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.

IN THE SENATE OF THE UNITED STATES

DECEMBER 3, 2009

Mr. KERRY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE.

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

SEC. 2. FINDINGS, POLICIES, AND GOALS.

(a) FINDINGS.—The Congress finds that—

(1) a disturbing increase in the number of disorders of the human endocrine system is seriously undermining the health and wealth of the Nation;

(2) these disorders include attention deficit hyperactivity disorder (ADHD), autism, learning disabilities, asthma, juvenile cancer, juvenile and adult diabetes, autoimmune diseases, cryptorchidism, hypospadias, endometriosis, obesity, osteoporosis, testicular cancer, male dysgenesis syndrome, breast cancer, prostate cancer, Parkinson’s disease, and Alzheimer’s dementia;

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

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

(5) today, among the fourth generation of children exposed in the womb, one in three children and one in two minority children will develop diabetes; one in six children is born with neurological damage;
one in 100 children has an autism spectrum disorder and among boys the occurrence is one in 58; one in 125 boys is born with hypospadias, a condition where the urethra does not open at the end of the penis; in 2007, an age-independent decline in testosterone levels over the past twenty years was discovered in American men; and declines in male reproductive health have been traced back to damage in the womb;

(6) evidence from human epidemiological and laboratory animal studies links these disorders to prenatal and later life exposure to endocrine disrupting chemicals (EDCs);

(7) the endocrine system is a complex system of organs regulated by over eighty known hormones as well as hundreds of auxiliary chemical signaling systems, and it assures the perpetuity and integrity of human life;

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

(9) thousands of chemicals have become an integral part of confined environments (homes,
schools, cars, planes, offices, theaters, malls), contributing to continual, ubiquitous exposure, and it is vital to be able to identify which are EDCs;

(10) many plant and animal species are showing signs of ill health due to exposure to endocrine disrupting chemicals, which can cause small, but critical, changes in the chemical makeup of an environment that are enough to trigger outcomes that could lead to population decline and loss of biodiversity;

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

(12) all vertebrates (fish, amphibians, reptiles, birds, and mammals, including humans) are fundamentally similar during early embryonic development, so scientists can use the evidence acquired on other species to make predictions about endocrine disrupting effects on humans;

(13) traditional toxicology and risk assessment, which evaluate one chemical at a time, and only at
high concentrations, have failed to sufficiently ad-

dress the effects of low doses of chemicals at mul-
tiple early life stages and have not prevented the
alarming increase of endocrine disorders sweeping
across the Northern Hemisphere;

(14) since the early 1990s, independent govern-
ment-funded scientists in academic and institutional
laboratories around the world have published data
demonstrating the ability of a broad selection of
chemicals to interfere with human development and
function by affecting a number of endocrine mecha-

nisms, and have discovered endocrine disruptive ef-
fects for some widely used chemicals at concentra-
tions several thousand times lower than government
“safe” levels derived through traditional toxicological
tests;

(15) these scientists have developed a new para-
digm for disease, the developmental basis of disease,
which states that disease starts during development
and is influenced by exposures to environmental

chemicals, stress and nutrition interacting on the de-
veloping organism;

(16) the developmental basis of disease changes
the focus from curing disease to prevention and to
understanding gene-environment-nutrition interactions during development;

(17) the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP) have conducted important studies on the environmental connection to human diseases, and have in place a 5-tier scale of concern by which to evaluate chemicals based on the weight of scientific evidence and toxicity and exposure information;

(18) while research has established that exposure to EDCs induces delayed toxicity that results in disease weeks, months, years, or decades later in life, Federal regulatory agencies generally are not using the results of this research to restrict production and use of even the most egregious chemicals;

(19) although Congress directed the Environmental Protection Agency in the Food Quality Protection Act of 1996 to develop, not later than August 3, 1998, “a screening program using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the
Administrator may designate”, the Agency did not release test orders announcing the availability of initial standardized screens and testing protocols until October 21, 2009, and no chemical has been tested for its impact on development and function from fertilization to birth, despite the expenditure of more than $100,000,000;

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

(21) the costs to society of not taking action include medical expenses of treating these chronic diseases, lost productivity, impaired fertility, compromised quality of life for those affected, their families and communities, so prevention is the key.

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

(1) to promote family health and the perpetuation of the human species as a paramount national goal, recognizing that in order to protect the embryo, fetus, and infant during their most vulnerable stages of development, parents’ bodies must be free
of EDCs prior to conception, during gestation, and throughout lactation;

(2) to prevent harmful exposure to EDCs in homes, workplaces, schools, public and private transportation vehicles, indoor and outdoor recreational environments, and in drinking water, foods, and consumer products;

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

(4) to promote research into endocrine disruption by encouraging the multidisciplinary, multi-institutional, and international collaborations that in the past have produced many breakthroughs in knowledge;

(5) to create graduate-level scholarships and post-doctoral fellowships to train young scientists who can meet the demand for technicians and public health and health care personnel in endocrine disruption prevention;

(6) to determine which chemicals in commerce have the potential to disrupt the human endocrine system and to remove these chemicals, and products containing them, from the market; and
(7) to prevent the introduction of new chemicals, and products containing them, that have the potential to disrupt the human endocrine system by requiring testing for these effects before these chemicals and products are released on the market.

SEC. 3. ENDOCRINE DISRUPTION PREVENTION PROGRAM.

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

“SEC. 463C. ENDOCRINE DISRUPTION PREVENTION.

“(a) Program.—The Director of the National Institute of Environmental Health Sciences shall establish a program, to be known as the Endocrine Disruption Prevention Program, consisting of research, workshops, and fora under subsection (b).

“(b) Research, Workshops, and Fora.—

“(1) Research.—The Director of the Institute shall conduct and support multidisciplinary research, to improve the understanding of endocrine disruption. Such research shall—

“(A) include research to design and develop sensitive tests to screen chemicals using assays that are effective for identifying chemicals with the potential to disrupt the human endocrine system;
“(B) address the full range of possible health outcomes, including—

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

“(ii) brain (behavioral and intellectual) disorders;

“(iii) metabolic syndrome, pre-diabetes, diabetes, improper glucose and fat metabolism, obesity, and cardiovascular disorders;

“(iv) effects on the pituitary, hypothalamus, hippocampus, thyroid, adrenal, immune, bone, cardiovascular, and other endocrine organs and systems throughout all life stages;

“(v) hormonally driven cancer; and

“(vi) other related effects;

“(C) be appropriately sensitive to detect a chemical’s potential to disrupt the human endocrine system at ambient exposure dosing levels;

“(D) consider the potential for additive and synergistic effects and need not be based solely on expectations of monotonic effects where the dose reflects the toxicity;
“(E) be carried out using a multidisciplinary approach to assure connections among multiple levels, from molecular to organ to whole animal or human research; and

“(F) be designed to develop biomarkers of exposure and effect that can be further developed and translated for use in human epidemiological and public health studies focused on defining the role of endocrine disrupting chemicals in disease etiology across the lifespan.

“(2) WORKSHOPS AND FORA.—

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

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

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

“(iii) review the state of the science and provide recommendations for a research, testing, and training agenda; and
“(iv) educate attendees about endo-
crine disrupting chemicals.

“(B) WORKSHOPS.—

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

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

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

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

“(II) in selecting such partici-
pants, include scientists and health
professionals who are knowledgeable
about the endocrine system and envi-
ronmental exposures that may influ-
ence the endocrine system;

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

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

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

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

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

“(e) EXPERT PANEL.—

“(1) ESTABLISHMENT.—The Director of the
Institute shall establish an Endocrine Disruption
Program Panel (in this section referred to as the 'Panel') not later than one year after the date of the enactment of this section.

“(2) Members.—The Director of the Institute shall appoint the members of the Panel from among individuals who—

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

“(B) provide assurances they will perform their duties in a manner free of conflicts of interest (as determined by the Director), including by complying with section 208 of title 18, United States Code; and

“(C) represent diverse disciplines, including developmental biology, endocrinology, developmental and neurological biology, embryology, biochemistry, physiology, epidemiology, endocrine driven oncology, and medical research.

“(3) Duties.—The Panel shall—

“(A) provide advice to the Director of the Institute on the conduct and support of research under subsection (b);

“(B) evaluate existing population-level biomonitoring and biobanking surveillance and re-
search programs and recommend changes needed to develop data on human exposures and effects to support the Endocrine Disruption Prevention Program; and

“(C) develop a list of chemicals of concern for endocrine disruption effects and make findings with respect to such chemicals in accordance with paragraph (4).

“(4) CHEMICALS OF CONCERN.—

“(A) LIST.—The Panel shall—

“(i) develop a list of chemicals of concern for endocrine disruption effects; and

“(ii) update such list annually.

“(B) QUALITATIVE EVALUATION SYSTEM.—The Panel shall create a tiered qualitative evaluation system, modeled after that of the National Toxicology Program, in order to express the Panel’s level of concern that a chemical on the list under subparagraph (A) has the potential to disrupt the human endocrine system.

“(C) REQUIRED FINDINGS.—For each chemical identified in the list under subparagraph (A), the Panel shall review peer-reviewed studies and other relevant data and issue a
finding, based on all of the available evidence, regarding—

“(i) the level of the Panel’s concern, under the tiered qualitative evaluation system, that the chemical has the potential to disrupt the human endocrine system;

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

“(iii) the need for assays to be developed to provide the data necessary to support a determination as to the level of concern associated with the chemical’s potential to disrupt the human endocrine system.

“(D) SUFFICIENT DATA.—If the Panel finds under subparagraph (C)(i) that data are sufficient to determine the extent to which a chemical has the potential to disrupt the human endocrine system, the Panel shall publish an explanation of this determination and include the supporting data.

“(E) MINIMAL LEVEL OF CONCERN.—If the Panel finds under subparagraph (C)(i) that
data are sufficient to determine (under the tiered qualitative evaluation system established under subparagraph (B)) that there is at least a minimal level of concern associated with a chemical’s potential to disrupt the human endocrine system, the Panel shall describe the routes and sources of exposure to the chemical that may cause effects to human health.

“(F) ADDITIONAL DATA NEEDED.—If the Panel finds under subparagraph (C)(ii) that additional data are needed to determine the level of concern associated with the chemical’s potential to disrupt the human endocrine system, the Panel shall—

“(i) identify such data; and

“(ii) recommend a process for developing such data directly or by grant or contract.

“(G) ASSAYS NEEDED.—If the Panel finds under subparagraph (C)(iii) that assays need to be developed to provide the data necessary to support a determination as to the level of concern associated with the chemical’s potential to disrupt the human endocrine system, the Panel shall identify such assays to the extent possible.
“(H) ANNUAL REPORT.—The Panel shall submit to the Director of the Institute and to the Congress an annual report on the Panel’s activities. Each such report shall include—

“(i) an updated version of the list developed under subparagraph (A); and

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

“(I) NO JUDICIAL REVIEW.—A finding or other determination of the Panel under this paragraph shall not be subject to judicial review, nor to correction under section 515 of the Treasury and General Government Appropriations Act, 2001 (commonly referred to as the ‘Information Quality Act’).

“(J) PETITIONS.—

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

“(ii) RULES.—The Director shall adopt rules that provide for—
“(I) the form and procedure for filing of petitions under this subpara-
graph; and
“(II) the procedural rights of persons filing such petitions.
“(d) Transmission of Certain Findings to Other Agencies.—
“(1) in General.—If the Panel finds under subsection (c)(4)(C)(i) that data are sufficient to de-
termine (under the tiered qualitative evaluation sys-
tem established under subsection (c)(4)(B)) that there is at least a minimal level of concern associ-
ated with a chemical’s potential to disrupt the human endocrine system, the Director of the Insti-
tute shall transmit the finding, including the Panel’s description of the routes and sources of exposure to the chemical and any other relevant information, to each Federal agency with authority to regulate the chemical or the route or source of human exposure to the chemical.
“(2) Public Availability.—Whenever the Di-
rector of the Institute transmits to one or more agencies a finding under paragraph (1) regarding a chemical, the Director shall publish in the Federal Register the names of the agencies and the chemical.
“(e) Authorization of Appropriations.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2011 through 2021.”.

SEC. 4. FEDERAL AGENCY ACTION.

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

(1) not later than 180 days after the date of such receipt, shall issue a reply in writing to the Director of the National Institute of Environmental Health Sciences (in this Act referred to as the “Institute”) describing—

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

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

(C) the proposed course of action to be taken by the agency in response to the Panel’s finding, including but not limited to further testing by the Institute or the issuance of regulations, orders, or public notices under the
agency’s existing authorities, in furtherance of protecting human health from the potential endocrine disruption effects of exposure to the chemical; and

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

(b) No Additional Regulatory Authority.—This section does not vest any agency with additional authority to regulate a chemical or the route or source of human exposure to a chemical.

(c) Citizen Suits.—

(1) Authority to bring civil actions.—Any person may commence a civil action to compel any agency action required by subsection (a).

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

SEC. 5. TRAINING IN FIELDS RELATED TO THE PREVENTION OF ENDOCRINE DISRUPTION.

(a) In General.—The Director of the Institute shall establish a program to support, directly or by making
grants, graduate and postdoctoral training in fields related to the prevention of endocrine disruption.

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