

SECRET SCIENCE REFORM ACT OF 2014

NOVEMBER 12, 2014.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. SMITH of Texas, from the Committee on Science, Space, and Technology, submitted the following

R E P O R T

[To accompany H.R. 4012]

[Including cost estimate of the Congressional Budget Office]

The Committee on Science, Space, and Technology, to whom was referred the bill (H.R. 4012) to prohibit the Environmental Protection Agency from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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I. REPORTED BILL

SECTION 1. SHORT TITLE.

This Act may be cited as the “Secret Science Reform Act of 2014”.

**SEC. 2. DATA TRANSPARENCY.**

Section 6(b) of the Environmental Research, Development, and Demonstration Authorization Act of 1978 (42 U.S.C. 4363 note) is amended to read as follows:

“(b)(1) The Administrator shall not propose, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action is—

“(A) specifically identified; and

“(B) publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.

“(2) Nothing in the subsection shall be construed as requiring the public dissemination of information the disclosure of which is prohibited by law.

“(3) In this subsection—

“(A) the term ‘covered action’ means a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance; and

“(B) the term ‘scientific and technical information’ includes—

“(i) materials, data, and associated protocols necessary to understand, assess, and extend conclusions;

“(ii) computer codes and models involved in the creation and analysis of such information;

“(iii) recorded factual materials; and

“(iv) detailed descriptions of how to access and use such information.”.

**II. PURPOSE AND SUMMARY**

The purpose of H.R. 4012, the “Secret Science Reform Act of 2014”, is to prohibit the Environmental Protection Agency (EPA) Administrator from finalizing, proposing, or disseminating a covered action unless all scientific and technical information relied on to support the covered action is specifically identified and publicly available in a manner that is sufficient for independent analysis and substantial reproduction.

**III. BACKGROUND AND NEED FOR THE LEGISLATION**

Science has been central to EPA’s mission and functions since its establishment in 1970. The Agency’s recently-finalized Scientific Integrity Policy describes science as “the backbone of the EPA’s decision-making.”<sup>1</sup> Efforts to encourage and guarantee open scientific research and assessment at the EPA are based in a number of historical, legal, and administrative origins.

In 1983, then-Administrator William Ruckelshaus wrote a memo to all EPA employees dictating that the agency should operate as though it were “in a fishbowl.” The memo stressed the importance of being as open as possible, while also providing the fullest possible public participation in decision making.<sup>2</sup> EPA Administrator Gina McCarthy echoed this priority in her confirmation hearing, stating that “The rule of law, along with sound science and transparency, is one of EPA’s core values and, if I am confirmed, it will continue to guide all EPA actions.”<sup>3</sup> Similarly, she stated that, “EPA is committed to transparency with regard to the scientific bases of agency decision making.”<sup>4</sup> Science is a critical component of EPA’s regulatory decisions related to several environmental laws, including the Environmental Research, Development, and

<sup>1</sup> [http://www.epa.gov/osa/pdfs/epa\\_scientific\\_integrity\\_policy\\_20120115.pdf](http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf)

<sup>2</sup> <http://www2.epa.gov/aboutepa/ruckelshaus-takes-steps-improve-flow-agency-information-fishbowl-policy#memo>.

<sup>3</sup> [http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing\\_id=d71fd4b6-ce77-3a98-46a0-fb02b0cae0ed](http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_id=d71fd4b6-ce77-3a98-46a0-fb02b0cae0ed)

<sup>4</sup> *Ibid.*

Demonstration Authorization Act, the Clean Air Act, the Clean Water Act, and the Safe Drinking Water Act.

Recent EPA and White House scientific integrity, regulatory, and open access policies indicate strong support for open access to scientific information, including the information underlying Federal regulatory actions. Executive Order 13563 requires that regulations “be based upon the best available science.”<sup>5</sup> Similarly, President Obama’s March 2009 Scientific Integrity Memo states that “[t]o the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.”<sup>6</sup>

Following up on this direction, the White House Office of Science and Technology Policy (OSTP) Memo from December 2010 states that “agencies should expand and promote access to scientific information by making it available online in open formats. Where appropriate, this should include data and models underlying regulatory proposals and policy decisions.”<sup>7</sup> OSTP also issued a 2013 Memorandum on “Increasing Access to the results of Federally Funded Scientific Research,” in which the President’s Science Advisor John Holdren explained that, “The Administration is committed to ensuring that, to the greatest extent and with the fewest constraints possible and consistent with law and the objectives set out below, the direct results of federally funded scientific research are made available to and useful for the public, industry, and the scientific community. Such results include peer-reviewed publications and digital data.”<sup>8</sup>

In order to provide Agency-specific guidelines emanating from the President’s and OSTP’s Scientific Integrity Memos, EPA’s 2012 final Scientific Integrity Policy states: “Scientific research and analysis comprise the foundation of all major EPA policy decisions. Therefore, the Agency should maintain vigilance toward ensuring that scientific research and results are presented openly and with integrity, accuracy, timeliness, and the full public scrutiny demanded when developing sound, high-quality environmental science.”<sup>9</sup>

Developed in response to Office of Management and Budget (OMB) guidelines issued following provisions of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106–554; H.R. 5658), EPA’s *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency* state that the Agency is “committed to providing public access to environmental information” and that, in order to fulfill its mission, “EPA must rely upon information of appropriate quality for each decision we make.” EPA also notes the limitations of these guidelines, stating that they “provide non-binding policy and procedural guidance, and are therefore not intended to create legal rights, impose legally binding requirements or obligations on EPA or the

<sup>5</sup> <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>

<sup>6</sup> <http://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09>

<sup>7</sup> <http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf>.

<sup>8</sup> [http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp\\_public\\_access\\_memo\\_2013.pdf](http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf).

<sup>9</sup> [http://www.epa.gov/osa/pdfs/epa\\_scientific\\_integrity\\_policy\\_20120115.pdf](http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf).

public when applied in particular situations, or change or impact the status of information we disseminate, nor to contravene any other legal requirements that may apply to particular agency determinations or other actions.”<sup>10</sup>

OMB Circular A–110 also indicates that the federal government has a right to data produced under certain federally-funded research awards. In 1999, following an amendment to the Omnibus Appropriations Act for FY1999 (often referred to as the “Shelby Amendment” due to the role of Senator Richard Shelby) OMB revised this circular to “ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act.”<sup>11</sup>

Despite a seemingly strong position in favor of openness and transparency regarding the science behind regulations, the Administration has yet to make public the scientific data that is behind numerous EPA regulations. Some outside researchers have sought the scientific data behind these regulations and have been denied access. The Committee issued a subpoena for the scientific data behind these regulations and EPA responded that it was unable to provide all of the data. EPA further indicated in its response to the Committee received on March 7, 2014, that “Any other data. . . are not (and were not) in the possession, custody, or control of the EPA, nor are they within the authority to obtain data that the agency identified.” EPA acknowledged that “the data provided are not sufficient in themselves to replicate the analyses in the epidemiological studies, nor would they allow for the one to one mapping of each pollutant and ecological variable to each subject.” Without this scientific information, the public is required to blindly trust the EPA’s scientific findings that are the basis of some of the most costly regulations in history.

#### IV. HEARING SUMMARY

In the 113th Congress, the Subcommittee on Environment held a hearing on February 11, 2014, focused on H.R. 4012 and *Ensuring Open Science at EPA*. The Subcommittee received testimony from expert witnesses, which informed the Committee on the need for improved transparency and reproducibility of regulatory science used by the Environmental Protection Agency. Witnesses were also asked to provide comments on H.R. 4012, the “Secret Science Reform Act of 2014.” The Subcommittee received testimony from the Honorable John Graham, Dean, School of Public and Environmental Affairs, Indiana University; Dr. Louis Anthony Cox, Jr., Chief Sciences Officer, Next Health Technologies, Clinical Professor, Biostatistics and Informatics, Colorado Health Sciences Center, and President, Cox Associates; Dr. Ellen Silbergeld, Professor, Bloomberg School of Public Health, Johns Hopkins University; and Mr. Raymond Keating, Chief Economist, Small Business & Entrepreneurship Council.

On November 14, 2013, the Committee on Science, Space, and Technology held a hearing entitled, *Strengthening Transparency and Accountability within the Environmental Protection Agency*.

<sup>10</sup> [http://www.epa.gov/quality/informationguidelines/documents/EPA\\_InfoQualityGuidelines.pdf](http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf).

<sup>11</sup> <http://www.whitehouse.gov/sites/default/files/omb/fedreg/a110-finalnotice.html>

The purpose of this hearing was to review science and technology activities at the EPA, including: agency-wide policies and practices related to the development and use of science in regulatory decisions; the role of independent scientific advisory bodies such as the EPA Science Advisory Board and the EPA Clean Air Scientific Advisory Committee; and the importance of transparency and integrity in the Agency's science activities. The Committee received testimony from The Honorable Gina McCarthy, the Administrator of the U.S. Environmental Protection Agency.

In the 112th Congress, the Committee held two hearings focused on science at the EPA. On November 30, 2011, the Subcommittee on Energy and Environment held a hearing entitled, *Fostering Quality Science at EPA: Perspectives on Common Sense Reform*. The purpose of the hearing was to provide external perspectives on the need to reauthorize and reform science, research and development activities at EPA; explore the intersection of Agency-supported science and its regulatory mission; and receive focused recommendations to raise the level, quality, usefulness, and objectivity of EPA science, including any necessary changes to the Environmental Research, Development and Demonstration Authorization Act. The subcommittee received testimony from Ms. Susan Dudley, Director, Regulatory Studies Center, and Research Professor of Public Policy & Public Administration, The George Washington University; Dr. Alan Moghissi, President, Institute for Regulatory Science; Dr. Kenneth Green, Resident Scholar, American Enterprise Institute; and Dr. Gary Marchant, Professor of Law and Executive Director, Center for Law, Science & Innovation, Arizona State University.

On February 3, 2012, the Subcommittee on Energy and Environment held a second hearing to provide external perspectives on the need to reauthorize and reform science and research and development activities at the EPA. The Subcommittee received testimony from Mr. Daniel Greenbaum, President and Chief Executive Officer, Health Effects Institute; Dr. Deborah Swackhamer, Professor, Environmental Health Sciences, University of Minnesota, and Chairwoman, EPA Science Advisory Board; Mr. Michael Walls, Vice President, Regulatory and Technical Affairs, American Chemistry Council; Dr. Richard Belzer, President, Regulatory Checkbook; Dr. Jerald Schnoor, Allen S. Henry Chair in Engineering, Department of Civil and Environmental Engineering, University of Iowa; and Dr. S. Stanley Young, Assistant Director for Bioinformatics, National Institute of Statistical Sciences.

#### V. COMMITTEE CONSIDERATION

On February 6, 2014, H.R. 4012 was introduced by Rep. Schweikert and referred to the Committee on Science, Space, and Technology.

On June 24, 2014, the Committee on Science, Space, and Technology met in open markup session and adopted H.R. 4012, by a vote of 17 Ayes, 13 Nays.

## VI. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The Committee adopted H.R. 4012 by a vote of 17 Ayes, 13 Nays; a motion to order H.R. 4012 favorably reported to the House, as amended, was agreed to by unanimous consent.

During Full Committee consideration of H.R. 4012, the following amendments were considered:

**COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY**  
**June 24, 2014**

**AMENDMENT ROSTER**

H.R. 4012, the "Secret Science Reform Act of 2014"

No.	Amendment	Summary	
1	<b>Amendment in the Nature of a Substitute Offered by Ms. Bonamici (OR) #001</b>	This amendment would strike the entire bill and instead require the Administrator to implement a public access policy to make EPA-funded peer-reviewed articles, but not the underlying data, publically available without charge no more than 12 months after the date of publication. The amendment also includes procedures for the use of non-public information, public access to research data through the Freedom of Information Act. The amendment requires that the administrator shall only consider research from scholarly publications that discloses the entity that funded it and that, in developing agency action, the Administrator shall not exclude research data that is not public because the disclosure would constitute an invasion of privacy.	<b>Not Agreed to by Voice Vote</b>
2	<b>Amendment Offered by Mr. Kennedy (MA) #003</b>	This amendment would remove the requirement that scientific and technical information relied on to support covered actions by EPA be publically available in manner sufficient for independent analysis, and removes the corresponding language that nothing in the act requires public dissemination of information, the disclosure of which is prohibited by law.	<b>Not Agreed to by Voice Vote</b>

## VII. SUMMARY OF MAJOR PROVISIONS OF THE BILL

The bill prohibits the EPA Administrator from finalizing, proposing, or disseminating a covered action unless all scientific and technical information relied on to support the covered action is specifically identified and publicly available in a manner that is sufficient for independent analysis and substantial reproduction. Nothing in the language of the bill is to be construed as requiring public dissemination of information, the disclosure of which is prohibited by law.

The bill also defines “covered action” to mean a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance. The section defines “scientific and technical information” to include materials, data, and associated protocols necessary to understand, assess, and extend conclusions, computer codes and models involved in the creation and analysis of information, recorded factual materials, and detailed descriptions of how to assess and use such information.

## VIII. COMMITTEE VIEWS

H.R. 4012, The Secret Science Reform Act of 2014, requires that the Environmental Protection Agency base its regulations and assessments on science that is publicly available in a manner sufficient for independent analysis and scientific replication. This approach to regulatory science is consistent with the data access requirements of major scientific journals as well as the transparency policy of this Administration. Transparency and reproducibility are basic tenets of science. Costly environmental regulations should only be based upon data that is available to independent scientists and the public.

This legislation is consistent with the White House’s scientific integrity policy, the President’s Executive Order 13563, data access provisions of major scientific journals, and the recommendations of the Administration’s top science advisors and the Bipartisan Policy Center. In 2012, the President’s Science Advisor testified that “Absolutely, the data on which regulatory decisions and other decisions are based should be made available to the Committee and should be made public unless there is a classification reason.” Also in 2012, the Chair of EPA’s Science Advisory Board in response to follow-up questions after a hearing titled *Fostering Quality Science at EPA: Need for Common Sense Reform (Day II)* stated that EPA’s advisors recommend, “that literature and data used by EPA be peer-reviewed and made available to the public. When the SAB conducts peer reviews and evaluations, it prefers to review all data associated with the document in question. It is my experience that EPA makes its best effort to provide all data to the SAB, subject to ethical and legal restrictions.”

The Committee received a letter of support from over 80 scientists, academic experts, and former EPA officials. Signatories include Ivy League professors, two former chairs of EPA science advisory committees, medical doctors, statisticians, deans of major universities, and environmental scientists. This legislation is similar to the data access provisions of major scientific journals like *Science* and *Nature*, as well as independent research entities like the Health Effects Institute.



H.R. 4012 makes clear that no protected information will be disclosed. This bill only requires information that is sufficient for independent scientists to validate and reproduce the results of this regulatory science. The bill does not require the public dissemination of information, the disclosure of which is prohibited by law. To this end, the Committee received a letter of support from more than 80 scientists, experts, and doctors which states that “complying with H.R. 4012 can be accomplished without imposing unnecessary burdens, discouraging research, or raising confidentiality concerns. Across different disciplines, numerous statistical and technical approaches exist to protect any sensitive information.” Additionally, the National Academy of Sciences has confirmed that transparency and reproducibility in science is possible without any risks to confidentiality or privacy. In 2005, the Panel on Data Access for Research Purposes of the National Research Council stated in its report *Expanding Access to Research Data: Reconciling Risks and Opportunities*: “Nothing in the past suggest that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach.” This Committee has received testimony from some respected experts that the provisions of H.R. 4012 would not raise confidentiality issues.

The legislation covers critical scientific documents related to “covered actions” in order to ensure that significant non-regulatory information is subject to basic standards of transparency and reproducibility. As Dr. John Graham, Indiana University and former head of White House Office of Information and Regulatory Affairs, testified that: “When a federal agency makes a determination that a product, technology or substance is hazardous, the determination itself—without any formal regulatory action—can create a stigma in the marketplace that causes a loss of sales, jobs and so forth. The stigma can also trigger lawsuits against companies under the common laws of the fifty states. If the scientific and technical data underpinning the determinations are not transparent and reproducible, it can be quite difficult for scientists in an impacted company—or any scientist—to determine whether the determination is valid.” The definition of scientific and technical information in the bill is based on data access policies from leading science publications and EPA-funded research institutes.

#### IX. COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held an oversight hearing and made findings that are reflected in the descriptive portions of this report.

#### X. STATEMENT ON GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal to prohibit the EPA Administrator from finalizing, proposing, or disseminating a covered action unless all scientific and technical information relied on to support the covered action is specifically identified and publically available in a manner

that is sufficient for independent analysis and substantial reproduction.

#### XI. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

#### XII. ADVISORY ON EARMARKS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4012, the “Secret Science Reform Act of 2014,” contains no earmarks.

#### XIII. COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

#### XIV. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, October 3, 2014.*

Hon. LAMAR SMITH,  
*Chairman, Committee on Science, Space, and Technology,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4012, the Secret Science Reform Act of 2014.

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

Sincerely,

DOUGLAS W. ELMENDORF, *Director.*

Enclosure.

*H.R. 4012—Secret Science Reform Act of 2014*

H.R. 4012 would amend the Environmental Research, Development, and Demonstration Authorization Act of 1978 to prohibit the Environmental Protection Agency (EPA) from proposing, finalizing, or disseminating a “covered action” unless all scientific and technical information used to support that action is publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results. Covered actions would include assessments of risks, exposure, or hazards; documents speci-

fyng criteria, guidance, standards, or limitations; or regulations and regulatory impact statements.

CBO estimates that implementing H.R. 4012 would cost about \$250 million a year for the next few years, subject to appropriation of the necessary amounts. Costs in later years would probably decline gradually from that level. The additional discretionary spending would cover the costs of expanding the scope of EPA studies and related activities such as data collection and database construction for all of the information necessary to meet the legislation's requirements.

Enacting H.R. 4012 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. H.R. 4012 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, and tribal governments.

Under current law, EPA typically spends about \$500 million each year to support research and development activities, including assessments to determine the potential risk to public health from environmental contaminants. EPA relies on the findings of many scientific studies to develop regulations and perform other covered actions. The number of studies involved in such cases depends on the complexity of the issue being addressed. For example, when addressing a recent issue with flaring at petroleum refineries, EPA relied on a dozen scientific studies. In contrast, when reviewing the National Ambient Air Quality Standards, the agency relied on thousands of scientific studies. In total, the agency relies on about 50,000 scientific studies annually to perform its mission—although some of those studies are used more than once from year to year.

The costs of implementing H.R. 4012 are very uncertain because it is not clear how EPA would meet the bill's requirements. Depending on their size and scope, the new activities called for by the bill would cost between \$10,000 and \$30,000 for each scientific study used by the agency. If EPA continued to rely on as many scientific studies as it has used in recent years, while increasing the collection and dissemination of all the technical information used in such studies as directed by H.R. 4012, then implementing the bill would cost at least several hundred million dollars a year. However, EPA could instead rely on significantly fewer studies each year in support of its mission, and limit its spending on data collection and database construction activities to a relatively small expansion of existing study-related activity; in that scenario, implementing the bill would be much less costly.

Thus, the costs of implementing H.R. 4012 would ultimately depend on how EPA adapts to the bill's requirements. (It would also depend on the availability of appropriated funds to conduct the additional data collection and database construction activities and related coordination and reporting activities under the legislation.) CBO expects that EPA would modify its practices, at least to some extent, and would base its future work on fewer scientific studies, and especially those studies that have easily accessible or transparent data. Any such modification of EPA practices would also have to take into consideration the concern that the quality of the agency's work could be compromised if that work relies on a significantly smaller collection of scientific studies; we expect that the agency would seek to reduce its reliance on numerous studies with-

out sacrificing the quality of the agency's covered actions related to research and development.

On balance—recognizing the significant uncertainty regarding EPA's potential actions under the bill—CBO expects that the agency would probably cut the number of studies it relies on by about one-half and that the agency would aim to limit the costs of new activities required by the bill, such as data collection, correspondence and coordination with study authors, construction of a database to house necessary information, and public dissemination of such information. As a result, CBO estimates the incremental costs to the agency would be around \$250 million a year initially, subject to appropriation of the necessary amounts. In our assessment that figure lies near the middle of a broad range of possible outcomes under H.R. 4012.

CBO expects that the additional costs to implement the legislation would decline over time as EPA became more adept and efficient at working with authors and researchers to ensure that the data used to support studies are provided in a standardized and replicable form. Costs could be even lower if EPA were to more severely restrict the number of studies it relies on to support its decisions regarding environmental standards, regulations, and risk assessments. However, if EPA were to continue its recent practice of relying on roughly 50,000 studies each year, the costs to implement H.R. 4012 would be much higher.

The CBO staff contact for this estimate is Susanne S. Mehlman. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

#### XV. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

#### XVI. COMPLIANCE WITH H. RES. 5

A. Directed Rule Making. The bill does not direct any executive branch official to conduct any specific rule-making proceedings.

B. Duplication of Existing Programs. This bill does not establish or reauthorize a program of the federal government known to be duplicative of another program. Such program was not included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139 or identified in the most recent Catalog of Federal Domestic Assistance published pursuant to the Federal Program Information Act (Public Law 95-220, as amended by Public Law 98-169) as relating to other programs.

#### XVII. FEDERAL ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

#### XVIII. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or

accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

#### XIX. SECTION-BY-SECTION ANALYSIS

##### *Section 1. Short title*

This section establishes the short title of the Act as the “Secret Science Reform Act of 2014.”

##### *Section 2. Data transparency*

Section 2 amends the Environmental Research, Development, and Demonstration Authorization Act to:

(1) Prohibit the Administrator of EPA from finalizing, proposing, or disseminating a covered action unless all scientific and technical information relied on to support the covered action is:

- a. Specifically identified, and
- b. Publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.

(2) Clarify that nothing in the section shall be construed as requiring public dissemination of information, the disclosure of which is prohibited by law.

(3) Define “covered action” to mean a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance. The section defines “scientific and technical information” to include materials, data, and associated protocols necessary to understand, assess, and extend conclusions, computer codes and models involved in the creation and analysis of information, recorded factual materials, and detailed descriptions of how to assess and use such information.

#### XX. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

#### **ENVIRONMENTAL RESEARCH, DEVELOPMENT, AND DEMONSTRATION AUTHORIZATION ACT OF 1978**

\* \* \* \* \*

SEC. 6. (a) \* \* \*

[(b) The Administrator, after consultation with the Science Advisory Board, shall submit to the President and the Congress a report concerning the desirability and feasibility of establishing a national environmental laboratory, or a system of such laboratories, to assume or supplement the long-term environmental research functions created by subsection (a) of this section. Such report shall be submitted on or before March 31, 1978, and shall include findings and recommendations concerning—

[(1) specific types of research to be carried out by such laboratory or laboratories;

【(2) the coordination and integration of research to be conducted by such laboratory or laboratories with research conducted by existing Federal or other research facilities;

【(3) methods for assuring continuing long-range funding for such laboratory or laboratories; and

【(4) other administrative or legislative actions necessary to facilitate the establishment of such laboratory or laboratories.】

*(b)(1) The Administrator shall not propose, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action is—*

*(A) specifically identified; and*

*(B) publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.*

*(2) Nothing in the subsection shall be construed as requiring the public dissemination of information the disclosure of which is prohibited by law.*

*(3) In this subsection—*

*(A) the term “covered action” means a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance; and*

*(B) the term “scientific and technical information” includes—*

*(i) materials, data, and associated protocols necessary to understand, assess, and extend conclusions;*

*(ii) computer codes and models involved in the creation and analysis of such information;*

*(iii) recorded factual materials; and*

*(iv) detailed descriptions of how to access and use such information.*

\* \* \* \* \*

**XXI. PROCEEDINGS OF THE FULL  
COMMITTEE  
MARKUP ON H.R. 4012,  
SECRET SCIENCE REFORM ACT OF 2014**

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**Tuesday, June 24, 2014**

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY  
WASHINGTON, D.C.

The Committee met, pursuant to call, at 10:00 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Lamar Smith [Chairman of the Committee] presiding.

Chairman SMITH. The Committee on Science, Space, and Technology will come to order.

Without objection, the Chair is authorized to declare recesses of the Committee at any time. Pursuant to Committee Rule 2(f) and House Rule XI(2)(h)(4), the Chair announces that he may postpone roll call votes.

Let me recognize myself for an opening statement and then I will recognize the Ranking Member, Ms. Johnson, from Texas.

Today, we will consider H.R. 4012, the Secret Science Reform Act of 2014, offered by Environment Subcommittee Chairman David Schweikert. H.R. 4012 is a short, common sense bill. It requires that the Environmental Protection Agency base its regulations on data that is made public. The American people foot the bill for the EPA's billion-dollar regulations and they have the right to see the underlying data.

The EPA's regulatory process is both hidden and flawed. It hides the data and then handpicks scientists to review it. Unfortunately, the EPA continues to resist basic accountability. Every major air quality regulation proposed by this Administration has been justified by nontransparent data and unverifiable claims. This includes the recent plan to regulate greenhouse gas emissions from existing power plants. This proposal will result in the loss of thousands of jobs and spike electricity costs, all for no discernible effect on global temperatures. Upcoming ozone standards, which even the Administration admits will be the most expensive in history, also rely on hidden data.

The EPA clearly sees transparency and accountability as a threat. Speaking before the National Academy of Sciences two months ago, EPA Administrator Gina McCarthy said that her Agency needed to protect the science "from those not qualified to analyze it." Aside from the arrogance that is indicative of the EPA,

Administrator McCarthy herself testified to this committee that the information should be available for independent review and verification. The American people are still waiting.

If the EPA has nothing to hide, and if their data really justifies their regulations, why not make the information public? Is it because the EPA knows the data will not justify their regulations?

The bill we consider today reforms EPA's regulatory process and is consistent with the data access requirements of major scientific journals, the White House Scientific Integrity Policy, and the recommendations of independent groups like the Administrative Conference of the United States and the Bipartisan Policy Center.

A 2013 poll from the Institute for Energy Research found that 90 percent of Americans agree that studies and data used to make Federal Government decisions should be made public. There also is substantial support for this bill from the scientific and business communities. From deans of major universities to former EPA scientists to the U.S. Chamber of Commerce, dozens of experts and organizations support the provisions of this bill.

A letter from more than 80 scientists and academics stated, "Complying with H.R. 4012 can be accomplished without imposing unnecessary burdens, discouraging research, or raising confidentiality concerns."

The principles behind the bill also have been supported by top officials in the self-described "most transparent Administration in history." The President's own Science Advisor, Dr. John Holdren, testified in this room that "absolutely, the data on which regulatory decisions are based should be made available to the Committee and should be made public." The Chair of EPA's independent Science Advisory Board echoed that sentiment a few months later.

The Secret Science Reform Act does not require any disclosure of confidential information. It would only prohibit EPA's use of secret science. Data sharing is becoming increasingly common across scientific disciplines. The legislation requires that EPA science be available for validation and replication.

Americans impacted by EPA regulations have a right to see the data and determine for themselves if the Agency's actions are based on sound science or a partisan agenda. This bill ensures transparency and accountability. The American people deserve the facts and so does good policy.

[The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF CHAIRMAN LAMAR S. SMITH

Good morning. Today we will consider H.R. 4012, the Secret Science Reform Act of 2014, offered by Environment Subcommittee Chairman Schweikert.

H.R. 4012 is a short, common-sense bill. It requires that the Environmental Protection Agency (EPA) base its regulations on data that is made public. The American people foot the bill for the EPA's billion dollar regulations and they have the right to see the underlying data.

The EPA's regulatory process is both hidden and flawed. It hides the data and then handpicks scientists to review it. Unfortunately, the EPA continues to resist basic accountability. Every major air quality regulation proposed by this Administration has been justified by nontransparent data and unverifiable claims.

This includes the recent plan to regulate greenhouse gas emissions from existing power plants. This proposal will result in the loss of thousands of jobs and spike electricity costs, all for no discernible effect on global temperatures. Upcoming ozone



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A 2013 poll from the Institute for Energy Research found that 90 percent of Americans agree that studies and data used to make federal government decisions should be made public. There also is substantial support for this bill from the scientific and business communities. From deans of major universities to former EPA scientists to the U.S. Chamber of Commerce, dozens of experts and organizations support the provisions of this bill.

A letter from more than 80 scientists and academics stated, “Complying with H.R. 4012 can be accomplished without imposing unnecessary burdens, discouraging research, or raising confidentiality concerns.”

The principles behind the bill also have been supported by top officials in the self-described “most transparent Administration in history.” The President’s own Science Advisor, Dr. John Holdren, testified in this room that “absolutely, the data on which regulatory decisions are based should be made available to the Committee and should be made public.” The Chair of EPA’s independent Science Advisory Board echoed that sentiment a few months later.

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Americans impacted by EPA regulations have a right to see the data and determine for themselves if the agency’s actions are based on sound science or a partisan agenda. This bill ensures transparency and accountability.

The American people deserve the facts. And so does good policy.

Chairman SMITH. That concludes my opening statement, but before the gentlewoman from Texas I would like to enter into the record the following letters in support of H.R. 4012: a letter to the Committee from over 80 scientists and experts; a letter from the U.S. Chamber of Commerce, the world’s largest business federation; a letter from other 30 trade associations; a letter from the Dean of Indiana University and the former head of the Office of Information and Regulatory Affairs, Dr. John Graham; a letter from Dr. McClellan, former Chairman of EPA’s Clean Air Scientific Advisory Committee; and particularly persuasive is an op-ed in today’s Wall Street Journal on the subject of the EPA’s data, which I happened to write. Without objection, those documents will be made a part of the record.

[The information appears in Appendix II]

Chairman SMITH. And at this point I will recognize the gentlewoman from Texas, Ms. Johnson, the Ranking Member of this committee.

Ms. JOHNSON. Thank you very much, Mr. Chairman.

Today, the Committee is marking up H.R. 4012, the Secret Science Reform Act of 2014. It is my opinion that this bill is an insidious attack on the EPA’s ability to use the best science to protect public health, and this markup is a culmination of one of the most

anti-science and anti-health campaigns in the history of this esteemed committee.

The genesis of this legislation is the majority's long-standing obsession with two seminal scientific studies conducted by Harvard University and the American Cancer Society, which linked increasing air pollution with death and disease. The majority has harassed EPA for more than two years in an attempt to get access to the raw data used in these studies. Since these studies involve hundreds of thousands of human volunteers who submitted sensitive personal health information to the researchers, the raw data is stringently protected from public disclosure. The EPA explained this to the Chairman, but he nonetheless issued a subpoena to the EPA Administrator to turn over data that the EPA has no legal right to access and for which there are strict legal prohibitions against public disclosure.

The majority's solution to this problem, a problem of their own creation, is H.R. 4012. Rather than explain the problems with this legislation myself, I will simply quote from a letter we received from the American Lung Association and the American Thoracic Society, two leading, trusted public health organizations. They state, "The legislation before the Committee will compel the U.S. Environmental Protection Agency to either ignore the best science by prohibiting the Agency from considering peer-reviewed research that is based on confidential patient information or force EPA to publicly release confidential patient information, which would violate Federal law." This is an untenable outcome that would completely undermine the ability of the EPA to perform its responsibilities under the Clean Air Act and a myriad of other Federal laws. The legislation will not improve EPA's actions; rather, it will stifle public health protections.

I also want to take a moment to comment on the process that led us to where we are today. In the formulation of both the EPA's subpoena and the legislation before us, the majority has shown a disturbing pattern of relying upon the advice of researchers and other individuals with strong financial ties to the tobacco industry. When the Committee met in August to authorize subpoenas to obtain the data from Harvard and the Cancer Society studies, we questioned what legitimate researchers didn't already have access to the data.

The Chairman named Dr. James Enstrom as someone who didn't have access to the data and apparently someone to whom the Chair intended to provide the data. As I have noted in the letters to the Chairman, Dr. Enstrom has a long history of ties to the tobacco industry that includes receiving research funding from and performing consultant work for tobacco companies. When the majority had their legislative hearing on this bill, they called three witnesses to testify all of whom had past financial connections to the tobacco industry. In fact, the only scientist who was called by the majority to testify had an extensive history of tobacco industry research funding and consulting work.

This should be profoundly disturbing to the members of this committee. The tobacco industry was a responsible—was responsible for perpetuating or perpetrating one of the greatest scientific frauds in history on the American people. They committed this

fraud to subvert and delay the imposition of health regulations on their industry. As a consequence of the delayed implementation of tobacco regulations, millions of people needlessly suffered and died. It defies logic that the majority would be relying on these people to justify their bill.

On the other hand, a diverse set of voices from the scientific, public health, legal, and environmental communities have criticized this legislation. We have received letters or statements expressing concern with the bill from the American Association for Advancement of Science, the American Lung Association, the American Thoracic Society, the American Association for Justice, the Center for Effective Government, the Union of Concerned Scientists, the Natural Resources Defense Council, Clean Water Action, Earth Justice, Environmental America, and the Environmental Defense Fund, Friends of the Earth, League of Conservation Voters, the Sierra Club, the Center for Progressive Reform, and I will ask that these letters be placed in the record.

Chairman SMITH. Without objection.

[The information appears in Appendix II]

Ms. JOHNSON. Thank you, Mr. Chairman.

To close, when the Committee of Science has taken its cues from people tied to the tobacco industry instead of from legitimate scientists and public health professionals, then something is profoundly wrong. Whatever views my fellow Members may have about specific EPA rules and regulations, I would hope that they will see this bill for what it is, a pernicious assault on EPA's ability to use the best science to protect public health. It is a bill that diminishes our committee by the very fact that we are marking it up today. I strongly urge my colleagues on both sides of the aisle to oppose this legislation. I yield back.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF RANKING MEMBER EDDIE BERNICE JOHNSON

Thank you Chairman Smith. Today the Committee is marking up H.R. 4012, the Secret Science Reform Act of 2014. This bill is an insidious attack on the EPA's ability to use the best science to protect public health, and this markup is the culmination of one of the most anti-science and anti-health campaigns in the history of this esteemed Committee.

The genesis of this legislation is the Majority's longstanding obsession with two seminal scientific studies conducted by Harvard University and the American Cancer Society which linked increasing air pollution with death and disease. The Majority has harassed the EPA for more than two years in an attempt to get access to the raw data used in those studies.

Since those studies involved hundreds of thousands of human volunteers who submitted sensitive personal health information to the researchers, the raw data is stringently protected from public disclosure.

The EPA explained this to the Chairman, but he nonetheless issued a subpoena to the EPA Administrator to turn over data that the EPA had no legal right to access and for which there are strict legal prohibitions against public disclosure.

The Majority's solution to this "problem"—a problem of their own creation—is H.R. 4012. Rather than explain the problems with this legislation myself, I will simply quote from a letter we received from the American Lung Association and the American Thoracic Society, two leading and trusted public health organizations. They state:

"The legislation before the committee will compel the U.S. Environmental Protection Agency to either ignore the best science by prohibiting the agency from considering peer-reviewed research that is based on confidential patient information or force EPA to publically release confidential patient information, which would

violate federal law. This is an untenable outcome that would completely undermine [the] ability of the EPA to perform its responsibilities under the Clean Air Act and myriad other federal laws. The legislation will not improve EPA's actions; rather it will stifle public health protections."

I also want to take a moment to comment on the process that led us to where we are today. In the formulation of both the EPA subpoena and the legislation before us, the Majority has shown a disturbing pattern of relying upon the advice of researchers and other individuals with strong financial ties to the tobacco industry. When the Committee met in August to authorize subpoenas to obtain the data from the Harvard and Cancer Society studies, we questioned what legitimate researchers didn't already have access to the data. The Chairman named Dr. James Enstrom as someone who didn't have access to the data, and, apparently, someone to whom the Chair intended to provide the data.

As I've noted in letters to the Chairman, Dr. Enstrom has a long history of ties to the tobacco industry that include receiving research funding from and performing consulting work for tobacco companies. When the Majority had their legislative hearing on this bill, they called three witnesses to testify, all of whom had past financial connections to the tobacco industry. In fact, the only scientist who was called by the Majority to testify had an extensive history of tobacco industry research funding and consulting work.

This should be profoundly disturbing to the Members of this Committee.

The tobacco industry was responsible for perpetrating one of the greatest scientific frauds in history on the American people. They committed this fraud to subvert and delay the imposition of health regulations on their industry. As a consequence of the delayed implementation of tobacco regulations, millions of people needlessly suffered and died. It defies logic that the Majority would be relying on these people to justify their bill.

On the other hand, a diverse set of voices from the scientific, public health, legal, and environmental community have criticized this legislation.

We have received letters or statements expressing concern with the bill from the American Association for the Advancement of Science, the American Lung Association, the American Thoracic Society, the American Association for Justice, the Center for Effective Government, the Union of Concerned Scientists, the Natural Resources Defense Council, Clean Water Action, Earthjustice, Environment America, the Environmental Defense Fund, Friends of the Earth, the League of Conservation Voters, the Sierra Club, and the Center for Progressive Reform, and I'd ask that these letters be placed in the record.

Mr. Chairman, to close, when the Committee on Science is taking its cues from folks tied to the tobacco industry instead of from legitimate scientists and public health professionals, then something is profoundly wrong.

Whatever views my fellow Members may have about specific EPA rules and regulations, I would hope that they will see this bill for what it is—a pernicious assault on EPA's ability to use the best science to protect public health. It is a bill that diminishes our Committee by the very fact that we are marking it up today. I strongly urge my colleagues on both sides of the aisle to oppose this legislation, and I yield back.

Chairman SMITH. Thank you, Ms. Johnson.

Pursuant to notice, I now call up H.R. 4012, the Secret Science Reform Act of 2014. The clerk will report the bill.

The CLERK. H.R. 4012, a bill to prohibit the Environmental Protection Agency from proposing, finalizing, or disseminating regulations or—

[H.R. 4012 appears in Appendix I]

Chairman SMITH. Without objection, the bill will be considered as read.

If there is no further discussion on the bill, the bill will be open to amendment at this point. And we will go to the first amendment on our roster, and that is going to be offered by the gentlewoman from Oregon, Ms. Bonamici, and she is recognized for that purpose.

Ms. BONAMICI. Thank you very much, Mr. Chairman. I have an amendment at the desk.

Chairman SMITH. And the clerk will report the amendment.

The CLERK. Amendment in the nature of a substitute to H.R. 4012, offered by Ms. Bonamici—

Chairman SMITH. Without objection, the amendment will be considered as read.

And the gentlewoman from Oregon is recognized to explain her amendment.

Ms. BONAMICI. Thank you very much, Mr. Chairman.

My amendment is the Promoting Public Access and Transparency Act of 2014. It takes an important step forward to increase public access to federally funded research, and unlike the base bill we are marking up today, it does so in a way that does not risk the health of Americans or the environment.

Taxpayers support most of the research conducted at our universities, and I agree that more can and should be done to provide the public with access to the results of that research. I was glad to support the bipartisan amendment to the FIRST Act offered by my colleagues Mr. Sensenbrenner and Ms. Lofgren to require Federal science agencies to develop open access policies for publications resulting from federally funded research.

The amendment I am offering today extends the language adopted in the FIRST Act to the EPA as well and would require the Administrator formulate and implement a public access policy to ensure that the American people have access to the research papers resulting from EPA-sponsored work. The amendment contains specific provisions that set up the structure for public access policy including provisions that address metadata, electronic access, repositories, stakeholder coordination, and a process to petition for modification of the embargo period if doing so would be in the public interest. And importantly, unlike in the base bill, relevant terms are defined. This amendment ensures that the best available science is considered by the EPA while also continuing to protect patient privacy and confidentiality.

Many have raised concerns that, as written, the underlying bill will result in certain scientific research being ignored by the EPA because of the need to protect patient privacy and confidentiality. Mr. Chairman, my colleagues and I, along with much of the scientific community, are concerned that the underlying bill before us today will undermine EPA's ability to fulfill its mission to protect human health and the environment.

As the Ranking Member noted, we have received letters of opposition from, among others, the American Association for the Advancement of Science, the American Lung Association, the Union of Concerned Scientists, and the Center for Progressive Reform, which is a group of environmental and administrative law professors.

Additionally, on this committee we have heard at length about concerns with the so-called secret science, but those concerns expressed to date ignore the fact that often transparency is lacking when it comes to disclosing the source of research for—funding for research. Now, I am not suggesting that industry-funded research is bad, only that it should be subjected to the same transparency and accountability as federally sponsored research. This underlying bill treats them differently. My amendment would address this issue by requiring that the EPA only consider peer-reviewed re-

search results and scholarly publications that disclose the entity that funded the research.

Mr. Chairman, my amendment achieves the transparency and accountability that is the stated rationale for the bill before us today and it does so in a way that preserves the EPA's ability to make use of the best science available and serve its mission of protecting public health. I urge Members to support this amendment and I yield back the balance of my time.

Thank you, Mr. Chairman.

Chairman SMITH. Thank you, Ms. Bonamici. And the gentleman from Arizona, Mr. Schweikert, the author of this bill, is recognized.

Mr. SCHWEIKERT. Thank you, Mr. Chairman.

And to my friend, the gentlewoman from Oregon, there are probably three things here that are problematic. I am not going to UC it or do a procedural objection—but the amendment is actually multiple times larger than the underlying bill and has some germaneness issues. But if you actually read through the amendment and walk through the mechanics, it actually creates significant loopholes to avoid actually what we are trying to accomplish.

There is also another thematic problem because have you ever had one of these discussions—and this is—I am not picking on anyone, but you sort of feel like you are in parallel universes where, for those of us who have been working on this bill for a while, we are seeing this sort of egalitarian access to information that I don't think favors the right, the left, the universities, the private academician, the person with a good computer in their basement that likes to do statistics. It is information. And if you can do public policy, it should be by public data and public data for public policy and this ability to try to argue to gain the data.

There is also something I think is a misnomer and I really do want to correct it. If the bureaucracy—if the EPA actually reaches out and uses industry data in creation of their rule set, they need to disclose those data sets. So it may happen one day that there is a President of a different party and it would be amusing to see if the arguments in this room all of a sudden, because of that partisan change, the arguments flip upside down and go the other direction.

It is public data to make public policy. And if you are going to have a public policy, don't we all, every single person in this room, every person on this committee, and our constituents have the right to those underlying data sets?

The very last thing, I am almost embarrassed to hear someone use the language of, well, this is secret, personal data. Come on. And tell me every agency out there, there are protocols. So if that argument is going to be used, should the Census Bureau, should the CFPB, should the, you know, the universities, should—I mean every agency out there collects very personal data on us. There is mechanisms that have been around since time immemorial to blind data. I remember being in a freshman stats class and we were instructed on how to blind data. It is an absurd argument.

And with that, Mr. Chairman, I yield back.

Chairman SMITH. Thank you, Mr. Schweikert. Are there other Members who wish to be heard?

The gentlewoman from Texas, Ms. Johnson, is recognized.

Ms. JOHNSON. Thank you, Mr. Chairman. I would like to strike the last word.

Chairman SMITH. The gentlewoman is recognized for five minutes.

Ms. JOHNSON. Thank you.

I want to commend Ms. Bonamici for her amendment. The gentlelady's amendment takes a commonsense approach to increased public access to federally funded research results at EPA.

As my colleagues are aware, in 2010 COMPETES bill, former Chairman Gordon set into motion an interagency process for the development of public access plans for all of our Federal research agencies. Last year, OSTP issued guidance based on that process. And last month, the only bipartisan amendment adopted by the part of the FIRST Act codified OSTP's guidance and the development of open-access policies in a number of agencies within the Committee's jurisdiction.

Ms. Bonamici's amendment rightfully extends that policy to EPA. This is the right approach to increasing transparency and public access at the Agency. It does not take the reckless approach of the underlying bill, which keeps EPA from using the best science available to inform their regulatory process.

The amendment also does not ignore the fact that we need to address the issue of transparency as it relates to industry-funded research. The underlying bill is in effect a witch-hunt for Members of the other side of the aisle to force EPA to disclose data that is strictly protected by the law to ensure patient confidentiality. If the majority wants to pursue legitimate efforts to increase public access to federally funded research, then they will support the adoption of this amendment.

The gentlelady's amendment ensures that EPA can fulfill their mission by protecting public health and the environment while also increasing public access to research results supported by the Agency. I urge my colleagues to support this amendment.

Thank you and I yield back.

Chairman SMITH. Thank you, Ms. Johnson.

The gentleman from Indiana, Mr. Bucshon, is recognized.

Mr. BUCSHON. Thank you, Mr. Chairman. I would like to strike the last word.

Chairman SMITH. The gentleman is recognized for five minutes.

Mr. BUCSHON. Transparency and reproducibility are basic tenets of science. I am a medical doctor, practicing cardiothoracic surgery for over 15 years, and written multiple medical journals that have grouped patient information that protects the privacy of the individual patient. So hiding behind regulations like HIPAA law and saying that this information can't be used in a fashion that can protect patient privacy just isn't true.

Costly environmental regulations should only based upon data that is available to independent scientists and the public. H.R. 4012 makes very clear that no protected information will be disclosed and any confidential information can easily be coded through existing statistical methods. Dr. John Graham, Dean of the Indiana University School of Public and Environmental Affairs, stated in testimony supporting the bill in February 2014 that "once environmental scientists have published their work in the peer-reviewed

scientific community is already common practice for them to share their data with other scientists who have an interest in their research.”

This committee has also received significant testimony from respected experts that the provisions of H.R. 4012 would not raise confidentiality issues. For this reason, I would ask my colleagues to oppose the amendment.

I yield back.

Chairman SMITH. Thank you, Dr. Bucshon.

If there is no further discussion, the question is on the amendment in the nature of a substitute offered by Ms. Bonamici.

All in favor, say aye.

Those opposed, say no.

In the opinion of the Chair, the noes have it. The amendment is not agreed to.

We will now go to the next amendment to be offered by the gentleman from Massachusetts, Mr. Kennedy, and he is recognized for that purpose.

Mr. KENNEDY. Thank you, Mr. Chairman. I have an amendment at the desk.

Chairman SMITH. The clerk will read the amendment.

The CLERK. Amendment to H.R. 4012 offered by Mr. Kennedy of Massachusetts, amendment #003.

Chairman SMITH. Without objection, the amendment will be considered as read.

And the gentleman from Massachusetts, Mr. Kennedy, is recognized to explain his amendment.

Mr. KENNEDY. Thank you, Mr. Chairman.

Mr. Chairman, today we have heard a bit about the importance of scientific integrity and transparency, and I want to agree with my colleagues on both sides of the aisle and say that that is two fundamental principles with which I could not agree more.

However, I am concerned that the bill before us today doesn't achieve those goals and instead puts our country at greater risk of not being able to use the best available, most up-to-date science to protect our health and public safety. Currently, the EPA incorporates science in the regulatory process through a number of procedures, including extensive outside peer-reviewed prior to consideration of the Agency's internal process. Prior to any action, the EPA must go through an extensive rulemaking process that incorporates printing all relevant information in a Federal Register, which is publicly available, a draft rule, a public comment period, responding to those public comments, and then issuing a final rule, a process that takes considerable amount of time with extensive input from interested parties.

Last, as the majority indicated in a memorandum of today's markup, all Federal agencies that support scientific research are already under direction by the President and the Office of Science and Technology Policy to make said research publicly available where appropriate, include data and models used to support the science. The EPA is currently in the process of developing its own public access policy consistent with OSTP.

Unfortunately, I am concerned that the underlying bill only creates unnecessary bureaucratic hurdles and actually prohibits the



EPA from using sound science. It creates confusing and likely unworkable requirements limiting the scientific research that can be used unless it can be publicly accessible. The EPA relies on science that often includes personally identifiable information which cannot simply be made public—excuse me—publicly available due to privacy concerns, which is why EPA already has important peer-reviewed standards in place as previously supported independent analyses of studies in accordance with privacy protections set forth by law.

In this committee, we have talked about the importance of the Federal Government protecting private information. I cannot support an effort to either require the EPA to disclose protected health information or simply not use it. My amendment upholds the high standards set by the EPA using the latest, most up-to-date science. It prohibits EPA from proposing, finalizing, or disseminating a covered action unless all science and technical information is specifically identified, requiring the EPA to identify the science being used to engage in any regulatory action. It ensures we—excuse me—you base regulations on sound science and allows EPA to continue their efforts to make all information publicly available, as applicable by law in coordination with the OSTP directive.

Mr. Chairman, specifically, the amendment basically—if you look to the text, it strikes—on page 2, lines 10 through 15, it puts in that—it leads in Subsection A and it says that has to be specifically identified. I am concerned that the language of actually—I take—my colleague's comments on the last amendment are well noted. I am concerned that the way the language is actually drafted, it creates a bit of an ambiguity saying that the EPA, unless—noting—and from Subsection 2, noting that nothing shall be construed as requiring public dissemination of information, the disclosure of which is prohibited by law. If there is private information there that the EPA cannot disclose by law, then they cannot actually implement the regulation because of Subsection B. And what I am basically saying is take out that ambiguity, keep in the specifically identified so that we know what the research actually is so that there is accountability, but to try to remove that ambiguity of creating a requirement that the EPA cannot comply with under law. That is essentially what we are trying to do is just simplify the regulation.

And I yield back.

Chairman SMITH. Thank you, Mr. Kennedy.

The gentleman from Arizona, Mr. Schweikert, is recognized.

Mr. SCHWEIKERT. Sorry. Thank you, Mr. Chairman. Strike the last word.

To my friend from Massachusetts who has actually been very kind to my office, and if anyone wants to know the story, I will tell you later—

Mr. KENNEDY. Please don't.

Mr. SCHWEIKERT. Please don't. Actually, I appreciate the explanation because reading over the amendment I am not sure your language actually gets you to where you want. There is actually lots and lots—I mean already in protocols—actually it is already an order from the Administration to do this and we will put that into the record a little bit later.

If we are blessed enough or I am blessed enough to have this bill move towards the Floor, I will work with you on this because maybe there is a sentence I can make crisper, but having been around this sort of for a while, I don't think your amendment gets you to where you want because what we are all talking about here is in large data sets you are going to have these occasions where you get down to either the data identifies one because you have someone who is out in the tail, you know, is the one outlier, and that becomes an ability to identify the individual or clusters of particular difficulties down to being able to identify those individuals. There are protocols all up and down our government that blinds that data, and I think that is what you are after is I never wanted something personally identifying of an individual, right?

I don't think your amendment gets you there, but if we move forward on this, I promise you we will work on—because I think we can just capture some language that has already been proposed both—actually, it has already been—it is not proposed; it is the rules given out from the Administration to all agencies. It is just not being carried out right now at the EPA.

And with that, Mr. Chairman, I yield back.

Chairman SMITH. Thank you, Mr. Schweikert.

Let me ask the gentleman from Arizona and the gentleman from Massachusetts, do you all want to continue this discussion between now and the next step for this bill or, Mr. Kennedy, do you want to proceed without prejudice to have a vote on your amendment?

Mr. GRAYSON. Mr. Chairman, I would like to be heard. I move to strike the last word before we vote on the amendment.

Chairman SMITH. Okay. The gentleman from Florida, Mr. Grayson, is recognized.

Mr. GRAYSON. Thank you.

As I read this and in connection with the Kennedy amendment, I am concerned about one particular scenario, which is this: Let's say that the EPA relies upon a published report in Nature based upon a Harvard study and it is—obviously Nature is a reputable journal. There is no reason to think that it is unreliable information, but it simply is whatever 15 pages of data is put in the journal. In that situation, EPA would have no access to the underlying data. Harvard is under no obligation to provide that information even to Nature, much less to the EPA, and if I read this bill correctly, without the Kennedy amendment, this means that in that situation the EPA would not be able to go forward with any rule relying upon a published Harvard study in the journal Nature. That seems to me to be a fatal flaw in this bill.

And I will yield to anybody who is a proponent of this bill to explain why that is not the case.

Chairman SMITH. The gentleman from Florida, Mr. Posey, is recognized.

Mr. POSEY. Thank you, Mr. Chairman. I would like to strike the last word.

Chairman SMITH. The gentleman is recognized for five minutes.

Mr. POSEY. I would like to yield to Congressman Schweikert.

Mr. SCHWEIKERT. Thank you, Mr. Posey.

Two points, go grab your copy of Nature right now and go into the front section and look at the data release requirements for

peer-review there. Actually—and also in Scientific America, Science, they actually, as part of their language and standards—where do you think some of this language came from? Go look at Nature and Scientific America and in their data release discussions in their peer-reviewed publications, that is where this came from.

Also, remember, because we have already heard the misnomer twice now and I want to clear it up, if the Agency uses industry data in creating a rule set, they need to make that base data public. One more time, public policy by public data. And maybe because I have a fixation on the crowd having access to information, purifying—and also to my friend from Florida, you know—and I am not going to refer to the trial bar, but whatever side you are on, the ability to get the data and test it and merge it with other data, who knows? You may find that we are not going far enough. But that data belongs to the public.

I yield back.

Mr. GRAYSON. Mr. Chairman, I actually—

Mr. SCHWEIKERT. I will give it to Mr. Posey.

Mr. GRAYSON. —had not used to my time up and I would like to reclaim my time.

Chairman SMITH. The gentleman from Florida continues to have the time.

Mr. GRAYSON. Thank you. Listen, I don't find that answer, with all due respect, satisfying. I think that what you are doing as you are tying the hands of the EPA based upon what you claim to be are provisions in Nature's own internal policies, which may not be true. As far as I know, they are not true, respectfully, and even if they were true, could change tomorrow. So you are basically making the EPA's rulemaking ability contingent upon the policies adopted by scientific journals and I think that that is completely unacceptable.

I will yield to whoever wants to respond to that if you want or I will just yield back my time.

Chairman SMITH. The gentleman yields back his time.

Are there any other Members who wish to be heard on this amendment?

Mr. SWALWELL. Mr. Chairman.

Chairman SMITH. The gentleman, Mr. Swalwell, is recognized.

Mr. SWALWELL. Thank you, Mr. Chairman. I move to strike the last word.

Chairman SMITH. The gentleman is recognized for five minutes.

Mr. SWALWELL. And, Mr. Chairman, I do have some questions for the Chair that I would be happy to yield to. And as the Chair knows, when Congress enacted HIPAA, it required the Secretary of HHS to issue regulations governing the use and disclosure of protected health information. This privacy rule which we are referring to insures that an individual's medical condition as well as their Social Security number and other personal identifiable information are protected and only shared in a limited and specific way. And one of my concerns and one of the concerns that has been expressed by my colleagues particularly from Oregon and Massachusetts is that this could require the researchers to violate the privacy rules.

And so my question, Mr. Chair, is that it sounds like this legislation and the Chair would be requiring researchers and the EPA to violate HIPAA by putting the underlying data up on the internet. And I was wondering if that is the case.

Chairman SMITH. Let me respond real quickly and then I can yield to Mr. Schweikert if he wants to add more than he has, but I think you have been particularly articulate on the subject.

On page 2 of the bill you have got Section 2, "Nothing in this subsection shall be construed as requiring the public dissemination of information, the disclosure of which is prohibited by law." So the law that you referred to yourself a minute ago would prohibit the disclosure of the information you are concerned about. And again, that is the whole purpose of the bill and that is what the gentleman from Arizona has recognized as well.

Mr. SWALWELL. And reclaiming my time, Mr. Chair, then is it the Chair's position that the EPA can only rely on research results where the underlying data is publicly available as a part of its rulemaking?

Chairman SMITH. I think the—I don't want to—

Mr. SWALWELL. And yielding back.

Chairman SMITH. Okay. The gentleman will yield. And I will be happy to yield to the gentleman from Arizona. But the point of the bill is actually full disclosure of data sets that the EPA is now not willing to be made public. And there is good reason for that, as has already been explained, and I am kind of amazed that anybody would object to the full disclosure of that data. As I mentioned in my opening statement, you have the Administrator of the EPA herself testifying on this room that that data should be made public. You have got the Science Advisor to the President testifying in this room that that data should be made public. So I am happy to follow their good suggestions.

Mr. SWALWELL. And reclaiming my time, Mr. Chair, how would the Chair respectfully envision the EPA complying with this disclosure without violating patient privacy and confidentiality?

And I would yield again.

Chairman SMITH. Okay. Thank you for yielding again.

That is kind of self-explanatory I think. The way for the EPA to comply without violating the law is to comply without violating the law. And that is what the bill does.

Mr. SWALWELL. Thank you, Mr. Chair.

And reclaiming my time, my fear again is that the underlying or raw data that the Chair and this legislation are seeking to obtain from the Harvard Six studies and the American Cancer Society studies through EPA include what we believe are protected health information. And because we have not been successful—because my colleagues across the aisle have not been successful in obtaining that information because it is protected by privacy and confidentiality laws, instead we are pushing it through with this bill, which would effectively tie the hands of the EPA and threaten public health and privacy.

And with that, Mr. Chair, I would thank you for responding to my questions and I would yield back the balance of my time.

Chairman SMITH. Thank you, Mr. Swalwell.

Are there other Members who wish to be heard on this amendment?

And the gentlewoman from California, Ms. Lofgren.

Ms. LOFGREN. Yes. I move to strike the last word.

Chairman SMITH. The gentlewoman is recognized for five minutes.

Ms. LOFGREN. I have some related questions regarding the effect the bill would have on previous actions taken by the EPA. Now, the bill says the EPA cannot propose or finalize a covered action unless all the scientific information the action is based on is publicly available in a manner that is sufficient for independent analysis and substantial reproduction of results. But it also says the Administrator cannot disseminate a covered action like guidance unless the scientific information is also publicly available.

Now, here is the question. It seems to me that the language suggests the legislation is retroactive, which—in which case it would impact—

Chairman SMITH. If the gentlewoman would yield, the bill is not retroactive.

Ms. LOFGREN. It is not retroactive?

Chairman SMITH. That is correct.

Ms. LOFGREN. All right. Then that does answer my question. But it is not clear in the language of the bill that that is the case, so I think, knowing how dismissive courts are to legislative history, I think it would be an important component to make sure that in the bill itself it is clear that it is prospective.

Chairman SMITH. If the gentlewoman would yield, if we need to clarify that language, we will do so because that is the—

Ms. LOFGREN. Thank you. Mr. Chairman, I yield back.

Chairman SMITH. That is the intent.

The gentlewoman yield back.

The gentlewoman from Oregon, Ms. Bonamici, is recognized for five minutes.

Ms. BONAMICI. Thank you, Mr. Chairman.

And certainly this discussion today, as well as the letters we have received, raises a lot of concerns about how this bill would be implemented and interpreted. And I note that when we did have a hearing on the bill, we did not have anyone from the EPA to talk about how it would be implemented and interpreted. And I know a lot of the question and concern is about the substantial reproduction language and I want to yield the balance of my five minutes to the gentleman from Florida.

Mr. GRAYSON. Thank you. Our illustrious staff actually has come up with the restrictions regarding the availability of data from Nature itself. Thank you very much, staff, for doing that.

What it says is that the authors are allowed to qualify the availability of material to the public as long as the qualification is not “undue” and as long as they disclose that at the time of the submission and indicate it in the manuscript. So clearly under those circumstances it is true that the authors of a paper Nature like, for instance, a Harvard study would be able to withhold information from Nature, from the readers, from the EPA while still being able to publish it in Nature.

The result of that, including the fact that although EPA might conceivably have access to such information under some circumstances under no existing duty to actually get it means that we are holding the regulatory process at EPA hostage to whether or not individual authors of individual studies that deign to allow the public as well as the EPA to get the information that is required here as well as having the EPA actually ask for it. That seems to me to be essentially hogtying the regulatory process and making it impossible for EPA to function in any practical way.

I yield back.

Chairman SMITH. Thank you, Ms. Bonamici. Thank you, Mr. Grayson.

Are there other Members who wish to be heard on the Kennedy amendment?

The gentlewoman from Texas, Ms. Johnson, is recognized.

Ms. JOHNSON. Thank you, Mr. Chairman.

I would like to commend Mr. Kennedy for this amendment and simply say that the gentleman's amendment ensures that EPA is able to consider the best available science during its rulemaking process and the bill language the amendment removes is an attempt to constrain the EPA in the guise of promoting transparency. Perhaps the only transparent part of this bill is its intent, and that is to stop EPA from taking any action to protect the health of the American people.

As written in this section, it ensures that EPA and the American people will not be able to use the best science to protect the air they breathe and the water they drink. The EPA relies on peer-reviewed scientific research from our universities as the backbone of their mission to protect public health and the environment. Studies containing public health information would not satisfy the requirements of this bill, eliminating significant scientific research from EPA consideration. For example, this bill would prevent EPA from establishing a drinking water standard or health advisory based on clinical research where the study is not reproducible because of restrictions on confidential patient information.

Limiting or prohibiting what science EPA uses should not be a consequence of this bill, unintended or otherwise. The gentleman's amendment safeguards EPA's ability to fulfill its mission without needless restrictions. I urge my colleagues to support this common-sense amendment. Thank you.

I yield back.

Chairman SMITH. Thank you, Ms. Johnson.

If there is no further discussion, the vote is on the Kennedy amendment.

All in favor, say aye.

I thought someone was seeking recognition. That was the reason for my hesitancy.

If not, the vote is on the Kennedy amendment.

All in favor, say aye.

Opposed, nay.

In the opinion of the Chair, the noes have it and the amendment is not agreed to.

Are there any other amendments?

If not, the next item of business is reporting the bill, H.R. 4012.

And the question is on the bill, H.R. 4012.

Those in favor, say aye.

Ms. JOHNSON. I would like a recorded vote.

Chairman SMITH. And that request has been noted. And pursuant to Committee Rule 2(f) and House Rule 11(2)(h)(4), proceedings on this vote will be postponed.

And let me explain what we are going to do. We had a number of requests from Members because there were so many conflicts this morning as to what time we might expect votes. The best estimate we had is at 11:45, so if Members will return in 30 minutes, we will have our final vote on passage of the bill.

Oh, I am sorry. It is an hour from now, not 30 minutes from now. It will be 11:45. We will return to the room and have a vote on passage of the bill. We stand in recess until that time.

[Recess.]

Chairman SMITH. Are you ready? The Science, Space, and Technology Committee will reconvene. Pursuant to the previous order, we will now proceed on the postponed roll call vote. And the question is on the bill H.R. 4012.

And the clerk will call the roll.

The CLERK. Mr. Smith?

Mr. SMITH. Aye.

The CLERK. Mr. Smith votes aye.

Mr. Rohrabacher?

Mr. ROHRABACHER. Aye.

The CLERK. Mr. Rohrabacher votes aye.

Mr. Hall?

Mr. HALL. Aye.

The CLERK. Mr. Hall votes aye.

Mr. Sensenbrenner?

Mr. SENSENBRENNER. Aye.

The CLERK. Mr. Sensenbrenner votes aye.

Mr. Lucas?

Mr. LUCAS. Aye.

The CLERK. Mr. Lucas votes aye.

Mr. Neugebauer?

Mr. NEUGEBAUER. Aye.

The CLERK. Mr. Neugebauer votes aye.

Mr. McCaul?

[No response.]

The CLERK. Mr. Broun?

Mr. BROUN. Aye.

The CLERK. Mr. Broun votes aye.

Mr. Palazzo?

Mr. PALAZZO. Aye.

The CLERK. Mr. Palazzo votes aye.

Mr. Brooks?

Mr. BROOKS. Aye.

The CLERK. Mr. Brooks votes aye.

Mr. Hultgren?

Mr. HULTGREN. Aye.

The CLERK. Mr. Hultgren votes aye.

Mr. Bucshon?

Mr. BUCSHON. Aye.

The CLERK. Mr. Bucshon votes aye.  
Mr. Stockman?  
Mr. STOCKMAN. Aye.  
The CLERK. Mr. Stockman votes aye.  
Mr. Posey?  
Mr. POSEY. Aye.  
The CLERK. Mr. Posey votes aye.  
Mrs. Lummis?  
[No response.]  
The CLERK. Mr. Schweikert?  
Mr. SCHWEIKERT. Aye.  
The CLERK. Mr. Schweikert votes aye.  
Mr. Massie?  
Mr. MASSIE. Aye.  
The CLERK. Mr. Massey votes aye.  
Mr. Cramer?  
[No response.]  
The CLERK. Mr. Bridenstine?  
[No response.]  
The CLERK. Mr. Weber?  
[No response.]  
The CLERK. Mr. Collins?  
Mr. COLLINS. Aye.  
The CLERK. Mr. Collins votes aye.  
Mr. Johnson?  
Mr. JOHNSON. Aye.  
The CLERK. Mr. Johnson votes aye.  
Ms. Johnson?  
Ms. JOHNSON. No.  
The CLERK. Ms. Johnson votes no.  
Ms. Lofgren?  
[No response.]  
The CLERK. Mr. Lipinski?  
Mr. LIPINSKI. No.  
The CLERK. Mr. Lipinski votes no.  
Ms. Edwards?  
[No response.]  
The CLERK. Ms. Wilson?  
[No response.]  
The CLERK. Ms. Bonamici?  
Ms. BONAMICI. No.  
The CLERK. Ms. Bonamici votes no.  
Mr. Swalwell?  
[No response.]  
The CLERK. Mr. Maffei?  
Mr. MAFFEI. No.  
The CLERK. Mr. Maffei votes no.  
Mr. Grayson?  
Mr. GRAYSON. No.  
The CLERK. Mr. Grayson votes no.  
Mr. Kennedy?  
Mr. KENNEDY. No.  
The CLERK. Mr. Kennedy votes no.  
Mr. Peters?



Mr. PETERS. No.  
The CLERK. Mr. Peters votes no.  
Mr. Kilmer?  
[No response.]  
The CLERK. Mr. Bera?  
Mr. BERA. No.  
The CLERK. Mr. Bera votes no.  
Ms. Esty?  
Ms. ESTY. No.  
The CLERK. Ms. Esty votes no.  
Mr. Veasey?  
[No response.]  
The CLERK. Ms. Brownley?  
Ms. BROWNLEY. No.  
The CLERK. Ms. Brownley votes no.  
Ms. Kelly?  
Ms. KELLY. No.  
The CLERK. Ms. Kelly votes no.  
Ms. Clark?  
Ms. CLARK. No.  
The CLERK. Ms. Clark votes no.  
Chairman SMITH. Are there any other Members who wish to vote  
or Members who want to change their vote?  
The CLERK. Mr. Kilmer?  
Mr. KILMER. No.  
The CLERK. Mr. Kilmer votes no.  
Mr. Chairman, 17 Members voted aye, 13 Members voted nay.

**COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY - 113<sup>th</sup>**  
Full Committee Roll Call

Working Quorum: 14      Reporting Quorum: 21

DATE: 6-24-2014

Bill: H.R. 4012  
ROLL CALL NO. 1

FINAL PASSAGE

PASSED

MEMBER	AYE	NO	PRESENT	NOT VOTING
1 Mr. SMITH, <i>Chair</i> - TX	•			
2 Mr. ROHRBACHER - CA **	•			
3 Mr. HALL - TX	•			
4 Mr. SENSENBRENNER - WI	•			
5 Mr. LUCAS - OK	•			
6 Mr. NEUGEBAUER - TX	•			
7 Mr. MCCAUL - TX				
8 Mr. BROUN - GA	•			
9 Mr. PALAZZO - MS	•			
10 Mr. BROOKS - AL	•			
11 Mr. HULTGREN - IL	•			
12 Mr. BUCSHON - IN	•			
13 Mr. STOCKMAN - TX	•			
14 Mr. POSEY - FL	•			
15 Mrs. LUMMIS - WY				
16 Mr. SCHWEIKERT - AZ	•			
17 Mr. MASSIE - KY	•			
18 Mr. CRAMER - ND				
19 Mr. BRIDENSTINE - OK				
20 Mr. WEBER - TX				
21 Mr. COLLINS - NY	•			
22 Mr. JOHNSON - OH	•			
<hr/>				
1 Ms. JOHNSON, <i>Ranking</i> - TX		•		
2 Ms. LOFGREN - CA				
3 Mr. LIPINSKI - IL		•		
4 Ms. EDWARDS - MD				
5 Ms. WILSON - FL				
6 Ms. BONAMICI - OR		•		
7 Mr. SWALWELL - CA				
8 Mr. MAFFEI - NY		•		
9 Mr. GRAYSON - FL		•		
10 Mr. KENNEDY - MA		•		
11 Mr. PETERS - CA		•		
12 Mr. KILMER - WA		•		
13 Mr. BERA - CA		•		
14 Ms. ESTY - CT		•		
15 Mr. VEASEY - TX				
16 Ms. BROWNLEY - CA		•		
17 Ms. KELLY - IL		•		
18 Ms. CLARK - MA		•		
TOTALS	17	13		

\*\* Vice Chair

Chairman SMITH. The bill is agreed to.

And without objection, the Motion to Reconsider is laid upon the table.

I move that the bill H.R. 4012 be favorably reported to the House and the staff be authorized to make any necessary technical and conforming changes.

If there is no further discussion, that completes our business and this concludes the full committee markup.

Without objection, the Committee stands adjourned.

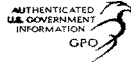
[Whereupon, at 11:52 a.m., the Committee was adjourned.]



## Appendix I

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H.R. 4012, SECRET SCIENCE REFORM ACT OF 2014  
SECTION-BY-SECTION ANALYSIS, AMENDMENTS  
AMENDMENT ROSTER



I

113TH CONGRESS  
2D SESSION

# H. R. 4012

To prohibit the Environmental Protection Agency from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 6, 2014

Mr. SCHWEIKERT (for himself, Mr. SMITH of Texas, Mr. HALL, Mr. BROWN of Georgia, Mr. CULBERSON, Mr. BRIDENSTINE, Mrs. LUMMIS, Mr. ROHRBACHER, Mr. COLLINS of New York, Mr. BURGESS, Mr. OLSON, Mr. CRAMER, Mr. BUCSHON, Mr. HULTGREN, Mr. NEUGEBAUER, Mr. PALAZZO, Mr. BROOKS of Alabama, Mr. SALMON, and Mr. FRANKS of Arizona) introduced the following bill; which was referred to the Committee on Science, Space, and Technology

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## A BILL

To prohibit the Environmental Protection Agency from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible.

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 “Secret Science Reform  
5 Act of 2014”.

1 **SEC. 2. DATA TRANSPARENCY.**

2 Section 6(b) of the Environmental Research, Devel-  
3 opment, and Demonstration Authorization Act of 1978  
4 (42 U.S.C. 4363 note) is amended to read as follows:

5 “(b)(1) The Administrator shall not propose, finalize,  
6 or disseminate a covered action unless all scientific and  
7 technical information relied on to support such covered ac-  
8 tion is—

9 “(A) specifically identified; and

10 “(B) publicly available in a manner that is suf-  
11 ficient for independent analysis and substantial re-  
12 production of research results.

13 “(2) Nothing in the subsection shall be construed as  
14 requiring the public dissemination of information the dis-  
15 closure of which is prohibited by law.

16 “(3) In this subsection—

17 “(A) the term ‘covered action’ means a risk, ex-  
18 posure, or hazard assessment, criteria document,  
19 standard, limitation, regulation, regulatory impact  
20 analysis, or guidance; and

21 “(B) the term ‘scientific and technical informa-  
22 tion’ includes—

23 “(i) materials, data, and associated proto-  
24 cols necessary to understand, assess, and ex-  
25 tend conclusions;

1           “(ii) computer codes and models involved  
2           in the creation and analysis of such informa-  
3           tion;

4           “(iii) recorded factual materials; and

5           “(iv) detailed descriptions of how to access  
6           and use such information.”.

○



SECTION-BY-SECTION ANALYSIS OF  
H.R. 4012, SECRET SCIENCE REFORM ACT OF 2014

**Section 1. Short Title.**

This section establishes the short title of the Act as the “Secret Science Reform Act of 2014.”

**Section 2. Data Transparency**

Section 2 amends the Environmental Research, Development, and Demonstration Authorization Act to:

- 1) Prohibit the Administrator of EPA from finalizing, proposing, or disseminating a covered action unless all scientific and technical information relied on to support the covered action is:
  - a. Specifically identified, and
  - b. Publically available in a manner that is sufficient for independent analysis and substantial reproduction of research results.
- 2) Clarify that nothing in the section shall be construed as requiring public dissemination of information, the disclosure of which is prohibited by law.
- 3) Define “covered action” to mean a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance. The section defines “scientific and technical information” to include materials, data, and associated protocols necessary to understand, assess, and extend conclusions, computer codes and models involved in the creation and analysis of information, recorded factual materials, and detailed descriptions of how to assess and use such information.

## AMENDMENT ROSTER

**COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY**  
**June 24, 2014**

**AMENDMENT ROSTER**

**H.R. 4012, the "Secret Science Reform Act of 2014"**

No.	Amendment	Summary	
1	<b>Amendment in the Nature of a Substitute Offered by Ms. Bonamici (OR) #001</b>	This amendment would strike the entire bill and instead require the Administrator to implement a public access policy to make EPA-funded peer-reviewed articles, but not the underlying data, publically available without charge no more than 12 months after the date of publication. The amendment also includes procedures for the use of non-public information, public access to research data through the Freedom of Information Act. The amendment requires that the administrator shall only consider research from scholarly publications that discloses the entity that funded it and that, in developing agency action, the Administrator shall not exclude research data that is not public because the disclosure would constitute an invasion of privacy.	<b>Not Agreed to by Voice Vote</b>
2	<b>Amendment Offered by Mr. Kennedy (MA) #003</b>	This amendment would remove the requirement that scientific and technical information relied on to support covered actions by EPA be publically available in manner sufficient for independent analysis, and removes the corresponding language that nothing in the act requires public dissemination of information, the disclosure of which is prohibited by law.	<b>Not Agreed to by Voice Vote</b>

## Appendix II

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LETTERS SUBMITTED FOR THE RECORD

June 23, 2014

The Honorable Lamar Smith, Chairman  
House Committee on Science, Space, and Technology  
2321 Rayburn House Office Building  
Washington, D.C 20515

Dear Chairman Smith,

We write in support of the principles contained in H.R. 4012, the Secret Science Reform Act. This legislation supports a basic tenet: the Environmental Protection Agency's regulations should be based on transparent and reproducible science.

Potentially costly regulations should be grounded in data and analyses that are available to academic, government, and independent scientists. Pushing EPA to ensure that the data, models, and methods it relies on are open to public and scientific scrutiny will make the Agency's regulations more accountable, credible, and enforceable.

While we hail from a variety of scientific and academic disciplines, we agree that the provisions of this legislation could be satisfied by EPA without difficulty. The bill is also consistent with recent trends toward access among major scientific journals across these fields. Transparency and reproducibility in EPA regulatory science will encourage more robust analysis of findings by investigators with diverse perspectives while allowing the Agency to base its policy decisions on the best available science. Complying with H.R. 4012 can be accomplished without imposing unnecessary burdens, discouraging research, or raising confidentiality concerns. Across different disciplines, numerous statistical and technical approaches exist to protect any sensitive information.

We support passage of this legislation and thank your Committee for its leadership on this important issue.

Sincerely,

Dr. Charles A. Ager, PhD  
Founder and Chairman, Nanominerals Corp

Dr. Ralph B. Alexander, PhD  
Former Associate Professor, Physics, Wayne State University

Mr. Robert A. Ashworth  
Chemical Engineer

Dr. Charles R. Anderson, PhD  
President and Principal Scientist, Anderson Materials Evaluation, Inc.

Dr. J. Scott Armstrong, PhD  
Professor, Marketing, Wharton School, University of Pennsylvania

Dr. James R. Barrante, PhD  
Professor Emeritus, Physical Chemistry, Southern Connecticut State University

Dr. Charles Battig, M.D.  
President, Piedmont Chapter, Virginia Scientists and Engineers for Energy and Environment

Dr. Denis Beller, PhD  
Research Professor, Nuclear Engineering, University of Nevada Las Vegas

Dr. David J. Benard, PhD  
Physicist (ret.)

Dr. Michael A. Berry, PhD  
Former Deputy Director, National Center for Environmental Assessment, USEPA (ret.) and  
Research Professor, Environmental Sciences, University of North Carolina at Chapel Hill

Dr. Charles A. Berst, PhD  
Emeritus Professor, English, University of California, Los Angeles

Dr. William M. Briggs, PhD  
Statistical Consultant and Adjunct Professor of Statistical Science, Cornell University

Dr. Edward Calabrese, PhD  
Professor, Environmental Health Sciences, University of Massachusetts Amherst

Dr. Angelo J. Campanella, PhD  
Principal, Campanella Acoustics

Dr. Alan Carlin, PhD  
Senior Operations Research Analyst, USEPA (ret.)

Dr. Lawrence M. Cathles, PhD  
Professor, Geological Sciences, Cornell University

Dr. Charles R. Christensen, PhD  
Research Physicist, Retired from Weapon Sciences Directorate, US Army Aviation and Missile Command.

Dr. Dustin Chambers, PhD  
Associate Professor, Economics, Salisbury University

Dr. Michael S. Coffman, PhD  
President, Environmental Perspectives, Inc.

Dr. Roger Cohen, PhD  
Fellow, American Physical Society

Dr. William F. Condon, PhD  
Emeritus Professor, Chemistry, Southern Connecticut State University

Dr. Louis Anthony Cox, Jr., PhD  
Chief Sciences Officer, Next Health Technologies; Clinical Professor, Biostatistics and Informatics, University of Colorado Health Sciences Center; and President, Cox Associates

Dr. James Crosswell, MD  
Physician

Dr. Tim Davis, PhD  
Licensed Specialist Clinical Social Worker

Dr. Ulrich Decher, PhD  
Adjunct Faculty, University of Hartford

Dr. Arthur Desrosiers, ScD  
Environmental Health Physicist

Dr. Pamela C. Dodds, PhD  
Registered Professional Geologist

Dr. Harold H. Doiron, PhD  
Chairman, The Right Climate Stuff Research Team

Dr. Nicholas Drapela, PhD  
Former Professor, Chemistry, Oregon State University

Mr. John Droz, Jr.  
Physicist and Executive Director of the Alliance for Wise Energy Decisions

Mr. John Dale Dunn, MD, JD  
Consultant Emergency Services/Peer Review, Civilian Faculty, Emergency Medicine Residency,  
Carl R. Darnall Army Medical Center, Fort Hood

Dr. James E. Enstrom, PhD  
Researcher (ret.), School of Public Health, University of California, Los Angeles and President,  
Scientific Integrity Institute

Dr. Dan Ervin, PhD  
Professor, Finance, Perdue School of Business, Salisbury University

Dr. Irvin H. Forbing, DDS  
Dentist

Dr. Patrick Frank, PhD  
Research Chemist

Dr. Gordon J. Fulks, PhD  
Astrophysicist

Dr. Laurence I. Gould, PhD  
Professor, Physics, University of Hartford

Dr. Shawn Grannell, PhD  
Inventor

Dr. William M. Gray, PhD  
Professor Emeritus, Department of Atmospheric Science, Colorado State University

Dr. Tim Groseclose, PhD  
Professor, American Politics and Public Policy, University of California, Los Angeles

Dr. William Happer, PhD  
Professor, Physics, Princeton University

Dr. Victor Davis Hanson, PhD  
Senior Fellow, Hoover Institution at Stanford University

Dr. Doug L. Hoffman, PhD  
Former Research Professor, Computer Science, University of North Carolina at Chapel Hill

Dr. Albert Kris Huber, PhD  
Electrical Engineer

Dr. W. Reed Johnson, PhD  
Professor Emeritus, Nuclear Engineering, University of Virginia

Dr. Jason S. Johnston, PhD  
Professor of Law, University of Virginia

Mr. Brian T. Kennedy  
President, The Claremont Institute

Dr. E. Christian Kopff, PhD  
Associate Professor, Classics, University of Colorado, Boulder

Dr. Patricia A. Lapoint, PhD  
Professor, Management, McMurry University

Dr. Lubert Leger, PhD  
Former Assistant Chief, Materials Division, Engineer Directorate, Johnson Space Center, NASA

Dr. Jay Lehr, PhD  
Science Director, The Heartland Institute



Dr. Jonathan A. Lesser, PhD  
President, Continental Economics

Dr. Richard E. Lindstrom, PhD  
Professor Emeritus, University of Connecticut

Dr. Anthony Lupo, PhD  
Professor, Atmospheric Science, University of Missouri

Dr. Matthew A. Malkan, PhD  
Professor, Physics and Astronomy, University of California, Los Angeles

Dr. Martin J. Mangino, PhD  
Professor, Surgery, Virginia Commonwealth University

Dr. Calvin Luther Martin, PhD  
Associate Professor of History (ret.), Rutgers University

Dr. John Martinis, PhD  
Professor, Physics, University of California, Santa Barbara

Dr. Robert J. Michaels, PhD  
Professor, Economics, California State University, Fullerton

Dr. Henry I. Miller, M.D.  
Robert Wesson Fellow in Scientific Philosophy and Public Policy, Hoover Institution at Stanford University

Dr. Ferenc M. Miskolczi, PhD  
Former Senior Principal Scientist, NASA Langley Research Center

Dr. Dennis M. Moltz, PhD  
Owner, High Desert Nuclear Technologies

Dr. Michael Newton, PhD  
Professor Emeritus, Forest Ecology, Oregon State University

Dr. Helen Schwiesow Parker, PhD  
Licensed Clinical Psychologist

Dr. Nina Pierpont, MD, PhD  
Former Clinical Professor of Pediatrics, College of Physicians and Surgeons, Columbia University; currently a pediatrician in private practice

Dr. Jerry L. Punch, PhD  
Professor Emeritus, Department of Communicative Sciences and Disorders, Michigan State University

Dr. Forrest J. Remick, PhD  
Emeritus Professor, Nuclear Engineering, and Emeritus Associate Vice President, Research, The Pennsylvania State University; and Commissioner (Retired), US Nuclear Regulatory Commission

Dr. James H. Rust, PhD  
Professor of Nuclear Engineering (ret.), Georgia Tech

Mr. Donald F. Shaw, Sr.  
Senior Engineering Advisor

Dr. Thomas Sheahen, PhD, PE  
Physicist

Dr. S. Fred Singer, PhD  
Professor Emeritus, Environmental Science, University of Virginia, and Director, Science and Environmental Policy Project

Dr. Thomas L. Steepy, PhD  
Plant Pathologist

Dr. Gary Steinberg, DMD  
Dentist

Dr. Glenda Tannahill, PhD  
CEO/CFO, Good Samaritan

Dr. George S. Taylor, PhD  
Director, Palmetto Energy Institute

Dr. David E. Thompson, PhD  
Founder and President, Metric Echo, Inc, and Dean Emeritus, College of Engineering, University of Idaho

Dr. Marc Trachtenberg, PhD  
Professor, Political Science, University of California, Los Angeles

Dr. Michael Trigoboff, PhD  
Instructor, Computer Science, Portland Community College

Dr. Stanley W. Trimble, PhD  
Professor Emeritus, Department of Geography, UCLA

Dr. Kirby Tyndall, PhD  
Environmental Toxicologist

Dr. James Wanliss, PhD  
Associate Professor, Physics, Presbyterian College

Dr. Robert Whitsett, PhD  
Former Staff Scientist, Lawrence Berkeley National Laboratory

Dr. Charles Wolf, Jr., PhD  
Distinguished Chair in International Economics, RAND Corporation and Professor, Pardee  
RAND Graduate School

Dr. George T. Wolff, PhD  
Principal Scientist, Air Improvement Resource, Inc.; Former Chair, EPA Clean Air Scientific  
Advisory Committee

Dr. Peter W. Wood, PhD  
President, National Association of Scholars

Dr. Steven B. Young, PhD  
Former Professor of Biology, Middlebury University

Dr. S. Stanley Young, PhD  
Assistant Director for Bioinformatics, National Institute of Statistical Sciences

cc: Eddie Bernice Johnson, Ranking Member, House Committee on Science, Space, and  
Technology

**Roger O. McClellan, DVM, MMS, DSc (Honorary),  
Diplomate-ABT and ABVT  
Fellow-ATS, SRA, AAAR, HPS, AAAS and Member-Institute of Medicine  
Advisor, Toxicology and Human Health Risk Analysis  
13701 Quaking Aspen Place N.E.  
Albuquerque, NM 87111-7168  
Tel: 505-296-7083  
E-mail: [roger.o.mcclellan@att.net](mailto:roger.o.mcclellan@att.net)**

June 18, 2014

The Honorable Lamar Smith, Chairman  
House Committee on Science, Space and Technology  
2321 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Smith:

I am writing to offer my strong support for the principles contained in H.R. 4012, the Secret Science Reform Act. This important legislation is directed at what should be a core tenet of the U.S. Environmental Protection Agency – all of the Agency’s regulations and actions should be grounded in sound science that is transparent and reproducible. My strong support for the legislation is based on my personal knowledge of the Agency’s development and promulgation of the National Ambient Air Quality Standards (NAAQS), knowledge I gained as Chair of the EPA’s Clean Air Scientific Advisory Committee (CASAC) and service on numerous CASAC Panels dealing with all six criteria pollutants.

I consider myself a student of the Clean Air Act and the role of the NAAQS in improving air quality in the United States. It is vitally important that the NAAQS be based on sound science informing the Administrator’s policy judgments. The attached figure illustrates the regulatory pyramid used to promulgate the NAAQS. The base of that pyramid is Sound Science that should be presented in a transparent manner and reproducible. If the science has not been presented in a transparent manner and is not reproducible, there is a high probability that the policy judgments made by the Administrator will be arbitrary and capricious. The result may be flawed NAAQS that fail to deliver the intended public health benefits. In short, the NAAQS regulatory pyramid must have a solid scientific foundation.

Transparent and reproducible science is multi-faceted. It requires that large and complex data sets that frequently cost tens of millions of dollars to assemble are shared with other responsible scientists to (a) reproduce the original findings, and (b) perform alternative analyses. The methods and models used in the analyses must also be shared. Technical and statistical approaches are available today to achieve these objectives while protecting confidential personal data on individual subjects.

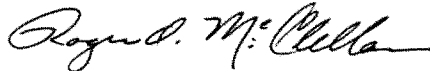
I have had 40 years of experience serving on CASAC Panels, including 4 years as CASAC Chair, advising on the science under-girding the Administrator's policy judgments in setting NAAQS. On numerous occasions, the results from a single data set analyzed by a single group of investigators played a central role in the advice offered to the Administrator. In my opinion, there is a high likelihood different scientific findings and conclusions would have emerged if another group had analyzed the same data. I say that because in the few instances where the same data set has been analyzed by multiple teams, new and different results have emerged.

As you know, the regulations developed by the EPA under the CAA have extraordinarily large potential impact on human health and the U.S. economy. The potential impact is even greater with EPA's involvement in climate change. In reviewing the EPA's "Regulatory Impact Analysis for the Proposed Carbon Pollution Guidelines for Existing Power Plants and Emission Standards for Modified and Reconstructed Power Plants," I noted how a few papers reporting results that had not been replicated had enormous impact. This is exactly what was observed in setting some of the NAAQS. Indeed, some of the papers whose results have not been adequately replicated have been used over and over to support multiple regulations.

The changes in scientific practices called for in HR 4012 are long overdue. It is unfortunate that legislative remedies are required for development of a common sense approach the Agency should have initiated long ago.

I urge passage of this legislation and, indeed, hope for volunteer action by the Agency in advance of passage of the legislation.

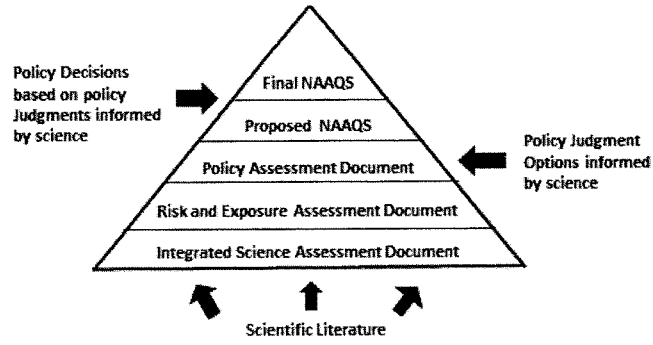
Respectfully,



Roger O. McClellan  
Former Chair, EPA Clean Air Scientific Advisory  
Committee  
Member, Institute of Medicine of the National Academy  
of Science

Attachment: Role of Science and Policy Judgments in Setting  
National Ambient Air Quality Standards

cc: Eddie Bernice Johnson, Ranking Member  
House Committee on Science, Space and Technology



Role of Science and Policy Judgments in Setting National Ambient Air Quality Standards

CHAMBER OF COMMERCE  
OF THE  
UNITED STATES OF AMERICA

R. BRUCE JOSTEN  
EXECUTIVE VICE PRESIDENT  
GOVERNMENT AFFAIRS

1615 H STREET, N.W.  
WASHINGTON, D.C. 20062-2000  
202/463-5310

June 16, 2014

The Honorable David Schweikert  
Chairman  
Subcommittee on Environment  
Committee on Science, Space, and  
Technology  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Suzanne Bonamici  
Ranking Member  
Subcommittee on Environment  
Committee on Science, Space, and  
Technology  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Schweikert and Ranking Member Bonamici:

The U.S. Chamber of Commerce, the world's largest business federation representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and dedicated to promoting, protecting, and defending America's free enterprise system, supports H.R. 4012, the "Secret Science Reform Act of 2014," which would improve the transparency and reliability of scientific and technical information that is relied upon to support Federal actions.

H.R. 4012 would ensure that the studies and data Federal agencies rely upon when they write new regulations, standards, guidance, assessments of risks/exposures/hazards—or take other regulatory action—are clearly identified and made available for public review. Additionally, this bill would require that information must be sufficiently transparent to allow study findings to be reproduced and validated. This would be a critical safeguard to assure the public that the data Federal agencies rely on is scientifically sound and unbiased.

H.R. 4012 would improve the transparency and trustworthiness of scientific and technical information that agencies cite to justify regulatory actions that can significantly affect society. Accordingly, the Chamber supports this bill and looks forward to working with you and your colleagues on this important issue.

Sincerely,



R. Bruce Josten

cc: Members of the Subcommittee on Environment

The Honorable Lamar Smith  
Chairman, Committee on Science, Space, and Technology  
United States House of Representatives  
Washington, DC 20515

June 23, 2014

Dear Mr. Chairman:

We are writing on behalf of the American Alliance for Innovation (AAI) in support of H.R. 4012, the Secret Science Reform Act of 2014. AAI is a large and diverse coalition of trade associations representing a broad spectrum of the American economy, including businesses both large and small. Our organization represents many major industry sectors, all along the chemicals value chain, including aerospace, agriculture, apparel, automotive, building and construction materials, chemical and raw material production, consumer and industrial goods, distribution, electronics, energy, equipment manufacturers, food and grocery, footwear, healthcare products and medical technology, information technology, mining and metals, plastics, retail, and travel goods.

It is paramount that chemicals and metals producers, manufacturers, distributors, importers, users, and the public have confidence that regulatory decisions reached by the U.S. Environmental Protection Agency (EPA) are grounded in transparent and reproducible science. Many of EPA's regulatory programs affect the sectors we represent, which is why we support your efforts to help the Agency advance its decision making process.

Ensuring that EPA utilizes high quality science and provides more clarity on how decisions are made will only increase their value, utility, and credibility for ensuring public safety. Improving the scientific quality and sharing of information underpinning EPA's decisions is critical to fostering a regulatory environment that will allow our members to continue to develop safe and cost-effective products on which Americans depend as part of their everyday life.

Furthermore, we believe the goal of this legislation is consistent with the Obama Administration's science integrity goals and will help EPA meet its obligation to protect human health and the environment.

We support the passage of this legislation and thank your Committee for its leadership on this important issue.

Sincerely,

American Apparel & Footwear Association  
American Chemistry Council  
American Coatings Association  
American Composites Manufacturers Association  
American Foundry Society  
American Fuel & Petrochemical Manufacturers  
American Petroleum Institute  
American Wood Council  
Auto Care Association



Corn Refiners Association  
Council of Producers & Distributors of Agrotechnology  
EPS Industry Alliance  
Fashion Jewelry and Accessories Trade Association  
Industrial Minerals Association - North America  
Institute of Makers of Explosives  
International Institute of Synthetic Rubber Producers  
IPC – Association Connecting Electronics Industries  
National Association for Surface Finishing  
National Association of Chemical Distributors  
National Black Chamber of Commerce  
National Electrical Manufacturers Association  
National Lumber and Building Material Dealers Association  
National Oilseed Processors Association  
National Stone, Sand & Gravel Association  
Pine Chemicals Association, Inc.  
Plumbing Manufacturers International  
Styrene Information and Research Center  
The Fertilizer Institute  
Treated Wood Council  
Window & Door Manufacturers Association



**INDIANA UNIVERSITY**

SCHOOL OF PUBLIC AND  
ENVIRONMENTAL AFFAIRS

June 12, 2014

Dear Congressman Smith:

I am pleased to offer my personal endorsement of H.R. 4012, a bill with the simple mission of ensuring that the science underpinning EPA regulation is transparent and available to the scientific community for re-analysis. I have already submitted both written and oral testimony at the Committee's public hearing earlier this year but I want you to know that I enthusiastically support passage of the bill.

Please be aware that my views are strictly my own, and should not be attributed to Indiana University or the School of Public and Environmental Affairs. Please do not hesitate to contact me if you have any questions or desire any additional information.

Sincerely,

A handwritten signature in black ink that reads "John D. Graham". The signature is written in a cursive style with a large initial "J".

John D. Graham, Ph.D.

Dean



## California Construction Trucking Association

334 N. Euclid Avenue ♦ Upland, CA 91786  
 (909) 982-9898 ♦ Fax (909) 985-2348  
 CalConTrk.org

June 17, 2014

The Honorable Lamar Smith, Chairman  
 House Committee on Science, Space, and Technology  
 2321 Rayburn House Office Building  
 Washington, D.C 20515

Re: Letter in support of H.R. 4012

Dear Chairman Smith,

I am writing to express our association's support of legislation (H.R. 4012) that would prohibit the U.S. Environmental Protection Agency (U.S. EPA) from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible.

The California Construction Trucking Association (CCTA) is a 501(c)(6) trade association incorporated in 1941 and headquartered in Upland, California. The CCTA is constituted of four conferences, each designed to represent and provide for the distinctive needs of a particular segment of the trucking industry. While our members still predominantly operate dump trucks made up of every style and configuration, our collective membership operates virtually every type of commercial motor vehicle imaginable. We actively maintain transportation conferences for oversized (permitted) lowbed loads, water trucks, concrete boom and trailer pumps, and most recently interstate motor carriers under the conference name- Western Trucking Alliance. Collectively, our members and affiliates operate nearly 20,000 commercial motor vehicles.

As a California-based trade association our members have firsthand knowledge of the price paid for unnecessary regulations based on faulty science which is the the reason we support H.R. 4012. The California Air Resources Board (CARB)<sup>1</sup> has issued the most draconian diesel engine emissions regulations in the nation – endorsed by the U.S. EPA through approval of California's State Implementation Plan (SIP). With the recent EPA (2012) approval of this SIP, CARB mandated the obsolescents of mostly EPA-compliant heavy-duty diesel powered vehicles in or that come to California equipped with pre-2010 emissions engines. This is one of the most expensive regulatory assaults on small-businesses in the nation acknowledged to cost the trucking industry into the tens of billions of dollars!

The very basis for CARB's diesel engine regulations (besides the special status California enjoys under the Clean Air Act to independently regulate emissions which every state can adopt if they choose) is the absolutely unproven and specious claims that diesel particulate emissions (PM 2.5) is prematurely killing thousands of Californians annually.

In 1998, at a time when diesel engine manufacturers and their technology were making great strides to clean diesel engine emissions, California became the only political entity on the planet to declare diesel exhaust a "toxic air contaminant" and the individual responsible for that designation was primarily UCLA professor John Froines PhD who chaired the states Scientific Review Panel on Toxic Air Contaminants. Mr. Froines is one of the overlooked members of the Chicago Seven charged with

<sup>1</sup> On-Road Heavy-Duty Diesel Vehicles (In-Use) Regulation – see: <http://www.arb.ca.gov/msprog/onrdiesel/onrdiesel.htm>

conspiracy and inciting to riot during the 1968 Democratic National Convention.<sup>2</sup> Dr. Froines radical views on how society should be governed and controlled found a home in the environmental movement where his scientific research and conclusions found a willing audience all too ready to believe in manufactured data to support their collective belief system.

As California promulgated their anti-truck regulations, a CARB employee Hein Tran, key author of the mortality study used as a basis to justify regulating both off-road and in-use diesel powered trucks was found to have faked his academic credentials. The doctorate he claimed to have earned from the University of California at Davis was in fact bought from a New York City diploma mill – and a public health agency claiming to adhere to high academic standards – CARB, still employees Mr. Tran.

Throughout this entire tawdry process, the CCTA exposed all of the fraud and deceit in an attempt to thwart an agency intent on regulating without any sound scientific basis and access to American Cancer Society mortality data. We have sued the agency in federal court, introduced a relevant but un-utilized 2010 NIOSH mortality study on truck drivers that showed truckers diesel exhaust exposure and mortality<sup>3</sup> are not linked, networked with many academics that have contrary data indicating CARB's assumptions are not science based, and still the agency plows forward destroying many transportation businesses all with the help of the U.S. EPA. It's no wonder that California's Inland Empire is being economically compared to Appalachian America in terms of unemployment, lost economic activity, and poor health outcomes as a direct result of overzealous environmental regulation.

To further burst the bubble of both academics and state and federal agencies intent on "buying" the research results they want in order to justify regulations, none other than the United Nations Economic Commission for Europe issued a report just last month that completely upends the rationale utilized by both the U.S. EPA and CARB to regulate heavy-duty diesel truck owners. The report is titled "Diesel Engine Exhausts: Myths and Realities"<sup>4</sup> and unequivocally states, "...diesel driven road vehicles came to the centre of attention to the extent that they have become "demonized" and the studies author further said, "In fact, road transport counts for only three per cent of diesel emissions in the United States of America and 15 per cent in the European Union." The U.N. report concluded, "...with a high degree of reliability that it is misleading to claim that people's exposure to diesel engines of road motor vehicles is the cause of increased risk of lung cancer. Therefore, the claim that emissions from diesel engine exhausts from road transport are the main cause of lung cancer in humans needs to be seriously challenged."

For these reasons and a long list of data access requests (and denials) our organization has been involved with, we support H.R. 4012 as the only means to protect individuals and businesses from unnecessary government regulation based on "junk science." Government agencies should not be afraid of transparency in the data-sets they utilize to promulgate regulations. If study results used to regulate cannot be independently reproduced, then U.S. EPA shouldn't be allowed to push forward with job killing mandates all to placate a vocal minority of environmental activists.

Sincerely,



Lee Brown  
Executive Director  
California Construction Trucking Association  
334 N. Euclid Avenue  
Upland, CA. 91786

<sup>2</sup> See: [http://articles.latimes.com/1990-01-30/news/vw-1032\\_1\\_radical-past](http://articles.latimes.com/1990-01-30/news/vw-1032_1_radical-past)

<sup>3</sup> <http://www.caltransnews.com/trucker-to-trucker/2266-mortality-study-on-owner-ops-disproves-claims-of-risk-from-exposure-to-pm25>

<sup>4</sup> [http://www.unecce.org/fileadmin/DAM/trans/main/wp5/publications/Diesel\\_Engines\\_Exhausts\\_Myths\\_and\\_Realities\\_2014.pdf](http://www.unecce.org/fileadmin/DAM/trans/main/wp5/publications/Diesel_Engines_Exhausts_Myths_and_Realities_2014.pdf)

7/15/2014

Lamar Smith: What Is the EPA Hiding From the Public? - WSJ

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OPINION

## What Is the EPA Hiding From the Public?

*The agency shouldn't get to decide who sees the science behind its rules. Open the research to outside analysis.*

By LAMAR SMITH

June 23, 2014 6:45 p.m. ET

The climate is changing and, yes, humans play a role. But that does not mean, as Environmental Protection Agency Administrator Gina McCarthy would have us believe, that the debate—over how much the climate is changing, how big a role humans play, and what can reasonably be done about it—is over. Still less does it mean that anyone who questions her agency's actions, particularly the confidential research it uses to justify multimillion and billion-dollar air rules, is a denier at war with science.

The EPA's regulatory process today is a closed loop. The agency funds the scientific research it uses to support its regulations, and it picks the supposedly independent (but usually agency-funded) scientists to review it. When the regulations are challenged, the courts defer to the agency on scientific issues. But the agency refuses to make public the scientific research it uses.



Environmental Protection Agency Administrator Gina McCarthy *Getty Images*

The House Science Committee will vote Tuesday on legislation to open up this closed loop. The Secret Science Reform Act, which I co-sponsored, has a simple goal: EPA regulations should be based on legitimate science and data that are open to the public.

Scientific journals in a variety of disciplines have moved toward data transparency. Ms. McCarthy sees this effort as a threat. Speaking before the National Academy of Sciences in late April, she defended her agency's need to protect data "from

those who are not qualified to analyze it."

The EPA essentially decides who is or is not allowed access to the scientific research they use—research that is paid for with public funds, appropriated by Congress, on behalf of American taxpayers. This is wholly improper.

I recently received a letter of support for the Secret Science Reform Act that was signed by more than 80 scientists, including physicians, and professors of environmental science, physics,

<http://online.wsj.com/articles/lamar-smith-what-is-the-epa-hiding-from-the-public-1403563536#printMode>

1/2

7/15/2014

Lamar Smith: What Is the EPA Hiding From the Public? - WSJ

statistics, economics and engineering. The signatories included George Wolff, former chair of the EPA's Clean Air Scientific Advisory Committee in the Clinton administration and Forrest J. Remick, former commissioner of the U.S. Nuclear Regulatory Commission in the George H.W. Bush administration. They wrote that the bill would "make the agency's regulations more accountable, credible, and enforceable" and that its transparency requirements "can be accomplished without imposing unnecessary burdens, discouraging research, or raising confidentiality concerns."

Costly environmental regulations must be based on publicly available data that independent scientists can verify. For example, take the administration's recently proposed plan to regulate greenhouse gas emissions from existing power plants—regulations that could cost hundreds of thousands of jobs and spike electricity rates.

In the announcement of her agency's 645-page Clean Power Plan, Ms. McCarthy claimed "The science is clear. The risks are clear. And the high costs of climate inaction keep piling up." Yet any reporter willing to read beyond the EPA press release would find that the reality doesn't match the rhetoric.

Monday's Supreme Court decision (*Utility Air Regulatory Group v. EPA*) underscores the need for scrutiny of agency claims. The court called EPA's rewriting of the Clean Air Act "outrageous," and said that "When an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,' we typically greet its announcement with a measure of skepticism." Such skepticism is well deserved.

Virtually all of the EPA's health claims for its latest power-plant rules, including that they would save thousands of lives a year, are based on data that haven't been made public. In any event, for most of the EPA's 2030 projections, a majority of the health benefits claimed have nothing to do with carbon dioxide. They come from reductions in air pollutants already regulated by the EPA such as particulate matter and ozone.

The EPA also claims that its Clean Power Plan will yield climate benefits, such as lower sea levels, which the agency calculates using its "social cost of carbon." But a recent analysis by Ted Gayer, vice president and director of economic studies at the Brookings Institution, found that most of these alleged benefits take place outside the U.S. Even using the EPA's own numbers, the costs of this regulation may exceed the direct, domestic benefits.

The EPA, like every other government institution, should be accountable to the American people. We need to protect our environment, but this should be done on the basis of open and honest information. That is the goal of the Secret Science Reform Act.

*Mr. Smith, a Republican from Texas, is chairman of the House Committee on Science, Space, and Technology.*

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Alan I. Leshner  
Chief Executive Officer and  
Executive Publisher, *Science*

June 23, 2014

The Honorable Lamar Smith  
Chairman, House Science, Space,  
and Technology Committee  
2321 Rayburn House Office Building  
Washington, DC 20515

The Honorable Eddie Bernice Johnson  
Ranking Member, House Science, Space,  
and Technology Committee  
394 Ford House Office Building  
Washington, DC 20515

Dear Chairman Smith and Ranking Member Johnson,

I write on behalf of the American Association for the Advancement of Science (AAAS) to express concerns regarding the Secret Science Reform Act of 2014 (H.R. 4012). As the Committee considers this legislation in markup this week, we encourage Members of the Committee to take additional time to evaluate the unintended consequences of this bill.

AAAS is concerned about how some of the key terms in the bill could be interpreted or misinterpreted, especially terms such as “materials”, “data”, and “reproducible”. Would the agency be excluded from utilizing research that involved physical specimens or biological materials that are not easily accessible? How would the agency address research that combines both public and private data?

With respect to reproducibility of research, some scientific research, especially in areas of public health, involves longitudinal studies that are so large and of great duration that they could not realistically be reproduced. Rather these studies are replicated, utilizing statistical modeling. The same may be true for scientific data from a one-time event (e.g., Deepwater Horizon Gulf Oil Spill) where data is being gathered in real time. We could foresee a situation whereby the agency would be constrained from making a proposal or even disseminating public information in a timely fashion.

Finally, the legislation could impose additional uncompensated burdens of cost and effort on those recipients of federal research grants where the research results are expected to be “relied on to support a covered action.” The bill is not clear on whether it is the EPA’s or the research institution’s responsibility to cover the costs associated with sharing and archiving this information.

The America COMPETES Reauthorization Act of 2010 required that the Office of Science and Technology Policy (OSTP) work with federal agencies to establish access to data policies that relate “to the dissemination and long-term stewardship of the results of unclassified research, including digital data and peer-reviewed scholarly publications.” Agencies are expected to finalize their data access policies by the end of the year, and given the complexities associated with access to research data as outlined above we suggest that the Committee wait to review the policies before imposing new statutory requirements via H.R. 4012.

Sincerely,

Alan I. Leshner

American Association for the Advancement of Science  
1200 New York Avenue, NW, Washington, DC 20005 USA  
Tel: 202 326 6639 Fax: 202 371 9526  
E-mail: aleshner@aaas.org

6/23/2014

Yet Another House Bill Would Limit EPA's Ability to Protect the Public and Environment



Published on *Center for Effective Government* (<http://www.foreffectivegov.org>)



### **Blog: The Fine Print**

## **Yet Another House Bill Would Limit EPA's Ability to Protect the Public and Environment**

by Katie Weatherford, 6/23/2014

On June 24, the House Science Committee will meet to review the Secret Science Reform Act of 2014 (H.R. 4012), a bill that seeks to stifle the U.S. Environmental Protection Agency's (EPA) ability to protect the public and environment from harm, even when there is overwhelming scientific evidence to support agency action.

The bill would prohibit EPA from issuing safeguards or even sharing information with the public about potential harms unless the agency makes publically available all scientific data and technical information used to support its action. The information that EPA would be required to publicize must be "specifically identified" and presented "in a manner that is sufficient for independent analysis and substantial reproduction of research results." However, these ambiguous terms are not defined anywhere in the bill, ultimately leaving their meaning to be decided during litigation.

Despite claims by some members of Congress and their industry allies that this bill would improve transparency and verifiability of scientific studies relied upon by EPA to justify new or updated safeguards, the plain language of the bill proves that the real objective is to delay EPA from its important work of protecting the public and environment from harm.

A key concern with the legislation is that it would severely restrict EPA's ability to act, even when the agency is unable or even legally prohibited from sharing the scientific data or technical information it relied on to justify taking action. While the bill would not require EPA to release this information to the public, the bill would still prohibit the agency from taking action based on that information, no matter how credible or conclusive the studies may be. In other words, EPA could no longer rely on peer-reviewed scientific studies if underlying data is protected by privacy laws, as is the case for human health studies.

The Union of Concerned Scientists (UCS) sent a letter to members of Congress in February warning that this bill would likely prevent EPA "from using any study that uses personal health data. . . . Since many EPA rules are health-based standards, this rule would severely restrict the ability of the agency to base rules on science." The group also warned that "new scientific methods and data may be restricted by intellectual property protections or industry trade secret exemptions."

The bill would also likely prevent EPA from considering many industry studies, which often contain confidential business information (CBI), to justify agency actions that benefit public health and the environment. Yet, in certain instances that benefit industry such as permitting, the bill allows EPA to take action without disclosing industry data containing CBI.

According to another letter sent by the Natural Resources Defense Council (NRDC), "The bill would make it harder for <http://foreffectivegov.org/print/13111>



6/23/2014


Yet Another House Bill Would Limit EPA's Ability to Protect the Public and Environment

EPA to consider confidential information from industry in many instances, limiting the agency's ability both to protect the public and to reduce the costs of regulation." "At the same time," the letter states, "the bill unfairly caters to industry by exempting permitting and other agency actions from its ambit and underscoring the CBI protections in existing law."

NRDC also identified several examples illustrating how this bill would "limit EPA's ability to review relevant information that current law allows EPA to consider." According to NRDC:

- EPA could not establish a drinking water standard or health advisory for a contaminant under the Safe Drinking Water Act based on information that industry claims was protected by confidential business information (CBI).
- EPA could not issue a risk/hazard assessment or a cancellation of a pesticide based upon (1) studies containing CBI; (2) epidemiological or clinical studies where the medical records of the patient are confidential under . . . patient confidentiality requirements; or (3) where the study would not be "reproducible" because of restrictions on access to confidential patient information.
- EPA could not regulate or issue guidance to prevent lead poisoning of children in housing . . . based upon clinical or epidemiological studies, where the medical records of the patients are confidential under . . . patient confidentiality requirements, or where the study would not be "reproducible" because of restrictions on access to confidential patient information.
- EPA could not conduct risk/hazard assessments necessary to inform and govern the cleanup of Superfund sites, to the extent that potentially responsible parties asserted CBI protections over company information potentially implicating their contribution to a site, or CBI relating to specific chemicals.

Instead of working to reduce EPA's ability to rely on critical scientific and technical information to keep the public and environment safe, Congress should be working to ensure EPA has the authority and resources it needs to enhance our health and environmental safeguards. When this bill comes before the House Science Committee for review on Tuesday, the committee should ensure that this bill is put to rest and more worthy proposals receive due consideration.

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June 18, 2014

The Hon. Lamar Smith  
 Chair, Committee on Science, Space,  
 and Technology  
 2321 Rayburn HOB  
 Washington, DC 20515

The Hon. Eddie Bernice Johnson  
 Ranking Member, Committee on Science, Space,  
 and Technology  
 2321 Rayburn HOB  
 Washington, DC 20515

The Hon. David Schweikert  
 Chair, Subcommittee on Environment  
 2321 Rayburn HOB  
 Washington, DC 20515

The Hon. Suzanne Bonamici  
 Ranking Member, Subcommittee on Environment  
 2321 Rayburn HOB  
 Washington, DC 20515

Dear Chairs and Ranking Members:

I am writing in strong opposition to H.R. 4012, the Secret Science Reform Act of 2014. The legislation represents a solution in search of a problem that does not exist. The EPA already makes the data, methodology, and peer-reviewed research it relies on in its rule-making processes as transparent as possible. Moreover, the additional restrictions imposed by this proposed bill would make it almost impossible to base public protections on the best available scientific information. In particular, if enacted, the language appears to indicate that the agency would be inhibited by the following challenges:

- **The EPA wouldn't be able to use most health studies.** The agency would likely be prevented from using any study that uses personal health data. The confidentiality of such data is usually protected by institutional review boards (IRB); thus, the data could not be made publicly available as demanded. Since many EPA rules are health-based standards, this rule would severely restrict the ability of the agency to base rules on science.
- **The EPA wouldn't be able to draw from industry data sources.** The agency would be prevented from using data provided by industry to the agency. Since information from industry sources is often not publicly available, a law requiring as such would prevent the agency from utilizing industry data, a source of information that often provides otherwise unknown data to inform EPA rule-making.
- **The EPA wouldn't be able to use new and innovative science.** New scientific methods and data may be restricted by intellectual property protections or industry trade secret exemptions. This proposed bill would limit EPA's ability to rely on the best available science including novel approaches that may not yet be publicly available.

- **Long-term and meta analyses would be unavailable.** Many of EPA's health-based standards rely on long-term exposure studies that assess the link between chronic diseases/mortality and pollutants; or on meta analyses that include many different studies and locations to provide a more robust look at the science. In H.R. 4012, the provision that studies be "in a manner that is sufficient for independent analysis and substantial reproduction of research" may prevent use of these vital studies by the EPA, as it is unclear whether such spatially and temporally comprehensive studies would be considered "sufficient for substantial reproduction."

I strongly urge you to oppose the Secret Science Reform Act of 2014. The proposed bill would inhibit the EPA's ability to carry out its science-based mission to protect human health and the environment

Sincerely,

A handwritten signature in black ink, appearing to read "A. Rosenberg", with a stylized flourish at the end.

Andrew A. Rosenberg, Ph.D.  
Director, Center for Science and Democracy  
Union of Concerned Scientists



February 10, 2014

The Honorable Suzanne Bonamici  
 Ranking Member, Subcommittee on Environment  
 Committee on Science, Space and Technology  
 U.S. House of Representatives  
 Washington, DC 20515

Dear Representative Bonamici:

We are writing to express our opposition to H.R. 4012 the Secret Science Reform Act of 2014. The American Lung Association is the oldest voluntary health organization in the United States. The Lung Association's mission is to save lives by improving lung health and preventing lung disease. We achieve our mission through research, advocacy and education. The American Thoracic Society is a medical professional society dedicated to the prevention, detection, treatment and cure of pulmonary disease, critical care illness and sleep-disordered breathing through research, education and advocacy

Science is the bedrock of sound regulatory decision making. The best science underscores everything our organizations do to improve health. We strongly believe in a transparent and open regulatory process. A vital element of research is patient confidentiality. Physicians and researchers have earned the trust of their patients by steadfastly maintaining patient confidentiality. Patient confidentiality is a clear legal and ethical obligation.

The legislation before the committee will compel the U.S. Environmental Protection Agency to either ignore the best science by prohibiting the agency from considering peer-reviewed research that is based on confidential patient information or force EPA to publicly release confidential patient information, which would violate federal law. This is an untenable outcome that would completely undermine ability of the EPA to perform its responsibilities under the Clean Air Act and myriad other federal laws. The legislation will not improve EPA's actions; rather it will stifle public health protections.

The kind of information disclosure envisioned in this legislation exceeds that required by peer-reviewed journals. We believe much of the intent of this legislation is already achieved through the current peer-review process required by all academic journals. The vast majority of peer-reviewed journals require manuscript authors to register any trial using human subjects with [clinicaltrials.gov](http://clinicaltrials.gov). This public registry collects key information on the study population, research goals and methods that allow outside reviewers and scientists to either challenge or attempt to reproduce study results. Additionally, the peer-review process and publication of results invites the broader scientific community to debate study findings. Trial registry and manuscript publications are only part of the process by which scientific endeavors operate in a transparent environment.

Private organizations, public charities, research universities, the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs, corporations and many other entities conduct medical research. Many of these organizations compile large longitudinal data sets that track patients over a period of time.

These data serve as the basis of many studies that permit epidemiologists to track disease and risk factor information for large patient populations.

The published peer-reviewed information from such data often inform regulatory decision making at the EPA and other federal agencies as well as future research. Not only do these data inform regulatory action, they help inform efforts to educate the public about the magnitude of a disease, risk factors and steps individuals can take to improve their health. In order for EPA to set the most appropriate standards, it must be informed by the best information.

Understanding the impact of air pollution on human health and the magnitude of harm caused by pollution at specific levels helps the agency meet its obligations under the Clean Air Act. Absent these data, it is unclear upon what basis the agency could make sound decisions.

We urge the committee to reject H.R. 4012.

Sincerely,

Harold Wimmer  
National President & CEO  
American Lung Association

Stephen C. Crane, PhD, MPH  
Executive Director  
American Thoracic Society



NATURAL RESOURCES DEFENSE COUNCIL

February 11, 2014

Honorable Lamar Smith, Chairman  
Committee on Science, Space, and Technology  
2321 Rayburn House Office Building  
Washington, DC 20515

Honorable Eddie Bernice Johnson, Ranking Member  
Committee on Science, Space, and Technology  
2321 Rayburn House Office Building  
Washington, DC 20515

Honorable David Schweikert, Chairman  
Subcommittee on Environment  
Committee on Science, Space, and Technology  
2318 Rayburn House Office Building  
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Honorable Suzanne Bonamici, Ranking Member  
Subcommittee on Environment  
Committee on Science, Space, and Technology  
2318 Rayburn House Office Building  
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TEL 202 289-6868

Dear Chairman Smith, Ranking Member Johnson, Chairman Schweikert and Ranking Member Bonamici,

On behalf of the Natural Resources Defense Council, I am writing to provide information that I hope will inform the Environment Subcommittee members' consideration of topics for your February 11th hearing on the discussion draft of a bill entitled the "Secret Science Reform Act of 2014."

The discussion draft of the bill is deeply troubling and should be rejected by subcommittee members. The draft legislation would effectively amend numerous environmental statutes, and it marks a radical departure from longstanding practices. Its end result would be to make it much more difficult to protect the public by forcing EPA to ignore key scientific studies, including those submitted by industry.

The bill proceeds from a faulty premise from which it then undermines EPA's ability to carry out its most basic responsibilities. The notion of "secret science" is a canard and ignores longstanding practices, recognized in law, that protect patient information, intellectual property and industrial secrets. This letter inventories some of the key ways such information is used, and needs to be used by EPA. The Subcommittee has done nothing to demonstrate how the public has suffered as a result before seeking to overthrow law and practice. But it is easy to show how the public would suffer if the bill's proscriptions and restrictions were put into effect.

This letter will elaborate on these points:

- The whole notion of "secret science," based on studies of fine soot pollution conducted almost two decades ago, is unfounded.
- The bill would make it impossible for EPA to use many kinds of studies that it necessarily relies on to protect the public because those studies use data that has long been understood to be legitimately confidential.
- The bill would make it impossible for EPA to use many kinds of economic models it routinely relies on because those models are proprietary.
- The bill advantages industry by exempting from its coverage EPA activities where industry is the primary party likely to submit confidential information, such as permitting.

Nonetheless, the bill would make it harder for EPA to consider confidential information from industry in many instances, limiting the agency's ability both to protect the public and to reduce the costs of regulation.

#### Covered Actions

The draft bill defines a "covered action" to mean "a risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance." This definition creates a fundamental double standard biased in favor of corporations and against public health and safety. The draft legislation (1) restricts the information EPA can use to take a series of actions to protect public health and the environment, while it (2) simultaneously leaves untouched a host of actions that industry needs and desires—notwithstanding that these industry-

avored actions often rely on industry-supplied scientific and technical information that industry may shield from the public.

Consider just a few examples of EPA actions that industry wants or needs EPA to take, and that do *not* fall under the definition of “covered action.” For these actions, EPA can continue to rely on so-called “secret science” supplied by industry that remains shielded:

- Industry permit approvals, revisions and renewals under the Clean Air Act, Clean Water Act and RCRA;
- Industry pesticide registrations, exemptions, and tolerances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);
- Applicability determinations under EPA statutes and adjudications under the Administrative Procedure Act that determine whether regulations do or do not apply;
- Requests under some EPA regulations for industry exemptions that may be granted without need for proposed or final regulations by the agency;
- Certifications and compliance reports for vehicles, engines and equipment for various Clean Air Act motor vehicle regulations.

The draft legislation exempts all of these industry-desired or needed agency actions from the bill’s strictures as well as from the bill’s purported concern for transparency.

#### Examples of Health Protections That the Draft Bill Would Obstruct

The following examples are drawn from just some of the statutory responsibilities and authorities that EPA has under current law. The draft bill would limit EPA’s ability to review relevant information that current law allows EPA to consider to protect public health, safety and the environment:

- EPA could not establish a drinking water standard or health advisory for a contaminant under the Safe Drinking Water Act based on information that industry claims was protected confidential business information (CBI).
- EPA could be hindered in responding to emergency situations. For example, initially some of the data on the chemical Freedom Industries spilled last month in West Virginia was not publicly disclosed. It was eventually released in response to a letter from Congressman Waxman to the manufacturer of the chemical, Eastman Chemical. The draft legislation is problematic in the extreme by allowing industry to decide selectively what information EPA can use to issue a health advisory or a risk or hazard assessment, based on industry claiming that information to be CBI.
- EPA could not establish a drinking water standard or health advisory based on epidemiological evidence or clinical studies where the medical records of the patients were confidential under the Health Insurance Portability and Accountability Act (HIPAA) or other patient confidentiality requirements, or where the study would not be “reproducible” because of restrictions on access to confidential patient information. These confidentiality safeguards for patient data are routine in the field of medical research, yet the draft legislation renders important advances and understandings in health and environmental research off-limits to EPA when carrying out the law to protect Americans.



- EPA could not issue a risk/hazard assessment or a cancellation of a pesticide based upon (1) studies containing CBI; (2) epidemiological or clinical studies where the medical records of the patients are confidential under HIPAA or other patient confidentiality requirements; or (3) where the study would not be “reproducible” because of restrictions on access to confidential patient information. For example, studies completed by Columbia University doctors have shown certain pesticides used indoors harm pregnant mothers and their fetuses, causing smaller head circumferences, and interfering with children’s brains’ development as they grow up. These patient records have been aggregated and published in peer-reviewed journal literature, but underlying medical records are required to be kept confidential under HIPAA and agreements with patients.
- EPA could not regulate or issue guidance to prevent lead poisoning of children in housing being renovated, or lead-contaminated water or plumbing, based upon clinical and epidemiological studies, where the medical records of the patients are confidential under HIPAA or other patient confidentiality requirements, or where the study would not be “reproducible” because of restrictions on access to confidential patient information. For example, many of the studies of the adverse impacts of lead follow patients who have been exposed to lead, and those records would be protected from public disclosure.
- EPA could not conduct risk/hazard assessments necessary to inform and govern the cleanup of Superfund sites, to the extent that potentially responsible parties asserted CBI protections over company information potentially implicating their contribution to a site, or CBI relating to specific chemicals. The draft legislation thus would allow any assertion of confidentiality claims by responsible parties engaged in Superfund cleanups to delay or thwart those cleanups in local communities, including the jobs associated with those activities.

In each of these examples, the draft legislation would mark a radical retreat from current law, by preventing EPA from considering key studies in deciding how to protect public health, safety and the environment.

#### Hazard Assessments and Imminent and Substantial Endangerment

The draft bill would prohibit EPA from taking actions under federal laws like the Resource Conservation and Recovery Act (RCRA) and the Clean Air Act to protect Americans against “imminent and substantial endangerment,” to the extent EPA relies upon any health studies involving confidential patient data or relies upon industry CBI. The latter could include industrial chemical or product formulations, process data, industry testing or research or trade secrets. EPA must conduct hazard and risk assessments to understand the nature of chemical and oil spills, explosions or other hazards endangering the public. Under current law, there are no restrictions on EPA conducting those hazard assessments, protecting the industry CBI *and* safeguarding the public. The draft legislation radically changes that. To the extent that any information covered by the draft bill is relied upon by EPA, the agency could not act against imminent and substantial endangerment of public health nor could EPA even “disseminate” warnings to the public.

“Dissemination,” Censorship and Reckless Retroactivity

The draft bill’s astonishingly broad language prohibits EPA from “disseminating” any “risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance” that relied on scientific and technical information meeting the bill’s criteria. This language produces the perverse result that EPA would be barred from publishing on its website—or indeed even in the Code of Federal Regulations—*prior and existing* regulations, reports, guidance, risk, exposure or hazard assessments that relied on scientific and technical information before the draft bill’s consideration. This results in a reckless retroactivity and censorship of duly enacted regulations and agency reports that one cannot imagine even the draft legislation’s authors intended. (Of course, prohibiting EPA from disseminating adopted regulations would not cause those regulations to be repealed; it would just make it immeasurably harder for anyone to find and follow the law.) But that is the consequence of the plain language of the draft bill, and such a “dissemination” prohibition would result in the massive censorship of valuable public health and safety information.

Illegal Delay and the Circular Problem of “Reproducibility”

The draft bill prohibits EPA from taking any covered actions unless all scientific and technical information relied on is “publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.” The perverse problem with this language is that it could be read to mean that the only way to know with any certainty whether information is sufficiently reproducible is to allow time for independent parties to attempt to reproduce those research results. We know from experience that this can take years and involve great expenses.

The draft bill’s prohibition thus would prevent EPA from complying with statutory deadlines created by Congress under numerous federal laws. Before EPA may even propose or finalize a regulation to meet a statutory deadline, the agency would need to await confirmation of reproducibility, or else face constant anti-regulatory attacks from the earliest stages of a rulemaking that some scientific or technical information is not reproducible. This dynamic would poison EPA rulemakings either with massive delay or inescapable uncertainty, fundamentally obstructing EPA’s responsibilities under its various statutes to protect human health and the environment.

Moreover, this provision could actually create a perverse incentive for regulated industries with the financial means to do so either to (1) not undertake efforts to reproduce research results, so they may continue to charge that results are not reproducible; or (2) withhold from EPA research results that do prove the information is reproducible. And of course members of the public that lack the resources to conduct such reproduction studies, that want EPA to protect public health and the environment, will be unable to clear this hurdle in the draft bill.

Regulations Granting Industry Flexibility or Regulatory Relief

Industry sometimes appeals to EPA during the course of proposed rulemakings, or even prior to the initiation of rulemaking, to loosen the rigor of agency regulations, accord industry operational flexibilities, extend compliance deadlines or take other actions to reduce alleged

regulatory burdens. Frequently industry does so by submitting information particular to a specific company or industry sector; a particular chemical or product formulation; or a particular process unit or manufacturing process. These submissions frequently are accompanied by claims that information is CBI, due to the company-specific or industry-specific nature of information that may be proprietary, confidential or trade secrets. Industry parties sometimes submit health studies or risk assessments they have conducted that may contain confidential clinical data or other information that they do not wish to make publicly available.

The draft legislation would create a dynamic in which EPA is unable to consider that CBI or otherwise confidential health or risk data in deciding whether to adopt regulations or issue guidance that grants industry the requested regulatory flexibilities. When EPA exercises its regulatory authorities, at least, the draft bill also constrains the agency's ability to be flexible or relieve regulatory obligations, precisely where it might be needed most: by being responsive to particular demonstrations made by specific companies based on persuasive information that also happens to be CBI. It does not appear that the draft bill's co-sponsors could have intended this outcome.

#### Proprietary Models

The bill prohibits EPA from taking covered actions to enforce the law and protect the public if doing so involves relying on "computer codes and models" for creating and analyzing scientific and technical information. Section 6(b)(3)(B). This provision has the perverse effect of barring EPA from relying on proprietary models or computer programs whose software, design features and other inputs were created by and are owned by the private sector. There are undoubtedly numerous proprietary models used by EPA,<sup>1</sup> but a widely used model under the Clean Air Act serves as a useful example to highlight the bill's irresponsible—and probably unintended—consequences.

The Integrated Planning Model (IPM) is the most widely used model "to analyze the impact of air emissions policies on the U.S. electric power sector."<sup>2</sup> It is employed by EPA, state governments, the private sector and public interest organizations, and was developed by ICF Consulting, Inc., which owns the rights to the model and its utilization. EPA explains the purpose of the IPM and its value thusly:

EPA uses the Integrated Planning Model (IPM) to analyze the projected impact of environmental policies on the electric power sector in the 48 contiguous states and the District of Columbia. Developed by ICF Consulting, Inc. and used to support public and

<sup>1</sup> For other examples of proprietary models employed by EPA, see [http://www.epa.gov/pesticides/science/models\\_pg.htm](http://www.epa.gov/pesticides/science/models_pg.htm). The agency has said that "EPA prefers using non-proprietary models when available. However, the Agency acknowledges there will be times when the use of proprietary models provides the most reliable and best-accepted characterization of a system." [http://www.epa.gov/crem/library/cred\\_guidance\\_0309.pdf](http://www.epa.gov/crem/library/cred_guidance_0309.pdf), at 31. We respectfully submit that EPA should be asked to identify all proprietary models used by the agency, and how restrictions on their use would impede the agency's ability to enforce the law and protect public health and the environment.

<sup>2</sup> <http://www.epa.gov/powersectormodeling/>.

private sector clients, IPM is a multi-regional, dynamic, deterministic linear programming model of the U.S. electric power sector. It provides forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting energy demand and environmental, transmission, dispatch, and reliability constraints. IPM can be used to evaluate the cost and emissions impacts of proposed policies to limit emissions of sulfur dioxide (SO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), carbon dioxide (CO<sub>2</sub>), hydrogen chloride (HCl), and mercury (Hg) from the electric power sector.

The IPM relies on computer codes and model characteristics whose content, features, inputs and other elements are not “specifically identified” and “publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.”

Thus, the draft bill would prohibit EPA from proposing, finalizing or disseminating covered actions if it relied on the IPM, or it would require EPA to abandon use of the IPM altogether. This would produce the following harmful outcomes:

- When proposing or finalizing regulations, regulatory impact analyses or other covered actions, the draft bill would prohibit EPA from using the sophisticated IPM to analyze the projected impact of its power plant regulations on the electricity grid and its reliability, transmission lines, dispatch, jobs in the power and coal mining sectors, emissions control and retirement decisions, among other information generated by the IPM;
- The draft bill would prohibit EPA from “disseminating” to Congress, the public, industry officials and state and local government any covered action (such as a regulatory impact analysis) that contained or relied upon any information generated from the proprietary IPM;
- The draft bill would prohibit EPA from proposing or finalizing regulations to lessen regulatory impacts on the power sector, adopt exemptions or issue flexibility guidance to the extent that EPA relied upon the proprietary IPM;
- The draft bill would prohibit EPA from conducting risk, exposure or hazard assessments at the request of Congress to analyze the impact of proposed Clean Air Act legislation or EPA regulations on the power sector, or “disseminating” such results to Congress, to the extent that EPA relied on the IPM;
- Had the draft bill been enacted into law at the time, the Bush administration would have been unable to supply members of Congress or the public with all the useful IPM results generated to assess the impacts of Clear Skies legislation in the House and the Senate, as well as the Bush administration’s Clean Air Interstate Rule and Clean Air Mercury Rule.<sup>3</sup> Indeed, members of Congress, President Bush and administration officials drew heavily upon these IPM results in promoting the Clear Skies bills during congressional deliberations and in statements from their offices.<sup>4</sup>

<sup>3</sup> Information still available on EPA’s website demonstrates the vast extent to which the Bush administration relied upon the IPM to analyze the Clear Skies bills as well as EPA’s related regulatory actions. See, e.g., [http://www.epa.gov/clearskies/tech\\_adden.pdf](http://www.epa.gov/clearskies/tech_adden.pdf); [http://www.epa.gov/clearskies/tech\\_addendum.pdf](http://www.epa.gov/clearskies/tech_addendum.pdf); & <http://www.epa.gov/clearskies/clearskiessummary04-11.pdf>.

<sup>4</sup> See, e.g., <http://yosemite.epa.gov/opa/admpress.nsf/6427a6b7538955c585257359003f0230/c1b111b0d87d>

Another example of an EPA model that the draft legislation likely would render unavailable is the agency's use of various physiologically based pharmacokinetic (PBPK) models to conduct chemical assessments under the Integrated Risk Information System (IRIS). EPA says that "these models represent an important class of dosimetry models that are useful for predicting internal dose at target organs for risk assessment applications."<sup>5</sup> It is likely that some widely-employed PBPK models would not pass muster under this draft legislation, due to their proprietary nature, the public unavailability of information or the inability to sufficiently reproduce model results.

In one recent example, EPA relied upon a PBPK model to propose non-cancer risk estimates for methanol at, or nearly at, an order of magnitude weaker than those proposed previously. The draft legislation could prohibit EPA from relying upon this PBPK model to lower the risk estimates for methanol. Moreover, any other attempt by industry to persuade EPA to weaken risk assessments for chemicals in IRIS could not rely upon PBPK models failing to meet the draft bill's criteria. Nor could those industry efforts rely upon health studies, risk assessments, research, product or process information or business information claimed by industry to be confidential. The draft bill would make this true for all risk, hazard and exposure assessments under IRIS and other EPA programs.

Finally, the draft bill is so poorly drafted that it could conceivably prevent EPA from using commercially available software to carry out basic computing functions, because the computer codes behind that software are proprietary and not publicly available. Again, we do not believe this absurd result was intended by the authors of the draft legislation, but this is the plain reading of its language.

#### Obstructing Clean Air Act Enforcement

The draft legislation, coupled with the unwarranted subpoena steps by the Committee majority, plainly is targeting a few clean air health studies that show causal associations between fine soot pollution (PM<sub>2.5</sub>) and premature mortality. One of the draft bill's co-sponsors has suggested that the massive body of scientific evidence showing a causal association between soot pollution and mortality comes down to "secret" data from just two studies.<sup>6</sup> This is incorrect. A much broader body of scientific studies examines and reaffirms the causal association between fine soot pollution and mortality. These studies post-date the so-called "Harvard Six Cities" and

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591385256c0500625054!OpenDocument; <http://www.inhofe.senate.gov/epw-archive/press/bchairman-inhofe-introduces-the-administrations-clear-skies-initiative/b/>; & [http://www.epw.senate.gov/107th/smi\\_061202.htm](http://www.epw.senate.gov/107th/smi_061202.htm); <http://georgewbush-whitehouse.archives.gov/news/releases/2002/02/20020214-5.html>.

<sup>5</sup> <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?dcid=135427>.

<sup>6</sup> Rep. Lema Smith, "The EPA's Game of Secret Science," The Wall Street Journal (July 29, 2013). <http://online.wsj.com/news/articles/SB10001424127887323829104578624562008231682?mg=rno64-wsj&url=http%3A%2F%2Fonline.wsj.com%2Farticle%2FSB10001424127887323829104578624562008231682.html>.

"American Cancer Society" studies, some of them independently re-analyze the studies, and they consistently find the same causal soot-mortality relationship.<sup>7</sup>

Committee Chairman Smith has charged that the data in the Harvard and American Cancer Society studies "have not been subjected to scrutiny and analysis by independent scientists."<sup>8</sup> This too is incorrect.

In December 2012, a seminal report entitled the 2010 Global Burden of Disease<sup>9</sup> "estimate[d] over 2.1 million premature deaths and 52 million years of healthy life lost in 2010 due to ambient fine particle air pollution, fully 2/3 of the burden worldwide." Drawing upon a broad body of data and studies from around the world, the report examined the risks of premature mortality linked to soot pollution and independently affirmed the results of the Harvard Six Cities study. The Global Burden of Disease researchers found significant mortality impacts from fine particulate pollution. They concluded that "[t]he magnitude of disease burden from particulate matter is substantially higher than estimated in previous comparative risk assessment analyses."

As explained in a release<sup>10</sup> by the esteemed Health Effects Institute, a contributor to the report, "[t]he 2010 [Global Burden of Disease report] was produced by a rigorous scientific process involving over 450 global experts and led by the Institute of Health Metrics and Evaluation (IHME) at the University of Washington along with its partner institutions: the World Health Organization, the University of Queensland, Australia, Johns Hopkins University, and Harvard University."

Similarly, in July 2000, the Health Effects Institute issued a special report<sup>11</sup> entitled "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality." The explicit goal of that study was "to conduct a rigorous and independent assessment of the findings of the Six Cities and ACS Studies of air pollution and mortality." (p.ii) To accomplish this goal, the team of researchers had "access to the original data" once they entered into contractual agreements and a Memorandum of Understanding to ensure that confidentiality was protected. (p.4). The report concluded that

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<sup>7</sup> In revising and updating National Ambient Air Quality Standards (NAAQS) for fine particulate matter, EPA devotes an entire chapter of its Regulatory Impact Analysis (RIA) to cataloguing and reviewing updated health effects studies, and explaining how they were incorporated into the agency's 2012 standards review. See, e.g., <http://www.epa.gov/ttn/ecas/regdata/RIAs/finalria.pdf> (at pp. 5-7 to 5-8 listing 5 updates from the proposed 2012 RIA; fig 5-4 at p. 5-73; pp. 5-31 to 5-35).

<sup>8</sup> *Supra* note 6.

<sup>9</sup> [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(12\)61766-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)61766-8/fulltext).

<sup>10</sup> <http://www.healtheffects.org/International/GBD-Press-Release.pdf>. The Health Effects Institute is "a nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the health effects of air pollution." Funded jointly by the federal government and industry, it is an honest broker that has garnered widespread respect for its scientific expertise, integrity and research excellence.

<sup>11</sup> <http://pubs.healtheffects.org/getfile.php?u=274>.

“reanalyses assured the quality of the original data, replicated the original results, and tested those results against alternative risk models and analytic approaches.” (pp.iii-iv).

EPA's Integrated Science Assessment<sup>12</sup> for the PM<sub>2.5</sub> standards explained (p. 7-95) that the Harvard and ACS studies have “undergone extensive independent reanalysis,” and “were based on cohorts that were broadly representative of the U.S. population.” Reviewing this assessment and the broader body of epidemiological and toxicological studies, EPA's official Clean Air Science Advisory Committee (CASAC) recommended “‘upgrading’ the causal classification for PM<sub>2.5</sub> and total mortality to ‘causal’ for both the short-term and long-term time frames.” CASAC further found “[t]here are epidemiological studies showing a positive association of all-cause mortality with PM<sub>2.5</sub>.”

Despite this extensive body of evidence, thorough re-analysis, and reaffirmation by governmental scientific advisory bodies, the draft bill is founded on an obvious agenda to deny EPA the ability to rely upon peer-reviewed medical studies that involve commitments to patient confidentiality, when the agency carries out its statutory responsibilities to safeguard public health and clean air. The truth is there is a basic difference between “secret science” and confidential patient data subject to confidentiality agreements reached to conduct important medical research. The American people understand this difference. The legitimate researchers and reanalysis initiatives that committed to the confidentiality policies of the relevant research institutions, as HEI and the Global Burden of Disease teams did, were able to access the patient data.

EPA has squarely rejected the effort to create doubt through secrecy charges concerning these same health studies:

The EPA is transparent with regard to the scientific bases of agency decision making and disagrees with assessments and your assertion that the agency relies on ‘secret’ data in regulatory actions and of health benefits. In setting the National Ambient Air Quality Standards (NAAQS) and in assessing health benefits anticipated from air pollution regulations, the EPA relies on the scientific studies that are published in the peer-reviewed literature. The EPA provides the information used in regulatory decisions, including the epidemiological studies, in the publicly available docket accompanying each rulemaking.<sup>13</sup>

The Committee has now gone so far as to use its unfounded charges to write a bill that would block the use of a breathtaking range of science that has long been used to safeguard the public.

#### Technology-Based Emission Standards

The draft legislation would thwart EPA's responsibility to carry out health safeguards required by Congress under the Clean Air Act and Clean Water Act. For example, both of these statutes contain “technology-based” emission standards for industry based on emissions

<sup>12</sup> <http://cfpub.epa.gov/ncea/CFM/recordisplay.cfm?deid=216546#Download>.

<sup>13</sup> <http://switchboard.nrdc.org/blogs/jwalke/04-10-13%20EPA%20letter%20to%20Senator%20Vitter.pdf>.

reductions deemed achievable by state-of-the-art technology.<sup>14</sup> EPA sometimes solicits from corporations information about an industrial sector's pollution control technology, process units and other types of regulated or potentially regulated equipment. Industry requests that some of the information it submits to EPA be treated as CBI. Similarly, when industry representatives submit comments in response to proposed technology-based emissions standards, these commenters request that various information contained in those comments be treated as CBI.

The draft bill would create a perverse dynamic in which corporate officials could thwart EPA's development of statutorily required technology standards, by designating as CBI information that is crucial to determining what emissions reductions are achievable by state-of-the-art technology. Indeed, the draft bill's design would particularly obstruct the implementation and enforcement of technology-based safeguards for air and water, because industry representatives could so easily seek to designate a wide variety of technology and process information to be CBI. Accordingly, even though the draft bill does not purport to amend the Clean Air Act or Clean Water Act, and even though your Committee lacks the jurisdiction to do so, the draft bill would have the effect of radically re-working and weakening the purpose and effectiveness of these laws.

#### Toxic Substances Control Act

The draft bill would fundamentally obstruct EPA's responsibility to protect the public by regulating toxic substances under the Toxic Substances Control Act (TSCA), which relies extensively upon industry claims of confidential business information.

For example, Section 8(e) of TSCA requires chemical manufacturers, importers and processors to report immediately to EPA whenever they obtain evidence "that reasonably supports the conclusion that [a substance or mixture] presents a substantial risk of injury to health or the environment."

Typically, these industry reports claim the information provided is protected confidential business information—including the identity of the chemical, the name of the company submitting the information, as well as health and safety studies about the chemical.<sup>15</sup> The most recent list of section 8(e) studies from April 2013 shows just how pervasive these industry CBI claims are.<sup>16</sup>

Members of the public can only see the sanitized version of the 8(e) reports, which might show the results of lab testing for human or aquatic toxicity and which "reasonably support the

<sup>14</sup> See, e.g., Clean Air Act section 112(d) (Maximum Achievable Control Technology (MACT) standards).

<sup>15</sup> EPA has allowed these CBI claims to be asserted even though TSCA section 14(b) does not allow it. The current abuse of CBI under TSCA is a widely recognized problem. EPA is not required even to review all CBI submissions for their validity. There is no up-front justification requirement that must accompany CBI claims. Once CBI status is granted under TSCA it has no sunset and is rarely if ever re-opened. This has resulted in massive overuse and abuse of the CBI designation. For more information, see, e.g., <http://blogs.edf.org/health/2010/02/12/worse-than-we-thought-decades-of-out-of-control-cbi-claims-under-tsca/>.

<sup>16</sup> <http://www.epa.gov/oppt/tsca8e/pubs/8emonthlyreports/2013/8eapr2013.html>.



conclusion that [the substance] presents *a substantial risk of injury* to health or the environment.” (emphasis added). Although the public will not have access to this information, EPA will, and they use 8(e) reports to prioritize chemicals for greater reporting, or testing, potential regulation, potential voluntary agreements with companies to restrict or phase out the use of particular substances, as well as possible enforcement actions.

A very similar function occurs under the new chemicals program of TSCA (Section 5). Industry officials submit Pre-Manufacturing Notices and claim that information about their proposed new chemicals is CBI. This includes health and safety studies that should not be eligible for treatment as CBI under TSCA, but that EPA routinely treats as CBI anyway. While the public does not see information submitted as CBI, the agency does, and can use that information to take several steps: (1) reject a PMN, for example if the new substance is persistent, bioaccumulative and toxic; (2) require additional testing under a TSCA section 5(e) consent order; or (3) restrict some uses of the new chemical using a Significant New Use Rule (SNUR).

The draft legislation irresponsibly prohibits EPA from taking or even proposing to take the aforementioned actions by relying on the submitted industry information to the extent that industry claims it to be CBI. This creates the perverse result that industry is allowed to prevent EPA from taking necessary steps to address “substantial risk of injury to health or the environment” caused or potentially caused by the industry’s own chemicals, based on the decision entirely within industry’s control to designate submitted information as CBI. And the particular perversity of the draft legislation is that information may well be CBI under current law; but current law does not restrict EPA from protecting the public simply because industry has legally protected interests over its CBI.

Consider the following example under TSCA. A chemical manufacturer submits a Pre-Manufacturing Notice for a new chemical under TSCA Section 5, and the notice contains data or information that the manufacturer claims to be CBI.

EPA has 90 days (plus an option for a 90-day extension) to review the notice and determine whether or not it wants to allow the new chemical to start being manufactured, whether it wants to require more testing, impose some restrictions, or stop the chemical entirely. If EPA takes *no action* on a PMN within the 90-day review period, the company submitting the notice can begin to manufacture the chemical. Once a new chemical is allowed to be manufactured, the chemical is then added to the TSCA inventory. This allows any other company to begin using the chemical for any other purpose (including in greater volumes than proposed in the original notice, and for different kinds of uses, including uses that may be much more dispersive and lead to greater human exposure, *e.g.*, in a flame retardant).

The definition of “covered action” in the draft legislation does not include *inaction* by EPA. Accordingly, the chemical manufacturer and other industrial users that follow-on may begin manufacturing new chemicals based upon the submission of CBI—“secret science” to use the nomenclature of the draft bill—all without any of that information needing to be publicly available or reproducible when EPA fails to take any action on receipt of the notice.

If EPA does have health and safety concerns, however, based in part on the information submitted as CBI, TSCA authorizes EPA to take several steps: (1) require the company to do

more testing; (2) impose restrictions on the original notice submitter; and (3) restrict other entities from using the chemical for different uses or different volumes.

The draft legislation treats all of *these* EPA actions under TSCA as “covered actions,” because they involved proposed or final regulations and/or the need for risk or hazard assessments. Accordingly, the draft bill prohibits EPA from taking any of these actions to protect the public, to the extent the agency needs to rely upon the industry CBI that raised the concerns in the first instance.

So the draft legislation is an irresponsible one-way ratchet: industry may proceed to manufacture new chemicals based on EPA’s consideration (or even non-consideration) of “secret” CBI. But EPA may not regulate identified dangers or risks to the public from those chemicals based on consideration of that same “secret” industry CBI.

#### Conclusion

In sum, this draft legislation would effectively amend numerous environmental statutes in a manner that would obstruct the development and implementation of health and environmental safeguards. It would do so in a fashion that would also restrict industry’s ability to inform EPA decision-making, potentially raising the costs of regulation. At the same time, the bill unfairly caters to industry by exempting permitting and other agency actions from its ambit and underscoring the CBI protections in existing law.

The Subcommittee ought to abandon this misguided project of chasing the phantom notion of “secret science.” With this draft bill, the Subcommittee has moved from reviving baseless charges about clean air science that were disproved over a decade ago to damaging EPA’s ability to use science for decades ahead. Surely there are more productive ways to spend its time.

Sincerely,

John Walke  
Clean Air Director  
Natural Resources Defense Council



June 23, 2014

The Honorable Lamar Smith  
Chair,  
Committee on Science, Space, and  
Technology  
2321 Rayburn House Office Building  
Washington, DC 20515

The Honorable Eddie Bernice Johnson  
Ranking Member,  
Committee on Science, Space and  
Technology  
2321 Rayburn House Office Building  
Washington, DC 20515

The Honorable David Schweikert  
Chair,  
Subcommittee on Environment  
2321 Rayburn House Office Building  
Washington, DC 20515

The Honorable Suzanne Bonamici  
Ranking Member,  
Subcommittee on Environment  
2321 Rayburn House Office Building  
Washington, DC 20515

Dear Chairs and Ranking Members:

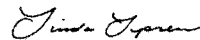
We are writing in strong opposition to H.R. 4012, the Secret Science Reform Act of 2014. The American Association for Justice (AAJ), formerly the Association of Trial Lawyers of America (ATLA) with members in United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote injury prevention and foster public health and safety of numerous individuals who have been harmed by unsafe chemicals. AAJ is an advocate for strong chemical safety regulation and healthy environment, in combination with a strong civil justice system in order to protect the health and wellbeing of all Americans. In this capacity, AAJ robustly objects to the Secret Science Reform Act of 2014.

This legislation would severely limit the science that the Environmental Protection Agency (EPA) can consider while implementing public protections; upending numerous environmental statutes and longstanding Agency practices and is severely overbroad. In fact, the Secret Science Reform Act of 2014 may make it impossible for the EPA to regulate at all. The EPA would no longer be able to use most health studies including peer-reviewed research as a result of the limitation on using data that is not "publicly available". Many accurate and reliable health studies contain personal health data that is currently and rightfully protected. Under the Secret Science Act, however, these studies would be erroneously excluded from use by the EPA, substantially narrowing the science the EPA may rely when considering public safeguards.

In addition, H.R. 4012 will also restrict the use of new and innovative science and well as long-term exposure studies. Oftentimes the newest and most innovative science and data may not be publically available. However, this shouldn't mean that the EPA is precluded from using it. Lastly, many of EPA's standards rely on long-term exposure studies that assess the link between diseases and pollutants; or on meta analyses that combine many different studies. If the Secret Science Act of 2014 becomes law these studies may also be barred from EPA use because they will be unable to be "substantially reproduced". The end result of this legislation is that the EPA will no longer be able to rely on the best science in order to protect American health and the environment.

We urge you to oppose the Secret Science Reform Act of 2014. This bill would seriously inhibit the EPA from protecting human health and the environment through its improper limitation on the use of sound science.

Sincerely,



Linda Lipsen  
Chief Executive Officer  
American Association for Justice

June 24, 2014

Honorable Lamar Smith, Chairman  
Committee on Science, Space, and Technology  
2321 Rayburn House Office Building  
Washington, DC 20515

Honorable Eddie Bernice Johnson, Ranking Member  
Committee on Science, Space, and Technology  
2321 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Smith and Ranking Member Johnson,

We are writing to express our strong opposition to H.R. 4012, the Secret Science Reform Act of 2014. This legislation would effectively amend numerous environmental statutes and make it much more difficult for EPA to protect the public.

Specifically, the bill 1) Prevents the EPA from using the best available science when developing new standards, by limiting EPA only to research, including data and models, that are publically available; and 2) Creates enormous administrative burden and costs for both EPA and the scientific community.

While this legislation's stated goal is "transparency" between the EPA and the public, the legislation in fact favors industry interests and undermines the EPA's scientifically rigorous and comprehensive decision-making process. This bill, put simply, is an attempt to tie the hands of EPA, and nothing more. H.R. 4012 would prevent EPA from functioning efficiently and would block the agency from using the best available scientific information.

This bill restricts the agency's access to vital and relevant studies that are essential in maintaining the scientific integrity of EPA's decision-making process. Under this legislation, the EPA would be unable to use a majority of health studies, including confidential patient health records, which are usually not publically available because they are protected by institutional review boards. As many of EPA's rules address the health and safety of the public, restricted access to this information would diminish the ability of the EPA to issue standards using the best science available.

We strongly urge the Committee to reject H.R. 4012.

Sincerely,

Clean Water Action

Earthjustice

Environment America

Environmental Defense Fund

Friends of the Earth

League of Conservation Voters

Natural Resources Defense Council

Sierra Club