

111TH CONGRESS
1ST SESSION

H. R. 4160

To amend the Public Health Service Act to authorize the National Institute of Environmental Health Sciences to conduct and coordinate a research program on hormone disruption, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 1, 2009

Ms. SLAUGHTER (for herself, Mrs. CAPPS, Mr. ELLISON, Mr. HINCHEY, Ms. MCCOLLUM, Ms. SCHAKOWSKY, Ms. WOOLSEY, Mr. GRIJALVA, Mr. MCGOVERN, Mr. GEORGE MILLER of California, Mr. ISRAEL, Mr. DOGGETT, and Mr. STARK) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Rules, 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 Service Act to authorize the National Institute of Environmental Health Sciences to 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 Hor-
5 mone Disruption Research Act of 2009”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) Many compounds found or introduced into
4 the environment by human activity are capable of
5 disrupting the hormone system of humans and ani-
6 mals. The consequences of such disruption can be
7 profound because of the crucial role hormones play
8 in controlling development and metabolism. Few
9 standardized and validated screens or tests have
10 been developed to routinely and systematically assess
11 chemicals for disruptive effects on hormone systems.
12 Even fewer have statistical power to detect sufficient
13 problems.

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 disorder and attention deficit hyperactivity dis-
19 order, autism, thyroid disorders, learning disabilities,
20 cognitive impairment, and auto-immune disorders.
21 Exposure to hormone-disrupting pollutants may be
22 contributing to these increases. The impact on chil-
23 dren's health as a result of prenatal exposures in
24 particular needs further research.

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

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

7 (4) Many wildlife populations have disrupted re-
8 production or development, including birds, fish, am-
9 phibians, and mammals. The effects vary among
10 species, and some are due to exposure to hormone-
11 disrupting substances.

12 (5) Observed disruptions in wildlife include thy-
13 roid dysfunction, decreased fertility, decreased
14 hatching success, gross birth deformities, metabolic
15 and behavioral abnormalities, demasculinization and
16 feminization of male organisms, deformation and
17 masculinization of female organisms, and com-
18 promised immune systems. If due to exposure to
19 hormone-disrupting substances, then these effects
20 may signal hazards to human health.

21 (6) Laboratory studies have corroborated stud-
22 ies of some effects in wildlife and have identified bio-
23 logical mechanisms to explain the effects shown. The
24 chemicals found in wildlife are also found in hu-
25 mans.

1 (7) Hormone disruption might occur at very low
2 environmental doses, especially when exposure oc-
3 curs in the womb or immediately after birth, periods
4 during which rapid development is occurring.

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

12 (9) In 1999, in response to a request from Con-
13 gress and funded through the Environmental Protec-
14 tion Agency and the Department of the Interior, the
15 National Academy of Sciences compiled a lengthy
16 list of research, monitoring, and testing priorities re-
17 lated to hormone disruption.

18 (10) The National Institute of Environmental
19 Health Sciences conducts much of the Federal Gov-
20 ernment’s research on hormone disruption, often
21 working in partnership with other agencies.

22 (11) While recognizing the many contributions
23 of animal testing to understanding toxic hazards, the
24 Congress also recognizes the desirability of speeding
25 the use of validated nonanimal screens and tests (to

1 reduce animal suffering and to reduce costs) and ex-
2 pediting judgments about hazards from toxic chemi-
3 cals.

4 (12) The Department of the Interior has con-
5 siderable experience assessing the occurrence of
6 chemicals in the environment, ecological health, and
7 the hazards to wildlife health and associated human
8 health posed by chemicals in the environment, as a
9 result of monitoring by the Department of the Na-
10 tion’s water resources and wildlife disease, and re-
11 search by the Department on the effects of chemi-
12 cals on wildlife.

13 (13) The National Academy of Sciences has
14 recognized the expertise of the United States Geo-
15 logical Survey (“USGS”) in such areas as food web
16 contamination and water quality assessment and has
17 encouraged more coordinated work on human health
18 between the USGS and the National Institutes of
19 Health.

1 **SEC. 3. NATIONAL INSTITUTE OF ENVIRONMENTAL**
2 **HEALTH SCIENCES; DIRECTED NATIONAL**
3 **PROGRAM OF RESEARCH ON HORMONE DIS-**
4 **RUPTION.**

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

8 **“SEC. 463C. DIRECTED NATIONAL PROGRAM OF RESEARCH**
9 **ON HORMONE DISRUPTION.**

10 “(a) RESEARCH.—

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

14 “(A) carry out research on the health ef-
15 fects on women and children that may result
16 through disruption of the hormone systems;

17 “(B) carry out research, development, and
18 demonstrations with respect to technologies to
19 mitigate the occurrence of hormone-disrupting
20 pollutants in the environment and their unin-
21 tended effects on ecological and wildlife health,
22 in cooperation with the United States Geologi-
23 cal Survey (referred to in this section as the
24 ‘USGS’);

1 “(C) coordinate research on hormone dis-
2 ruption in the United States with such research
3 conducted in other nations; and

4 “(D) provide for the dissemination of in-
5 formation described in paragraph (2) to the
6 public.

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

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

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

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

24 “(iii) exposure of wildlife species to
25 hormone-disrupting pollutants and possible

1 health effects associated with such expo-
2 sures.

3 “(B) Research, in coordination with the
4 Environmental Protection Agency and the
5 USGS, on mechanisms by which hormone-dis-
6 rupting pollutants interact with biological sys-
7 tems.

8 “(C) Research on improved in vitro, in
9 vivo, and in silico methods to screen and test
10 hormone disruption.

11 “(D) Research on the identity, levels,
12 transport, and fate of hormone-disrupting pol-
13 lutants in the environment.

14 “(b) DIRECTOR’S DUTIES.—

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

21 “(2) AGREEMENT.—Not later than 6 months
22 after the date of the enactment of the Environ-
23 mental Hormone Disruption Research Act of 2009,
24 the Director of the Institute and the Director of the

1 USGS shall enter into an agreement to carry out the
2 research program established under subsection (a).

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

7 “(4) REPORT.—The Director of the Institute,
8 in consultation with the Director of the USGS, shall
9 make available to the public, every 2 years following
10 the date of the enactment of the Environmental
11 Hormone Disruption Research Act of 2009, a report
12 summarizing findings and conclusions on the extent
13 to which hormone disruption by pollutants in the en-
14 vironment poses a threat to human health and the
15 environment.

16 “(c) INTERAGENCY COMMISSION.—

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

1 “(2) MEMBERSHIP.—The Interagency Commis-
2 sion shall be composed of 14 members, as follows:

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

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

7 “(C) The Director of the National Insti-
8 tute of Child Health and Human Development.

9 “(D) The Commissioner of Food and
10 Drugs.

11 “(E) The Director of the Centers for Dis-
12 ease Control and Prevention.

13 “(F) The Administrator of the National
14 Oceanic and Atmospheric Administration.

15 “(G) The Director of the National Insti-
16 tute for Occupational Safety and Health.

17 “(H) The Administrator of the Agency for
18 Toxic Substances and Disease Registry.

19 “(I) The Director of the Fish and Wildlife
20 Service.

21 “(J) The Secretary of Defense.

22 “(K) The Administrator of the Environ-
23 mental Protection Agency.

24 “(L) The Chairman of the Consumer
25 Product Safety Commission.

1 “(M) The Director of the National Science
2 Foundation.

3 “(N) The Director of the National Insti-
4 tute of Neurological Disorders and Stroke.

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

9 “(4) RECOMMENDATIONS.—Not later than 12
10 months after the date of the enactment of the Envi-
11 ronmental Hormone Disruption Research Act of
12 2009, the Interagency Commission shall recommend
13 to the Director of the Institute and the Director of
14 the USGS a research program, including levels of
15 funding for intramural and extramural research.

16 “(5) PUBLIC COMMENT.—The Director of the
17 Institute, through publication of notice in the Fed-
18 eral Register, shall provide the general public with
19 an opportunity to comment on the recommendations
20 of the Interagency Commission.

21 “(6) REPORT.—Not later than 4 years after the
22 date of the enactment of the Environmental Hor-
23 mone Disruption Research Act of 2009, the Inter-
24 agency Commission shall conduct a review of the
25 program established under subsection (a) and sub-

1 mit a report on the results of such review to the Di-
2 rector of the Institute and to the Hormone Disrup-
3 tion Research Panel established under subsection
4 (e).

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

8 “(d) FINANCIAL ASSISTANCE.—The Director of the
9 Institute may provide financial assistance and enter into
10 grants, contracts, and interagency memoranda of under-
11 standing to conduct activities under this section. Research
12 conducted pursuant to interagency memoranda of under-
13 standing may be conducted through intramural and extra-
14 mural agency research programs, subject to appropriate
15 scientific peer review.

16 “(e) HORMONE DISRUPTION RESEARCH PANEL.—

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

20 “(2) DUTIES.—The Panel shall make rec-
21 ommendations to the Interagency Commission with
22 respect to the duties of the Interagency Commission
23 under subsection (c)(1) and advise the Secretary and
24 the Director of the Institute with respect to the de-
25 sign and implementation of the program under sub-

1 section (a), including preparation of solicitations for
2 proposals to conduct research under the program.

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

5 “(A) 15 voting members to be appointed
6 by the President, in consultation with the Di-
7 rector of the Institute.

8 “(B) Such nonvoting, ex officio members
9 as the Director of the Institute determines to
10 be appropriate.

11 “(4) VOTING MEMBERS.—Of the 15 voting
12 members of the Panel—

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

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

17 “(C) at least 2 members but not more
18 than 7 shall be from industry;

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

21 “(E) a majority of the members shall be
22 selected from among scientists and environ-
23 mental health professionals who—

24 “(i) are not officers or employees of
25 the United States;

1 “(ii) represent multiple disciplines, in-
2 cluding clinical, basic, public, and ecologi-
3 cal health sciences;

4 “(iii) represent different geographical
5 regions of the United States;

6 “(iv) are from practice settings, aca-
7 demic settings, and for-profit or not-for-
8 profit research settings;

9 “(v) have experience in review of re-
10 search on endocrine disruption; and

11 “(vi) possess a relevant advanced de-
12 gree from an accredited college or univer-
13 sity.

14 “(5) TERMS.—The members of the Panel shall
15 be appointed for an initial term of 3 years and shall
16 be eligible for reappointment for 1 additional term
17 of 2 years.

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

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

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

3 “(9) TERMINATION.—The Panel shall terminate
4 not later than the end of the 5-year fiscal period de-
5 scribed in subsection (j)(1).

6 “(f) SOLICITATION AND SELECTION OF PRO-
7 POSALS.—

8 “(1) IN GENERAL.—Within 15 months after the
9 date of the enactment of the Environmental Hor-
10 mone Disruption Research Act of 2009, and as often
11 thereafter as appropriate, the Director of the Insti-
12 tute shall, in consultation with the Interagency Com-
13 mission, solicit and select proposals to conduct ac-
14 tivities under the program under subsection (a).

15 “(2) CONSULTATION WITH PANEL.—In pre-
16 paring solicitations for such proposals, the Director
17 of the Institute shall consult with the Hormone Dis-
18 ruption Research Panel.

19 “(3) PEER REVIEW PANELS.—Before a pro-
20 posal to conduct activities under the program under
21 subsection (a) may be selected by the Director of the
22 Institute, such proposal shall be submitted to, and
23 evaluated by, at least one scientific and technical
24 peer review panel.

25 “(g) REPORTS.—

1 “(1) REPORT UPON COMPLETION OF ACTIV-
2 ITY.—Any person who conducts activities under the
3 program under subsection (a) shall, upon completion
4 of the activity, submit to the National Academy of
5 Sciences, the Interagency Commission, and the Hor-
6 mone Disruption Research Panel a report summa-
7 rizing the activities and results thereof.

8 “(2) REPORT TO INTERAGENCY COMMISSION
9 AND PANEL.—The Director of the Institute shall
10 enter into appropriate arrangements with the Na-
11 tional Academy of Sciences under which the Acad-
12 emy shall periodically submit to the Interagency
13 Commission and the Hormone Disruption Research
14 Panel a report that evaluates the research activities
15 under the program under subsection (a). The report
16 shall include recommendations to promote the effec-
17 tive transfer of information derived from such re-
18 search activities. The Director of the Institute shall
19 be responsible for expenses incurred by the Academy
20 in connection with the preparation of such reports.

21 “(3) REPORT TO CONGRESS.—The Interagency
22 Commission, in consultation with the Hormone Dis-
23 ruption Research Panel, shall submit to the Sec-
24 retary and the Congress—

1 “(A) not later than December 31, 2013, a
2 report summarizing the progress of the research
3 program under subsection (a); and

4 “(B) not later than September 30, 2016, a
5 final report stating the Interagency Commis-
6 sion’s findings and conclusions on the effects, if
7 any, of hormone-disrupting pollutants in the en-
8 vironment on human health and remedial ac-
9 tions, if any, that may be needed to minimize
10 any such health effects.

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

17 “(i) DEFINITIONS.—For purposes of this section:

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

23 “(2) HORMONE-DISRUPTING.—The term ‘hor-
24 mone-disrupting’ means producing effects similar to
25 those of naturally occurring hormones or interfering

1 with hormone signaling or hormone interaction with
2 receptors.

3 “(3) HORMONE DISRUPTION.—The term ‘hor-
4 mone disruption’ means interference with the syn-
5 thesis, secretion, transport, binding, action, or elimi-
6 nation of natural hormones in the body that are re-
7 sponsible for the maintenance of homeostasis, repro-
8 duction, development, function, or behavior.

9 “(j) AUTHORIZATION OF APPROPRIATIONS.—

10 “(1) GENERAL AUTHORIZATION.—There are
11 authorized to be appropriated such sums as may be
12 necessary for the 5-fiscal-year period beginning with
13 fiscal year 2011 to carry out this section. Amounts
14 appropriated pursuant to this paragraph shall re-
15 main available until expended.

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

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

23 “(B) ADMINISTRATIVE EXPENSES OF THE
24 DIRECTOR.—Of the total amount of funds made
25 available under this section for any fiscal year,

1 not more than 2 percent of such funds may be
2 used for administrative expenses of the Director
3 of the Institute in carrying out this section.

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

10 **SEC. 4. COMMITTEE HEARING ON IMPLEMENTATION.**

11 (a) IN GENERAL.—The Committee on Energy and
12 Commerce of the House of Representatives shall hold a
13 hearing on the implementation by the Director of the Na-
14 tional Institute of Environmental Health Sciences of sec-
15 tion 463C of the Public Health Service Act, as added by
16 section 3 of this Act.

17 (b) EXERCISE OF RULEMAKING AUTHORITY.—Sub-
18 section (a)—

19 (1) is enacted as an exercise of the rulemaking
20 power of the House of Representatives and, as
21 such—

22 (A) shall be considered as part of the rules
23 of the House; and

1 (B) shall supersede any other rule of the
2 House only to the extent that rule is incon-
3 sistent therewith; and

4 (2) is enacted with full recognition of the con-
5 stitutional right of the House to change such rules
6 (so far as relating to the procedure in the House)
7 at any time, in the same manner, and to the same
8 extent as in the case of any other rule of the House.

○