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STRENGTHENING PROTECTIONS FOR CHILDREN AND COMMUNITIES FROM DISEASE CLUSTERS ACT

SEPTEMBER 19, 2012.—Ordered to be printed

Mrs. BOXER, from the Committee on Environment and Public Works, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany S. 76]

[Including cost estimate of the Congressional Budget Office]

The Committee on Environment and Public Works, to which was referred the bill (S. 76) to direct the Administrator of the Environmental Protection Agency to investigate and address cancer and disease clusters, including in infants and children, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

PURPOSES OF THE LEGISLATION

To direct the Administrator of the Environmental Protection Agency to investigate and address cancer and disease clusters, including in infants and children.

GENERAL STATEMENT AND BACKGROUND

S. 76 seeks to increase the transparency, accountability and coordination of federal actions to investigate and address cancer and disease clusters. The bill authorizes the Administrator of the Environmental Protection Agency to investigate and address cancer and disease clusters, in conjunction with other federal public health agencies. The bill also increases the involvement of the public in

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participating in disease cluster investigations and actions to address the potential causes of such clusters.

The need to modernize and update the federal government's approach to addressing disease clusters is clear. Over the last century, society has made tremendous advances in public health protections. Clean drinking and wastewater systems have reduced the number of people who die from typhoid and cholera. New medical systems, including early detection techniques, have helped to reduce deaths from heart disease and stroke. However, studies have shown the rates of some diseases have increased and the rates of other diseases, and associated deaths, still impact significant numbers of people, including children.

For example, according to the Environmental Protection Agency (EPA), from 1975 to 2007, rates of childhood cancer have increased by almost 30 percent. Leukemia is the most common form of childhood cancer, accounting for 20 percent of the incidences. Between 1976 and 2005 there was a 24 percent increase in acute lymphoblastic leukemia in children.

According to the National Cancer Institute, roughly 2,200 children a year are diagnosed with cancer of the central nervous system, including of the brain and brain stem. The Department of Health and Human Services has found that birth defects are the leading cause of infant death in the first year of life, accounting for about 20 percent of infant deaths in 2006.

Diseases can have complex causes and researchers can have great difficulty fully describing the factors that cause children and other people to contract cancer and other illnesses. Experts focus on multiple potential causes, which often involve both environmental and genetic factors.

Recently, the President's Cancer Panel issued its 2008–2009 annual report, titled: "Reducing Environmental Cancer Risk: What We Can Do Now." The report states that:

> "In 2009 alone, approximately 1.5 million American men, women, and children were diagnosed with cancer, and 562,000 died from the disease. With the growing body of evidence linking environmental exposures to cancer, the public is becoming increasingly aware of the unacceptable burden of cancer resulting from environmental and occupational exposures that could have been prevented through appropriate national action."

The President's Cancer Panel went on to highlight the need to more fully address environmental links to cancer: "The Panel was particularly concerned to find that the true burden of environmentally induced cancer has been grossly underestimated. . . . The Panel urges you [the President] most strongly to use the power of your office to remove the carcinogens and other toxins from our food, water, and air that needlessly increase health care costs, cripple our Nation's productivity, and devastate American lives."

The Committee also received testimony from people who have been impacted by childhood disease. The Committee notes the testimony of Mr. Trevor Schaefer, who is a twenty-one-year-old brain cancer survivor from McCall, ID. Mr. Schaefer was diagnosed with a malignant medullablastoma in November of 2002 at the age of thirteen. He successfully fought the disease following treatment for

his cancer and, thereafter, has helped to lead efforts to address the causes of childhood disease clusters. S. 76, which is also known as "Trevor's Law," is designed to help children and other people like Mr. Schaefer who are affected by disease clusters.

To accomplish goal, the bill seeks to strengthen federal agency coordination and accountability when investigating and helping to address potential disease clusters; increase resources to communities who may be impacted by potential disease clusters, including by providing for community-based committees that play an integral role in actions to investigate and help address such clusters; and enhance federal, state and academic capacity to investigate and help address such clusters, including through partnerships and grants and by developing new pollution and disease tracking tools to facilitate investigation and actions to address clusters.

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

Section 1 provides that the short title of the bill is the "Strengthening Protections for Children and Communities From Disease Clusters Act".

Sec. 2. Findings

Section 2 contains the findings made to highlight the need for the bill and the actions authorized by the bill.

Sec. 3. Purposes

Section 3 defines the purposes for which the bill was created.

Sec. 4. Goals

Section 4 defines the goals that the bill seeks to achieve.

Sec. 5. Definitions

Section 5 contains the definitions of the bill.

Sec. 6. Guidelines for environmental investigations of disease clusters

Section 6 describes the establishment and requirements for federal disease cluster investigation guidelines.

Subsection (a) directs the Administrator of the EPA, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary of Health and Human Services, and the Director of the National Institute of Environmental Health Sciences to develop, publish, and periodically update guidelines that describe a systematic, integrated approach that uses the best available science to investigate suspected or potential disease clusters, environmental pollutants or toxic substances associated with one or more suspected or potential disease clusters, or the potential causes of such clusters.

Subsection (b) describes the requirements for these guidelines, including the definition of key concepts and actions; identification and reporting protocols; standardized methods of reviewing and categorizing data, guidance for using, in a health-protective way, an appropriate epidemiological, statistical, or other approach for the circumstances of an investigation; procedures for peer review of

key documents by individuals who have no direct or indirect conflict of interest; and a description of roles and responsibilities of federal agencies in conducting investigations.

Subsection (c) describes the timing for the proposed and final guidelines.

Sec. 7. Enhanced support for environmental investigations of disease clusters

Subsection (a) describes the establishment of regional disease cluster information and response centers and teams. The subsection describes the federal agencies included in the process of creating these administrative structures and, to promote accountability and transparency, makes the Administrator of the EPA principally responsible for directing, coordinating and approving federal authorized under this section. This subsection also describes the coordination, grants and cooperative agreements, timing of creation, and the authorization of appropriations for these activities.

Subsection (b) describes the response teams' membership and leadership structure and the activities authorized to be undertaken by the teams. The subsection provides for a petition process to request that a response team conduct an investigation or take other action to address the potential causes of disease clusters, and requires the issuance of criteria for the consideration of such petitions. The subsection describes the response teams' use of data and the requirements for transparency and accountability in conducting their activities. The subsection also provides for the creation of a database to assist the response teams and other efforts in investigating and addressing disease clusters.

Subsection (c) describes the creation of community disease cluster advisory committees that are created to provide oversight, guidance, and advice relating to the investigation of suspected and potential disease clusters, and for other purposes. The subsection describes the membership of the committees and prohibits direct and indirect conflicts of interest by such members. The subsection authorized technical assistance, including grants, to groups of individuals that may be affected by a suspected or potential disease cluster and allows such grants to be used to facilitate active involvement in all aspects of Committee activities and to assist Committee members in obtaining technical assistance in interpreting information related to the investigation of suspected or potential disease clusters, and for other purposes.

Subsection (d) describes the types of environmental research and analysis authorities that federal agencies shall utilize when undertaking authorized activities.

Sec. 8. Federal reports to Congress

Subsection (a) describes the timing of reports to Congress on activities authorized to be undertaken by this bill.

Subsection (b) describes the types of activities and information that should be included in the reports.

Subsection (c) describes the submission and availability of such reports.

Sec. 9. Authorization of appropriations

This section authorizes appropriations as are necessary to carry out this Act.

Sec. 10. Effect on other laws

This section states that nothing in this Act modifies, limits, or otherwise affects the application of, or obligation to comply with, any law, including any environmental or public health law.

LEGISLATIVE HISTORY

S. 76 was introduced by Senator Boxer on January 25, 2011. The bill was received, read twice, and referred to the Committee on Environment and Public Works. On June 9, 2011, the Committee on Environment and Public Works met to consider the bill. The bill was ordered reported favorably without amendment by voice vote.

HEARINGS

In the 112th Congress, on March 29, 2011, the full Committee on Environment and Public Works held a hearing entitled, "Oversight Hearing on Disease Clusters and Environmental Health."

ROLLCALL VOTES

The Committee on Environment and Public Works met to consider S. 76 on June 9, 2011. The bill was ordered reported favorably by voice with Senator Inhofe recorded as "No".

REGULATORY IMPACT STATEMENT

In compliance with section 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes evaluation of the regulatory impact of the reported bill. The Committee finds that this legislation does not have substantial regulatory impacts.

MANDATES ASSESSMENT

In compliance with the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), the Committee finds that this legislation does not impose intergovernmental mandates or private sector mandates as those terms are defined in the Unfunded Mandates Reform Act (UMRA). The Congressional Budget Office concurs, finding S. 76 contains no intergovernmental or private-sector mandates as defined in the UMRA and would not affect the budgets of state, local, or tribal governments.

JUNE 22, 2011.

Hon. BARBARA BOXER,
Chairman, Committee on Environment and Public Works,
U.S. Senate, Washington, DC.

DEAR MADAM CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 76, the Strengthening Protections for Children and Communities from Disease Clusters Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Susanne Mehlman.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

S. 76—Strengthening Protections for Children and Communities from Disease Clusters Act

Summary: S. 76 would require the Environmental Protection Agency (EPA) to develop guidelines for establishing a systematic and integrated approach to investigating suspected disease clusters. (Disease clusters are defined as the occurrence of a greater-than-expected number of cases of a particular disease within a group of individuals, geographical area, or time period.) This legislation also would require EPA to establish and operate two regional response centers and response teams to investigate potential disease clusters or environmental pollutants or toxic substances associated with those disease clusters. In addition, S. 76 would authorize EPA to provide grants and enter into cooperative agreements with institutions of higher education to support research and operational activities performed by the response teams. Under the bill, EPA also could make technical assistance grants to any group of individuals affected by a suspected disease cluster.

Based on information from EPA, CBO estimates that implementing S. 76 would cost about $76 million over the 2012–2016 period, subject to appropriation of the necessary amounts. That funding would provide for additional personnel, contractors, grants and cooperative agreements, and other administrative activities.

Pay-as-you-go procedures do not apply to this legislation because enacting the bill would not affect direct spending or revenues.

S. 76 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 76 is shown in the following table. The costs of this legislation fall within budget function 300 (natural resources and environment).

	By fiscal year, in millions of dollars—					
	2012	2013	2014	2015	2016	2012–2016
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Grants and Cooperative Agreements with Institutions of Higher Learning:						
Estimated Authorization Level	5	5	5	5	5	25
Estimated Outlays	2	4	5	5	5	21
Grants to Affected Groups:						
Estimated Authorization Level	0	4	4	4	4	16
Estimated Outlays	0	4	4	4	4	16
Support for Response Centers and Teams:						
Estimated Authorization Level	4	4	4	4	4	20
Estimated Outlays	3	4	4	4	4	19
Other EPA Administrative Support:						
Estimated Authorization Level	4	4	4	4	4	20
Estimated Outlays	4	4	4	4	4	20
Total Changes:						
Estimated Authorization Level	13	17	17	17	17	81
Estimated Outlays	9	16	17	17	17	76

Note: EPA = Environmental Protection Agency.

Basis of estimate: For this estimate, CBO assumes that S. 76 will be enacted by the end of fiscal year 2011 and that the necessary amounts will be appropriated each year.

Based on information from EPA, CBO estimates that in 2012 EPA would spend about $9 million to establish the guidelines for investigating disease clusters and to establish and provide some initial support for the response centers and teams responsible for investigating those disease clusters. Included in that cost is funding for about 25 additional personnel, contractors, a small number of grants and cooperative agreements for institutions of higher learning, and other administrative support. In subsequent years when the response centers and teams are fully operational, CBO expects that EPA would spend additional resources to provide grants and enter into cooperative agreements with institutions of higher education to support those response centers and teams and to provide grants to affected groups. As a result, EPA's costs would increase to $16 million in 2013 and $17 million annually in subsequent years.

Intergovernmental and private-sector impact: S. 76 contains no intergovernmental mandates or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments. State, local, and tribal governments could receive grants and technical assistance authorized by the bill.

Estimate prepared by: Federal Spending: Susanne Mehlman; Impact on State, Local, and Tribal Governments: Ryan Miller; Impact on the Private Sector: Amy Petz.

Estimate approved by: Theresa Gullo, Deputy Assistant Director for Budget Analysis.

MINORITY VIEWS OF SENATORS INHOFE, VITTER

Protecting communities including pregnant women, infants, and children is of the utmost importance. Physicians and local public health departments are on the front lines of caring for these communities and vulnerable subpopulations while defending them from illness and diseases every day. A "cluster" is defined by the Center for Disease Control (CDC) as "an unusual aggregation, real or perceived, of health events that are grouped together in time and space and that is reported to a public health department."

Currently, at the federal level, CDC through the Agency for Toxic Substances and Disease Registry (ATSDR) investigates and addresses cancer and disease clusters. ATSDR is an agency with a long history in public health and possesses the expertise and knowledge necessary to identify and deal with disease clusters. It has an existing infrastructure that facilitates cooperation between states and local public health departments, as well as local physicians communication ATSDR has labeled "essential in recognizing and responding to disease cluster concerns." ATSDR has also outlined procedures for investigating disease clusters at the federal, state, and local levels.

S. 76, the "Strengthening Protections for Children and Communities from Disease Clusters Act," needlessly shifts authorities away from local and federal public health experts at the CDC, ATSDR, and public health departments, to the Environmental Protection Agency (EPA), a regulatory agency with far less expertise and experience in identifying and responding to disease clusters.

This legislation ignores the critical roles of CDC and ATSDR, but also of local doctors as well as public health departments in dealing with disease clusters in favor of a top down bureaucratic approach. Local physicians have the primary role in confirming diagnosis and completing applicable exposure histories as well as recognizing abnormal event patterns. This information is then reported to the appropriate local public health departments who have a critical role of their own in the investigation of disease clusters. They collect case information, conduct local surveillance and surveys, conduct environmental and occupational exposure assessments, ensure appropriate communication and education of the public as well as health professionals, and initiate effective and timely actions to allay potential factors associated with disease clusters.

The stated purposes of this bill are to provide the EPA Administrator with broad new authorities "to help conduct investigations" and "to undertake actions" to help investigate and address "potential environmental pollution and toxic substances that may contribute to the creation of disease clusters." Inclusion of "potential" is highly problematic. Potential refers to the possibility of a relationship, not likelihood. This would direct EPA onto "fishing expeditions" in search of "potential" chemical "causes" of disease clus-

ters. It is at odds with EPA's expertise in risk assessment, under which EPA incorporates chemical specific hazard and exposure information developed under validated laboratory screens, tests and assessment of potential exposures, to determine the potential risk of harm from a specific exposure to a chemical substance. These risk assessments do not identify causes of disease and thus EPA's chemical specific risk assessment expertise is not readily transferrable to investigations of disease clusters. That expertise is held by physicians and public health agencies. Under S. 76, there is no requirement to show causality at all, let alone a rigorous weight of evidence assessment. EPA is given, by a literal reading, almost limitless authority. This new authority is nothing more than an attempt to circumvent appropriate jurisdictional and congressional limitations on the EPA, The foremost enumerated goal of this legislation is to protect individuals "who have been, are, or could be harmed by, and become part of, a disease cluster." Reading that goal literally, who does not meet the criteria of someone who "could be harmed by, and become part of, a disease cluster?"

Throughout this legislation, the rightful responsibilities of Congress are intentionally subrogated to the EPA, allowing the Agency great discretion in defining key terms, and even its own authorities. S. 76 assigns unelected EPA bureaucrats the lead role in implementing broad and vague authorities in any manner they desire.

In S. 76, there is no definition of the term "disease." The term "disease cluster" is loosely defined in part as "the occurrence of a greater-than-expected number of cases of a particular disease within a group of individuals, a geographical area, or period of time." There is no reference to how or where the "greater-than-expected" determination should be scientifically determined. Moreover, to determine expected numbers would require an immense database on the distributions of an array of various health endpoints, taking into account population statistics and comparative prevalence of disease within each subpopulation. This database simply does not exist. The definition goes on to also include "the occurrence of a particular disease in such number of cases, or meeting such other criteria, as the Administrator . . . may determine," leaving EPA in consultation with ATSDR and the Director of the National Institute of Environmental Health Sciences (NIEHS)—limitless discretion to label virtually any situation as a "disease cluster."

The terms "environmental pollutants or toxic substances" and "potential causes of a disease cluster" are defined similarly to include as wide a range as possible, including contaminants and pollutants regulated by the Clean Water and Safe Drinking Water Acts. While these are established environmental pollutants, this definition also includes any chemical substance regulated under the Toxic Substances Control Act regardless of any scientific findings that such substances are either toxic or pose significant exposures to humans.

Under Section 6 of S. 76, the EPA Administrator is also in the lead role of developing guidelines for disease cluster investigations. These guidelines include defining "key concepts and actions," developing "disease cluster identification and reporting protocols," and "guidance for using . . . appropriate epidemiological, statistical, or other approach for the circumstances of an investigation" in a

"health-protective way." This is extremely troubling, as the term "health-protective" is not defined and is open for interpretation, appearing to steer investigations on the use of overly conservative risk models and assumptions that are often controversial rather than the best available science. These guidelines further go on to include allowing the EPA Administrator the lead in assigning the "roles and responsibilities" of federal officials and creating "procedures for peer review" that have no prohibition on individuals who possess a blatant appearance of partiality.

EPA's largely unfettered grant of power continues into Section 7, entitled "Enhanced Support for Environmental Investigations of Disease Clusters." This section directs the Agency to lead in the establishment and operation of Regional Disease Cluster Information and Response Centers ("Response Centers") and Regional Disease Cluster Information and Response Teams ("Response Teams"). Under the subsection (a)(1)(B), the EPA Administrator is directed to "be principally responsible for directing, coordinating, and approving Federal efforts and assistance authorized under this section."

The Response Teams, whose scope of activities are established through an EPA-led consultation process, are to be staffed using a loose set of criteria including requirements of individuals with "community outreach" experience. Similarly to S. 76's peer review criteria, Response Team membership has no prohibition against a lack of appearance of impartiality. One of the Response Teams' primary responsibilities is responding to petitions from "any person . . . that requests that a Response team conduct an investigation or take other action to address the potential causes of disease clusters in accordance with this Act." These responses are regarding the broadly-labeled need "to investigate suspected or potential disease clusters, environmental pollutants or toxic substances associated with these disease clusters, and potential causes of disease clusters."

Petitions made to Response Teams are to be considered using criteria to be established through an EPA-led process, again using "health-protective factors" rather than the best available science. Considerations are also required to include evidence of environmental releases of substances without any reference to human health impacts and the blanket provision including "such other factors as the Administrator determines are necessary." This fails to recognize that there are many biological steps that must occur before exposure to a chemical or substance can cause an adverse outcome and it is imperative not to make blanket presuppositions that any exposure to any chemical or substance necessarily causes harm. Furthermore, this approach seems to grossly discount factors recognized by the National Cancer Institute and other reputable health based scientific organizations that potential causes for cancer and disease clusters such as heredity and behavior and lifestyle including diet, use of tobacco, drugs, alcohol, and even exposure to sunlight.

Another troubling piece of this legislation is Section 7's requirement of a public database. While there is an important need for government transparency, there is also a need to recognize the serious potential for harm to be caused by disseminating inaccurate

and incomplete information. The required database would be publically accessible through the internet and provide information relating to ongoing incomplete reports, substances and illnesses "associated with suspected or potential disease clusters" regardless if this information is irrefutably shown later to have been groundless—and often with disease cluster allegations, that is the conclusion. Such a database, then, could serve as an unsubstantiated inventory of chemicals for people to fear unnecessarily and even as a list of chemicals for businesses to avoid absent any scientific basis. These are just some of the potential pitfalls of this database that could have devastating impacts on local economies, businesses, and home values, often with absolutely no demonstrable health benefits.

In further attempt to usurp and/or duplicate the authorities of other Federal Agencies and increase the bureaucratic expansion of EPA, this bill requires the EPA Administrator alone to establish Community Disease Cluster Advisory Committees. The purpose of these committees is to "provide oversight, guidance, and advice" relating to the investigations of suspected and potential disease clusters and associated causes or pollutants. These committees too are required to have be comprised of a loosely defined membership which includes any individuals "as determined by the Administrator" of EPA along with some consultation. Of most concern is the broad required membership category which includes "individuals who are or may be impacted by a suspected or potential disease cluster, and the designee of such an individual who may participate with or in the place of such and individual." This loose definition could include almost anyone and to make matters even more troubling, it includes any individuals "designee" which could encompass activists from outside of the communities or investigated areas.

Finally, this bill provides no express opportunity for judicial review of any determinations made, and there is no requirement for EPA or any other Federal Agency to do any sort of economic analysis considering potential job losses and associated health impacts resulting from the implementation of any potential actions stemming from S. 76. Within S. 76, there are some areas requiring EPA and other federal agencies to provide for public notice of draft criteria and guidelines and some minimal opportunity for public comment; however, the timeframe for responses is too short to solicit meaningful review, and there is no requirement for the agencies to respond to any substantive comments.

It is vitally important that we continue our efforts to identify, treat, and diagnose disease clusters using the best available science. S. 76 is nothing more than a misguided attempt to take authority away from science based public health and disease experts and give it to a regulatory agency far less qualified for the job.

CHANGES IN EXISTING LAW

Section 12 of rule XXVI of the Standing Rules of the Senate requires the committee to publish changes in existing law made by the bill as reported. Passage of this bill will make no changes to existing law.

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