### 109TH CONGRESS 1ST SESSION H.R. 3313

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

#### IN THE HOUSE OF REPRESENTATIVES

#### JULY 14, 2005

Ms. SLAUGHTER (for herself and Mr. HOLT) 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 authorize the National Institute of Environmental Health Sciences to develop multidisciplinary research centers regarding women's health and disease prevention and 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 Health
- 5 Research Act of 2005".

#### 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. No standardized and 9 validated screens or tests have been developed to 10 routinely and systematically assess chemicals for dis-11 ruptive effects on hormone systems.

12 (2) In the last 30 years, the United States has 13 experienced an increase in the incidence of such 14 human disorders as childhood cancers, testicular 15 cancer, hypospadias, juvenile diabetes, attention def-16 icit-like hyperactivity disorders, autism, thyroid dis-17 orders, learning disabilities, cognitive impairment, 18 and auto-immune disorders. Exposure to hormone-19 disrupting chemicals may be contributing to these 20 increases. The impact on children's health as a re-21 sult of prenatal exposures in particular needs further 22 research.

(3) In 2001, the Centers for Disease Control
and Prevention's "National Report on Human Exposure to Environmental Chemicals" reported on
human exposure to 27 chemicals, and found unexHR 3313 IH

pectedly high levels of certain chemicals used in con sumer products. The hazards to humans of these
 chemicals, singly and in combination, are not well
 understood.

5 (4) Many wildlife populations have been af6 fected by hormone-disrupting substances, including
7 birds, fish, reptiles, and mammals. The effects vary
8 among species and compounds.

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

17 (6) Laboratory studies have corroborated stud18 ies of effects in wildlife and have identified biological
19 mechanisms to explain the effects shown.

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

(8) Hormone disruption can occur at very lowdoses, especially when exposure occurs in the womb

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or immediately after birth, periods during which
 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.

(10) In 1998, a research committee on hormone disrupters, organized under the auspices of the Office of Science and Technology Policy, concluded that "scientific knowledge is inadequate to fully inform public policy, and a government-wide coordinated research effort that addresses the key scientific uncertainties . . . is needed".

(11) In 1999, in response to a request from
Congress and funded through the Environmental
Protection Agency and the Department of the Interior, the National Academy of Sciences compiled a
lengthy list of research, monitoring, and testing priorities related to hormone disruption.

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

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.

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working in partnership with other agencies.

ernment's research on hormone disruption, often

of animal testing to understanding toxic hazards, the

Congress also recognizes the desirability of speeding

(13) While recognizing the many contributions

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1 SEC. 3. 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. 285l et seq.) is amended by adding
9 at the end the following section:

 10 "SEC. 463C. MULTIDISCIPLINARY RESEARCH CENTERS RE 

 11
 GARDING WOMEN'S HEALTH AND DISEASE

 12
 PREVENTION.

"(a) IN GENERAL.—The Director of the Institute 13 shall make grants to public or nonprofit private entities 14 15 for the development and operation of not more than 6 cen-16 ters whose purpose is conducting multidisciplinary re-17 search on environmental factors that may be related to the development of women's health conditions (as defined 18 19 in section 486). The Director of the Institute shall carry 20out this section in consultation with the Director of the 21 Office of Research on Women's Health and with the advi-22 sory council for the Institute.

23 "(b) RESEARCH, TRAINING, AND INFORMATION AND24 EDUCATION.—

1	"(1) IN GENERAL.—Each center under sub-
2	section (a) shall, with respect to the purpose de-
3	scribed in such subsection—
4	"(A) conduct basic and clinical research;
5	"(B) develop protocols for training physi-
6	cians, scientists, nurses, and other health and
7	allied health professionals;
8	"(C) conduct training programs for such
9	individuals;
10	"(D) develop model continuing education
11	programs for such professionals; and
12	"(E) disseminate information to such pro-
13	fessionals and the public.
14	"(2) Priority for prevention activities.—
15	In carrying out the activities described in paragraph
16	(1), each center under subsection (a) shall give pri-
17	ority to activities that are directed toward pre-
18	venting the development in women of the diseases
19	and conditions involved.
20	"(3) STIPENDS FOR TRAINING OF HEALTH PRO-
21	FESSIONALS.—A center under subsection (a) may
22	use funds under such subsection to provide stipends
23	for health and allied health professionals enrolled in
24	programs described in paragraph (1)(C).

1 "(c) COLLABORATION WITH COMMUNITY.—Each 2 center under subsection (a) shall establish and maintain 3 ongoing collaborations with community organizations in 4 the geographic area served by the center, including those 5 that represent women with disorders that appear to stem 6 from environmental factors and the health concerns of 7 their offspring.

8 "(d) COORDINATION OF CENTERS; REPORTS.—The 9 Director of the Institute shall, as appropriate, provide for 10 the coordination of information among centers under sub-11 section (a) and ensure regular communication between 12 such centers.

"(e) STRUCTURE OF CENTER.—Each center assisted
under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of cooperating
institutions, meeting such requirements as may be prescribed by the Director of the Institute.

18 "(f) DURATION OF SUPPORT.—Support of a center 19 under subsection (a) may be for a period not exceeding 20 5 years. Such period may be extended for 1 or more addi-21 tional periods not exceeding 5 years if the operations of 22 such center have been reviewed by an appropriate tech-23 nical and scientific peer review group established by the 24 Director of the Institute and if such group has recommended to the Director that such period should be ex tended.

3 "(g) AUTHORIZATION OF APPROPRIATIONS.—For the 4 purpose of carrying out this section, there are authorized 5 to be appropriated such sums as may be necessary for fis-6 cal years 2006 through 2010.".

# 7 SEC. 4. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT 8 TO PROVIDE FOR RESEARCH ON HORMONE 9 DISRUPTION.

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

## 14 "SEC. 463D. DIRECTED NATIONAL PROGRAM OF RESEARCH

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#### ON HORMONE DISRUPTION.

16 "(a) RESEARCH.—

17 "(1) IN GENERAL.—The Director of the Insti18 tute shall establish within the Institute a comprehen19 sive program to—

20 "(A) conduct research on the impact of
21 chemicals that affect the health of women and
22 children through disruption of the hormone sys23 tems;

24 "(B) conduct research on the occurrence of25 hormone-disrupting chemicals in the environ-

1	ment and their effects on ecological and wildlife
2	health, in cooperation with the United States
3	Geological Survey (referred to in this section as
4	the 'USGS');
5	"(C) coordinate the design of a multi-
6	agency research initiative on hormone disrup-
7	tion; and
8	"(D) coordinate research on hormone dis-
9	ruption in the United States with such research
10	conducted in other nations.
11	"(2) Issues.—The program established under
12	paragraph (1) shall provide for the following:
13	"(A) Collection, compilation, publication,
14	and dissemination of scientifically valid infor-
15	mation on—
16	"(i) possible human health effects of
17	hormone-disrupting chemicals, with empha-
18	sis on exposures to low doses of individual
19	chemicals and chemical mixtures during
20	critical life stages of development, particu-
21	larly effects of prenatal exposures on chil-
22	dren's health;
23	"(ii) the extent of human exposure to
24	hormone-disrupting chemicals, with par-
25	ticular emphasis on exposures during crit-

1	ical life stages of development and in resi-
2	dential and occupational settings; and
3	"(iii) exposure of wildlife species to
4	hormone-disrupting chemicals and possible
5	health effects associated with such expo-
6	sures.
7	"(B) Research on mechanisms by which
8	hormone-disrupting substances interact with bi-
9	ological systems.
10	"(C) Research on improved in vitro and in
11	vivo methods to screen and test hormone dis-
12	ruption.
13	"(D) Research on the identity, levels,
14	transport, and fate of hormone-disrupting
15	chemicals in the environment.
16	"(b) Director's Duties.—
17	"(1) IN GENERAL.—The Director of the Insti-
18	tute shall have principal responsibility, in consulta-
19	tion with the Director of the USGS, for conducting
20	and coordinating research on the effects of hormone-
21	disrupting chemicals on human health and the envi-
22	ronment.
23	"(2) AGREEMENT.—Not later than 6 months
24	after the date of enactment of the Environmental
25	Health Research Act of 2005, the Director of the

1 Institute and the Director of the USGS shall enter 2 into an agreement to carry out the research program 3 established under subsection (a). "(3) TRANSFER OF FUNDS.—The Director of 4 5 the Institute may transfer funds to other Federal 6 agencies to carry out the Director's responsibilities 7 under paragraph (1). 8 "(4) REPORT.—The Director of the Institute, 9 in consultation with the Director of the USGS, shall 10 make available to the public, every 2 years following 11 the date of enactment of the Environmental Health 12 Research Act of 2005, findings and conclusions on 13 the extent to which hormone disruption by chemicals 14 in the environment poses a threat to human health 15 and the environment. "(c) INTERAGENCY COMMISSION.— 16 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 enactment of the Environ-
11	mental Health Research Act of 2005, the Inter-
12	agency Commission shall recommend to the Director
13	of the Institute and the Director of the USGS a re-
14	search program, including levels of funding for in-
15	tramural 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 enactment of the Environmental Health Re-
23	search Act of 2005, the Interagency Commission
24	shall conduct a review of the program established
25	under subsection (a) and submit a report on the re-

1	sults of such review to the Director of the Institute
2	and to the Hormone Disruption Research Panel es-
3	tablished under subsection (e).
4	"(7) TERMINATION.—The Interagency Commis-
5	sion shall terminate not later than the end of the 5-
6	year fiscal period described in subsection $(h)(1)$ .
7	"(d) FINANCIAL ASSISTANCE.—The Director of the
8	Institute may provide financial assistance and enter into
9	grants, contracts, and interagency memoranda of under-
10	standing to conduct activities under this section. Research
11	conducted pursuant to interagency memoranda of under-
12	standing may be conducted through intramural and extra-
13	mural agency research programs, subject to appropriate
14	scientific peer review.
15	"(e) Hormone Disruption Research Panel.—
16	"(1) ESTABLISHMENT.—There is established in
17	the Institute a Hormone Disruption Research Panel
18	(referred to in this subsection as the 'Panel').
19	"(2) DUTIES.—The Panel shall advise the Di-
20	rector of the Institute concerning the scientific con-
21	tent of the program established under subsection
22	(a), the progress of such program, and public out-
23	reach, and shall provide such other advice as re-
24	quested by the Director of the Institute.

1	"(3) Membership.—The Panel shall be com-
2	posed of the following:
3	"(A) 15 voting members to be appointed
4	by the President, in consultation with the Di-
5	rector of the Institute.
6	"(B) Such nonvoting, ex officio members
7	as the Director of the Institute determines to
8	be appropriate.
9	"(4) Voting members.—Of the 15 voting
10	members of the Panel—
11	"(A) at least 2 members shall be from en-
12	vironmental protection organizations;
13	"(B) at least 2 members shall be from
14	public health and consumer organizations;
15	"(C) at least 2 members shall be from in-
16	dustry;
17	"(D) at least 1 member shall be from an
18	animal welfare organization; and
19	"(E) a majority of the members shall be
20	selected from among scientists and environ-
21	mental health professionals who—
22	"(i) are not officers or employees of
23	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; and
9	"(v) have experience in review of re-
10	search on endocrine disruption.
11	"(5) TERMS.—The members of the Panel shall
12	be appointed for an initial term of 3 years and shall
13	be eligible for reappointment for 1 additional term
14	of 2 years.
15	"(6) CHAIRPERSON.—The members of the
16	Panel appointed under paragraph (3) shall elect a
17	chairperson from among such members.
18	"(7) MEETINGS.—The Panel shall meet at the
19	call of the chairperson or upon the request of the
20	Director of the Institute, but in no case less often
21	than once each year.
22	"(8) Administrative support.—The Institute
23	shall provide administrative support to the Panel.

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

4 "(f) CONFLICTS OF INTEREST.—All grants and con5 tracts entered into under this section shall include conflict6 of-interest provisions that require any person conducting
7 a project under this section to disclose any other source
8 of funding received by the person to conduct other related
9 projects.

10 "(g) DEFINITIONS.—For purposes of this section:

"(1) HORMONE.—The term 'hormone' means a
substance produced in a cell or tissue that triggers
a biological response. Hormone activity may be localized to the cell in which the substance is produced,
or may be in nearby or distant tissues or organs.

16 "(2) HORMONE DISRUPTION.—The term 'hor-17 mone disruption' means interference by a substance 18 with the synthesis, secretion, transport, binding, ac-19 tion, or elimination of natural hormones in the body 20 that are responsible for the maintenance of homeo-21 stasis, reproduction, development, function, or be-22 havior.

23 "(h) AUTHORIZATION OF APPROPRIATIONS.—

24 "(1) GENERAL AUTHORIZATION.—There are25 authorized to be appropriated such sums as may be

1	necessary for the 5-fiscal-year period beginning with
2	fiscal year 2006 to carry out this section. Amounts
3	appropriated pursuant to this paragraph shall re-
4	main available until expended.
5	"(2) Restrictions on use of funds.—
6	"(A) Construction and rehabilita-
7	TION OF FACILITIES AND EQUIPMENT.—Not
8	more than 0.5 percent of the funds made avail-
9	able under this section may be used for the con-
10	struction or rehabilitation of facilities or fixed
11	equipment.
12	"(B) Administrative expenses of the
13	DIRECTOR.—Of the total amount of funds made
14	available under this section for any fiscal year,
15	not more than 2 percent of such funds may be
16	used for administrative expenses of the Director
17	of the Institute in carrying out this section.
18	"(C) PUBLIC OUTREACH.—Of the total
19	amount of funds made available under this sec-
20	tion for any fiscal year, at least 1 percent, but
21	not more than 5 percent, shall be used for out-
22	reach to the public concerning the activities and
23	results of the program.".

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