall submit each  
25 report prepared under subsection (a) to the Director of

1 NIH for inclusion in the report submitted to the President  
2 and the Congress under section 403.

3 **“SEC. 486C. AUTHORIZATION OF APPROPRIATIONS.**

4 “For the purpose of carrying out this part, there are  
5 authorized to be appropriated \$25,000,000 for fiscal year  
6 1994, and such sums as may be necessary for each of the  
7 fiscal years 1995 and 1996.”.

8 (b) REQUIREMENT OF SUFFICIENT ALLOCATION OF  
9 RESOURCES OF INSTITUTES.—Section 402(b) of the Pub-  
10 lic Health Service Act (42 U.S.C. 282(b)) is amended—

11 (1) in paragraph (10), by striking “and” after  
12 the semicolon at the end;

13 (2) in paragraph (11), by striking the period at  
14 the end and inserting “; and”; and

15 (3) by inserting after paragraph (11) the fol-  
16 lowing new paragraph:

17 “(12) after consultation with the Director of  
18 the Office of Research on Women’s Health, shall en-  
19 sure that resources of the National Institutes of  
20 Health are sufficiently allocated for projects of re-  
21 search on women’s health that are identified under  
22 section 486(b).”.

1 **SEC. 3. OBSTETRICS AND GYNECOLOGY PROGRAM OF NA-**  
2 **TIONAL INSTITUTE OF CHILD HEALTH AND**  
3 **HUMAN DEVELOPMENT.**

4 Subpart 7 of part C of title IV of the Public Health  
5 Service Act (42 U.S.C. 285g et seq.) is amended by adding  
6 at the end the following section:

7 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

8 “SEC. 452A. The Director of the Institute shall es-  
9 tablish and maintain within the Institute an intramural  
10 laboratory and clinical research program in obstetrics and  
11 gynecology.”.

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