### 108TH CONGRESS 1ST SESSION

# H. R. 852

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.

### IN THE HOUSE OF REPRESENTATIVES

February 13, 2003

Ms. Slaughter (for herself and Mr. Waxman) 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 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. 285l 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.".

#### SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT

2	TO PROVIDE FOR RESEARCH ON HORMONE
3	DISRUPTION.

- (a) FINDINGS.—The Congress finds as follows:
- (1) Many compounds found or introduced into the environment by human activity are capable of disrupting the hormone system of humans and animals. The consequences of such disruption can be profound because of the crucial role hormones play in controlling development. No standardized and validated screens or tests have been developed to routinely and systematically assess chemicals for disruptive effects on hormone systems.
  - (2) In the last 30 years, the United States has experienced an increase in the incidence of such human disorders as childhood cancers, testicular cancer, hypospadias, juvenile diabetes, attention deficit-like hyperactivity disorders, autism, thyroid disorders, and auto-immune disorders. Exposure to hormone-disrupting chemicals may be contributing to these increases. The impact on children's health as a result of prenatal exposures in particular needs further 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 unexpectedly high levels of certain chemicals used in consumer products. The hazards to humans of these chemicals, singly and in combination, are not well understood.
  - (4) Many wildlife populations have been affected by hormone-disrupting substances, including birds, fish, reptiles, and mammals. The effects vary among species and compounds.
  - (5) The effects in wildlife include thyroid dysfunction, decreased fertility, decreased hatching success, gross birth deformities, metabolic and behavioral abnormalities, demasculinization and feminization of male organisms, deformation and masculinization of female organisms, and compromised immune systems. These effects may signal hazards to human health.
  - (6) Laboratory studies have corroborated studies of effects in wildlife and have identified biological mechanisms to explain the effects shown.
  - (7) Since the chemicals found in wildlife are also found in humans, humans are exposed to the same chemicals as wildlife.
  - (8) Hormone disruption can occur at very low doses, especially when exposure occurs in the womb

- or immediately after birth, periods during which rapid development is occurring.
- (9) In the Food Quality Protection Act of 1996
  (21 U.S.C. 301 note), Congress recognized the special vulnerability of infants and children to pesticides
  and requested that the Environmental Protection
  Agency establish a program to screen and test hormone-disrupting chemicals. The Environmental Protection Agency has not yet required such screening
  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.
- (12) The National Institute of Environmental
   Health Sciences conducts much of the Federal Gov-

- ernment's research on hormone disruption, often working in partnership with other agencies.
  - (13) While recognizing the many contributions of animal testing to understanding toxic hazards, the Congress also recognizes the desirability of speeding the use of validated nonanimal screens and tests (to reduce animal suffering and to reduce costs) and expediting judgments about hazards from toxic chemicals.
    - (14) The United States Geological Survey (referred to in this section as the "USGS") has considerable experience assessing the occurrence of chemicals in the environment, ecological health, and the hazards to wildlife health and associated human health posed by chemicals in the environment, as a result of monitoring by the USGS of the Nation's water resources and wildlife disease, and research by the USGS on the effects of chemicals on wildlife.
    - (15) The National Academy of Sciences has recognized the expertise of the USGS in such areas as food web contamination and water quality assessment and has encouraged more coordinated work on human health between the USGS and the National 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	"(e) 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-

mental Health Research Act of 2003, the Interagency Commission shall recommend to the Director of the Institute and the Director of the USGS a research program, including levels of funding for in-

tramural and extramural research.

of the Interagency Commission.

- "(5) PUBLIC COMMENT.—The Director of the Institute, through publication of notice in the Federal Register, shall provide the general public with an opportunity to comment on the recommendations
  - "(6) Report.—Not later than 4 years after the date of enactment of the Environmental Health Research Act of 2003, the Interagency Commission shall conduct a review of the program established under subsection (a) and submit a report on the results of such review to the Director of the Institute and to the Hormone Disruption Research Panel established under subsection (e).
  - "(7) TERMINATION.—The Interagency Commission shall terminate not later than the end of the 5-year fiscal period described in subsection (h)(1).
- "(d) FINANCIAL ASSISTANCE.—The Director of the Institute may provide financial assistance and enter into grants, contracts, and interagency memoranda of understanding to conduct activities under this section. Research

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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

substance produced in a cell or tissue that triggers

a biological response. Hormone activity may be local-

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

"(2) HORMONE DISRUPTION.—The term 'hormone disruption' means interference by a substance with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body that are responsible for the maintenance of homeostasis, reproduction, development, function, or behavior.

### "(h) AUTHORIZATION OF APPROPRIATIONS.—

"(1) General authorization.—There are authorized to be appropriated such sums as may be necessary for the 5-fiscal-year period beginning with fiscal year 2004 to carry out this section. Amounts appropriated pursuant to this paragraph shall remain available until expended.

### "(2) Restrictions on use of funds.—

"(A) Construction and rehabilitation of facilities and equipment.—Not more than 0.5 percent of the funds made available under this section may be used for the construction or rehabilitation of facilities or fixed equipment.

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

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

"(C) Public outreach.—Of the total amount of funds made available under this section for any fiscal year, at least 1 percent, but not more than 5 percent, shall be used for outreach to the public concerning the activities and results of the program.".

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