

108TH CONGRESS  
1ST SESSION

# S. 1588

To authorize the National Institute of Environmental Health Sciences to develop multidisciplinary research centers regarding women's health and disease prevention and conduct and coordinate a research program on hormone disruption, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER 5, 2003

Ms. LANDRIEU introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To authorize the National Institute of Environmental Health Sciences to develop multidisciplinary research centers regarding women's health and disease prevention and conduct and coordinate a research program on hormone disruption, 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 "Environmental Health  
5       Research Act of 2003".

1 **SEC. 2. NATIONAL INSTITUTE OF ENVIRONMENTAL**  
2 **HEALTH SCIENCES; AWARDS FOR DEVELOP-**  
3 **MENT AND OPERATION OF MULTIDISCI-**  
4 **PLINARY RESEARCH CENTERS REGARDING**  
5 **WOMEN'S HEALTH AND DISEASE PREVEN-**  
6 **TION.**

7 Subpart 12 of part C of title IV of the Public Health  
8 Service Act (42 U.S.C. 2851 et seq.) is amended by adding  
9 at the end the following section:

10 “MULTIDISCIPLINARY RESEARCH CENTERS REGARDING  
11 WOMEN'S HEALTH AND DISEASE PREVENTION

12 “SEC. 463B. (a) IN GENERAL.—The Director of the  
13 Institute shall make grants to public or nonprofit private  
14 entities for the development and operation of not more  
15 than 6 centers whose purpose is conducting multidisci-  
16 plinary research on environmental factors that may be re-  
17 lated to the development of women's health conditions (as  
18 defined in section 486). The Director of the Institute shall  
19 carry out this section in consultation with the Director of  
20 the Office of Research on Women's Health and with the  
21 advisory council for the Institute.

22 “(b) RESEARCH, TRAINING, AND INFORMATION AND  
23 EDUCATION.—

24 “(1) IN GENERAL.—Each center under sub-  
25 section (a) shall, with respect to the purpose de-  
26 scribed in such subsection—

1           “(A) conduct basic and clinical research;

2           “(B) develop protocols for training physi-  
3 cians, scientists, nurses, and other health and  
4 allied health professionals;

5           “(C) conduct training programs for such  
6 individuals;

7           “(D) develop model continuing education  
8 programs for such professionals; and

9           “(E) disseminate information to such pro-  
10 fessionals and the public.

11           “(2) PRIORITY FOR PREVENTION ACTIVITIES.—

12           In carrying out the activities described in paragraph  
13 (1), each center under subsection (a) shall give pri-  
14 ority to activities that are directed toward pre-  
15 venting the development in women of the diseases  
16 and conditions involved.

17           “(3) STIPENDS FOR TRAINING OF HEALTH PRO-  
18 FESSIONALS.—A center under subsection (a) may  
19 use funds under such subsection to provide stipends  
20 for health and allied health professionals enrolled in  
21 programs described in paragraph (1)(C).

22           “(c) COLLABORATION WITH COMMUNITY.—Each  
23 center under subsection (a) shall establish and maintain  
24 ongoing collaborations with community organizations in  
25 the geographic area served by the center, including those

1 that represent women with disorders that appear to stem  
2 from environmental factors.

3 “(d) COORDINATION OF CENTERS; REPORTS.—The  
4 Director of the Institute shall, as appropriate, provide for  
5 the coordination of information among centers under sub-  
6 section (a) and ensure regular communication between  
7 such centers.

8 “(e) STRUCTURE OF CENTER.—Each center assisted  
9 under subsection (a) shall use the facilities of a single in-  
10 stitution, or be formed from a consortium of cooperating  
11 institutions, meeting such requirements as may be pre-  
12 scribed by the Director of the Institute.

13 “(f) DURATION OF SUPPORT.—Support of a center  
14 under subsection (a) may be for a period not exceeding  
15 5 years. Such period may be extended for 1 or more addi-  
16 tional periods not exceeding 5 years if the operations of  
17 such center have been reviewed by an appropriate tech-  
18 nical and scientific peer review group established by the  
19 Director of the Institute and if such group has rec-  
20 ommended to the Director that such period should be ex-  
21 tended.

22 “(g) AUTHORIZATION OF APPROPRIATIONS.—For the  
23 purpose of carrying out this section, there are authorized  
24 to be appropriated such sums as may be necessary for fis-  
25 cal years 2004 through 2007.”.

1 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT**  
2 **TO PROVIDE FOR RESEARCH ON HORMONE**  
3 **DISRUPTION.**

4 (a) FINDINGS.—The Congress finds as follows:

5 (1) Many compounds found or introduced into  
6 the environment by human activity are capable of  
7 disrupting the hormone system of humans and ani-  
8 mals. The consequences of such disruption can be  
9 profound because of the crucial role hormones play  
10 in controlling development. No standardized and  
11 validated screens or tests have been developed to  
12 routinely and systematically assess chemicals for dis-  
13 ruptive effects on hormone systems.

14 (2) In the last 30 years, the United States has  
15 experienced an increase in the incidence of such  
16 human disorders as childhood cancers, testicular  
17 cancer, hypospadias, juvenile diabetes, attention def-  
18 icit-like hyperactivity disorders, autism, thyroid dis-  
19 orders, and auto-immune disorders. Exposure to  
20 hormone-disrupting chemicals may be contributing  
21 to these increases. The impact on children's health  
22 as a result of prenatal exposures in particular needs  
23 further research.

24 (3) In 2001, the Centers for Disease Control  
25 and Prevention's "National Report on Human Expo-  
26 sure to Environmental Chemicals" reported on

1 human exposure to 27 chemicals, and found unex-  
2 pectedly high levels of certain chemicals used in con-  
3 sumer products. The hazards to humans of these  
4 chemicals, singly and in combination, are not well  
5 understood.

6 (4) Many wildlife populations have been af-  
7 fected by hormone-disrupting substances, including  
8 birds, fish, reptiles, and mammals. The effects vary  
9 among species and compounds.

10 (5) The effects in wildlife include thyroid dys-  
11 function, decreased fertility, decreased hatching suc-  
12 cess, gross birth deformities, metabolic and behav-  
13 ioral abnormalities, demasculinization and feminiza-  
14 tion of male organisms, deformation and  
15 masculinization of female organisms, and com-  
16 promised immune systems. These effects may signal  
17 hazards to human health.

18 (6) Laboratory studies have corroborated stud-  
19 ies of effects in wildlife and have identified biological  
20 mechanisms to explain the effects shown.

21 (7) Since the chemicals found in wildlife are  
22 also found in humans, humans are exposed to the  
23 same chemicals as wildlife.

24 (8) Hormone disruption can occur at very low  
25 doses, especially when exposure occurs in the womb

1 or immediately after birth, periods during which  
2 rapid development is occurring.

3 (9) In the Food Quality Protection Act of 1996  
4 (21 U.S.C. 301 note), Congress recognized the spe-  
5 cial vulnerability of infants and children to pesticides  
6 and requested that the Environmental Protection  
7 Agency establish a program to screen and test hor-  
8 mone-disrupting chemicals. The Environmental Pro-  
9 tection Agency has not yet required such screening  
10 or tests.

11 (10) In 1998, a research committee on hormone  
12 disrupters, organized under the auspices of the Of-  
13 fice of Science and Technology Policy, concluded  
14 that “scientific knowledge is inadequate to fully in-  
15 form public policy, and a government-wide coordi-  
16 nated research effort that addresses the key sci-  
17 entific uncertainties . . . is needed”.

18 (11) In 1999, in response to a request from  
19 Congress and funded through the Environmental  
20 Protection Agency and the Department of the Inte-  
21 rior, the National Academy of Sciences compiled a  
22 lengthy list of research, monitoring, and testing pri-  
23 orities related to hormone disruption.

24 (12) The National Institute of Environmental  
25 Health Sciences conducts much of the Federal Gov-

1       ernment’s research on hormone disruption, often  
2       working in partnership with other agencies.

3               (13) While recognizing the many contributions  
4       of animal testing to understanding toxic hazards, the  
5       Congress also recognizes the desirability of speeding  
6       the use of validated nonanimal screens and tests (to  
7       reduce animal suffering and to reduce costs) and ex-  
8       pediting judgments about hazards from toxic chemi-  
9       cals.

10              (14) The United States Geological Survey (re-  
11       ferred to in this section as the “USGS”) has consid-  
12       erable experience assessing the occurrence of chemi-  
13       cals in the environment, ecological health, and the  
14       hazards to wildlife health and associated human  
15       health posed by chemicals in the environment, as a  
16       result of monitoring by the USGS of the Nation’s  
17       water resources and wildlife disease, and research by  
18       the USGS on the effects of chemicals on wildlife.

19              (15) The National Academy of Sciences has  
20       recognized the expertise of the USGS in such areas  
21       as food web contamination and water quality assess-  
22       ment and has encouraged more coordinated work on  
23       human health between the USGS and the National  
24       Institutes of Health.

1 (b) AMENDMENT.—Subpart 12 of part C of title IV  
2 of the Public Health Service Act (42 U.S.C. 2851 et seq.),  
3 as amended by section 2, is further amended by adding  
4 at the end the following:

5 “DIRECTED NATIONAL PROGRAM OF RESEARCH ON  
6 HORMONE DISRUPTION

7 “SEC. 463C. (a) RESEARCH.—

8 “(1) IN GENERAL.—The Director of the Insti-  
9 tute shall establish within the Institute a comprehen-  
10 sive program to—

11 “(A) conduct research on the impact of  
12 chemicals that affect human health through dis-  
13 ruption of the hormone systems;

14 “(B) conduct research on the occurrence of  
15 hormone-disrupting chemicals in the environ-  
16 ment and their effects on ecological and wildlife  
17 health, in cooperation with the United States  
18 Geological Survey (referred to in this section as  
19 the ‘USGS’);

20 “(C) coordinate the design of a multi-  
21 agency research initiative on hormone disrup-  
22 tion;

23 “(D) coordinate research on hormone dis-  
24 ruption in the United States with such research  
25 conducted in other nations; and

1           “(E) report to the public every 2 years on  
2           the extent to which hormone disruption by  
3           chemicals in the environment poses a threat to  
4           human health and the environment.

5           “(2) ISSUES.—The program established under  
6           paragraph (1) shall provide for the following:

7           “(A) Collection, compilation, publication,  
8           and dissemination of scientifically valid infor-  
9           mation on—

10           “(i) possible human health effects of  
11           hormone-disrupting chemicals, with empha-  
12           sis on exposures to low doses of individual  
13           chemicals and chemical mixtures during  
14           critical life stages of development, particu-  
15           larly effects of prenatal exposures on chil-  
16           dren’s health;

17           “(ii) the extent of human exposure to  
18           hormone-disrupting chemicals, with par-  
19           ticular emphasis on exposures during crit-  
20           ical life stages of development and in resi-  
21           dential and occupational settings; and

22           “(iii) exposure of wildlife species to  
23           hormone-disrupting chemicals and possible  
24           health effects associated with such expo-  
25           sures.

1           “(B) Research on mechanisms by which  
2 hormone-disrupting substances interact with bi-  
3 ological systems.

4           “(C) Research on improved in vitro and in  
5 vivo methods to screen and test hormone dis-  
6 ruption.

7           “(D) Research on the identity, levels,  
8 transport, and fate of hormone-disrupting  
9 chemicals in the environment.

10       “(b) DIRECTOR’S DUTIES.—

11           “(1) IN GENERAL.—The Director of the Insti-  
12 tute shall have principal responsibility, in consulta-  
13 tion with the Director of the USGS, for conducting  
14 and coordinating research on the effects of hormone-  
15 disrupting chemicals on human health and the envi-  
16 ronment.

17           “(2) AGREEMENT.—Not later than 6 months  
18 after the date of enactment of the Environmental  
19 Health Research Act of 2003, the Director of the  
20 Institute and the Director of the USGS shall enter  
21 into an agreement to carry out the research program  
22 established under subsection (a).

23           “(3) TRANSFER OF FUNDS.—The Director of  
24 the Institute may transfer funds to other Federal

1 agencies to carry out the Director’s responsibilities  
2 under paragraph (1).

3 “(4) REPORT.—The Director of the Institute,  
4 in consultation with the Director of the USGS, shall  
5 make available to the public, every 2 years following  
6 the date of enactment of the Environmental Health  
7 Research Act of 2003, findings and conclusions on  
8 the extent to which hormone disruption by chemicals  
9 in the environment poses a threat to human health  
10 and the environment.

11 “(c) INTERAGENCY COMMISSION.—

12 “(1) ESTABLISHMENT.—The Secretary shall es-  
13 tablish a commission to be known as the Hormone  
14 Disruption Research Interagency Commission (re-  
15 ferred to in this section as the ‘Interagency Commis-  
16 sion’) to advise the Director of the Institute and the  
17 Director of the USGS on the development of a com-  
18 prehensive agenda for conducting research on hor-  
19 mone disruption.

20 “(2) MEMBERSHIP.—The Interagency Commis-  
21 sion shall be composed of 12 members, as follows:

22 “(A) The Director of the Institute, who  
23 shall serve as the Chairperson.

24 “(B) The Director of the USGS, who shall  
25 serve as the Vice Chairperson.

1           “(C) The Commissioner of the Food and  
2 Drug Administration.

3           “(D) The Director of the Centers for Dis-  
4 ease Control and Prevention.

5           “(E) The Administrator of the National  
6 Oceanic and Atmospheric Administration.

7           “(F) The Director of the National Insti-  
8 tute for Occupational Safety and Health.

9           “(G) The Administrator of the Agency for  
10 Toxic Substances and Disease Registry.

11           “(H) The Director of the Fish and Wildlife  
12 Service.

13           “(I) The Secretary of Defense.

14           “(J) The Administrator of the Environ-  
15 mental Protection Agency.

16           “(K) The Chairman of the Consumer  
17 Product Safety Commission.

18           “(L) The Director of the National Science  
19 Foundation.

20           “(3) STAFF.—Each department or agency rep-  
21 resented by a member on the Interagency Commis-  
22 sion shall provide appropriate staff to carry out the  
23 duties of the Interagency Commission.

24           “(4) RECOMMENDATIONS.—Not later than 12  
25 months after the date of enactment of the Environ-

1 mental Health Research Act of 2003, the Inter-  
2 agency Commission shall recommend to the Director  
3 of the Institute and the Director of the USGS a re-  
4 search program, including levels of funding for in-  
5 tramural and extramural research.

6 “(5) PUBLIC COMMENT.—The Director of the  
7 Institute, through publication of notice in the Fed-  
8 eral Register, shall provide the general public with  
9 an opportunity to comment on the recommendations  
10 of the Interagency Commission.

11 “(6) REPORT.—Not later than 4 years after the  
12 date of enactment of the Environmental Health Re-  
13 search Act of 2003, the Interagency Commission  
14 shall conduct a review of the program established  
15 under subsection (a) and submit a report on the re-  
16 sults of such review to the Director of the Institute  
17 and to the Hormone Disruption Research Panel es-  
18 tablished under subsection (e).

19 “(7) TERMINATION.—The Interagency Commis-  
20 sion shall terminate not later than the end of the 5-  
21 year fiscal period described in subsection (h)(1).

22 “(d) FINANCIAL ASSISTANCE.—The Director of the  
23 Institute may provide financial assistance and enter into  
24 grants, contracts, and interagency memoranda of under-  
25 standing to conduct activities under this section. Research

1 conducted pursuant to interagency memoranda of under-  
2 standing may be conducted through intramural and extra-  
3 mural agency research programs, subject to appropriate  
4 scientific peer review.

5 “(e) HORMONE DISRUPTION RESEARCH PANEL.—

6 “(1) ESTABLISHMENT.—There is established in  
7 the Institute a Hormone Disruption Research Panel  
8 (referred to in this subsection as the ‘Panel’).

9 “(2) DUTIES.—The Panel shall advise the Di-  
10 rector of the Institute concerning the scientific con-  
11 tent of the program established under subsection  
12 (a), the progress of such program, and public out-  
13 reach, and shall provide such other advice as re-  
14 quested by the Director of the Institute.

15 “(3) MEMBERSHIP.—The Panel shall be com-  
16 posed of the following:

17 “(A) 15 voting members to be appointed  
18 by the President, in consultation with the Di-  
19 rector of the Institute.

20 “(B) Such nonvoting, ex officio members  
21 as the Director of the Institute determines to  
22 be appropriate.

23 “(4) VOTING MEMBERS.—Of the 15 voting  
24 members of the Panel—

1           “(A) at least 2 members shall be from en-  
2           vironmental protection organizations;

3           “(B) at least 2 members shall be from  
4           public health and consumer organizations;

5           “(C) at least 2 members shall be from in-  
6           dustry;

7           “(D) at least 1 member shall be from an  
8           animal welfare organization; and

9           “(E) a majority of the members shall be  
10          selected from among scientists and environ-  
11          mental health professionals who—

12                 “(i) are not officers or employees of  
13                 the United States;

14                 “(ii) represent multiple disciplines, in-  
15                 cluding clinical, basic, public, and ecologi-  
16                 cal health sciences;

17                 “(iii) represent different geographical  
18                 regions of the United States;

19                 “(iv) are from practice settings, aca-  
20                 demic settings, and for-profit or not-for-  
21                 profit research settings; and

22                 “(v) have experience in review of re-  
23                 search on endocrine disruption.

24           “(5) TERMS.—The members of the Panel shall  
25          be appointed for an initial term of 3 years and shall

1 be eligible for reappointment for 1 additional term  
2 of 2 years.

3 “(6) CHAIRPERSON.—The members of the  
4 Panel appointed under paragraph (3) shall elect a  
5 chairperson from among such members.

6 “(7) MEETINGS.—The Panel shall meet at the  
7 call of the chairperson or upon the request of the  
8 Director of the Institute, but in no case less often  
9 than once each year.

10 “(8) ADMINISTRATIVE SUPPORT.—The Institute  
11 shall provide administrative support to the Panel.

12 “(9) TERMINATION.—The Panel shall terminate  
13 not later than the end of the 5-year fiscal period de-  
14 scribed in subsection (h)(1).

15 “(f) CONFLICTS OF INTEREST.—All grants and con-  
16 tracts entered into under this section shall include conflict-  
17 of-interest provisions that require any person conducting  
18 a project under this section to disclose any other source  
19 of funding received by the person to conduct other related  
20 projects.

21 “(g) DEFINITIONS.—For purposes of this section:

22 “(1) HORMONE.—The term ‘hormone’ means a  
23 substance produced in a cell or tissue that triggers  
24 a biological response. Hormone activity may be local-

1        ized to the cell in which the substance is produced,  
2        or may be in nearby or distant tissues or organs.

3            “(2) HORMONE DISRUPTION.—The term ‘hor-  
4        mone disruption’ means interference by a substance  
5        with the synthesis, secretion, transport, binding, ac-  
6        tion, or elimination of natural hormones in the body  
7        that are responsible for the maintenance of homeo-  
8        stasis, reproduction, development, function, or be-  
9        havior.

10        “(h) AUTHORIZATION OF APPROPRIATIONS.—

11            “(1) GENERAL AUTHORIZATION.—There are  
12        authorized to be appropriated such sums as may be  
13        necessary for the 5-fiscal-year period beginning with  
14        fiscal year 2004 to carry out this section. Amounts  
15        appropriated pursuant to this paragraph shall re-  
16        main available until expended.

17            “(2) RESTRICTIONS ON USE OF FUNDS.—

18            “(A) CONSTRUCTION AND REHABILITA-  
19        TION OF FACILITIES AND EQUIPMENT.—Not  
20        more than 0.5 percent of the funds made avail-  
21        able under this section may be used for the con-  
22        struction or rehabilitation of facilities or fixed  
23        equipment.

24            “(B) ADMINISTRATIVE EXPENSES OF THE  
25        DIRECTOR.—Of the total amount of funds made

1 available under this section for any fiscal year,  
2 not more than 2 percent of such funds may be  
3 used for administrative expenses of the Director  
4 of the Institute in carrying out this section.

5 “(C) PUBLIC OUTREACH.—Of the total  
6 amount of funds made available under this sec-  
7 tion for any fiscal year, at least 1 percent, but  
8 not more than 5 percent, shall be used for out-  
9 reach to the public concerning the activities and  
10 results of the program.”.

○