

111TH CONGRESS  
1ST SESSION

# H. R. 4190

To amend the Public Health Service Act to authorize the National Institute of Environmental Health Sciences to conduct a research program on endocrine disruption, to prevent and reduce the production of, and exposure to, chemicals that can undermine the development of children before they are born and cause lifelong impairment to their health and function, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 3, 2009

Mr. MORAN of Virginia (for himself, Mrs. LOWEY, Mr. GEORGE MILLER of California, Ms. MCCOLLUM, Mr. GRIJALVA, Mr. MCGOVERN, Mr. HINCHHEY, and Mr. KENNEDY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to authorize the National Institute of Environmental Health Sciences to conduct a research program on endocrine disruption, to prevent and reduce the production of, and exposure to, chemicals that can undermine the development of children before they are born and cause lifelong impairment to their health and function, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Endocrine Disruption  
3 Prevention Act of 2009”.

4 **SEC. 2. FINDINGS, POLICIES, AND GOALS.**

5 (a) FINDINGS.—The Congress finds that—

6 (1) a disturbing increase in the number of dis-  
7 orders of the human endocrine system is seriously  
8 undermining the health and wealth of the Nation;

9 (2) these disorders include attention deficit hy-  
10 peractivity disorder (ADHD), autism, learning dis-  
11 abilities, asthma, juvenile cancer, juvenile and adult  
12 diabetes, autoimmune diseases, cryptorchidism,  
13 hypospadias, endometriosis, obesity, osteoporosis,  
14 testicular cancer, male dysgenesis syndrome, breast  
15 cancer, prostate cancer, Parkinson’s disease, and  
16 Alzheimer’s dementia;

17 (3) these disorders began to increase noticeably  
18 at the population level in the early 1970s when the  
19 first generation exposed in the womb to post-World  
20 War II synthetic chemicals reached maturity;

21 (4) prior to 1950, these disorders were rare,  
22 which rules out the influence of inherited disorders;

23 (5) today, among the fourth generation of chil-  
24 dren exposed in the womb, one in three children and  
25 one in two minority children will develop diabetes;  
26 one in six children is born with neurological damage;

1 one in 100 children has an autism spectrum disorder  
2 and among boys the occurrence is one in 58; one in  
3 125 boys is born with hypospadias, a condition  
4 where the urethra does not open at the end of the  
5 penis; in 2007, an age-independent decline in testos-  
6 terone levels over the past twenty years was discov-  
7 ered in American men; and declines in male repro-  
8 ductive health have been traced back to damage in  
9 the womb;

10 (6) evidence from human epidemiological and  
11 laboratory animal studies links these disorders to  
12 prenatal and later life exposure to endocrine dis-  
13 rupting chemicals (EDCs);

14 (7) the endocrine system is a complex system of  
15 organs regulated by over eighty known hormones as  
16 well as hundreds of auxiliary chemical signaling sys-  
17 tems, and it assures the perpetuity and integrity of  
18 human life;

19 (8) recent bio-monitoring demonstrates that  
20 embryos, fetuses, infants, and children in the United  
21 States carry hundreds of synthetic chemicals in their  
22 blood and tissue, including EDCs, and similar re-  
23 sults have been found for adults;

24 (9) thousands of chemicals have become an in-  
25 tegral part of confined environments (homes,

1 schools, cars, planes, offices, theaters, malls), con-  
2 tributing to continual, ubiquitous exposure, and it is  
3 vital to be able to identify which are EDCs;

4 (10) many plant and animal species are show-  
5 ing signs of ill health due to exposure to endocrine  
6 disrupting chemicals, which can cause small, but  
7 critical, changes in the chemical makeup of an envi-  
8 ronment that are enough to trigger outcomes that  
9 could lead to population decline and loss of biodiver-  
10 sity;

11 (11) one out of five male black bass in nine  
12 river basins across the United States exhibit intersex  
13 organs and up to 100 percent of smallmouth bass at  
14 some sites in the Potomac River basin during  
15 spawning season exhibit the same organ changes,  
16 which scientists say suggests they have been exposed  
17 to EDCs;

18 (12) all vertebrates (fish, amphibians, reptiles,  
19 birds, and mammals, including humans) are fun-  
20 damentally similar during early embryonic develop-  
21 ment, so scientists can use the evidence acquired on  
22 other species to make predictions about endocrine  
23 disrupting effects on humans;

24 (13) traditional toxicology and risk assessment,  
25 which evaluate one chemical at a time, and only at

1 high concentrations, have failed to sufficiently ad-  
2 dress the effects of low doses of chemicals at mul-  
3 tiple early life stages and have not prevented the  
4 alarming increase of endocrine disorders sweeping  
5 across the Northern Hemisphere;

6 (14) since the early 1990s, independent govern-  
7 ment-funded scientists in academic and institutional  
8 laboratories around the world have published data  
9 demonstrating the ability of a broad selection of  
10 chemicals to interfere with human development and  
11 function by affecting a number of endocrine mecha-  
12 nisms, and have discovered endocrine disruptive ef-  
13 fects for some widely used chemicals at concentra-  
14 tions several thousand times lower than government  
15 “safe” levels derived through traditional toxicological  
16 tests;

17 (15) these scientists have developed a new para-  
18 digm for disease, the developmental basis of disease,  
19 which states that disease starts during development  
20 and is influenced by exposures to environmental  
21 chemicals, stress and nutrition interacting on the de-  
22 veloping organism;

23 (16) the developmental basis of disease changes  
24 the focus from curing disease to prevention and to

1 understanding gene-environment-nutrition inter-  
2 actions during development;

3 (17) the National Institute of Environmental  
4 Health Sciences (NIEHS) and the National Toxi-  
5 cology Program (NTP) have conducted important  
6 studies on the environmental connection to human  
7 diseases, and have in place a 5-tier scale of concern  
8 by which to evaluate chemicals based on the weight  
9 of scientific evidence and toxicity and exposure infor-  
10 mation;

11 (18) while research has established that expo-  
12 sure to EDCs induces delayed toxicity that results in  
13 disease weeks, months, years, or decades later in  
14 life, Federal regulatory agencies generally are not  
15 using the results of this research to restrict produc-  
16 tion and use of even the most egregious chemicals;

17 (19) although Congress directed the Environ-  
18 mental Protection Agency in the Food Quality Pro-  
19 tection Act of 1996 to develop, not later than Au-  
20 gust 3, 1998, “a screening program using appro-  
21 priate validated test systems and other scientifically  
22 relevant information, to determine whether certain  
23 substances may have an effect in humans that is  
24 similar to an effect produced by a naturally occur-  
25 ring estrogen, or such other endocrine effect as the

1 Administrator may designate”, the Agency did not  
2 release test orders announcing the availability of ini-  
3 tial standardized screens and testing protocols until  
4 October 21, 2009, and no chemical has been tested  
5 for its impact on development and function from fer-  
6 tilization to birth, despite the expenditure of more  
7 than \$100,000,000;

8 (20) given these delays and the alarming trends  
9 in endocrine-related disorders, the United States  
10 must expeditiously take preventive action based on  
11 an entirely new approach to reducing children’s ex-  
12 posure before birth to EDCs; and

13 (21) the costs to society of not taking action in-  
14 clude medical expenses of treating these chronic dis-  
15 eases, lost productivity, impaired fertility, com-  
16 promised quality of life for those affected, their fam-  
17 ilies and communities, so prevention is the key.

18 (b) POLICIES AND GOALS.—It is the policy of the  
19 United States—

20 (1) to promote family health and the perpetua-  
21 tion of the human species as a paramount national  
22 goal, recognizing that in order to protect the em-  
23 bryo, fetus, and infant during their most vulnerable  
24 stages of development, parents’ bodies must be free

1 of EDCs prior to conception, during gestation, and  
2 throughout lactation;

3 (2) to prevent harmful exposure to EDCs in  
4 homes, workplaces, schools, public and private trans-  
5 portation vehicles, indoor and outdoor recreational  
6 environments, and in drinking water, foods, and con-  
7 sumer products;

8 (3) to develop scientific support for Federal  
9 public health strategies based on the entire body of  
10 peer-reviewed public literature in an environment  
11 that is free from conflicts of interest;

12 (4) to promote research into endocrine disrup-  
13 tion by encouraging the multidisciplinary, multi-in-  
14 stitutional, and international collaborations that in  
15 the past have produced many breakthroughs in  
16 knowledge;

17 (5) to create graduate-level scholarships and  
18 post-doctoral fellowships to train young scientists  
19 who can meet the demand for technicians and public  
20 health and health care personnel in endocrine dis-  
21 ruption prevention;

22 (6) to determine which chemicals in commerce  
23 have the potential to disrupt the human endocrine  
24 system and to remove these chemicals, and products  
25 containing them, from the market; and

1           (7) to prevent the introduction of new chemi-  
2           cals, and products containing them, that have the  
3           potential to disrupt the human endocrine system by  
4           requiring testing for these effects before these  
5           chemicals and products are released on the market.

6 **SEC. 3. ENDOCRINE DISRUPTION PREVENTION PROGRAM.**

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:

10 **“SEC. 463C. ENDOCRINE DISRUPTION PREVENTION.**

11           “(a) PROGRAM.—The Director of the National Insti-  
12           tute of Environmental Health Sciences shall establish a  
13           program, to be known as the Endocrine Disruption Pre-  
14           vention Program, consisting of research, workshops, and  
15           fora under subsection (b).

16           “(b) RESEARCH, WORKSHOPS, AND FORA.—

17           “(1) RESEARCH.—The Director of the Institute  
18           shall conduct and support multidisciplinary research,  
19           to improve the understanding of endocrine disrup-  
20           tion. Such research shall—

21           “(A) include research to design and de-  
22           velop sensitive tests to screen chemicals using  
23           assays that are effective for identifying chemi-  
24           cals with the potential to disrupt the human en-  
25           docrine system;

1           “(B) address the full range of possible  
2 health outcomes, including—

3           “(i) male and female developmental  
4 and reproductive disorders;

5           “(ii) brain (behavioral and intellec-  
6 tual) disorders;

7           “(iii) metabolic syndrome, pre-diabe-  
8 tes, diabetes, improper glucose and fat me-  
9 tabolism, obesity, and cardiovascular dis-  
10 orders;

11           “(iv) effects on the pituitary,  
12 hypothalamus, hippocampus, thyroid, adre-  
13 nal, immune, bone, cardiovascular, and  
14 other endocrine organs and systems  
15 throughout all life stages;

16           “(v) hormonally driven cancer; and

17           “(vi) other related effects;

18           “(C) be appropriately sensitive to detect a  
19 chemical’s potential to disrupt the human endo-  
20 crine system at ambient exposure dosing levels;

21           “(D) consider the potential for additive  
22 and synergistic effects and need not be based  
23 solely on expectations of monotonic effects  
24 where the dose reflects the toxicity;

1           “(E) be carried out using a multidisci-  
2 plinary approach to assure connections among  
3 multiple levels, from molecular to organ to  
4 whole animal or human research; and

5           “(F) be designed to develop biomarkers of  
6 exposure and effect that can be further devel-  
7 oped and translated for use in human epidemio-  
8 logical and public health studies focused on de-  
9 fining the role of endocrine disrupting chemicals  
10 in disease etiology across the lifespan.

11           “(2) WORKSHOPS AND FORA.—

12           “(A) IN GENERAL.—The Director of the  
13 Institute shall conduct workshops and fora on  
14 the health effects associated with environmental  
15 agents that may affect the endocrine system in  
16 order to—

17           “(i) identify new chemicals of concern  
18 for research under paragraph (1);

19           “(ii) strategize on approaches for the  
20 development of sensitive tests to screen  
21 chemicals for endocrine disrupting activity  
22 using assays;

23           “(iii) review the state of the science  
24 and provide recommendations for a re-  
25 search, testing, and training agenda; and

1           “(iv) educate attendees about endo-  
2 crine disrupting chemicals.

3           “(B) WORKSHOPS.—

4           “(i) FIRST WORKSHOP.—The Director  
5 of the Institute shall invite the Secretary  
6 of the Interior, the Administrator of the  
7 Environmental Protection Agency, and the  
8 Director of the Centers for Disease Control  
9 and Prevention to participate in a work-  
10 shop under subparagraph (A) not later  
11 than 150 days after the date of the enact-  
12 ment of this section.

13           “(ii) SUBSEQUENT WORKSHOPS.—The  
14 Director of the Institute shall convene sub-  
15 sequent workshops under subparagraph  
16 (A) as the Director determines appro-  
17 priate.

18           “(iii) PARTICIPANTS.—The Director  
19 of the Institute shall—

20           “(I) invite additional participants  
21 to each workshop under subparagraph  
22 (A);

23           “(II) in selecting such partici-  
24 pants, include scientists and health  
25 professionals who are knowledgeable

1 about the endocrine system and envi-  
2 ronmental exposures that may influ-  
3 ence the endocrine system;

4 “(III) select as participants only  
5 those individuals who the Director de-  
6 termines will participate in a manner  
7 free of conflicts of interest; and

8 “(IV) in addition to the partici-  
9 pants invited under subclause (I),  
10 allow representatives of nongovern-  
11 mental organizations to attend each  
12 workshop under subparagraph (A) as  
13 observers.

14 “(C) FORA.—At least every 3 years, the  
15 Director of the Institute shall convene an open  
16 forum for all stakeholders—

17 “(i) to review the state of the science  
18 relevant to environmental agents that in-  
19 fluence the endocrine system; and

20 “(ii) to discuss the future direction of  
21 the Endocrine Disruption Prevention Pro-  
22 gram.

23 “(c) EXPERT PANEL.—

24 “(1) ESTABLISHMENT.—The Director of the  
25 Institute shall establish an Endocrine Disruption

1 Program Panel (in this section referred to as the  
2 ‘Panel’) not later than one year after the date of the  
3 enactment of this section.

4 “(2) MEMBERS.—The Director of the Institute  
5 shall appoint the members of the Panel from among  
6 individuals who—

7 “(A) have established expertise in the field  
8 of endocrine disruption research by publishing  
9 research in peer-reviewed literature;

10 “(B) provide assurances they will perform  
11 their duties in a manner free of conflicts of in-  
12 terest (as determined by the Director), includ-  
13 ing by complying with section 208 of title 18,  
14 United States Code; and

15 “(C) represent diverse disciplines, includ-  
16 ing developmental biology, endocrinology, devel-  
17 opmental and neurological biology, embryology,  
18 biochemistry, physiology, epidemiology, endo-  
19 crine driven oncology, and medical research.

20 “(3) DUTIES.—The Panel shall—

21 “(A) provide advice to the Director of the  
22 Institute on the conduct and support of re-  
23 search under subsection (b);

24 “(B) evaluate existing population-level bio-  
25 monitoring and biobanking surveillance and re-

1 search programs and recommend changes need-  
2 ed to develop data on human exposures and ef-  
3 fects to support the Endocrine Disruption Pre-  
4 vention Program; and

5 “(C) develop a list of chemicals of concern  
6 for endocrine disruption effects and make find-  
7 ings with respect to such chemicals in accord-  
8 ance with paragraph (4).

9 “(4) CHEMICALS OF CONCERN.—

10 “(A) LIST.—The Panel shall—

11 “(i) develop a list of chemicals of con-  
12 cern for endocrine disruption effects; and

13 “(ii) update such list annually.

14 “(B) QUALITATIVE EVALUATION SYS-  
15 TEM.—The Panel shall create a tiered quali-  
16 tative evaluation system, modeled after that of  
17 the National Toxicology Program, in order to  
18 express the Panel’s level of concern that a  
19 chemical on the list under subparagraph (A)  
20 has the potential to disrupt the human endo-  
21 crine system.

22 “(C) REQUIRED FINDINGS.—For each  
23 chemical identified in the list under subpara-  
24 graph (A), the Panel shall review peer-reviewed  
25 studies and other relevant data and issue a

1 finding, based on all of the available evidence,  
2 regarding—

3 “(i) the level of the Panel’s concern,  
4 under the tiered qualitative evaluation sys-  
5 tem, that the chemical has the potential to  
6 disrupt the human endocrine system;

7 “(ii) the need for additional data to  
8 determine the level of concern associated  
9 with the chemical’s potential to disrupt the  
10 human endocrine system; or

11 “(iii) the need for assays to be devel-  
12 oped to provide the data necessary to sup-  
13 port a determination as to the level of con-  
14 cern associated with the chemical’s poten-  
15 tial to disrupt the human endocrine sys-  
16 tem.

17 “(D) SUFFICIENT DATA.—If the Panel  
18 finds under subparagraph (C)(i) that data are  
19 sufficient to determine the extent to which a  
20 chemical has the potential to disrupt the human  
21 endocrine system, the Panel shall publish an ex-  
22 planation of this determination and include the  
23 supporting data.

24 “(E) MINIMAL LEVEL OF CONCERN.—If  
25 the Panel finds under subparagraph (C)(i) that

1 data are sufficient to determine (under the  
2 tiered qualitative evaluation system established  
3 under subparagraph (B)) that there is at least  
4 a minimal level of concern associated with a  
5 chemical's potential to disrupt the human endo-  
6 crine system, the Panel shall describe the routes  
7 and sources of exposure to the chemical that  
8 may cause effects to human health.

9 “(F) ADDITIONAL DATA NEEDED.—If the  
10 Panel finds under subparagraph (C)(ii) that ad-  
11 ditional data are needed to determine the level  
12 of concern associated with the chemical's poten-  
13 tial to disrupt the human endocrine system, the  
14 Panel shall—

15 “(i) identify such data; and

16 “(ii) recommend a process for devel-  
17 oping such data directly or by grant or  
18 contract.

19 “(G) ASSAYS NEEDED.—If the Panel finds  
20 under subparagraph (C)(iii) that assays need to  
21 be developed to provide the data necessary to  
22 support a determination as to the level of con-  
23 cern associated with the chemical's potential to  
24 disrupt the human endocrine system, the Panel  
25 shall identify such assays to the extent possible.

1           “(H) ANNUAL REPORT.—The Panel shall  
2 submit to the Director of the Institute and to  
3 the Congress an annual report on the Panel’s  
4 activities. Each such report shall include—

5                   “(i) an updated version of the list de-  
6 veloped under subparagraph (A); and

7                   “(ii) for each chemical on the list, the  
8 findings and recommendations of the Panel  
9 under subparagraphs (D) through (G).

10           “(I) NO JUDICIAL REVIEW.—A finding or  
11 other determination of the Panel under this  
12 paragraph shall not be subject to judicial re-  
13 view, nor to correction under section 515 of the  
14 Treasury and General Government Appropria-  
15 tions Act, 2001 (commonly referred to as the  
16 ‘Information Quality Act’).

17           “(J) PETITIONS.—

18                   “(i) IN GENERAL.—Any person may  
19 petition the Panel to determine whether a  
20 chemical should be listed pursuant to sub-  
21 paragraph (A) or revise a finding or other  
22 determination under this paragraph based  
23 on new information.

24                   “(ii) RULES.—The Director shall  
25 adopt rules that provide for—

1                   “(I) the form and procedure for  
2                   filing of petitions under this subpara-  
3                   graph; and

4                   “(II) the procedural rights of  
5                   persons filing such petitions.

6           “(d) TRANSMISSION OF CERTAIN FINDINGS TO  
7 OTHER AGENCIES.—

8                   “(1) IN GENERAL.—If the Panel finds under  
9                   subsection (c)(4)(C)(i) that data are sufficient to de-  
10                  termine (under the tiered qualitative evaluation sys-  
11                  tem established under subsection (c)(4)(B)) that  
12                  there is at least a minimal level of concern associ-  
13                  ated with a chemical’s potential to disrupt the  
14                  human endocrine system, the Director of the Insti-  
15                  tute shall transmit the finding, including the Panel’s  
16                  description of the routes and sources of exposure to  
17                  the chemical and any other relevant information, to  
18                  each Federal agency with authority to regulate the  
19                  chemical or the route or source of human exposure  
20                  to the chemical.

21                  “(2) PUBLIC AVAILABILITY.—Whenever the Di-  
22                  rector of the Institute transmits to one or more  
23                  agencies a finding under paragraph (1) regarding a  
24                  chemical, the Director shall publish in the Federal  
25                  Register the names of the agencies and the chemical.

1       “(e) AUTHORIZATION OF APPROPRIATIONS.—To  
2 carry out this section, there are authorized to be appro-  
3 priated such sums as may be necessary for fiscal years  
4 2011 through 2021.”.

5 **SEC. 4. FEDERAL AGENCY ACTION.**

6       (a) REQUIREMENTS.—Upon receipt of a transmission  
7 under section 463C(d) of the Public Health Service Act,  
8 as added by section 3 of this Act, containing a finding  
9 that there is at least a minimal level of concern associated  
10 with a chemical’s potential to disrupt the human endocrine  
11 system, a Federal agency—

12           (1) not later than 180 days after the date of  
13 such receipt, shall issue a reply in writing to the Di-  
14 rector of the National Institute of Environmental  
15 Health Sciences (in this Act referred to as the “In-  
16 stitute”) describing—

17           (A) the agency’s authorities in connection  
18 with the chemical;

19           (B) any past or ongoing actions taken by  
20 the agency in connection with the chemical; and

21           (C) the proposed course of action to be  
22 taken by the agency in response to the Panel’s  
23 finding, including but not limited to further  
24 testing by the Institute or the issuance of regu-  
25 lations, orders, or public notices under the

1           agency’s existing authorities, in furtherance of  
2           protecting human health from the potential en-  
3           doerine disruption effects of exposure to the  
4           chemical; and

5           (2) not later than one year after the date of  
6           such receipt, shall submit to the Congress and shall  
7           publish a report summarizing the actions taken by  
8           the agency in response to the Panel’s finding, as well  
9           as proposed future actions to be taken by the agen-  
10          cy.

11          (b) NO ADDITIONAL REGULATORY AUTHORITY.—  
12          This section does not vest any agency with additional au-  
13          thority to regulate a chemical or the route or source of  
14          human exposure to a chemical.

15          (c) CITIZEN SUITS.—

16                 (1) AUTHORITY TO BRING CIVIL ACTIONS.—Any  
17                 person may commence a civil action to compel any  
18                 agency action required by subsection (a).

19                 (2) JURISDICTION.—The United States courts  
20                 of appeals shall have exclusive original jurisdiction  
21                 over such an action.

22          **SEC. 5. TRAINING IN FIELDS RELATED TO THE PREVEN-**  
23                                 **TION OF ENDOCRINE DISRUPTION.**

24                 (a) IN GENERAL.—The Director of the Institute shall  
25                 establish a program to support, directly or by making

1 grants, graduate and postdoctoral training in fields related  
2 to the prevention of endocrine disruption.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—To carry  
4 out this section, there are authorized to be appropriated  
5 \$2,500,000 for fiscal year 2011 and such sums as may  
6 be necessary for fiscal years 2012 through 2021.

○