

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4709

To amend the Public Health Services Act to authorize the Director of the National Institute of Environmental Health Sciences to conduct and coordinate a research program on hormone disruption.

---

## IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2002

Ms. SLAUGHTER introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Resources, and Science, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

## A BILL

To amend the Public Health Services Act to authorize the Director of the National Institute of Environmental Health Sciences to conduct and coordinate a research program on hormone disruption.

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 “Hormone Disruption  
5 Research Act of 2002”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

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

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

20           (3) In 2001, the Centers for Disease Control  
21 and Prevention's "National Report on Human Expo-  
22 sure to Environmental Chemicals" reported on  
23 human exposure to 27 chemicals, and found unex-  
24 pectedly high levels of certain chemicals used in con-  
25 sumer products. The hazards to humans of these

1 chemicals, singly and in combination, are not well  
2 understood.

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

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

15 (6) Laboratory studies have corroborated stud-  
16 ies of effects in wildlife and have identified biological  
17 mechanisms to explain the effects shown.

18 (7) Since the chemicals found in wildlife are  
19 also found in humans, humans are exposed to the  
20 same chemicals as wildlife.

21 (8) Hormone disruption can occur at very low  
22 doses, especially when exposure occurs in the womb  
23 or immediately after birth, periods during which  
24 rapid development is occurring.

1           (9) In the Food Quality Protection Act of 1996  
2           (21 U.S.C. 301 note), Congress recognized the spe-  
3           cial vulnerability of infants and children to pesticides  
4           and requested that the Environmental Protection  
5           Agency establish a program to screen and test hor-  
6           mone disrupting chemicals. The Environmental Pro-  
7           tection Agency has not yet required such screening  
8           or tests.

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

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

22          (12) The National Institute of Environmental  
23          Health Sciences conducts much of the Federal Gov-  
24          ernment’s research on hormone disruption, often  
25          working in partnership with other agencies.

1           (13) Congress fully supports critical research  
2           being performed by the National Institute of Envi-  
3           ronmental Health Sciences on methods to reduce, re-  
4           fine, or replace animal tests in scientific and medical  
5           studies.

6           (14) Congress strongly supports protection of  
7           animal subjects and encourages all scientists to use  
8           alternatives to animal testing to the maximum ex-  
9           tent possible.

10          (15) 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          (16) 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 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICES**  
2 **ACT TO PROVIDE FOR RESEARCH ON HOR-**  
3 **MONE DISRUPTION.**

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

7 “DIRECTED NATIONAL PROGRAM OF RESEARCH ON  
8 HORMONE DISRUPTION

9 “SEC. 463B. (a) STUDY.—

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

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

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

22 “(C) coordinate the design of a multi-agen-  
23 cy research initiative on hormone disruption;

24 “(D) coordinate research on hormone dis-  
25 ruption in the United States with such research  
26 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 TO BE STUDIED.—The program,  
6           established under paragraph (1) shall provide for the  
7           following:

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

11                           “(i) possible human health effects of  
12                           hormone disrupting chemicals, with em-  
13                           phasis on exposures to low doses of indi-  
14                           vidual chemicals and chemical mixtures  
15                           during critical life stages of development,  
16                           particularly effects of prenatal exposures  
17                           on children’s health;

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

23                           “(iii) exposure of wildlife species to  
24                           hormone disrupting chemicals and possible

1 health effects associated with such expo-  
2 sures.

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

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

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

12 “(b) DIRECTOR’S DUTIES.—

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

19 “(2) AGREEMENT.—Not later than 6 months  
20 after the date of enactment of the Hormone Disrup-  
21 tion Research Act of 2002, the Director of the Insti-  
22 tute and the Director of the USGS shall enter into  
23 an agreement to carry out the research program es-  
24 tablished under subsection (a).



1           “(3) TRANSFER OF FUNDS.—The Director of  
2 the Institute may transfer funds to other Federal  
3 agencies to carry out the Director’s responsibilities  
4 under paragraph (1).

5           “(4) REPORT.—The Director of the Institute,  
6 in consultation with the Director of the USGS, shall  
7 make available to the public, every 2 years following  
8 the date of enactment of the Hormone Disruption  
9 Research Act of 2002, findings and conclusions on  
10 the extent to which hormone disruption by chemicals  
11 in the environment poses a threat to human health  
12 and the environment.

13           “(c) INTERAGENCY COMMISSION.—

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

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

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

1           “(B) The Director of the USGS, who shall  
2           serve as the Vice-Chairperson.

3           “(C) The Commissioner of the Food and  
4           Drug Administration.

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

7           “(E) The Administrator of the National  
8           Oceanic and Atmospheric Administration.

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

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

13          “(H) The Director of the Fish and Wildlife  
14          Service.

15          “(I) The Secretary of Defense.

16          “(J) The Administrator of the Environ-  
17          mental Protection Agency.

18          “(K) The Chairman of the Consumer  
19          Product Safety Commission.

20          “(L) The Director of the National Science  
21          Foundation.

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

1           “(4) RECOMMENDATIONS.—Not later than 12  
2 months after the date of enactment of the Hormone  
3 Disruption Research Act of 2002, the Interagency  
4 Commission shall recommend to the Director of the  
5 Institute and the Director of the USGS a research  
6 program, including levels of funding for intramural  
7 and extramural research.

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

13           “(6) REPORT.—Not later than 4 years after the  
14 date of enactment of the Hormone Disruption Re-  
15 search Act of 2002, the Interagency Commission  
16 shall conduct a review of the program established  
17 under subsection (a) and submit a report on the re-  
18 sults of such review to the Director of the Institute  
19 and to the Hormone Disruption Research Panel es-  
20 tablished under subsection (e).

21           “(d) FINANCIAL ASSISTANCE.—

22           “(1) IN GENERAL.—The Director of the Insti-  
23 tute may provide financial assistance and enter into  
24 grants, contracts, and interagency memoranda of  
25 understanding to conduct activities under this sec-

1       tion. Research conducted pursuant to interagency  
2       memoranda of understanding may be conducted  
3       through intramural and extramural agency research  
4       programs, subject to appropriate scientific peer re-  
5       view.

6       “(e) HORMONE DISRUPTION RESEARCH PANEL.—

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

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

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

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

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

24              “(4) VOTING MEMBERS.—Of the 15 voting  
25       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; and

7           “(D) a majority of the members shall be  
8           selected from among scientists and environ-  
9           mental health professionals who—

10                   “(i) are not officers or employees of  
11                   the United States;

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

15                   “(iii) represent different geographical  
16                   regions of the United States;

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

20                   “(v) have experience in review of  
21                   research on endocrine disruption.

22           “(5) TERMS.—The members of the Panel shall  
23           be appointed for an initial term of 3 years and shall  
24           be eligible for reappointment for 1 additional term  
25           of 2 years.

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

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

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

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

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

17           “(1) HORMONE.—The term ‘hormone’ means a  
18 substance produced in a cell or tissue that triggers  
19 a biological response. Hormone activity may be local-  
20 ized to the cell in which the substance is produced,  
21 or may be in nearby or distant tissues or organs.

22           “(2) HORMONE DISRUPTION.—The term ‘hor-  
23 mone disruption’ means interference by a substance  
24 with the synthesis, secretion, transport, binding, ac-  
25 tion, or elimination of natural hormones in the body

1 that are responsible for the maintenance of homeo-  
2 stasis, reproduction, development, function, or be-  
3 havior.

4 “(h) AUTHORIZATION OF APPROPRIATIONS.—

5 “(1) GENERAL AUTHORIZATION.—There are  
6 authorized to be appropriated \$500,000,000 for the  
7 5-fiscal-year period beginning with fiscal year 2003  
8 to carry out this section. Amounts appropriated pur-  
9 suant to this paragraph shall remain available until  
10 expended.

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

12 “(A) CONSTRUCTION AND REHABILITA-  
13 TION OF FACILITIES AND EQUIPMENT.—Not  
14 more than 0.5 percent of the funds made avail-  
15 able under this section may be used for the con-  
16 struction or rehabilitation of facilities or fixed  
17 equipment.

18 “(B) ADMINISTRATIVE EXPENSES OF THE  
19 DIRECTOR.—Of the total amount of funds made  
20 available under this section for any fiscal year,  
21 not more than 2 percent of such funds may be  
22 used for administrative expenses of the Director  
23 of the Institute in carrying out this section.

24 “(C) PUBLIC OUTREACH.—Of the total  
25 amount of funds made available under this sec-

1           tion for any fiscal year, at least 1 percent, but  
2           not more than 5 percent, shall be used for out-  
3           reach to the public concerning the activities and  
4           results of the program.”.

○