

ENSURING OPEN SCIENCE AT EPA

HEARING BEFORE THE SUBCOMMITTEE ON ENVIRONMENT COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY HOUSE OF REPRESENTATIVES ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

FEBRUARY 11, 2014

Serial No. 113-65

Printed for the use of the Committee on Science, Space, and Technology



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ENSURING OPEN SCIENCE AT EPA

WEDNESDAY, FEBRUARY 11, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENVIRONMENT,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittee met, pursuant to call, at 10:04 a.m., in Room 2318 of the Rayburn House Office Building, Hon. David Schweikert [Chairman of the Subcommittee] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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Subcommittee on Environment

Ensuring Open Science at EPA

Tuesday, February 11, 2014
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witnesses

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

Mr. Raymond Keating, Chief Economist, Small Business & Entrepreneurship Council

**U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON ENVIRONMENT**

HEARING CHARTER

Ensuring Open Science at EPA

Tuesday, February 11, 2014
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

PURPOSE

The Subcommittee on Environment will hold a hearing entitled *Ensuring Open Science at EPA* on Tuesday, February 11, 2014 in Room 2318 of the Rayburn House Office Building. The purpose of this hearing is to examine options to improve the transparency and reproducibility of regulatory science used by the Environmental Protection Agency (EPA) and to receive testimony on the *Secret Science Reform Act of 2014* (H.R. 4012), to prohibit EPA from proposing, finalizing, or disseminating regulations or assessments based upon scientific information unless such information is specifically identified and publically available in a manner sufficient for independent analysis and reproducibility.

WITNESS LIST

- **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
- **Mr. Raymond Keating**, Chief Economist, Small Business & Entrepreneurship Council

BACKGROUND

Science has been central to EPA's mission and functions since its establishment in 1970. The Agency's recent Scientific Integrity Policy describes science as "the backbone of the EPA's decision-making."¹ Efforts to encourage and guarantee open scientific research and assessment at the Environmental Protection Agency are based in a number of historical, legal, and administrative origins.

¹ http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf.

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.² EPA Administrator Gina McCarthy echoed this priority in her confirmation hearing, stating: “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.”³ Similarly, she stated that, “EPA is committed to transparency with regard to the scientific bases of agency decision-making.”⁴ The importance of science to EPA’s regulatory decisions is a critical component of several environmental laws, including the Environmental Research, Development, and 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 further support for open science. Executive Order 13563 requires that regulations “be based upon the best available science.”⁵ 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.”⁶

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.”⁷ OSTP also issued a Memorandum last year on “Increasing Access to the results of Federally Funded Scientific Research,” in which the President’s Science Advisor, John Holdren, explained: “The Administration is committed to ensuring that, to the greatest extent and with the fewest constraints possible... 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.”⁸

In order to provide Agency-specific guidelines emanating from the Administration’s Scientific Integrity Memos, EPA’s Scientific Integrity Policy issued in 2012 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.”⁹

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

³ http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_id=d71fd4b6-ce77-3a98-46a0-fb02b0cae0ed

⁴ Ibid.

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

⁶ <http://www.whitehouse.gov/the-press-office/2009/03/02/memorandum-heads-executive-departments-and-agencies-3-9-09>

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

⁸ http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

⁹ http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf

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 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."¹⁰

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" as the amendment was sponsored by 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."¹¹

ADDITIONAL READING

- Bipartisan Policy Center, Science for Policy Project, *Improving the Use of Science in Regulatory Policy*. August 2009. Available at: <http://bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fml.pdf>
- Office of Science and Technology Policy, Memorandum for the Heads of Executive Departments and Agencies, February 2013. Available at: http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf
- Committee on Science, Space, and Technology, *Strengthening Transparency and Accountability within the Environmental Protection Agency*, November 14, 2013. Available at: <http://science.house.gov/hearing/full-committee-hearing-strengthening-transparency-and-accountability-within-environmental>
- Committee on Science, Space, and Technology, *Scientific Integrity & Transparency*, March 5, 2013. Available at: <http://science.house.gov/hearing/subcommittee-research-scientific-integrity-transparency>
- Committee on Science, Space, and Technology, *Fostering Quality Science at EPA: Perspectives on Common Sense Reform – Day II*, February 3, 2012. Available at: <http://science.house.gov/hearing/energy-and-environment-subcommittee-hearing-fostering-quality-science-epa-perspectives-0>

¹⁰ http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

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

- Committee on Science, Space, and Technology, *EPA's Impact on Jobs and Energy Affordability: Understanding the Real Costs and Benefits of Environmental Regulations*, June 6, 2012. Available at: <http://science.house.gov/hearing/subcommittee-energy-and-environment-hearing-epa%E2%80%99s-impact-jobs-and-energy-affordability>



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.

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. LUMAIS, 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

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.”.

○

Chairman SCHWEIKERT. Let's have at it. The Subcommittee on Environment will come to order. And that was my gavel. Welcome to today's hearing "Ensuring Open Science at EPA." In front of you are packets containing the written testimony, biographies, and truth-in-testimony disclosures for today's witnesses.

This is also my very first hearing chairing this Subcommittee and so I was going to do something a little off the normal script. I first was going to turn to my soon-to-be very good friend from Oregon, Ranking Member Bonamici, and I have got to say thank you for your kindness. I am going to take a somewhat different tack than often happens at many of these. I actually have a fascination with the underlying science and want to try to do this as credibly as possible, you know, because this in some ways should be almost beyond the—sometimes the right/left paradigm we engage in. This is hopefully about facts.

On a philosophical level—and forgive me for going there—for today's hearing how do you have a civil society with our public when our leaders, when the people around us, almost no one trusts our institutions anymore? You know, how do you have a society and hold it together when we don't trust our government, we don't trust our agencies, we don't trust so much around us? And my great hope is this being sort of a first step is a movement towards a level of transparency where I don't care whether you are a group from the right, left, or just someone from academia. The ability in today's world—when my laptop computer is now more powerful than the quad Xeon server I have at home, for all of us, our ability to actually—if you were crazy enough or were interested enough in your quant class to take the data, to understand it, to analyze it, to have an opinion, does that openness, does that transparency—and the President actually talked about this when he was first elected, that a transparent, open government develops hopefully a faith and trust with its population. Can we head that direction?

And I know we get into certain things like I consider sort of red herrings, absurdities. There are ways to protect people's privacy. We do it every day. I come more from the financial side of the world having sat on Financial Services before, and data that was collected by CFPB and so many of the other agencies, they have systematic methodologies where they protect individuals' privacy.

But I am—my great hope here as we sort of move forward on H.R. 4012, that we are sort of building a precedence of how do I build public data for public policy and public policy by sort of egalitarian public data where we all have the right to know what is underlying?

And my last caveat for—and I have been thinking about this one a lot—and this is both for my friends on the right, the left, and our staff, you are going to have to step beyond sort of the confirmation bias. Let's say we are here a couple years from now and all of us have access to underlying baseline data and it is being used for regulatory or policy, don't think it is always going to say what you think it is going to say. There are going to be times when the data sets may say the agency isn't going far enough. There may be other times it turns around and says when you stress the data that we need to be going a very different approach, but at least it will be honest. And being fixated on sort of crowdsourcing of information,

I believe the crowd does purify policy and I hope we are going that direction.

[The prepared statement of Mr. Schweikert follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ON ENVIRONMENT

CHAIRMAN DAVID SCHWEIKERT

I actually have fascination with the underlying science. And I want to try and do this as credibly as possible. Because this, in some ways this should be almost beyond the sometimes left right paradigm we engage in, this should be about facts.

How do you have a civil society when our leaders, our public don't trust our institutions anymore? We don't trust our government, we don't trust our agencies, we don't trust so much around us. A transparent, open government develops, hopefully, a faith with its population.

My great hope is, this being sort of a first step, is movement towards a level of transparency, where I don't care if you a group from the right or the left, or just someone from academia the ability in today's world ... to take the data, to understand it, to have an opinion.

A transparent, open government develops, hopefully, a faith with its population. Can we head that direction? There are ways to protect people's privacy, we do it every day.

My great hope here is we sort of move forward on H.R. 4012, that we are sort of building a precedence on how do I build public data for public policy, and public policy by egalitarian public data, where we all have the right to know what is underlying.

You are going to have to steep beyond confirmation bias. Don't think it (the data) is always going to say what you think it is going to say. There is bound to be times when the data sets may say the agency isn't going far enough. There may be other times it says when you stress the data, we need to be going with a different approach.

I believe the crowd does purify policy, and I hope we are going in that direction.

Chairman SCHWEIKERT. And for an opening statement, my friend, Ms. Bonamici, Ranking Member.

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

I want to start by saying welcome and to offer my sincere congratulations to you on becoming our new Subcommittee Chairman. I am looking forward to working with you. I am hopeful that we can find common ground and develop meaningful solutions to our Nation's important environmental challenges.

And, I agree; improving transparency and public access, especially to federally funded research at the EPA or at any federal agency, is an important objective and one that I fully support. And although there may be disagreements about—among the Subcommittee Members about various actions that the EPA may be considering, I am confident that we all support increased transparency.

Unfortunately, it appears that the language in the bill we are discussing today called the Secret Science Reform Act may actually prohibit EPA from increasing transparency. And I hope that this isn't an attempt to prevent or impede the EPA from promulgating regulations and performing its congressionally mandated priority objective of protecting human health and the environment.

If implemented as written, this bill would actually prevent the EPA from using the best available science to inform its regulatory actions. The EPA relies on thousands of peer-reviewed articles as part of their scientific review, and under this proposal, if for any reason all of the scientific and technical information associated with those articles was not publicly available, the EPA would have

to proceed as if those studies did not exist. And that is not in the best interest of the American people who are our constituents. It is also not clear whether this proposal is retroactive. If so, then the legislation would essentially nullify all the progress we have made to date to improve the quality of the air our children and in fact all of our constituents breathe and the water that they drink.

I am also concerned about the potential negative impacts that the bill could have on the scientific community. Researchers and organizations may be hesitant to conduct EPA-funded research if they are required to disclose protected information like health records. Historically, researchers have been able to assure individuals participating in their studies that their personal information is safe, and that helps attract participants.

Now, last year, this Committee took the unusual action of issuing a subpoena to acquire data that the EPA relied on when developing air quality regulations. This data, the basis of the Harvard 6 studies and the American Cancer Society study, contains personal health records of hundreds of thousands of Americans. And I presume that this is an example of the so-called secret science that inspired this bill. But contrary to the assertion that the science behind those studies is secret, in fact, the legal owners of the data sets, Harvard University and the American Cancer Society, do allow legitimate researchers access to this information and they have procedures in place to protect it.

So it is interesting this Committee did spend a significant amount of time scrutinizing HealthCare.gov and claiming that the website actually puts personal health records at risk. Frankly, I am a bit surprised that my colleagues do not now recognize the importance of protecting studies that actually do contain personal health information.

But perhaps what is more troubling about this proposal—and I look forward to discussing it—is that it ignores the good work already done by this Committee. In 2010, this Committee reauthorized the *America COMPETES Act*, which requires the Office of Science and Technology Policy or OSTP to issue guidance to all federal agencies on the development of clear and coordinated policies to increase access to federally funded published research and digital scientific data. And it is my understanding that the EPA is currently in the process of developing policies pursuant to that guidance.

This bill also seems to be inconsistent with the data and public access provisions included in the majority's FIRST Act. Although there are some open questions about specific provisions of the FIRST Act, the bill takes the more appropriate government-wide approach and requires consultation and input from the scientific and stakeholder community. It is worth having a real discussion—and again, we look forward to that—about how we can improve transparency and data access across the federal government.

Additionally, as we have discussed, I hope we are able to have another hearing on this issue. I strongly encourage the participation of the EPA so that the Agency has an opportunity to appear before the Committee and provide on the record their analysis about the provisions of this bill. It would be logical—and I suggest this, Mr. Chairman—that we hold such a hearing in conjunction

with our colleagues on the Research and Technology Subcommittee because they are also examining this issue very closely.

Mr. Chairman, I truly hope we can work together to find a way to improve public access to federally funded research in a manner that does not compromise the EPA's mission to protect human health and the environment.

Thank you again, and welcome to the Committee, Mr. Chairman, and I yield back the balance of my time.

[The prepared statement of Ms. Bonamici follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ON ENVIRONMENT

RANKING MINORITY MEMBER SUZANNE BONAMICI

Thank you, Chairman Schweikert. I would like to start by saying welcome, and I offer sincere congratulations to you on becoming our new Subcommittee Chairman. I am looking forward to working with you and am hopeful that we can find common ground and develop meaningful solutions to our nation's important environmental challenges.

Improving transparency and public access to federally funded research at EPA, or at any federal agency, is an important objective and one that I fully support. Although there may be disagreements among the Subcommittee Members about various actions that the EPA may be considering, I am confident that we all support increased transparency.

Unfortunately, it appears the language in the bill we are discussing today, called the "Secret Science Reform Act," may actually prohibit EPA from increasing transparency. I hope that this is not an attempt to prevent or impede the EPA from promulgating regulations and performing its Congressionally-mandated priority objective of protecting human health and the environment.

If implemented, this bill would actually prevent the EPA from using the best available science to inform its regulatory actions. EPA relies on thousands of peer-reviewed articles as part of their scientific review. Under this proposal, if for any reason all of the scientific and technical information associated with those articles was not publicly available, EPA would have to proceed as if those studies did not exist. That is not in the best interest of the American people - our constituents.

It is also not clear whether this proposal is retroactive. If so, then the legislation would essentially nullify all the progress we've made to date to improve the quality of the air our children—and all of our constituents for that matter—breathe and the water they drink.

I am also concerned about the potential negative impacts that the bill could have on the scientific community. Researchers and organizations may be hesitant to conduct EPA-funded research if they are required to disclose protected information like health records. Historically, researchers have been able to assure individuals participating in their studies that their personal information is safe, and that helps attract participants.

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But contrary to the assertion that the science behind those studies is "secret, in fact the legal owners of these data sets, Harvard University and the American Cancer Society, allow legitimate researchers access to this information and have procedures in place to protect it.

It's interesting—this Committee spent a significant amount of time scrutinizing Healthcare.gov and claiming that the website puts personal health records of millions at risk; frankly I am a bit surprised that my colleagues do not now recognize the importance of protecting studies that actually do contain personal health information.

But perhaps what is more troubling about this proposal is that it ignores the good work already done by this Committee. In 2010, this Committee reauthorized the America COMPETES Act, which requires the Office of Science and Technology Policy (OSTP) to issue guidance to all federal agencies on the development of clear and coordinated policies to increase access to federally funded published research and

digital scientific data. It's my understanding that the EPA is in the process of developing policies pursuant to this guidance.

This bill also seems to be inconsistent with the data and public access provisions included in the Majority's FIRST Act. Although there are some open questions about specific provisions of the FIRST Act, the bill takes the more appropriate government-wide approach and requires consultation and input from the scientific and stakeholder community.

It is worth having a real discussion about how we can improve transparency and data access across the federal government. Additionally, as we have discussed, I hope we are able to have another hearing on this issue. I strongly encourage the participation of the EPA so that the agency has an opportunity to appear before the Committee and provide—on the record—their analysis about the provisions of this bill. It would be logical to hold such a hearing in conjunction with our colleagues on the Research and Technology Subcommittee because they have been examining this issue closely.

Mr. Chairman, I hope that we can work together to find a way to improve public access to federally funded research in a manner that does not compromise the EPA's mission to protect human health and the environment.

Thank you, Mr. Chairman and I yield back.

Chairman SCHWEIKERT. Thank you, Ranking Member Bonamici.

Now, I would like to turn to the Chairman of the full Committee, the gentleman—and I emphasize gentleman—from Texas, Mr. Smith, opening statement, please.

Chairman SMITH. Thank you, Mr. Chairman, and congratulations on chairing your first Subcommittee hearing.

The Secret Science Reform Act of 2014 is a result of more than two years of investigative work on the part of the Science, Space, and Technology Committee. This work was initiated when the Environmental Protection Agency failed to live up to its public commitment to make the data that supports its most costly air regulations available to the public. In September 2011, then-Assistant Administrator Gina McCarthy committed to provide this Committee with the data EPA relied upon to justify its claims about air quality and health effects. In 2012, the President's own science advisor John Holdren testified that "absolutely the data on which regulatory decisions are based should be made available to the Committee and should be made public."

The Committee sought this data for a simple reason: to see whether the science supports EPA's rules. An open and transparent government requires its disclosure. Through this process, we learned that much of the data either no longer exists or was never in the Agency's possession. Not only are EPA's claims not independently verifiable, the Agency cannot provide evidence to justify them. As a result, the American people have no way of knowing the truth.

The EPA's mission is to protect public health and the environment, but the Agency's regulations impact all aspects of our economy. Sound public policy requires precise decision-making that properly balances competing needs. While the Agency is charged with setting standards that are "requisite to protect public health," those standards should be no more restrictive than necessary. Transparency and independent verification are basic tenets of science and must inform sound environmental policy. When the EPA does not follow these basic steps, it fails in its obligation to the American people and raises suspicions about whether its regulations can be justified.

It is unfortunate that our Nation's environmental policy has become one of the most contentious issues in Washington, but a discussion about the merits of any particular regulation is meaningless if the public cannot trust the underlying science, and that is impossible if the information isn't even available.

Everyone agrees that we need to protect the environment, but it should be done in a way that is transparent and honest. This bill encourages those principles. The Secret Science Reform Act of 2014 has two basic elements. One, it prohibits EPA from issuing regulations unless all scientific and technical information relied upon is specifically identified; and two, it requires that information to be publicly available in a manner that is sufficient for independent analysis and reproduction of research results.

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. It is hard to imagine a single reason why anyone would oppose this basic principle that is consistent with the Administration's policies on transparency. James Madison may have explained this best when he said that "a popular government without popular information or the means of acquiring it is but a prologue to a farce or a tragedy, or perhaps both. Knowledge will forever govern ignorance, and a people who need to be their own governors must arm themselves with the power knowledge gives."

Given the EPA's aggressive agenda and its willingness to play fast and loose with the law, the Agency should be forced to live up to the claims of transparency it so readily espouses. The American people deserve the facts and so does good policy.

Thank you, Mr. Chairman. I yield back.

[The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF FULL COMMITTEE CHAIRMAN LAMAR S. SMITH

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In September 2011, then-Assistant Administrator Gina McCarthy committed to provide this Committee with the data EPA relied upon to justify its claims about air quality and health effects. In 2012, the President's Science Advisor, John Holdren, testified that, "Absolutely, the data on which regulatory decisions are based should be made available to the Committee and should be made public."

The Committee sought this data for a simple reason: to see whether the science supports EPA's rules. An open and transparent government requires its disclosure. Through this process, we learned that much of the data either no longer exists or was never in the agency's possession. Not only are EPA's claims not independently verifiable, the agency cannot provide evidence to justify them.

As a result, the American people have no way of knowing the truth. EPA's mission is to protect public health and the environment. But the agency's regulations impact all aspects of our economy.

Sound public policy requires precise decision-making that properly balances competing needs. While the agency is charged with setting standards that are "requisite to protect public health," those standards should be no more restrictive than necessary.

Transparency and independent verification are basic tenants of science and must inform sound environmental policy. When the EPA does not follow these basic steps,

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It's unfortunate that our nation's environmental policy has become one of the most contentious issues in Washington. But a discussion about the merits of any particular regulation is meaningless if the public cannot trust the underlying science. And that's impossible if the information isn't even available.

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Given the EPA's aggressive agenda and its willingness to play fast and loose with the law, the agency should be forced to live up to the claims of transparency it so readily espouses. The American people deserve the facts. And so does good policy.

Chairman SCHWEIKERT. Thank you, Chairman Smith.

I now want to recognize my other bookend from Texas, the Ranking Member of the full Committee, Ms. Johnson.

Ms. JOHNSON. Thank you very much, Mr. Chairman. And I would like to echo Ms. Bonamici in congratulating you on being named the Chair of the Subcommittee and look forward to working with you in this capacity and have been impressed with your particular statements, this meeting and others.

Unfortunately, I regret that today's hearing might be a rough start in that regard. That is because the Secret Science Reform Act of 2014 continues to be one of the most regrettable sagas in the history of this esteemed Committee. Out of all the years I have served on this Committee, this term has been the worst experience.

This saga began in the last Congress with majority requests for data associated with studies that the EPA relied on for certain clean air regulations. It continued in August of last year when the Chairman issued the first subpoena from this Committee in over 20 years to obtain that same data. And now, we are here today to discuss this misguided and mislabeled legislation.

I want to be clear. The Secret Science Reform Act of 2014 is built on a false premise. None of the science that have been in question during this two-year affair is secret. Is the data protected? Of course it is. The data contains the personally identifiable health information of hundreds of thousands of American citizens. Nonetheless, as the Democratic minority has repeatedly pointed out, legitimate researchers do have access to this data. So what is the problem? What legitimate researchers cannot already access this data?

At the August 1, 2013, meeting to authorize a subpoena, the Chairman indicated Dr. James Enstrom could not access the American Cancer Society data. As I have pointed out before, Dr. Enstrom has a long history of conducting research and performing consultant work for the tobacco industry.

Now, that brings us to today's hearing. Mr. Chairman, all three of the majority witnesses also have significant ties to the tobacco industry. First, we have Dr. John Graham. While he headed the Harvard Center for Risk Analysis, he personally solicited research funding from Philip Morris. Moreover, he invited Philip Morris public relation officials to review a draft chapter of his book on the subject of secondhand smoke. Dr. Graham's center ultimately received tens of thousands of dollars on grants from Philip Morris' subsidiary, Kraft General Foods.

Next, we have Dr. Tony Cox, who has received numerous research grants from Philip Morris tobacco and has collaborated on research with internal Philip Morris scientists. In addition, Dr. Cox has served as a litigation consultant for the Philip Morris and R.J. Reynolds tobacco companies.

Finally, we have Dr. Ray Keating. Dr. Keating's organization, the Small Business & Entrepreneurship Council, and its predecessor, the Small Business Survival Foundation, has solicited and received funding from tobacco companies. Moreover, documentation seems to suggest a large amount of collaboration with tobacco companies. For instance, in the mid-'90s, Dr. Keating released a series of reports of FDA tobacco regulations and their negative effects on small business and also filed comments with the FDA on the same topic. These reports relied upon a study commissioned by Dr. Keating's organization and conducted by the American Economics Group. What Dr. Keating didn't mention in his reports or FDA comments is that the Small Business Survival Foundation was acting as a go-between for the tobacco industry. Tobacco companies' emails show that the study in question was jointly funded and organized by Philip Morris and R.J. Reynolds tobacco.

The reason I highlight this, Mr. Chairman, is that EPA is a public health agency. I am a health professional. I find it deeply disturbing that the experts the majority seems to rely upon for advice in this arena of public health all have extensive ties to the tobacco industry. That is the same industry that was found by a federal court to have engaged in racketeering and wire fraud in order to subvert the public health of American people. And how did they accomplish this fraud? Through a well-documented history of funding researchers and third-party groups to cast doubt on the public health effects of tobacco.

Mr. Chairman, this is a serious subject because ultimately this is about protecting public health of our citizens. It is about protecting the health of our neighbors and our friends and family. If the majority is serious about moving forward with this ill-advised legislation, then we need to hear from a credible set of witnesses. Our citizens deserve no less. I thank you and yield back.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF FULL COMMITTEE

RANKING MEMBER EDDIE BERNICE JOHNSON

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Mr. Chairman, this is a serious subject, because ultimately this is about protecting the public health of our citizens. It’s about protecting the health of our neighbors, and friends, and family. If the Majority is serious about moving forward with this ill-advised legislation, then we need to hear from a credible set of witnesses. Our citizens deserve no less.

I yield back.

Chairman SCHWEIKERT. Thank you, Ranking Member Johnson.

If there are any Members who wish to submit additional opening statements, your statements will be added to the record at this point.

Chairman SCHWEIKERT. Our first witness, Hon. John Graham. Is it ultimately Professor or Doctor?

Dr. GRAHAM. Professor.

Chairman SCHWEIKERT. Professor Graham, Dean of the School of Public and Environmental Affairs at Indiana University. In March 2001, President George H.W. Bush nominated Dr. Graham to serve as Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget. He was confirmed by the Senate in July 2001 and served until 2006. Dr. Graham has also served as Dean of the Frederick Pardee RAND Graduate School, President of the Society of Risk Analysis, Professor of Policy and Decision Science at Harvard School of Public Health, and Founder and Director of the Harvard Center for Risk Analysis. Dr. Graham received his Ph.D. from Carnegie Mellon University. And one other just outlier, I think in my graduate school we used one of your books. Dr. Graham.

**TESTIMONY OF THE HONORABLE JOHN GRAHAM, DEAN,
SCHOOL OF PUBLIC AND ENVIRONMENTAL AFFAIRS,
INDIANA UNIVERSITY**

Dr. GRAHAM. Thank you, Mr. Chairman. You have my written remarks. I just want to use my brief time in the oral session to offer a case study of the value of transparency in data access from early in my career as an academic.

In 1981–83 period, I was a doctoral student at Carnegie Mellon, as you mentioned. The question I was looking at was do automobile safety regulations save lives? The first federal regulations were 1966 to 1968 in all the cars. They addressed safety belts, padded dashboards, collapsible steering columns, and head restraints. They all came in at roughly the same time. The engineering estimates, based upon laboratory testing, were that these measures would reduce the risk of death in a crash by about 25 to 35 percent. The question is would those lives really be saved when they were introduced in cars in the real world?

The first real-world valuation was published in 1975 by a professor named Sam Peltzman at the University of Chicago and he published it in one of the best peer-reviewed social science journals. What Peltzman did was he assembled national safety data from 1947 to 1974. He compared the death rates in cars before regulation and after regulation. His results, which were surprising, were that the passenger death rates were down only about seven percent, not 25 to 35 percent as predicted. And the so-called nonoccupant deaths—think of pedestrians—were up 20 percent. And as a result, the net of it all was he concluded that the regulations didn't save any lives. He then advanced the following theory for why this result had obtained. It is now called the theory of risk compensation. Drivers, sensing that they are in greater safety, drive faster or they are more likely to give their car to their teenage daughters or sons thinking they are safe.

As a young graduate student at Carnegie Mellon, I was quite frankly skeptical of this whole study, both the empirical work and the theory that was behind it. So I went eagerly and reassembled all of Professor Peltzman's data sources from the documentation that he had in his paper. I then reassembled all of his original data set since this was all publicly available data. I then re-estimated his equations using the equations that were in his article. And I found that what he had a purported in his paper was in fact the

result, given his assumptions. Then I did a reanalysis where I added three variables to his equation that he had not considered: the growth in the number of small cars in this country, which are more lethal than larger cars, the number of heavy trucks on the road and the traffic from heavy trucks, and the growth in the number of motorcycle registrations because he had included in nonoccupant deaths not just pedestrians but motorcyclists as well.

I then reanalyzed the data using his procedure. I found that the passenger death rate was about 25 percent lower than would have occurred without the regulatory standards and the nonoccupant deaths had basically unchanged when you controlled for the growth in motorcycling. I concluded that this was a highly successful federal regulation that saved thousands of lives.

With the help of my faculty advisor, we published this reanalysis in the peer-reviewed literature. It stimulated a whole bunch of debate, ten years of additional studies and so forth and so on, and I think it is fair to say today that most people would say reading this body of evidence that this regulation saved thousands of lives, maybe not as many as they originally projected, but a substantial number.

The lessons I would like you to consider from this example, which I lived through for years, is that the process of reanalysis cannot proceed without transparency of what the data sources are and without access to the actual original data to reanalyze the problem. Second of all, the reanalysis process is not always antiregulation. It is not always antigovernment. In some cases, reanalysis shows that government regulations work, save lives, reduce injuries, and enhance the public good. So the underlying premises and assumptions of the bill that we are discussing today in my view are politically neutral and they will work for both sides of the argument.

Final comment, when I served in OMB under President George W. Bush, we oftentimes had industry groups and environmental groups come to OMB with their data and analysis of why they wanted a regulation changed one way or the other. I think it would be a constructive thing if all of that information that they were required to give would satisfy these basic standards of transparency of what data sources were used and accessibility to the original data. That is a neutral—politically neutral outcome that both sides of this debate should be subjected to.

Thank you very much. I look forward to the questions.

[The prepared statement of Hon. Graham follows:]

Topic: Secret Science Reform Act of 2014

Statement of John D. Graham, Ph.D., Dean, School of Public and Environmental Affairs, Indiana University (Bloomington and Indianapolis) and former Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget (2001-6).

Committee on Science, Space and Technology, U.S. House of Representatives

Tuesday, February 11, 2014

My name is John D. Graham. I am Dean of the School of Public and Environmental Affairs (SPEA) at Indiana University (IU), one of the largest public affairs schools in the United States and one of the few that combines programs in environmental science with programs in public administration. I cannot resist reporting that, in the most recent rankings published by U.S. News and World Report, IU-SPEA was ranked #2 out of 266 programs with an accredited Master's Degree in Public Affairs (MPA). In this survey, for the first time in history, IU-SPEA was ranked ahead of Harvard's Kennedy School of Government and is the highest ranked MPA program at a public university in the United States.

Prior to serving at IU, I served as Dean of the Pardee RAND Graduate School at the RAND Corporation in Santa Monica (2006-8), Administrator of the Office of Information and Regulatory Affairs (OIRA) at the U.S. Office of Management and Budget (OMB), and Professor of Policy and Decision Sciences at the Harvard School of Public Health, where I founded and led the Harvard Center for Risk Analysis (1985-2001).

With regard to my educational background, I earned a BA in politics and economics at Wake Forest University (1978), an MA in public affairs at Duke University (1980), and a Ph.D. in urban and public affairs at Carnegie-Mellon University (1983). Before joining the Harvard faculty in 1985, I completed a post-doctoral fellowship in environmental science and public policy at the Harvard School of Public Health.

I am pleased that the Committee is giving priority to the topics of transparency, reproducibility, and quality in the science at the U.S. Environmental Protection Agency (EPA). This topic has been a strong interest of mine for decades. In 1988 I co-authored In Search of Safety: Chemicals and Cancer Risk (Harvard University

Press), which examined the scientific and political aspects of the federal government's regulation of two industrial chemicals: formaldehyde and benzene. In particular, we reviewed the relevant risk assessments at EPA, the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC). In 1991 I edited Harnessing Science for Environmental Regulation (Praeger Press), which explored alternative institutional models for strengthening the quality of science at EPA, including the constructive contributions of EPA's Science Advisory Board. In the late 1990s, I also worked with teams of environmental scientists from multiple countries to develop norms in the quest for greater transparency and reproducibility in environmental science studies that support regulatory decision making. Most recently, I organized an international team of scientists and practitioners to examine the scientific and policy aspects of regulating persistent, bioaccumulative and toxic chemicals http://www.indiana.edu/~spea/faculty/pdf/scientific_policy_analysis_of_persistent_bioaccumulative_and_toxic_chemicals_PBT_.pdf.

STATEMENT OF THE PROBLEM

No scientific organization can produce data, analytic results, and interpretations that are completely free of bias or error or misleading interpretation. Organizations, whether they be universities, think tanks, government laboratories or regulatory bodies are imperfect. They are imperfect in part because they are staffed by human beings, and people are imperfect. Consequently, mechanisms have been developed to enhance the quality of science produced by organizations. Those mechanisms range from strategies to enhance the scientific training of the personnel who perform the work to procedures of internal and external peer review to ensure that scientific products meet applicable information-quality objectives.

The quest for greater quality in the scientific products at EPA is particularly challenging for several reasons.

First, EPA's standards of quality generally need to be quite high, since the reports that are issued have an important impact on regulation, public health, environmental quality, affected businesses and workers, and the economy as a whole. An analytic mistake in an EPA report can cause numerous people to become sick or lose their lives due to inappropriately high levels of environmental pollution. If erroneous information about the hazards of an industrial chemical or pesticide is disseminated, the affected company can lose an entire product line and

people can lose their jobs. Entire sectors of the U.S. economy (e.g., energy, manufacturing, and agriculture) are strongly impacted by EPA regulation, and thus it is crucial that EPA's scientific determinations achieve a high level of quality.

Second, the scientific culture at EPA is fragile and still at an early stage of development. In my experience working with EPA, I have found that the political, legal and engineering cultures are fairly strong but the cultures of science and economics are highly variable across the agency's programs. The uneven role of science at EPA should not be surprising because EPA is seen as a mission-oriented agency more than as a science agency, and first-rate scientists who are interested in public service employment might be more inclined to launch a career at the National Institutes of Health or the National Science Foundation or the National Research Council/National Academy of Sciences than a career as a scientist at EPA. For years EPA has been taking constructive steps to enhance the scientific culture of the agency and there are numerous outstanding scientists working at the agency. Nonetheless, the effort to build a culture of sound science at EPA is a work in progress.

Third, the headquarters office for EPA, where many of the key regulatory decisions are made, is located in Washington, DC but many of the agency's top scientists are located elsewhere (Research Triangle Park, North Carolina; Cincinnati, Ohio; and Ann Arbor, Michigan, for example). From the sheer perspective of physical location, many scientists at EPA are more at the periphery than at the center of the Agency's decision making.

Fourth, the field of environmental science is full of uncertainties and the literature is constantly exploding with new scientific results and alternative interpretations of previous results. Keeping abreast of this field is quite challenging, as environmental science has to be one of the most dynamic fields within the physical and life sciences. Staying up to date is particularly challenging because of the multiple disciplines that contribute information, everything from environmental epidemiology and toxicology to nanotechnology and atmospheric chemistry.

Finally, the credibility of one of the Agency's most important scientific tools, risk assessment, is constantly under attack. Industry says the agency's risk assessments rely too much on conservative, default assumptions. Environmental groups say the agency's risk assessments are preoccupied with cancer and are downplaying the importance of persistence, bioaccumulation, and endocrine disruption in setting priorities for chemical risk assessment and regulation.

A series of reports from the National Research Council/National Academy of Sciences over the last fifteen years has documented persistent shortcomings in the quality, transparency and reproducibility of the agency's scientific determinations. Those reports have addressed specific substances such as fine particulate matter, dioxin, TCE, formaldehyde, to name just a few. A more recent report, Science and Decisions: Advancing Risk Assessment (NRC, 2009), addresses the way science and risk assessments are used in support of decision making at the agency.

TWO CASE STUDIES FROM MY OMB EXPERIENCE

During my tenure as OIRA administrator, I was periodically drawn into issues where EPA science issues consumed my time in ways that I could not have predicted. Here are two examples where shortcomings in EPA science caused significant diversion of energy inside the Executive Office of the President.

Example #1: perchlorate contamination

In the 2002-3 period, my boss at OMB, Mitch Daniels, called me into his office and asked me what I was doing about "perchlorate". I confessed that I did not know what he was talking about; indeed I thought he was referring to the solvent perchloroethylene that is widely used in dry cleaners. He was not. He was talking about a substance (primarily ammonium perchlorate) that is used as an oxidizer in solid rocket fuels and propellants for munitions. When rockets and other munitions are tested at US military sites, it is not uncommon for residual perchlorate to end up in the soil and in nearby surface water.

EPA was concerned about the perchlorate contamination. On the other hand, at that time, our troops in Afghanistan and Iraq were stretched to the limit, even though defense spending was growing rapidly. OMB could not duck a key resource-allocation issue: Would it be wise to spend billions of dollars cleaning up small concentrations of the perchlorate at military installations or to dredge the Colorado River in a quest to clean up sediments that contained perchlorate? I agreed to look into the issue.

I went back to my office and requested, along with the White House Office of Science Technology, an EPA briefing on perchlorate. EPA's response was straightforward. In 1985 perchlorate contamination had been detected in drinking water wells near California Superfund sites but it was not until 1997 that EPA

detected a national contamination issue. Apparently, more than 11 million people in the United States have perchlorate in their drinking water above the agency's minimum reporting level of 4 parts per billion (4 micrograms per liter). The reporting level is not a safety threshold but simply the lowest level that is required to be reported to the agency in its data system. No national drinking water standard for perchlorate had been set, the type of EPA standard that would be designed to protect public health. EPA had issued in 2002 a draft risk characterization for perchlorate that implied that a drinking water standard of 1 part per billion would be necessary to protect public health with an appropriate margin of safety. This figure is a factor of 30 more stringent than the interim guidance on perchlorate that EPA had issued in 1998 during the Clinton administration. EPA was working through comments on the new draft risk characterization and had already received scientific advice from a committee of the EPA's Science Advisory Board.

In a second meeting at OSTP, I learned that a bitter dispute about the safe level of exposure to perchlorate was being waged by scientists at EPA, the National Aeronautics and Space Administration (NASA), the Department of Defense (DOD) and the Department of Energy (DOE). EPA was relying on a standard analysis of animal data and protective uncertainty factors to make its determination; NASA, DOD and DOE were arguing that available human data could support a much more permissive safety determination, though their analytic approach would be different than the one EPA normally uses. The issue was important because the most sensitive group for exposure to perchlorate were the fetuses of pregnant women who might have hypothyroidism or iodide deficiency.

OSTP and OMB decided, after multiple meetings with the agencies, that it was best to refer the issue to an appropriate committee of health scientists at the National Research Council of the National Academy of Sciences. The relevant agencies reluctantly agreed, recognizing that the NRC/NAS review would take additional time. All of the agencies contributed funds to make the NAS report possible, not knowing what NRC/NAS would conclude.

To make a long story short, the NRC/NAS committee, after hearing the views of all the agencies and reviewing the scientific literature, concluded in 2005 that the EPA analysis of animal data was inappropriate and the human data on exposures to perchlorate should be utilized to determine a safe level of exposure. The committee went further and produced an analysis suggesting that EPA's draft figure of 1 part per billion was a factor of 24 too low, meaning that public health would not be at risk, even at much higher concentrations of perchlorate in drinking

water. (See National Research Council. Health Implications of Perchlorate Ingestion. National Academy Press, 2005.) I have not followed this issue closely since I left the federal government in 2006 but my understanding is that EPA has still not proposed a national drinking water standard for perchlorate, though they have plans to do so (see <http://water.epa.gov/drink/contaminants/unregulated/perchlorate/cfm>).

Example #2: fine particle pollution

According to EPA and OMB reports, one of the most beneficial suite of regulations issued by the federal government is a set of air quality rules aimed at reducing human exposure to fine particulate matter (sometimes called soot). Particles vary not only in size but in chemical composition. Carbon-containing particles are emitted directly by diesel engines while sulfate and nitrate particles may be formed in the atmosphere after the gases sulfur dioxide and nitrogen dioxide are emitted from electric power plants or other sources. From my faculty colleagues at the Harvard School of Public Health, I was already aware of two curious features of EPA's scientific position on particles.

First, EPA was assuming that all particles are equally toxic, regardless of their chemical composition. (By way of contrast, scientists at the European Commission in Brussels were producing benefit estimates in 2005 suggesting that sulfates are much less toxic than other forms of particles). Second, EPA was not reporting much uncertainty in its estimates of the benefits of reducing human exposures to fine particle matter. Thus, when EPA forecasted that (say) 1,000 lives might be saved from a particular regulation, it was not clear whether the truth could fall between 900 and 1100 or whether the truth could be anywhere from 0 to 10,000. I devoted three years of effort with my staff at OMB, nudging EPA in the direction of addressing these two curious features of their scientific position on the health benefits of reducing particle pollution.

I made more progress on the second issue than the first issue, in part because in 2002 the National Research Council/National Academy of Sciences released a report recommending that EPA do a better job of quantifying the degree of uncertainty in the agency's estimates of public health benefit from reduced exposure to particles. (See National Research Council. Estimating the Public Health Benefits of Proposed Air Pollution Regulations. National Academy Press, 2002.) By 2005 EPA was reporting quantitative uncertainty estimates that addressed some of the fundamental uncertainty about the pollution-mortality relationship.

My takeaway message from EPA's uncertainty work was not that EPA's lifesaving estimates were biased on the high side but that the truth could easily be a factor of 3 lower or higher than the agency's primary estimates. When all of the uncertainties in EPA's benefit analysis for particles are considered, I became convinced that decision makers should recognize that uncertainties were quite large indeed.

In the 2001-2006 period, one of the key barriers to doing comprehensive uncertainty analysis of particle-benefit estimates was that the original health data from the underlying epidemiology studies (e.g., the Harvard Six-Cities Study and the American Cancer Society cohort) were not being made publicly available to researchers through EPA's web site. I checked briefly on EPA's web site prior to preparing this testimony and – 10 years later – EPA has still not made the underlying data publicly available on their web site. To their credit, EPA did – in the 2000-2003 period subject the key particle-oriented health studies to a peer review, replication, and re-analysis by an independent team of scientists at the Health Effects Institute. Although the HEI replication did not discover any major errors, HEI did find some instability in coefficients depending on which pollutants are included in the statistical models (e.g., some of the results for sulphur dioxide and sulfates were unexpected). If the underlying data from the key health studies were made publicly available for all researchers to analyze (rather than just a select few appointed by HEI), I think it is quite possible that many new insights would be gleaned and some of the conventional wisdoms we now accept as fact would be dislodged or refined.

I made little progress at OMB trying to nudge the agency toward a more plausible position on the relative toxicity of different types of particles. The agency holds to a default position that all fine particles are equally toxic, and does not do any quantitative uncertainty analysis of this assumption. In fairness to the Agency, they have been supporting more than a decade of research at the Health Effects Institute (Cambridge, MA) on the relative effects of different particles but I am not aware that any of this HEI-sponsored research has yet had any quantitative impact on EPA estimates of the benefits of fine particle control.

I trust that these two case studies, from the trenches of my OMB experience, illustrate some of the challenges in bringing more rigor and humility to the scientific determinations of EPA.

OMB EFFORTS ON DATA ACCESS AND REPRODUCIBILITY

In October 1999 OMB issued Circular A-110 on data access that was intended to spur agencies to make available the original data from federally-funded studies. OMB actually softened what was intended by the underlying legislation (the “Shelby Amendment”) because OMB applied the data access requirement only to new studies, not to those that were initiated before the legislation and before OMB’s circular were finalized. As a result, OMB’s data access policies are not having much impact on public access to the key health data that support EPA’s air quality regulations.

When I served at OMB from 2001 to 2006, I led a government-wide effort to establish information-quality (IQ) guidelines pursuant to new information-quality legislation that was passed by Congress before the Bush administration began. We established IQ guidelines at OMB and then I supervised a process whereby each agency, including EPA, established their own IQ guidelines. A central theme of these IQ guidelines was transparency and reproducibility of original data and results from analytic models. The key operational feature of the agency guidelines was an opportunity for the public to petition an agency and accomplish a correction of agency information that does not meet the agency’s information-quality guidelines. Unfortunately, the impact of those guidelines has been weakened because federal courts have ruled that the agency’s IQ guidelines are not legally binding. Outside parties (e.g., businesses, labor unions and environmental groups) do not have access to the courts to seek relief in situations where a petition is handled arbitrarily by an agency, and thus the agencies know that the law has little teeth.

COMMENTS ON THE “SECRET SCIENCE REFORM ACT OF 2014”

The legislation you have asked me to comment upon is commendably short, and it is a proposed amendment to Section (b) of the Environmental Research, Development, and Demonstration Authorization Act of 1978. In summary, EPA is not permitted to issue regulations (or other “covered actions”) unless (A) all scientific and technical information relied upon is specifically identified; (B) such information is publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.

I fully support point A, as it is an elementary principle of transparency. A third party (or even another federal agency or OMB) cannot possibly evaluate the merits of a covered action if they do not know what specific scientific and technical information was relied upon by EPA.

I also support point B, which I believe is the heart of the legislation, as it requires both public access to the scientific and technical information, and access in a form that facilitates independent analysis and reproduction of research results. With regard to agency compliance, what I envision is simply a link on EPA's web site -- one for each covered action -- that contains one or more files of original scientific and technical information (including original data and analytic models and guidance about how to access and utilize the files) that are sufficiently detailed that a third party could process the information and thereby substantially reproduce the results that the agency is relying upon. The word "substantially" is preferred to a word such as "completely" because a reproduction within a certain number of significant figures is certainly adequate in the vast majority of cases. Or there may be cases where the agency results -- or the results of a third party -- contain a harmless numerical error that is judged to satisfy the standard of substantial reproduction but would not satisfy the standard of complete reproduction.

From a practical point of view, agency compliance with the public access provision is most straightforward for studies that the agency funds in the future. The agency will simply require the grantee to include with their final report files of data and guidance that satisfy the provisions of this legislation. The National Science Foundation already has a procedure for grantees to submit original information to NSF at the end of a grant period, and EPA could look at the NSF procedure as a possible model. NIH may also have some useful guidance of this sort. For a previously-funded EPA study (i.e., prior to enactment of this legislation), compliance should be addressed only at the point that EPA staff determine that they intend to use such a study in support of a covered action. At that point, agency staff should reach out to the relevant author(s) and seek submission of the underlying information. There may be situations where the authors no longer have possession of the underlying information (e.g., in the case of older studies) or do not have the time or money to prepare the research results in the form that EPA requests. In such cases, EPA may need to establish a consulting or contractual arrangement to obtain the underlying information or may decide instead to rely on a different source of scientific and technical information for the covered action.

Since the agency often relies on scientific and technical information that the agency has not funded (e.g., university-funded research in the peer-reviewed literature, technical submissions by scientists from industry and environmental groups, information submitted by other federal agencies, and so forth), compliance with this legislation may be facilitated by an EPA rule or guidance that explains how public access to such information will be accomplished. In the course of

preparing covered actions, agency personnel will often need to reach out to the authors of scientific and technical information and request that the underlying information that the Agency intends to rely upon be submitted to the Agency in a particular form. This type of information request and exchange is common throughout the scientific community on a day-to-day basis. In fact, many authors of scientific papers are now posting on their web sites supplementary information that supports a paper that has been published in a peer-reviewed journal. The supplementary information may include original data and descriptions of analytic models and computer code. In some cases, identifiers are removed to protect the confidentiality of human subjects. There may be some segments of the scientific community that perceive new data-access requirements to be onerous (particularly as they relate to older studies) but the vast majority of the environmental scientific community should not have difficulty satisfying the public access provision in the draft legislation. The last sentence does not mean that the Committee will not hear complaints from scientific societies about this legislation. I predict that you will hear complaints about how practical issues will be worked out but it is important to remember that the scientific community is not accustomed to being told by the government how to assemble and disclose their work products, particularly products that were published years ago. Working out the kinks in this process will take some time and consensus building.

I have already alerted Committee staff that the Institute of Medicine (Washington, DC) will soon be holding a public workshop (March 19, 2014) to address how “data sharing” should be accomplished in the field of environmental health, especially when data from human subjects are at issue. The summary of the charge to the workshop indicates that “Environmental health experts agree that the question is not “if” research data should be shared but “how.”” I encourage Committee staff to attend the workshop (Workshop on Principles and Best Practices for Sharing Data from Environmental Health Research, Institute of Medicine, March 19, 2014, 8:30 AM, <http://www.iom.edu/activities/environment/environmentalHealthRT/2014-Mar-19.aspx>).

With regard to the “covered actions,” it is extremely reassuring that this language goes beyond “regulations” to include technical documents used to support federal regulations (e.g., regulatory impact analyses) and scientific and technical documents issued by EPA that are known to influence subsequent regulations by EPA, the states and international bodies. In my experience, some of the most significant actions taken by EPA are scientific determinations rather than

regulations per se and they are often issued as guidance (e.g., IRIS determinations about chemicals are normally considered guidance).

With regard to (2) the clarification and exclusion regarding disclosures that are prohibited by law, I assume this covers confidential business information, some types of security-related information (e.g., how a chemical is used by the Defense Department in a particular weapon system) and possibly some privacy laws. I am not aware of any other kinds of disclosures that would be prohibited by law.

SUPPORT FROM ORGANIZATIONS

In conclusion, I would like to cite support for data access and reproducibility that was previously stated by authoritative organizations.

1. Administrative Conference of the United States (excerpts below)

http://acus.gov/sites/default/files/documents/Science%20Recommendation%20APPROVED-FINAL_1.pdf

“Disclosing Underlying Studies and Data. To the extent practicable and permitted by law and applicable policies, each agency should identify and make publicly available (on the agency website or some other widely available forum) references to the scientific literature, underlying data, models, and research results that it considered. In so doing, the agency should list all information upon which it relied in reaching its conclusions, as well as any information material to the scientific analysis that it considered but upon which it ultimately did not rely. Consistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines, each agency should ensure that members of the public have access to the information necessary to reproduce or assess the agency’s technical or scientific conclusions.”

“Data Disclosure. To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research, including both privately and federally funded research being considered by the agencies. Where practicable, such information should be disclosed in machine-readable format. Where such data are not subject to legal or other protections, and the data’s owners nonetheless will not provide such access, agencies should note that fact and explain why they used the results if they chose to do so. Agencies should review their confidential business information policies to ensure that they include appropriate mechanisms to prevent over-claiming.”

2. The submission guidelines for the prestigious journal Science.

“As a condition of publication, authors must agree to make available all data necessary to understand and assess the conclusion of the manuscript to any reader of *Science*.”

Thank you in advance for the invitation to testify. Please do not hesitate to contact me if I can answer any questions or if I can supply any additional information.

Biographical Sketch

John D. Graham was born (1956) and raised in Pittsburgh, PA, a son of an accomplished steel industry executive. He earned his B.A. (politics and economics) at Wake Forest University (1978) where he won national awards as an intercollegiate debater. He earned his M.A. degree in public policy at Duke University (1980) before serving as staff associate to Chairman Howard Raiffa's Committee on Risk and Decision Making of the National Research Council/National Academy of Sciences. His Carnegie-Mellon University Ph.D. dissertation on automobile safety, written at the Brookings Institution, was cited in pro-airbag decisions by the U.S. Supreme Court (1983) and by Secretary of Transportation Elizabeth Dole (1985).

Dr. Graham joined the Harvard School of Public Health as a post-doctoral fellow in 1983 and as an assistant professor in 1985. He taught the methods of decision analysis and cost-benefit analysis to physicians and graduate students in public health. His prolific writings addressed both the analytic and institutional aspects of lifesaving policies. Dr. Graham earned tenure at Harvard in 1991 at the age of thirty-four.

From 1990 to 2001 Dr. Graham founded and led the Harvard Center for Risk Analysis (HCRA). By raising over \$10 million in project grants and philanthropic contributions, Dr. Graham helped support eight new faculty positions and dozens of post-doctoral and doctoral students. By 2001 HCRA became internationally recognized for analytic contributions to environmental protection, injury prevention, and medical technology innovation.

In 1995 Dr. Graham was elected President of the Society for Risk Analysis (SRA), an international membership organization of 2,400 scientists and engineers. Dr. Graham reached out to risk analysts in Europe, China, Japan and Australia as he helped organize the first World Congress on Risk Analysis (Brussels, 2000). Later, in 2009, Dr. Graham received the SRA's Distinguished Lifetime Achievement Award, the society's highest award for excellence.

In March 2001 President George W. Bush nominated Dr. Graham to serve as Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. He was confirmed by the Senate in July 2001. Located in the Executive Office of the President, this small office of 50 career policy analysts oversees the regulatory, information and statistical activities of the federal government. In this capacity, Dr. Graham worked to slash the growth of regulatory costs by 70% while encouraging good regulations that save lives, prevent disease, and protect the environment.

From March 2006 to July 2008 Dr. Graham was Dean of the Frederick Pardee RAND Graduate School at the RAND Corporation in Santa Monica, California. PRGS is the largest doctoral program in policy analysis in the world. In this role, Dr. Graham streamlined the core curriculum, established new analytic concentrations, revised the program requirements to enable students to launch their dissertations more promptly, and raised funds from individuals and corporations to support scholarships, dissertation support and policy papers co-authored by students and RAND researchers.

On July 28, 2008 Dr. Graham assumed the Deanship of the Indiana University School of Public and Environmental Affairs (Bloomington and Indianapolis), one of the largest public policy schools in the United States. The School has about 1,500 undergraduate majors, over 300 master's students and about 80 doctoral students. The 75 full-time faculty include laboratory scientists, social scientists, lawyers and policy specialists.

Chairman SCHWEIKERT. Thank you, Professor Graham.

Our next witness is Dr. Tony Cox, Chief Sciences Officer at Next Health Technologies, Clinical Professor of Biostatistics and Informatics at Colorado Health Sciences Center, and President of Cox Associates. Next Health Technologies offers advanced data analytics solutions to healthcare plans to reduce health, financial, and member attrition risks. Dr. Cox is also the current editor-in-chief of the journal Risk Analysis. In 2012 he was inducted into the National Academy of Engineering and is a member of the National Academies Standing Committee on the use of public health data. Dr. Cox received his Ph.D. in risk analysis from MIT. Dr. Cox.

**TESTIMONY OF DR. LOUIS ANTHONY COX, JR.,
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CLINICAL PROFESSOR, BIostatISTICS AND INFORMATICS,
COLORADO HEALTH SCIENCES CENTER,
AND PRESIDENT, COX ASSOCIATES**

Dr. COX. Thank you for inviting me today to discuss whether the data underpinning regulations should be made openly available. I am testifying on my own behalf today in support of the Secret Science Reform Act. I have provided the Committee the detailed CV describing my academic, publishing, and business affiliations.

I am a risk analyst and I am happy to tell you why I think access to data is essential for high-quality analysis in the public interest. I can also tell you that it is not easy to get such access. Ms. Johnson or others with similar views might decide that researchers like me who have worked with cigarette manufacturers to quantify risks of smoking-associated diseases are not legitimate enough to deserve access to data, but without such access, we cannot correctly quantify what the risks are.

We are discussing a key question for science and policy today. Is the public interest best served by requiring that data behind science-based environmental regulations be made available to those who want to see it? Many who argue yes believe that the very essence of trustworthy science is reproducibility of results and sharing of the data said to drive them. For example, over 2/3 of recently surveyed professionals involved in risk assessment said it was very important to have access to the underlying raw data so that they could independently analyze the results, but only about 1/3 said that such access was usually the case. The proposed Secret Science Reform Act would help to close this gap.

A concern about sharing of data is that it might prove burdensome for the original investigators, exerting a chilling effect on their research, but keeping well-organized records, data, and lab notebooks so that others can check methods and results is or should be part of the training of every good scientist. It imposes no extraordinary burdens and has many benefits. Scientific journals can also facilitate sharing of the data behind published conclusions.

A second concern expressed by ALA and others is that making study data available might threaten the privacy of individuals. We have already heard that this morning. The technical issue of how to protect privacy while allowing valid statistical analysis is best addressed by technical solutions, and many excellent one such as multiple imputation are now available. They are already being

used successfully at the Census Bureau and elsewhere. So I think this concern is a bit of a red herring. We can meet it by applying existing technical methods.

But the most important concern I suspect is not technical. It is that bad people or people with agendas other than pure science and the public interest might delay good regulations by performing untrustworthy new analyses and reanalyses that would obscure the need for action. To address this concern, I think we must candidly assess how well our current scientific process delivers trustworthy results without much pressure from external reanalyses of data. It does not.

We are living in an age of catastrophic failure in the reproducibility and trustworthiness of scientific results as evidenced by articles such as “Why Most Published Research Articles Are False” from 2005 and “Trial and Error: Why Science Is Failing Us” from 2011 or an editorial just last month on reproducibility in *Science* magazine. A common theme is that there is too much pressure on original investigators to use dubious statistical methods to publish results that are sensational but not necessarily correct and there is not enough encouragement for original investigators to do unbiased research knowing that others will soon be reanalyzing their data and claims. Fixing this critical problem requires more scrutiny and greater access to original data, not less.

Let me end with two examples from my own experience in public health risk analysis. First, by applying causal analysis methods to the publicly available national mortality and morbidity air pollution study data, I recently discovered that air pollution levels are indeed correlated with mortality risks in 100 U.S. cities. This was already well known. For example, both were associated with cold winter days. But surprisingly, there was no evidence that reducing air pollution has caused any reductions in mortality rates. Open access to the data makes such unexpected discoveries possible and encourages others to check and possibly improve upon the results potentially informing important public policy.

As a last example, Dublin, Ireland, recently extended bans on coal burning based on research claiming that banning coal burning immediately reduced mortality rates. That research was done and publicized in part by U.S. investigators who have prominently shaped U.S. EPA’s science and claims about air pollution health effects. Yet a reexamination of the data last year funded by the Health Effects Institute revealed that its major conclusion was not true; mortality rates did not come down any faster where coal burning was banned from where it wasn’t. European researchers had already pointed out years ago the fallacy of assuming that just because pollution levels in mortality rates had both declined, that suggested that one caused the other. But without access to the original data, they cannot quickly and easily prove that the original conclusions did not follow from the data. By the time the original U.S. investigators were funded to take another look at the data, Irish public policy had already been made. Only ready access to the data would have enabled others to fix the problem in time to inform policy decisions.

We need not repeat such experiences here. We can choose to make data used to support regulatory decisions openly available for

others to analyze and not wait until policy has been made and changes enacted before allowing the public to find out whether better analyses would have led to different results. I believe that doing so will promote sounder science and hence strongly promote the public interest.

Thank you for your attention.

[The prepared statement of Dr. Cox follows:]

STATEMENT OF

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ON

ENSURING OPEN SCIENCE AT EPA

BEFORE THE

U. S. HOUSE SCIENCE COMMITTEE

SUBCOMMITTEE ON ENVIRONMENT

FEBRUARY 11, 2014

Chairman Schweikert and Members of the Subcommittee, thank you for inviting me to discuss whether regulatory science and the data on which it rests should be made openly available. I am testifying on my own behalf today, in support of the proposed Secret Science Reform Act. I need access to data for my work on health risk assessment, and am grateful for this opportunity to explain why. I have provided the Committee members with a detailed CV describing my academic, publishing, and consulting affiliations.

We are discussing a question of great current public, policy, and scientific interest: *Is the public interest well served by requiring that data used to support policy decisions be made available to those who want to see it?* Many who argue yes believe that the very essence of good science is reproducibility of results, and sharing of the observations and data that are said to drive them (Cox, 2009, p. 5). For these people, openness to scrutiny is a hallmark of sound scientific reasoning, and a prerequisite for sound scientific process and for trustworthy conclusions. Many scientists and analysts themselves are of this persuasion. For example, a recent survey of three professional societies involved in risk assessment found that “69 percent said it was ‘very important’ to have access to the underlying raw data for the most critical studies in order to do their own independent analysis of the results.” However, “only 36 percent said that having this access was often or always the case” (Butterworth, 2013). The proposed Secret Science Reform Act will help to address that gap.

Those who oppose requiring open sharing of data used to support regulations and policies typically cite several concerns (e.g., Neutra et al., 2006; Pearce and Smith, 2011). One is that the process might be abused by unscrupulous parties. Like the tobacco industry, others might seek to “manufacture doubt” to obscure the clear implications of good science and to delay socially beneficial actions by proposing alternative, inferior analyses. A second concern is that divulging data might threaten the privacy of individuals included in study populations. A third concern is that requiring data to be shared might prove burdensome for the original investigators, exerting a chilling effect on research in the public interest.

To these three objections, taken in reverse order, it might be replied that, first, the habit of keeping well-organized and documented records, data, and lab notebooks in expectations that others will use them later to try to independently reproduce and verify important claimed findings is – or should be – part of the training of every good scientist. No extraordinary burden is imposed by such good practices, Transparency of data and methods and scrutiny of results by others, perhaps using different methods, is something that scientists should expect and welcome. There is also much that scientific journals can do, and are doing, to encourage data transparency and to facilitate making documentation of data, models, and analyses readily available to those who want to use them.

Second, the concern that making study data available could threaten the privacy of individuals rests on an important, but purely technical, statistical issue: *Do statistical data in fact allow individual attributes or facts that should be protected to be discovered?* This technical problem is best addressed by technical solutions, and many excellent ones are now available to allow statisticians to do valid analyses while protecting individual data (Reiter, 2009; Klein et al., 2013). These methods, such as multiple imputation, have already been extensively developed, tested, and successfully applied, at the Census Bureau and elsewhere. So, I think that this concern should be viewed as a bit of a red herring: appropriate technical methods to handle it are already available and are being used in other areas.

But the most important concern, I suspect, is often not technical. It is about human behavior, and incentives, and the sociology of science. This is the concern that bad people will delay good regulations and remedial actions by misusing data and performing untrustworthy analyses to mislead the public and policy makers (Neutra et al., 2006). Such concerns have long been expressed about the use of risk analysis and technical analysis more generally (Silbergeld, 1993). To address them, I think we must candidly assess how well the scientific process delivers trustworthy results without much pressure from independent examination and reanalysis of data. It does not. We are now living in an age of catastrophic failure in the reproducibility and trustworthiness of scientific results, as witnessed by articles such as “Why most published research articles are false” (Ioannidis, 2005), “Trials and errors: Why science is failing us” (Lehrer, 2011), and “Beware the creeping cracks of bias” (Sarewitz, 2012). In the January 17th

issue of *Science* magazine this year, Editor-in-Chief Marcia McNutt noted that a worrisome proportion of peer-reviewed published results are not reproducible, and she announced plans to expand their editorial board, with advice from the American Statistical Association, “to ensure that manuscripts receive appropriate scrutiny in their methods of data analysis.” A common theme is that there is too much pressure on original investigators to use dubious statistical methods to publish results that are sensational but not necessarily true (false positives), and there is not enough encouragement for investigators to do high-quality, reproducible research, with the confident expectation that others will soon be looking over their shoulders and reanalyzing their data, perhaps using less biased methods. To fix what is manifestly broken takes more scrutiny and greater access to data, not less. As for the very legitimate fear that those who disagree with us might use open access to data and reanalyses to confuse and delay actions that we favor, this has been part of the cost and a great part of the benefit of free, democratic societies since well before John Stuart Mill wrote, in *On Liberty*, that “Wrong opinions and practices gradually yield to fact and argument: but facts and arguments, to produce any effect on the mind, must be brought before it. ... The beliefs which we have most warrant for, have no safeguard to rest on, but a standing invitation to the whole world to prove them unfounded.” The best defense against unscrupulous use or motivated interpretations of data – whether from regulators or from industry or from anyone else – is to make it openly available, so that the grounds of debate turn from who is privileged to see the facts to how one should best interpret them.

Let me end with two recent examples from my own experience in public health risk analysis. First, the public availability of the National Mortality and Morbidity Air Pollution Study (NMMAPS) data set recently allowed me to apply econometric tests for potential causality to air pollution and mortality data from 100 U.S. cities. An unexpected finding was that, although levels of air pollution are significantly associated with levels of elderly mortality rates (and both are associated with cold winter days), there is no evidence that reductions in air pollution levels have caused any reductions in mortality rates (Cox, 2012). This was a new finding from old data, using methods that other investigators had not

tried. It may be important information for policy-makers to consider. I hope that others will repeat and improve upon my analysis. Without open access to the data, that would not be possible.

Second, in 2012, Dublin extended bans on coal burning (DECLG, 2012) because of research (Clancy et al., 2002), done in part by U.S. investigators who have prominently shaped U.S. EPA beliefs, assuring them that cutting coal-burning had promptly and obviously reduced mortality rates, especially cardiovascular deaths (Harvard School of Public Health, 2002). A closer look at the data in 2013, funded by the Health Effects Institute, revealed that this was not true: these mortality rates did not decrease any faster where coal burning was banned than where it wasn't (HEI, 2013). The original investigators had not accounted for the general trend that mortality rates were coming down all over Ireland and Europe, due to better diagnosis, prevention, and treatment. Instead, they had simply misattributed that trend around Dublin to effects of the coal-ban (Cox, 2012). This mistake was ultimately fixed in 2013, after the bans had already been extended, when the Health Effects Institute paid one of the original investigators to go back and consider control groups. Although methodologists and risk analysts had already noted years ago that the fact that both pollution levels and mortality rates have declined over time does not warrant an inference that reducing one reduces the other (Wittmaack 2007; Pelucchi et al., 2009; Cox, 2012), without access to the original data, they could not quickly and easily show that the original conclusions did not follow from the data. That had to wait until the original investigators were funded by HEI to try again more carefully. And by then, Irish public policy, based on a mistaken belief about the human health benefits to be expected from extending the bans, had already been made (DECLG, 2012).

We need not repeat such experiences here. We can choose to make the data available and to invite methodologists to take a look. Whether reducing current and recent past levels of air pollution should be expected to cause any reductions in mortality rates, and if so by how much, remains a great unanswered question – unanswered, that is, by sound science and statistical analysis of data. Today, answers are often simply assumed, without sound factual support, for purposes of regulatory benefits calculations (Cox, 2012, Chapter 7). It is possible and desirable to do much better. To do so requires

making original data open for others to analyze, and not to wait until policy has been made and changes enacted before allowing the public to find out whether better analyses would have led to different results.

Thank you for your attention.

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Tony Cox is Chief Sciences Officer of NextHealth Technologies (www.nexthealthtechnologies.com), and Denver-based company offering advanced data analytics solutions to healthcare plans to reduce health, financial, and member attrition risks. President of Cox Associates (www.cox-associates.com), a Denver-based applied research company specializing in quantitative risk analysis, causal modeling, advanced analytics, and operations research. Since 1986, Cox Associates' mathematicians and scientists have applied computer simulation and biomathematical models, statistical and epidemiological risk analyses, causal data mining and machine learning, and operations research and artificial intelligence models to measurably improve health, business, and engineering risk analysis and decision-making for public and private sector clients. Since 1996, its sister company, NetAdvantage, has provided operations research services and software for telecommunications companies. In 2006, Cox Associates was inducted into the Edelman Academy of the Institute for Operations Research and Management Science (INFORMS), recognizing outstanding real-world achievements in the practice of operations research and the management sciences. In 2012, Dr. Cox was inducted into the National Academy of Engineering (NAE), "For applications of operations research and risk analysis to significant national problems." He is a member of the National Academies' Board on Mathematical Sciences and their Applications (BMSA) and a member of the National Academies Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs.

Dr. Cox holds a Ph.D. in Risk Analysis (1986) and an S.M. in Operations Research (1985), both from M.I.T.; an AB from Harvard University (1978); and is a graduate of the Stanford Executive Program (1993). He is Honorary Full Professor of Mathematics at the University of Colorado, Denver, where he has lectured on risk analysis, biomathematics, health risk modeling, computational statistics and causality; is on the Faculties of the Center for Computational Mathematics and the Center for Computational Biology; and is Clinical Professor of Biostatistics and Informatics at the University of Colorado Health Sciences Center. He has taught a variety of graduate and professional courses, including Game Theory for the Department of Mathematics and Decision Analysis for the Business School of the University of Colorado at Denver.

Dr. Cox is Editor-in-Chief of Risk Analysis: An International Journal, is Area Editor for Real World Applications for the *Journal of Heuristics*, and is on the Editorial Board of the *International Journal of Operations Research and Information Systems*. He is an Edelman Laureate of INFORMS, a member of the American Statistical Association (ASA), and a Fellow of the Society for Risk Analysis (SRA). In 2007, he won the Society of Toxicology's Outstanding Published Paper in Risk Assessment Award and the Society for Risk Analysis Outstanding Risk Practitioner Award. In 2008, his solution to a challenge on "Statistical Methods to Predict Clinical Response" won an InnoCentive Award. His work won the Society for Risk Analysis (SRA) Best Paper Awards in both 2002 and 2003 for modeling uncertain public health risks and benefits of animal antibiotics; and in 2011 for mathematical modeling of chronic obstructive pulmonary disease (COPD).

Dr. Cox has taught many graduate and professional courses in risk analysis, decision analysis, and advanced analytics. He has authored and co-authored about 200 journal articles and book chapters on these fields. His most recent books are *Improving Risk Analysis* (Springer, 2013), *Risk Analysis of Complex and Uncertain Systems* (Springer, 2009) and the *Wiley Encyclopedia of Operations Research and Management Science* (Wiley, 2011), which Dr. Cox co-edited. He has over a dozen U.S. patents on applications of artificial intelligence, signal processing, statistics and operations research in telecommunications. His current research interests include computational statistical methods for causal inference in risk analysis, data-mining, and advanced analytics for enterprise risk management, insurance, and public policy applications.

Chairman SCHWEIKERT. Thank you, Dr. Cox.

To introduce our next witness I am going to turn to the Ranking Member Bonamici.

Ms. BONAMICI. Thank you, Mr. Chairman.

I am pleased to introduce Dr. Ellen Silbergeld, a Professor of Environmental Health Science and Epidemiology at the Johns Hopkins Bloomberg School of Public Health. Dr. Silbergeld holds a Ph.D. in environmental engineering, completed postdoctoral fellowship in environmental medicine and neurosciences, and has more than 40 years of scientific research experience in fields related to environmental health. She has been an appointed expert to the EPA, the Department of Energy, and many other federal agencies. She is a MacArthur Genius Fellow among her many honors.

Thank you so much for being here to testify today, Dr. Silbergeld.

Chairman SCHWEIKERT. Dr. Silbergeld, five minutes.

**TESTIMONY OF DR. ELLEN SILBERGELD, PROFESSOR,
BLOOMBERG SCHOOL OF PUBLIC HEALTH,
JOHNS HOPKINS UNIVERSITY**

Ms. SILBERGELD. Thank you very much. I am appearing at your invitation to testify before the issues embodied in this bill and other issues that you have already alluded to, Mr. Chairman. And I have been a member, as indicated, of many expert panels involved in the evaluation of the scientific bases for regulation in the United States, the State of Maryland, and internationally. I also served as a member of the U.S. Delegation to the OECD during the development of the High Production Volume Chemicals Program which I would like to allude to.

First, I want to join with you and others on this panel stating that the principles of openness and fairness are fundamental to science including toxicology, epidemiology, and basic research. And I agree with the statement of many at this hearing that there is an important need to reduce the secrecy that confounds public access to the basis for some EPA decisions specifically. However, with respect to my experience, the major driver of secrecy in EPA rule-making is the deference given to industry in terms of shielding its studies from public view, and thus I am puzzled as to the uneven nature of the debate on this topic and I hope that your Committee can see to that balance.

The problem of nondisclosure by industry in fact was a key issue in developing the High Production Volume Chemicals Challenge Program by the OECD during the time that I was a member of the U.S. Delegation. And frankly, I have been very proud of the leadership role of American industry in the success of this program through which information held by industry was in fact made publicly available. And the current website of the American Chemistry Council makes clear that the industry shares justifiable pride in its disclosures and adherence to greater transparency data.

We need more information, and specifically, we need more information disclosure by industry. Information withheld is not informative. It—in fact, we can just look across the Potomac River to West Virginia and understand that if we had information, both the compulsion to produce it and to reveal it, how much better public

health authorities and civic authorities and the public itself could respond to that event.

I would like to also draw upon my experience as an editor-in-chief of a major peer-reviewed journal and my experience over the past 18 years in terms of how science evaluates the quality of data that is published in the form of a scientific paper. The peer-review process requires the inclusion of scientific and technical information, including—as stated in your bill, sir—materials, data, and associated protocols necessary to understand, assess, and extend conclusions. The rest of the items in Section (2)(b)(3) of this bill, with respect, do not contribute to this goal in my opinion.

We recognize that no study is perfect and frankly it is mostly protocol design and under-powering of studies rather than erroneous statistical approaches that have resulted in withdrawal of many papers in my experience, and this is why in science we rely on replication as the means of validating the findings and conclusions of any particular study. But replication is not the same as data reanalysis. Replication involves the design and conduct of a wholly independent study often with different methods to test the reliability of the same hypothesis that was first studied.

Let me also reflect on my experience with data analysis as part of the EPA's process of reviewing science related to major regulation, as others have done on this panel. I was part of an expert panel advisory to the EPA under the Clean Air Act consideration of revising the National Ambient Air Quality Standards for lead. A reanalysis of the actual raw data was demanded by industry and it was accomplished in a nonadversarial way through third-party review undertaken by an acknowledged academic expert in biostatistics not connected with government, industry, or the original investigators.

In conclusion, I would like to restate my strong philosophical support for increasing the transparency of information associated with government regulation. I suggest that we already have the tools to accomplish this goal and through the implementation certainly of the NIH covering data that is funded by that agency. I hope that your concerns can be reframed to apply to all sources of information in an effective and efficient manner because I know that some of my colleagues in industry have been vocal in calling for these steps. I call to them to tear down every wall—in the words of Ronald Reagan—that hides critically important information that is generated and held by industry.

Thank you.

[The prepared statement of Dr. Silbergeld follows:]

ENSURING OPEN SCIENCE AT EPA

HEARING BEFORE

THE SUBCOMMITTEE ON ENVIRONMENT

COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY

US HOUSE OF REPRESENTATIVES

TESTIMONY

OF

ELLEN KOVNER SILBERGELD, PhD

PROFESSOR

JOHNS HOPKINS BLOOMERG SCHOOL OF PUBLIC HEALTH

February 11, 2014

I am Ellen K Silbergeld, Professor of Environmental Health Sciences and Epidemiology at the Johns Hopkins Bloomberg School of Public Health. I am appearing at your invitation to testify on the issue of information disclosure and on the discussion draft entitled the "Secret Science Reform Act of 2014." The views and opinions presented here are my own, and do not represent the views and opinions to the Johns Hopkins University. By way of background and experience, I have conducted research related to environmental health for over 40 years. I have also served on numerous expert panels, advisory boards, and as a consultant to the State of Maryland, National Research Council, EPA, DoE, CDC, FDA, NIH, NSF, WHO, ILO, UNIDO, FAO, and UNEP. Thus, I am familiar with the processes by which regulatory and scientific agencies identify and evaluate scientific information as part of the process of regulation. I was a member of several expert groups convened by EPA and the NRC considering the health impacts of lead in the environment, during which a re-evaluation of research data was undertaken. I have submitted my resume to the Committee in advance of this hearing.

First, I want to state that the principles of openness and fairness are fundamental to science, including toxicology, epidemiology, and basic research. I have been a leader in the international movement towards adopting the principles of evidence based decision making in fields beyond clinical medicine and health care. I strongly support access to and sharing of scientific findings within the community of stakeholders in a manner consistent with principles of fairness and adherence to the goal of improving the process of decision making. These principles are described in my paper in ALTEX (attached).

I agree with the statement of Chairman Smith that at present there is an important need to reduce the secrecy that confounds public access to the basis for some EPA decisions. In my experience, the major driver of secrecy in EPA rulemaking is the deference given to industry in terms of shielding its studies from public view. For this reason, I am puzzled as to the uneven nature of the debate on this topic, which we discussed in our commentary published in EHP (attached). The proposed bill would continue to immunize industry from disclosure while increasing the burden on EPA and, by pass through, on non-industry researchers. As noted in an earlier statement by Chairman Lamar Smith (November 2013), the interest of the public in the right to

see data is such high importance that the clouds of secrecy should be dispelled whatever the source.

The problem of nondisclosure by industry was a key issue in the initiation of the High Production Volume Chemicals Challenge Program by the OECD (Organization for Economic Cooperation and Development). I was a member of the US delegation to the OECD Environment Program during the development of this voluntary process, which was initiated following a study by the Environmental Defense Fund (**Toxic Ignorance** http://www.edf.org/sites/default/files/243_toxicignorance_0.pdf of which I was a coauthor). I was proud of the leadership role of American industry in the success of this program through participation in a tripartite partnership among government, industry and NGOs, to overcome the lack of basic toxicity data on most chemicals in commerce and consumer products. The HPV program has revealed that in many cases the critical data had already been generated but not released by industry. As stated by the American Chemistry Council on its website:

Under the HPV Challenge Program, hundreds of chemical makers volunteered health and environmental information on 2,200 chemical products, representing approximately 95 percent of the commercial market by volume in the United States, to help create a database that is available to the public.

This voluntary initiative demonstrates that collaboration between public and private sectors can be an efficient method of developing safety information to help ensure the safety of the products of chemistry.

With respect, this proposed legislation constitutes a retreat from this highly responsible and effective policy of information disclosure accepted and led by US industry.

We need more information and more information disclosure by industry. Like trees falling unheard in the forest, information withheld is not informative. How much better would West Virginia have been able to respond last month if industry data were available and released on 4-methylcyclohexane methanol (MCHM) instead of the empty Material Safety Data Sheet:

Section III.	Hazards Identification
Acute Health Effects	No specific information is available in our data base regarding the toxic effects of this material for humans. However, exposure to any chemical should be kept to a minimum. Skin and eye contact may result in irritation. May be harmful if inhaled or ingested. Always follow safe industrial hygiene practices and wear proper protective equipment when handling this compound.
Chronic Health Effects	CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure to this compound is not known to aggravate existing medical conditions.

As a scientist, I conclude that the broad sweep of stipulations in the draft bill is without a strong basis in terms of improving science or expanding the evidence base for decision making. I am also the editor in chief of a major peer reviewed journal (**Environmental Research**) and in that role over the past 18 years I have considerable experience in and respect for the process of peer review as a method of quality assessment. The peer review process requires the inclusion of scientific and technical information including, as stated in the bill "materials, data, and associated protocols necessary to understand, assess, and extend conclusions." The rest of the items in Section 2(b) (3) do not contribute to this goal, in my opinion. In science, we recognize that no study is perfect. That is why science has relied on replication as a means of validating the findings and conclusions of a particular study. "Replication" is not to be confused with data re-analysis; replication involves the design and conduct of a wholly independent study (sometimes with different methods) to test the same hypothesis. These are critical criteria for evidence in the standard methods of the Cochrane Collaboration.

Let me also reflect on my experience of data re-analysis as part of the EPA's process of reviewing the science related to associated lead as a risk for children's neurobehavioral development relevant to the Clean Air Act. That re-analysis was demanded by industry and it was accomplished in a non-adversarial way through third party review undertaken by an acknowledged expert in biostatistics not connected with government, industry, or the original investigators. This review elicited some recommendations in terms of restating certain results but the main weight of the study was affirmed. And, of course, since that time, hundreds of independent studies have confirmed and extended the findings of that first publication.

In conclusion, I restate my philosophical support for increasing the transparency of information associated with government regulation. I suggest that we already have the tools to accomplish this goal, in an even handed manner, through the methods of systematic review for evidence based decision making. I hope that your concerns can be reframed to apply to all sources of

information in an effective and efficient manner. Given past history of contended regulations, as a scientist, an editor, and a citizen I am not convinced that the extraordinary and frankly arbitrary measures called for in this legislation will accomplish these goals. Because I know that some of my colleagues in industry have been vocal in calling for these steps, I would challenge them to tear down every wall, in the words of Ronald Reagan, that hides critically important information generated and held by industry.

I am prepared to respond to your questions to the best of my knowledge.



Evidence-Based Toxicology: Strait is the Gate, But the Road is Worth Taking

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Summary

The concept of evidence-based toxicology (EBT) was proposed in 2006, but progress since that time has been impeded by differing definitions and goals. This paper describes the parallels and discontinuities between the approach and methods of evidence-based medicine and health care and those proposed for toxicology. The critical element of an evidence-based approach for either discipline is the adoption of unbiased, transparent methodologies during the collection, appraisal, and pooling of evidence. This approach, implemented during the conduct of a systematic review, allows evaluation of the breadth and quality of available evidence. At present, systematic reviews are rarely done in toxicology by regulatory agencies, international organizations, or academic scientists. Adopting an EBT approach will necessitate significant changes in practice as well as attention to distinctive characteristics of toxicological studies, notably their emphasis on identifying harms and their reliance on experimental animal studies. An evidence-based approach does not obviate the role of judgment and values in decision making; its goal is to ensure provision of all available information in a transparent and unbiased manner.

Keywords: evidence-based toxicology, evidence-based medicine/health care, systematic reviews

1 Introduction

The concept of evidence-based toxicology (EBT) has been under discussion for several years (Hoffmann and Hartung, 2006). EBT is about assembling the evidence related to hazards and risks of exposure, or to the evaluation of methodologies for assessing toxicology for the purpose of using this systematically collected evidence during decision making. In this way it is similar to Evidence-based Medicine and Health Care (EBM/HC), which uses evidence derived from randomized controlled trials on which to base healthcare decisions. EBM/HC is defined as the application of systematically acquired evidence within the experience and expertise of the clinician, as well as patient values (Sackett et al., 1996). The essential premise is that decisions should be based on the evidence. It is important that the evidence be obtained in a transparent and systematic manner that is clearly described, enabling other investigators to obtain the same evidence. Like EBM, the impetus for EBT clearly is related to the increasingly important role of the discipline of toxicology in decision making related to public health as well as clinical and preclinical sciences. Progress in

EBT has been impeded by differing definitions (Guzelian et al., 2005; Griesinger et al., 2009), both of which advocate the use of methods developed for assessing and using evidence from randomized controlled trials for EBM, an approach that is not feasible for the study of agents suspected of toxicity, as we will discuss below. Efforts also were impeded by a relatively limited focus on the application of evidence-based approaches to the validation and acceptance of alternative methods in applied toxicology (Hartung, 2010).

Evidence-based decision making can be defined as the translation of information into accepted practice using methods that reduce bias and increase confidence (Grimshaw et al., 2006). As in the law, evidence-based methods involve the evaluation of information for its admission into consideration in decision making through the process of applying specified norms and methods. In order to avoid bias, these norms and methods must stand apart from the information under consideration, and their application must be undertaken with complete transparency.

These characteristics differentiate evidence-based approaches from current approaches used in the translation of toxicological studies into decision making by agencies concerned with

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occupational and environmental health and consumer protection, as we will demonstrate in this paper. In present practice, the identification of relevant primary studies and the norms by which these studies are evaluated in toxicology are largely implicit (the so-called Delphi method). As a result, the process clearly is not transparent and, because of this, it is difficult to avoid or reduce controversies over policy decisions incorporating toxicology. A previous paper commented on the opacity of the Delphi method often used in risk assessment (Silbergeld, 2009), in terms similar to critiques of medical decision making using these methods (Flower et al., 2007).

There is an understandable skepticism on the part of practitioners and experts in a field to the suggestion that the adoption of major changes in practice may be advantageous. This skepticism was expressed in the early days of EBM (Feinstein, 1995; Williams and Garner, 2002; Chalmers, 2005). We acknowledge and respect this natural skepticism in toxicology. This paper makes the case that adoption of evidence-based methods in toxicology may benefit from awareness of the history of evidence-based approaches in medicine and health care (EBM/HC). The goal of this paper is to introduce a consistent vocabulary for EBT and to examine the extent to which our experience in EBM/HC can inform the development of EBT.

At the outset, we recognize that it is reasonable to ask if adopting EBT will increase efficiency and quality of decision making. The history of EBM/HC demonstrates that the evidence-based approach has accomplished these goals in medicine and many health care-related fields (Dickersin and Manheimer, 1998). Moreover, this history shows that a commitment to an evidence-based approach in these fields has stimulated expansion and improvement in the field, specifically through the development of systematic reviews as the instrument for translating information into evidence. Systematic reviews often are considered the highest source of evidence in that primary studies are systematically identified and appraised and the totality of evidence is synthesized. This did not occur without considerable effort. When systematic reviews were initially conducted in medicine in the early '80s, many authors noted that methods associated with conducting systematic reviews were wanting in several areas, including reporting the primary studies, methods for identification and appraisal of the data, and methods for statistical pooling of the data (Mulrow, 1987; Oxman and Guyatt, 1988). The need to develop these approaches was not accepted readily by all practitioners (Chalmers, 2005). Nevertheless, over time, standards were developed through consensus for reporting primary studies (e.g., the CONSORT statement and its extensions¹), for reproducibly searching for these studies (Dickersin et al., 1994), and standardized methods to identify and account for biases in the primary studies (Moher et al., 1996). Also over time, further statistical methods and inferential models were put forward to synthesize similar research efforts. This focus on methods used during the conduct of a systematic review process, in turn, has

led both to greater transparency in reporting primary studies and to an increased focus on the quality of the studies comprising the evidence.

Also of interest to the field of toxicology, the focus on study quality in EBM/HC, in turn, has influenced researchers in relevant fields to improve the quality of their research designs and the rigor of their statistical analyses in order to meet the criteria for inclusion in systematic reviews as well as to support evidence-based strategies. From the perspective of the development of toxicological sciences, this may be one of the most important benefits to consider in adopting EBT.

There is concern that an evidence-based approach introduces rigidity into decision making (Gatchel and McGeary, 2002) and through this may exclude valuable information through the use of scoring systems and meta-analysis. In answer to these concerns, it should be noted that in EBM/HC the evidence provided by transparent systematic reviews provides only one stage of the evidence-based process of application of the evidence. This is not dissimilar to the role of toxicology in decision making as part of the overall process of risk management (NRC, 1994.) Any decisions made in EBM/HC or toxicology must include consideration of other factors, such as cost, feasibility, and the bounds of accepted practice. Thus, in medicine, application of systematically acquired evidence is done taking into account the needs and values of the individual seeking health care (Sackett et al., 1996). Moreover, there is no requirement for evidence-based decision making to employ formal meta-analysis or to use forest plots to express integrated findings.² The use of systematic tools, when appropriate, is an important means of ensuring reproducibility of analyses, as well as the quality of the review, by ensuring comparability in design and conduct across the individual data sources, and, above all, enhanced transparency of conclusions reached in the systematic review.

We argue that toxicologists should consider key lessons learned over the evolution of EBM/HC. First, such transitions are best managed by the community of researchers and practitioners, rather than by imposition from outsiders (such as regulators and other consumers of toxicological evidence). Second, as demonstrated in current practice in EBM/HC, evidence-based methods do not reduce or replace the importance of expert and experienced judgment. Rather, they simply provide the totality of evidence upon which to base those decisions. Third, the process in itself does not generate decisions. Simply put, an evidence-based approach assists the community by providing systematically collected information using clearly described methods that reliably represent the state of relevant knowledge. Thus, this approach assists decision makers in increasing the acceptability of their decisions by ensuring transparency during evidence collection. Fourth, a systematic and transparent approach to collecting and appraising the available evidence in EBM/HC has had a positive influence on researchers in terms of study design and data analysis.

¹ <http://www.consort-statement.org/>

² <http://www.cochrane.org/resources/handbook/index.htm>



2 Toxicology is not medicine or health care

Despite the relevance of understanding the history and experience in EBM/HC, there are characteristics of toxicology and its applications in public health that require more than simple adoption of EBM/HC methodologies. Some of these are related to differences in fundamental objectives. EBM/HC focuses primarily on developing evidence of the efficacy of therapy, together with an emerging focus on the accuracy of diagnostic tests, as well as some focus on etiology, prognosis, and screening. In contrast, the main focus of toxicology is on developing evidence for harms (hazard) and the magnitude or likelihood of harms (risk). Although questions of harm have occasionally been the subject of EBM systematic reviews, as discussed below, many study designs utilized in generating evidence in EBM are not specifically intended to detect or characterize harms. Second, EBM/HC draws almost exclusively upon studies conducted in humans and human populations; toxicology draws primarily upon studies conducted in nonhuman animals and nonanimal models in order to achieve its societal goals of preventing disease and disability. Thus it is important to recognize that adoption of evidence-based approaches for toxicology will require considerable work by the community, as discussed below.

3 Assessing current practice in toxicology

To date, there have been relatively few explorations of the application of evidence-based practices to resolving issues of importance in toxicology. Toxicology has matured in the context of increased demands for its information through the growth of public concerns and regulation in environmental and occupational health. The structure of information needs for decision making in these domains of public health is relatively well defined to include understanding the elements of relevant toxicological studies and the major decision rules into which these elements are to be incorporated. For the purposes of this paper, we focus on those toxicological studies related to defining hazard and quantifying risk; exposure assessment, which is the other element of risk-based decision making, involves other disciplines and methodologies. Hazard and risk are common to the practice of risk assessment and to application of the precautionary principle, which has been advanced as a partial alternative to risk assessment based methods related primarily to reducing the burden of information required for undertaking assessments (Silbergeld et al., 2004).

Current evaluations of toxicological information (from human and nonhuman subjects), almost without exception, have failed to utilize systematic or transparent methods. These limitations are exemplified by a review on lead and cancer by one author of this paper (Silbergeld, 2003) and a review of the carcinogenicity of lead compounds by the International Agency for Research on Cancer (IARC, 2006). Both of these examples are distinguished by lack of transparency such that it is not possible to determine or to replicate the process of identifying

studies or their selection for review. No information was provided on the search strategy or on screening criteria in terms of study quality. Without this information, it is not possible to ascertain the completeness of the review. There is no disclosure of which studies were discarded or why they were discarded. Further, there is no information on why certain studies were emphasized in the discussion. In the case of experimental studies, a similar lack of transparency informed the identification and selection of studies. A recent comment on the failure of IARC monographs to utilize systematic approaches or to cite systematic reviews echoed these same concerns with additional examples (Straif et al., 2012).

In these two examples, the review of epidemiological studies combined cross-sectional, longitudinal, cohort, or secondary analyses without acknowledgement or discussion of heterogeneity, even though it was unlikely that their results could be combined in any meaningful manner. Similarly, the *in vitro* studies were discussed without consideration of study design, dose or *in vitro* concentration, animal strain or cell line. Other sources of heterogeneity were obvious as well. Sometimes studies actually reported on different endpoints. These problems are increased when multiple experimental tests are used to define an endpoint, such as multiple *in vitro* systems and different animal strains (for example, in current US EPA guidelines for developmental neurotoxicity (Crofton et al., 2004) and endocrine disruption (Daston et al., 2003)). When the methods of such studies are so diverse, it may not be appropriate to combine results except in the most general way. Similarly, in EBM/HC studies are not combined if they show either clinical or statistical heterogeneity.

In place of a formal integration of results using clearly described methods (e.g., formal meta-analyses or focused narrative syntheses of the data), these reviews included only tables that summarize selected findings. The only qualified judgments relate to carcinogenicity using EPA or IARC criteria. Even more disturbing than these examples is the practice in some health assessments to base conclusions on only a few or even one study, judged to be the most appropriate or reliable (on nontransparent criteria). Facing two alternative conclusions, one must "choose" which one, if either, to believe. In contrast, a systematic approach uses all the accepted evidence on which to provide a basis for decision making. The concept of a "key study" is contrary to the notion of a systematic review because of its deliberate exclusion of the body of relevant information. This selective practice was followed in a recent NRC review of mercury, in which a nontransparent decision was made to reject one of two large prospective epidemiological studies on early exposures to methyl mercury and neurodevelopmental outcomes (NRC, 2001). Another approach on this same topic utilized a self-described Bayesian "integrative" approach to examine several studies, but no reason was provided for why only some pertinent studies were included (Axelrad et al., 2007). The recent NTP review of lead (2011) moves closer to the practice of systematic reviews as practiced using an evidence-based approach, but it is still a mixture of transparent and nontransparent methods. There are clear statements related to framing



specific questions and to some extent explicating the initial criteria for searching the literature for relevant primary studies, but it fails to present an explicit means by which these studies were identified or evaluated. In addition, as stated in the report, NTP explicitly relied upon other "authoritative sources" (from US government agencies) to identify citations for review, supplemented by some searches of the literature and consultation of experts rather than systematically reviewing all relevant citations. Thus, it is difficult overall to define the methods by which the primary studies were identified or selected, and it is likely to be difficult to replicate the process in an independent exercise. Most importantly, the document does not describe how these study results were integrated to support qualitative judgments based on IARC criteria. Tables in the document are rated as either "supporting" or "not supporting" these qualitative judgments without defining or describing the criteria used to classify a study as supporting or not. Furthermore, the authors appear to have selected which studies are cited in these tables rather than showing all data. Evaluation also involved nontransparent processes such as expert consultation and review by a selected panel. The conclusions were further influenced by the committee review, as well as by the conclusions of the "authoritative sources," which, as noted above, did not adopt or implement transparency.

4 Why EBT and why now

The need for EBT is arguably driven by several forces: the increased demand for transparency and a stronger scientific basis for decision making in both public and private sectors, as well as longstanding dissatisfaction with the pace and contentious nature of current modes of decision making in public health (EEA, 2001). Examples such as the divergent risk assessments for methyl mercury and bisphenol A in public health policy in the US and the EU (Beronius et al., 2010) do not encourage confidence. Stakeholders with an interest in efficient government and public health should be greatly concerned by the fact that EPA's evaluation of the human health effects of dioxins took 18 years. How the data used to make these decisions was obtained is neither clear nor replicable. EBT mandates the provision of methods used to develop a set of primary studies which are then used as the evidence for decision making. Clearly, the use of EBT can promote reduction of controversies, as all can obtain exactly the same data on which to base decisions; the methods used to obtain, assess, and integrate the data are described clearly enough to allow replication. In addition, through increasing the efficiency of decision making, EBT can respond to societal pressure to decrease the resources of time, money, and vertebrate animals utilized in reaching decisions related to hazard and risk (Rovida and Hartung, 2009). These pressures have increased interest in developing alternative methods that reduce the time required to obtain relevant information (NRC, 2007). For this reason, the need to validate these alternative methods adds further impetus to EBT.

5 Initial steps towards systematic reviews in toxicology

We have carried out some of the more detailed studies using principles of EBM/HC to evaluate the evidence for associations between environmental toxicants and human health risks, and this experience provides some perspective on the challenges in adopting and adapting these methods to EBT (Navas-Acien et al., 2005, 2006, 2007; Mault et al., 2012). These reviews follow the norms of transparency and methods that have been developed for systematic reviews of diagnostics and interventions in medicine and health care. They incorporate the following steps: development and explicit framing of research questions that can be answered by a systematic review plus explicit statement of a publicly available protocol for conducting the systematic review. This protocol includes a defined and annotated strategy for locating sources of evidence; *a priori* conditions for exclusion and inclusion; defined analytic procedures to evaluate study designs and statistical methods; criteria for evaluating selected studies; methods for integrating study results. These rules are based on the assumption that all studies are well intentioned but no study is perfect. The goal is to identify all relevant sources of information in an unbiased manner and then to screen this body of information by identifying aspects of each study that can increase bias or uncertainty and to consider the impact of these aspects on analytic confidence.

Our attempts to integrate toxicological studies into our reviews were limited in terms of availability of studies, due in most cases to the variability in study design or in the endpoints selected, as well as to differences or lack of precise information on dosing and dose duration, and uncertainty as to the relevance of measured outcomes to the inference of human health risk. Some of these issues relate to toxicology, in which a range of endpoints often are utilized as relevant indicators of human disease risk; this is related to the lack of accepted phenotypic animal (or *in vitro*) models for many human health endpoints and uncertainty as to mechanisms involved in human disease. Lacking a coherent nosology, toxicological studies are likely to be more varied in design and endpoint than epidemiological or clinical studies. Integration of different endpoints may be possible using a systems biology approach to group endpoints in terms of common pathways, but this has not been tested in practice. These concerns also were cited by Mault et al. (2012).

A similar experience is presented in an excellent recent systematic review of formaldehyde and reproductive and development endpoints (Duong et al., 2011). The review of epidemiological studies is a model in transparency and rigor. In contrast (and similar to our reviews on lead and arsenic mentioned above), the review of experimental animal studies was less transparent. No clear information is presented on search terms and criteria for inclusion or exclusion of studies. Large differences were noted among studies in terms of species, routes of exposure and dose, as well as endpoints, which probably impeded any attempt at integration such that only a summary of "key findings" was presented. A thorough narrative discussion of mechanisms and modes of action also was included.



6 Challenges for EBT

The results of our analyses, along with more recent experience from an expert working group convened by the National Institute of Environmental Health Sciences (NIEHS) to evaluate associations between environmental chemicals and diabetes, indicate that toxicologists have considerable work to do to implement an evidence-based approach (Silbergeld, 2009). Innovations and modifications are especially needed to develop evidence-based methods tailored for toxicology and experimental nonhuman studies. Some of the major limitations noted in our reviews are discussed here for human studies and experimental studies. First, the amount of primary information available from independently conducted epidemiological studies in the published literature is relatively sparse for many exposures of interest. Second, many of the available epidemiological studies have significant problems in terms of study design or data reporting such that it is difficult to identify biases in them. For example, in many studies of arsenic, there are limited or no data on individual exposures and many studies failed to collect or report information on important covariates and confounders or information sufficient to determine heterogeneity. Many studies are relatively small and likely underpowered; many of the studies of larger cohorts (such as NHANES) are not actually independent of each other, and none are longitudinal, and so causality cannot be inferred in terms of exposure preceding outcome. In addition, there are broad differences in definition and measurement of outcomes of interest. This is understandable for toxicological studies, but is also characteristic of many epidemiological studies on, for example, lead and arsenic. For the toxicological studies, there is enormous heterogeneity in all aspects of study design and interpretation, as discussed above and in Duong et al. (2011). These criticisms were similar to the evaluations of the medical literature in the early '80s when systematic reviews in EBM/HC were first widely applied and just beginning to be appreciated (Dickersin and Manheimer, 1998).

Nevertheless, our reviews demonstrated that important elements of the methodology of systematic reviews can be adopted by EBT with little change, notably an allegiance to transparency in methods for searching the available literature for potential evidence, in selecting studies for review, and application of *a priori* criteria for assessing each selected study. Toxicologists can examine existing criteria for systematic reviews of observational epidemiology (Blair et al., 1995; AMS, 2007; Longnecker et al., 1988). When appropriate, some of the methods for integrating results across studies also may be adopted. From our analyses, we also observed that the greatest challenges for developing EBT are related to handling information from experimental nonhuman studies, where there is no consensus on analytic procedures and where even the construction of research questions may be more complex owing to the many test systems and endpoints used in studies on the same topic. In addition, there is no consensus on methods for screening primary studies, for evaluating the selected studies,

and on appropriate statistical methods to integrate study results from the range of experimental designs. This challenge will not be met by selecting information only from standard toxicology test guidelines or Good Laboratory Practice requirements as the definition of acceptability for evidence-based decisions. Many of these designs are extremely limited and, while they may produce data of use in standard risk assessment methods, they are underpowered and not robust (Reuter et al., 2003). As has been noted in endocrine disruptor research, these types of studies may be less informative than research studies that are more specifically designed to investigate defined hypotheses rather than to generate minimal information on hazard (Myers et al., 2009). Rather, all relevant studies should be sought and then evaluated using methods for appraising sources of biases identified through a consensus process in order to determine the strength of the evidence provided by each. Achieving this goal will foster a closer relationship between environmental epidemiology and experimental research, going beyond the invocation of experimental research merely to satisfy one of Bradford Hill's recommendations.

Achieving the goals of evidence-based and systematic analysis, as argued by practitioners in EBM/HC, has involved two strategies implemented at the beginning: involvement of a broadly based community for achieving consensus in methods and evaluations and a commitment to complete transparency. These commitments are exemplified within the Cochrane Collaboration. At its inception, the Collaboration included only a few dedicated investigators with a shared vision to help people make good health care decisions. This goal drove the development of systematic reviews and the dissemination of these reviews, which now cover a broad range of topics related to health care interventions. Key principles of transparency and continuous improvement in methods based on empirical evidence underlie the growth of the Cochrane Collaboration and its influence in the field of EBM/HC.³ This paper argues that these strategies, as well as a commitment to continuous growth and improvement in methods, are equally critical for the successful development and adoption of EBT.

The decision for EBT involves a commitment by the field of toxicology, not only to science but to community. As noted above, practitioners in EBM/HC stress that its success has involved the engagement of a broadly based community for consensus evaluations and a commitment to complete transparency. These steps cannot be rushed by establishing structural frameworks and empty institutions but must be grown from an organic discussion among the community of stakeholders, including scientists, technicians, governments, private sector, and the public (Chalmers, 2005).

Our success may transform the field of toxicology, as well as the practice of decision making in regulation. EBT can contribute to the efficient adoption of alternative methods through consensus agreement on identifying the evidence and on criteria for evaluation, drawing on experience from diagnostic evaluations in EBM/HC. However, there must be a commitment to

³ <http://www.cochrane.org/resources/handbook/index.htm>



empirically testing the methodology for systematic reviews of toxicological data; without such methodological studies, the field cannot move forward. This will not be a simple task. Since toxicology is fundamentally a science of prevention (Silbergeld et al., 2004), its aim is to detect likely harms prior to human exposure. For this purpose, experimental studies are the only source of truly preventive information, and thus the focus of EBT should be on experimental toxicology and test methods in the broadest sense.

Adoption of an evidence-based approach does not mean the adoption of the clinical trial design as the "highest" or only form of reliable information (Silbergeld, 2009). Evidence may come from any type of study, and although many reviews focus on randomized clinical trials, the type of evidence (i.e., study design) required depends on the type of research question (e.g., the use of randomized controlled clinical trials to answer questions of efficacy and cohort or case-control studies to answer questions related to etiology). This has facilitated the development of both "rules of practice" and the *post hoc* evaluation of research results (Dickersin and Manheimer, 1998). EBM/HC also provides a rich source of valuable guidance to EBT in its methods for evaluating observational epidemiology (Blair et al., 1995; Longnecker et al., 1988; AMS, 2007). While we can learn from EBM/HC, as noted at the outset of this paper, the issues of concern to toxicology, for the most part, are not the same as those in medicine and health care. In EBM/HC, the evidence-based approach has been developed most fully for answering questions related to therapy and diagnosis. The evaluation of novel test methods (such as alternative systems) may draw usefully upon methods used in evaluating diagnostics. Systematic reviews using only evidence from randomized controlled trials (RCTs) are not well suited to identifying harms, primarily due to study designs focused on identifying benefit, often with insufficient power to detect adverse effects because of the relatively low number of individuals exposed and the short time frame of many RCTs (Chou and Helfand, 2005).

The investment of our community in developing EBT will be worthwhile. In the absence of an evidence-based process, decision making is dependent upon a pseudo-Delphi process, in which experts are convened to undertake a qualitative process of integrating and weighing information (e.g., the NTP and IARC). This is less and less satisfactory to the public and other stakeholders; it is also highly resource-intensive in terms of repetitious studies and expert consultation (Rovida and Hartung, 2009). EBT will lead us into new domains of science and assessment, but we should remember that, in identifying harms and assessing risks, as in the law, an evidence-based approach does not remove the need for the application of judgment (Sackett et al., 1996; NRC, 1994). The premise and promise of EBT is the reduction of uncertainties by assuring a consistent body of information and enhancing confidence in the selection and evaluation of this information through a fully transparent process dedicated to continuous improvement through experience. These were the goals that inspired Archie Cochrane and the early community of analysts; by adopting them, the com-

munity of toxicologists can enhance the development of science and better serve the social goals of health protection and safety assurance.

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Assuring Access to Data for Chemical Evaluations

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BACKGROUND: A database for studies used for U.S. Environmental Protection Agency (EPA) pesticide and chemical reviews would be an excellent resource for increasing transparency and improving systematic assessments of pesticides and chemicals. There is increased demand for disclosure of raw data from studies used by the U.S. EPA in these reviews.

OBJECTIVES: Because the Information Quality Act (IQA) of 2001 provides an avenue for request of raw data, we reviewed all IQA requests to the U.S. EPA in 2002–2012 and the U.S. EPA's responses. We identified other mechanisms to access such data: public access databases, the Freedom of Information Act (FOIA), and reanalysis by a third party.

DISCUSSION: Only two IQA requests to the U.S. EPA were for raw data. Both of these were fulfilled under FOIA, not the IQA. Barriers to the U.S. EPA's proactive collection of all such data include costs to the U.S. EPA and researchers, significant time burdens for researchers, and major regulatory delays. The U.S. EPA regulatory authority in this area is weak, especially for research conducted in the past, not funded by the U.S. government, and/or conducted abroad. The U.S. EPA is also constrained by industry confidential business information (CBI) claims for regulatory testing data under U.S. chemical and pesticide laws. The National Institutes of Health Clinical Trials database systematically collects statistical data about clinical trials but not raw data; this database may be a model for data from studies of chemicals and pesticides.

CONCLUSIONS: A database that registers studies and obtains systematic sets of parameters and results would be more feasible than a system that attempts to make all raw data available proactively. Such a proposal would not obviate rights under the IQA to obtain raw data at a later point.

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The U.S. Environmental Protection Agency (EPA) is one among many agencies covered by the Information Quality Act (IQA 2001), an amendment to the Treasury and General Government Appropriations Act for fiscal year 2001 that has been viewed as a mechanism to increase access to such information and to seek corrections if parties think that government agencies have used faulty information and analyses. The Office of Management and Budget (OMB) issued IQA guidelines that apply to all agencies in the Executive Branch: When these agencies provide "influential scientific, financial, or statistical information," they also "shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties" (OMB 2002). The law was enacted without debate or hearing. In the absence of an extensive legislative history and because both the IQA and OMB guidelines were silent about whether agency responses were judicially reviewable, some had viewed the act as providing a new avenue for legal challenges of agency decisions across the U.S. government. For example, in 2006 the U.S. Fourth Circuit Court of Appeals ruled that plaintiffs did not have standing to sue the Department of Health and Human Services under Title III of the IQA to compel access to a study conducted by the National Heart, Lung, and Blood Institute (NHLBI) that

was used to support action by the Food and Drug Administration (FDA) on dietary salt (Salt Institute *v.* Leavitt 2006). A number of industry groups had petitioned the NHLBI to make the raw data from the study available so that they could do subgroup reanalyses. The court found that the plaintiffs had received no injury from being denied access to the NHLBI data and thus did not have standing. However, the court also noted that the petitioners had a longstanding right to request the raw data from the study using the Freedom of Information Act (FOIA 1966). In its response, the NHLBI noted that it was preparing a public access data set for release, which it later made available (NHLBI 2005). Although this case was resolved under existing FOIA mechanisms, in the wake of this litigation there has been concern that the IQA does not provide outside parties sufficient access to the data for studies that underlie regulatory decisions made by U.S. government agencies. There is increasing interest in improving the methods by which chemical and pesticide hazards and risks are evaluated not only by government but also by independent scientists (Bucher et al. 2011; Woodruff et al. 2011). This interest has spurred increased demand for transparency and disclosure of the data used by the U.S. EPA to make evaluations that support regulatory decisions for chemicals and pesticides. In this context, we examine the role of the IQA in

making such data more accessible and suggest alternative approaches.

Review of Requests for Data

To find out how responsive the U.S. EPA has been to requests for raw data under the IQA, we reviewed 79 requests filed with the U.S. EPA between 2002 and 2012 either to correct or to reconsider the data that the U.S. EPA used in evaluations supporting its regulatory decisions during that period. Under OMB guidance for the IQA (OMB 2002), parties can request that agencies reconsider or correct any information used to support regulatory decisions; usually these requests are made in the form of letters. The U.S. EPA posted these 79 requests on its web site, according to OMB guidelines (U.S. EPA 2012a). Interestingly, only two of these requested raw data.

The first request for raw data was filed in December 2003 by the Perchlorate Study Group, an industry consortium of manufacturers and users of perchlorate (Aerojet, American Pacific Corporation, Kerr-McGee Chemical, and Lockheed Martin). They requested that the U.S. EPA provide raw data from experimental studies (Girard 2003). The U.S. EPA granted this request in September 2004 and provided access to brain images and contractor's reports (Gilman 2003).

The second case was filed by the Association of Battery Recyclers (ABR) in October 2008 (Steinwurtzel 2008). Now called America's Battery Recyclers, and formerly called the Secondary Lead Smelters Association, the ABR is a group of auto and industrial battery recyclers, primary lead producers, and users of recycled lead (America's Battery Recyclers 2012). The ABR requested raw data from a study of lead toxicity (Lanphear et al. 2005) that was among several published studies relied upon by the U.S. EPA in its development of the National Ambient Air Quality Standard (NAAQS) for lead under the Clean Air Act Amendments (1990). Because the ABR and others had taken the U.S. EPA to court to overturn the lead NAAQ rule at the same

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time, the U.S. EPA opted to postpone consideration of the request under the IQA pending the decision of the court. In its response to the request, the U.S. EPA noted that concerns about the data analysis had been noted in comments during the rule-making process and that the U.S. EPA had commissioned new external peer reviews of the study (U.S. EPA 2012a) in addition to a reanalysis of the data of Lanphear et al. (Rothenberg and Rothenberg 2005). After the lead NAAQS was upheld in July 2010, the ABR again requested that the U.S. EPA provide access to the Lanphear data (Steinwurtzel 2010). Meanwhile, litigation was filed over the delay in providing the data. This litigation was dropped when the U.S. EPA FOIA office worked out an agreement with the Cincinnati Children's Medical Center to obtain the Lanphear study data (Lanphear BP, personal communication; Pohl v. U.S. EPA et al. 2012). U.S. EPA attorneys determined that access to the data was required under the 1998 Shelby Amendment, which makes federally funded research data accessible to the public under FOIA (Treasury and General Government Appropriations Appropriations Act 1998). Thus, as for the request to the NHLBI to provide data concerning the salt study (Salt Institute v. Leavitt 2006), the resolution of the request was managed under FOIA.

Because requests for raw data are few and far between, it has not been onerous for the U.S. EPA to provide such data. Existing mechanisms have provided the ability to reanalyze data by a) development and availability of a public-access database (with suitable protections for the human subjects involved in such studies); b) provision of raw data via FOIA, for cases in which data are in possession of or can be obtained by the agency (e.g., the perchlorate case cited above); and c) reanalysis of data by a third party. As an example of the third mechanism, the widely publicized results from the Harvard Six Cities Study (Dockery et al. 1993) were used by the U.S. EPA in 1997 as a basis for developing new standards for fine particulate matter ($\leq 2.5 \mu\text{m}$ in aerodynamic diameter) air pollution (U.S. EPA 1997). Interested parties, mostly from industry, raised questions about study analysis and interpretation. The raw data were not in the possession of the U.S. EPA, and the U.S. EPA could not compel the submission of these data from Harvard University or the funding source, the American Cancer Society. Under pressure from government agencies and industry, Harvard and the American Cancer Society voluntarily requested that the Health Effects Institute (HEI) step in as a third party to supervise a reanalysis of their data. The HEI [a consortium of industry, academic, and government scientists established by the Clean Air Act Amendments (1990)] provided the data for reanalysis by a third party

selected by a science advisory committee that included representation from interested parties who had argued for an independent reanalysis, thus providing a process to address the uncertainties about the analysis and interpretation (HEI 2000).

Discussion

Over time, the U.S. EPA has come to rely increasingly on a large number of scientific studies to complete reviews for a single chemical. This is illustrated by the case of 2,3,7,8-TCDD (2,3,7,8-tetrachlorodibenzo-*p*-dioxin). In its recent assessment of TCDD, the U.S. EPA identified some 2,000 studies directly relevant to its review of dioxin toxicity. From these, the U.S. EPA selected 10 "key" epidemiologic studies and 74 "key" experimental animal studies. Even for this smaller subset of "key" studies, the raw data for each human study and animal experiment are substantial, and most of the data on TCDD were not in the possession of the U.S. EPA (2012b).

There are several mechanisms through which the U.S. EPA might obtain these data. The U.S. EPA could require that investigators submit their raw data to the agency upon completion of their research as a condition of U.S. EPA funding, but this would not completely solve the problem. Most research evaluated by the U.S. EPA for regulatory decision making is not funded by the U.S. EPA. In these cases, the U.S. EPA would have to undertake an extensive collection of raw data from study investigators, which would be costly to the U.S. EPA and burdensome to the research community. Not insignificantly, this would create major delays in rule making. In terms of resource allocation, it is reasonable to ask how much of the U.S. EPA's budget could be allocated to accomplish this, and where this would rank relative to other priorities, such as increasing the numbers of priority assessments to meet the U.S. EPA's statutory goals.

In addition to the burden on the U.S. EPA, there would be a significant burden on the scientific community that produces most of the relevant research, and it is very likely that there would be significant pushback from the academic community under the Paperwork Reduction Act (1995). In fact, the Paperwork Reduction Act, which was enacted to reduce the total amount of paperwork handled by the U.S. government, would not allow the U.S. EPA to undertake such a massive data collection without establishing that the burden imposed upon the research community would be justified by the benefits of providing the data.

At the least, scientists would need funding to respond to requests that are generated as a consequence of the use of their studies by the U.S. EPA rather than any action taken

by the investigators themselves. Burdened by other responsibilities and unable to fund such activities from grants provided by sources other than the U.S. EPA, scientists are not likely to voluntarily provide the U.S. EPA with raw data from studies conducted months to decades in the past simply because the U.S. EPA has decided to include those studies in their latest assessment.

Moreover, the U.S. EPA would not have clear legal authority to compel the submission of data from industry, federally funded studies conducted prior to the 1998 Shelby Amendment, studies funded by other federal agencies, or studies that are not funded by the U.S. government, including studies from non-U.S. investigators. We therefore conclude that a regulatory approach, in which the U.S. EPA compels the submission of raw data for all studies reviewed for rule making on pesticides and chemicals, would not be tenable. It could in fact have a chilling effect on the engagement of the global scientific community in research relevant to the protection of human health and the environment. Certainly, this is not in the best interests of science-based policy.

In addition, there are other feasibility issues. In the case of older studies, raw data may not exist or may be difficult to access because of storage on outdated media such as tapes. For epidemiologic studies, consideration would need to be given to ethical issues governing studies of human subjects. These include protection of confidentiality and privacy, and prevention of abuse of the data. For example, by marketing companies who may wish to identify patients with particular medical conditions. Clinical-trials investigators have been working for years to develop ways to disclose data from human studies, including mechanisms for placing data behind a barrier to universal access, so that it is accessible only to those who meet conditions of use. In the case of clinical trials, there are studies in which removal of all identifying data negates its scientific value; therefore access to the data would need to be limited to protect privacy (Hrynaskiewicz et al. 2010). With adequate resources and planning, these obstacles could be anticipated and/or overcome.

In the case of research data concerning chemicals and pesticides, the U.S. EPA also is constrained by legal constructs that have defined regulatory testing of pesticides as "confidential business information" (CBI) and that require the U.S. EPA to redact certain data and obtain affirmations from recipients that they will not give the remaining data to multinational companies that might seek to register the pesticide to market it in other countries (U.S. EPA Office of Pesticide Programs 2010). The U.S. EPA could improve the web access to summaries and analyses of

these data, which are publically available but often difficult to find in web searches. This would not be the same as providing access to raw data. We therefore suggest that, in the short run, industry should work with the U.S. EPA to identify approaches to provide more robust data sets for studies that they submit to the U.S. EPA. The U.S. EPA also could invite companies to voluntarily waive CBI claims on tests of pesticides and chemicals. In the long run, we think that Congress should amend the Toxic Substances Control Act (1976) and the Federal Insecticide, Fungicide, and Rodenticide Act (1972) as amended by the Food Quality Protection Act (1996) to ease CBI protections from pesticide and chemical test data.

In an ideal world we would always favor more disclosure over less, but it is not clear how this should be done, or who should pay for it. The HEI, which has an independent governing board and is supported by a consortium of funders including the U.S. EPA and the automobile and petrochemical industries, may be a useful precedent. The HEI requires that data from all HEI-funded studies be made available as expeditiously as possible,

(taking) into consideration the legitimate intellectual interests of the investigator to have the opportunity to benefit from his or her intellectual endeavors and to publish subsequent analyses from the data set (including additional analyses funded by HEI). (HEI 2010)

The HEI attempts to balance the interests of investigators with those of interested parties in cases of "studies of particularly high regulatory importance being used to inform decisions over a short time frame," and encourages its principal investigators to share the data except in situations where "providing the data would place an undue burden on the investigator" (HEI 2010). For example, in cases when there have been so many requests that it was difficult for the investigators to continue their research, the HEI has assisted investigators with data sharing. In addition, the HEI requires that data requesters provide "reasonable reimbursement for both the direct costs of providing the data, and for the time of the investigator and/or HEI staff to gather, transmit, and explicate the data" (HEI 2010). HEI also "will consider requests from the investigator for a reasonable budget of data archiving funds, to be provided as part of the project budget" (HEI 2010). From this precedent, it seems that proponents of increased access to raw data need to consider not only financial and time burdens on investigators, but also a way to reasonably balance the need for data access with the ability of investigators to realize the fruits of their own intellectual endeavors.

Another useful precedent that could serve as a model for data sharing is the National

Institutes of Health (NIH) clinical trials database (ClinicalTrials.gov; NIH 2012). It does not contain "raw data" but rather contains detailed and useful information about clinical-trial study designs and statistics that not only convey results in a standardized fashion but also identify important quality parameters (e.g., drop-out rates). Required by law (Section 113 of the Food and Drug Administration Modernization Act 1997), the clinical trials database was developed by the NIH with input from the FDA and the National Library of Medicine (NLM). Currently, many medical journals require that trials be registered in ClinicalTrials.gov prior to their publication; as of 3 December 2012, 136,605 studies in 182 countries were registered. Although many researchers are now calling for access to raw data for all clinical trials (Gorzsche 2011), the ClinicalTrials.gov database has greatly increased access to information about drug efficacy trials and drug safety, and the development of such a database for studies of chemicals and pesticides would be a major step toward increasing the transparency of the U.S. EPA's evaluations and making data more accessible to third parties.

Conclusions

At present, there does not seem to be a large demand for raw data related to U.S. EPA decision making; however, this may change as formal evidentiary reviews of environmental health research become increasingly common (Maull et al. 2012). Compared with clinical trials, the acquisition of raw data for chemicals and pesticides would be much more complex, in part because it would require a framework that can accommodate data from numerous types of studies: observational and experimental, animal, human, *in vitro*, and high throughput screening studies.

For human epidemiologic studies, clear and complete documentation would need to be provided for interpretation of the variables collected in such studies. This is no simple task given, for example, *a*) the wide range of possible study designs and the intricacies of design of questionnaires and subsequent coding and transformation of variables; *b*) environmental and biomarker sample-collection procedures, chain-of-custody and sample processing and storage, laboratory analyses, data analysis, and coding; and *c*) imputation of missing variables or laboratory nondetects. Although it is a standard practice to carefully document all of these details, there is currently no generally agreed-on manner in which to upload such data into an electronic database. There is a risk that people who were not involved in data collection can misunderstand these details and thus obtain erroneous results. Some effort would be required to develop a standardized system for reporting this kind of information. For experimental animal studies, there should

be parameters related to quality assessment (e.g., blinding of investigators, randomization, housing and care of animals).

If the U.S. EPA chose this path, the first step might be to develop a framework similar to ClinicalTrials.gov that would capture statistics and other parameters but would not necessarily require uploading raw data. With adequate funding, involvement of the NLM might provide more sophisticated informatics expertise to make the data more usable, and the NLM or the National Toxicology Program (NTP) could perhaps provide a "home" for the data. The U.S. EPA and other environmental agencies could also require (or request) that investigators register their studies with the database, and journals could require registration as a condition of publication (as some journals currently do for results of clinical trials) or suggest that it be done. Given resource limitations, especially for investigators in developing countries, this step might be difficult for many investigators compared with researchers who perform clinical trials.

A system that provides raw data might be possible if the U.S. EPA could pilot the development of a system that could handle raw data using data already in its possession [e.g., results of its intramural research, results of U.S. EPA-funded extramural research (where available), and any raw data that it has requested from investigators in support of risk-assessment activities]. Other federal agencies, such as the NTP and the National Institute for Occupational Safety and Health could contribute as well. The NTP already publishes all of its data and methods in its reports; however, it does not publish raw data or studies with nonstandard protocols online. In any case, busy investigators may oppose this not only because of the effort and resources required but also because they would be relinquishing exclusive access to their own raw data (and therefore the risk of being "scooped") for the possibility of future requests for reanalysis. Even in cases where investigators contemplate no further data analyses, they may have concerns about the effort to respond to questions about repeat analyses. In any case, additional resources would be required, and this is not a time of plenty for research in the United States or anywhere else. In short, as in all of life, there is no free lunch. We already have mechanisms for disclosure of data used by the U.S. EPA in decision making and even for obtaining raw data. It is doubtful that we can afford the luxury of having this information available for release prior to any request, and it is uncertain who should be responsible for the cost and effort required to provide it.

We conclude that, as is the case for clinical trials, a registry for studies that could handle a wide variety of methodologies and methods of analysis and provide a more complete and



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standardized presentation of statistical results and other parameters than is possible in the peer-reviewed literature would be a tremendous resource to society for increasing transparency and improving assessments of pesticides and chemicals. However, at present, there is no evidence that there is a net social benefit to requiring collection of and access to raw data for all studies utilized by the U.S. EPA prior to requests for such data from interested parties. As a first step the U.S. EPA, NTP, and NLM should begin to generate discussions among agencies and with interested outside parties, including academic researchers and the regulated industry, on the possible creation of a reporting system for environmental health studies of chemicals and pesticides that would systematically collect results and data about studies—but not raw data.

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Access to Chemical Data Used in Regulatory Decision Making

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It is clear from our commentary (Goldman and Silbergeld 2013), that we disagree with Lutter et al. (2013) about whether the public disclosure of all raw data used by the U.S. Environmental Protection Agency (EPA) for making regulatory decisions for chemicals is necessary to ensure the scientific basis for such decisions, and about the extent to which preemptive disclosure (prior to any request) is practical. However, the most important disagreement between us is the basis asserted by Lutter et al. in their commentary for this change in policy. Lutter et al. argued that it is necessary for the U.S. EPA—and anyone else who desires to do so—to reanalyze all data used in their assessments in order to “replicate” the findings and conclusions of the original investigators.

Lutter et al. (2013) repeatedly used the terms “replicability” and “replication” as synonymous with an “independent analysis” of raw data from an existing study. Replication in science is quite different; it involves performance of an independent study with the same hypothesis and then testing the extent to which this independent study reaches the same conclusions. Recalculation of study statistics or other reanalysis of an existing study data set is not a replication. Designing and conducting a replication study does not require access to raw data from the original study; this would abrogate the concept of independence. Moreover, an independent study will by definition utilize different sets of animal models or human populations, and as a consequence may employ different statistical techniques.

Their second argument is that disclosure of raw data will assist in identifying sources of scientific bias. We consider this unlikely because the most important sources of bias are usually related to problems in study design or limitations of the data collected. This is not identifiable through data recalculation; however, this type of bias can usually be identified in the text of the original study publication.

Lutter et al. (2013) noted (correctly) that applicants to the U.S. EPA for pesticide registrations must provide raw data from regulatory testing as part of the package submitted to the U.S. EPA. This is a very special case, in that these studies are neither peer reviewed nor accessible to the public because of the protection sought by industry and extended by law for confidential business information (CBI). The assumption of bias related to these studies is not unreasonable, given that they are conducted by or on behalf of commercial entities seeking to obtain pesticide registration. These studies are rarely published in the scientific literature or in any way subject to independent peer review other than review by the U.S. EPA. Many scientists and public policy practitioners consider the CBI cloak as a major impediment to transparency and confidence. Industry could demonstrate their commitment to transparency by declining this protection, thereby increasing the confidence of all.

Finally, Lutter et al. (2013) attempted to support their proposal by claiming that journals [*Nature* and the *Proceedings of the National Academy of Sciences of the United States (PNAS)*] and an expert body (the Bipartisan Policy Center) agree with them. However, these bodies have neither supported the concept of requiring that all raw data be reported to the U.S. EPA nor that the U.S. EPA carry out its own independent recalculation. Rather, *Nature* and *PNAS* require authors to agree to make data sets (as well as materials and protocols) available to editors, and to others, upon request (Nature Publishing Group

2012; PNAS 2012). One of us (L.R.G.) was a member of the Science for Policy Project; its final report (Bipartisan Policy Center 2009) also recommended this practice. Many journals require data, such as DNA and protein sequences, macromolecular structures, microarray data, and crystallographic data, to be made available on publicly accessible databases, but most of these are not “raw data” in the sense that Lutter et al. proposed. *Nature* also recommends that authors submit clinical trials data to external clinical trials databases (Nature Publishing Group 2012).

In summary, we disagree with the argument that raw data from every study used by the U.S. EPA to support a regulatory assessment should be made available to the agency and to the public. This proposal does not serve the purpose of “replication” or identification of bias, as asserted by Lutter et al. (2013). In practice, it may generate obstacles to good science and discourage researchers from studying issues of importance in environmental health. This proposal would also limit the U.S. EPA from using the results of research published in the peer-reviewed scientific literature by placing studies off-limits if the authors did not submit raw data sets to the U.S. EPA.

Finally, there is no obvious need for these changes. When the U.S. EPA has determined a need to reanalyze data, the current regulatory practice has not impeded such activities. Past history indicates that difficult cases are rare and do not warrant an intrusive and burdensome new requirement for the automatic submission of data from all studies.

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Access to Chemical Data: Lutter et al. Respond

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We appreciate the attention paid by Goldman and Silbergeld (2013) to the issue of data disclosure and agree that there has been “increased demand for transparency and disclosure of the data used by the U.S. EPA [Environmental Protection Agency] to make evaluations that support regulatory decisions.”

In their letter, Goldman and Silbergeld contend primarily that “replication” in science means to independently repeat a prior study to see if the same results can be obtained. They suggest that public availability of the prior study’s data is unnecessary because a subsequent study will generate its own data. In 2011, a special section of *Science* (Vol. 334, No. 6060) addressed replicability and reproducibility and made two general points. First, “replication,” as defined by Goldman and Silbergeld, while perhaps the cornerstone of the scientific method, can be difficult in many settings because of the uniqueness of the precise conditions surrounding field observations, the expense and time required to collect data (e.g., for longitudinal studies), and ethical constraints (e.g., Jasny et al. 2011). Second, in those cases where conduct of a second experiment may be impossible or infeasible, review and reanalysis of the first study’s data is still a meaningful step along the “reproducibility spectrum,” assists in understanding the differences between competing analyses, and “may be sufficient to verify the quality of the scientific claims” (Peng 2011; see also Ioannides and Khoury 2011; Santer et al. 2011).

Other empirical work also supports the view that data availability promotes reproducibility. In empirical economics, a discipline that uses large-scale statistical models broadly similar to those of epidemiologists, a famous study of replication of peer-reviewed research suggested that inadvertent errors may be “commonplace rather than rare occurrences” (Dewald et al. 1986). The *American Economic Review* (AER 2013) subsequently adopted a policy “to publish papers only if the data used in the analysis are clearly and precisely documented and are readily available to any researcher for purposes of replication.” Further, the AER conducted a recent evaluation of its policy and reported that about 80% of 39 sampled papers met the spirit of the data availability policy (Glandon 2010). Importantly, independent efforts at replication

of 9 selected papers found no serious errors (almost exact replication for 5 studies and “several small discrepancies ... immaterial to the conclusions” for another 4.) This result represents a marked improvement relative to the results of the original 1986 study of replication. The difference is presumably attributable, at least in part, to the difference in care and quality of work associated with the AER’s current policy of data availability. Although analytic methods underlying papers published in the AER are different from those used in chemical evaluation, the experience of the AER suggests that there is merit in promoting data availability for the purpose of improving the reliability of the results of published, peer-reviewed scientific papers, at least in disciplines that use complex statistical models.

Finally, we, like Goldman and Silbergeld, “disagree with the argument that raw data from every study used by the U.S. EPA to support a regulatory assessment should be made available to the agency and to the public.” Unlike Goldman and Silbergeld, we recommend that the U.S. EPA, when it uses results of a published study in a regulatory assessment, ask the authors for underlying data (Lutter et al. 2013). If the U.S. EPA does not receive such data, it should explain how it used the study results in light of the fact that data sufficient to assess reproducibility was not forthcoming. We believe our approach would facilitate and not obstruct good science and that it would not discourage researchers from studying issues of importance in environmental health. Moreover, it would not, as Goldman and Silbergeld state,

limit the U.S. EPA from using the results of research published in the peer-reviewed scientific literature by placing studies off-limits if the authors did not submit raw data sets to the U.S. EPA.

R.L., an independent consultant, consults for CropLife America (CLA) and received financial support from the CLA to moderate a forum and serve as principal author of this letter. C.B. consults for Dow AgroSciences LLC, an R&D-based agrochemical producer, registrant, and marketer. C.J.B. received CLA funding to review and analyze scientific literature on data quality. J.W.C. has previously received funding from the American Chemistry Council to author work on the quality of scientific research evaluating chemicals. D.E. consults for a variety of pesticide manufacturers and for the CLA. A.F. has consulted with nonprofit organizations funded by the CLA about pesticide issues.

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BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
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The Johns Hopkins University, Baltimore, MD	Post Doctoral Fellowship	1972-75	Env. Medicine and Neurosciences

A. Personal Statement

Since receiving my PhD in 1972, I have been engaged in regulatory policy as an appointed expert to EPA, FDA, OSHA, HUD, DoE, and numerous international institutions including IARC, WHO, ILO, and UNEP. This experience exposed me to the challenges in science based policymaking and particularly the difficulties of resolving controversies in risk assessment of toxic chemicals and other environmental exposures. Through my academic appointments in epidemiology and toxicology at the University of Maryland Medical School and adding an additional professorial appointments in health policy at Hopkins, I was introduced to the principles and methods of evidence based medicine (EBM), which may offer a way forward for environmental health. I co-authored three of the first applications of EBM to environmental health (Navas Acien et al 2005, 2006, 2007) and became engaged in the early discussions of "evidence based toxicology" (Silbergeld 2009). Since that time, my interactions with EBM have deepened through research and discussions with Hopkins colleagues in the US Center for the Cochrane Collaboration including Drs Roberta Scherer and Kay Dickersin. I am convinced that there is an urgent and important need to adopt an evidence based approach to improve decisionmaking, increase public confidence in policymaking, and enhancing the scientific basis of toxicology as well as its utility for other domains including drug regulation, assessing adverse effects, and incorporating mechanistic research into the evaluation of evidence. I have participated in workshops on this topic organized by EPA, CDC, and scientific societies, including the International Union of Toxicology. Through this process, I think that the time is now appropriate to draw together a workshop of stakeholders to begin the work of developing consensus based approaches for evidence based assessment of environmental risks, testing these approaches, and establishing a transparent and accessible process of continuous improvement that emulates the Cochrane model. The success of this project will also be valuable to FDA risk assessment processes as well as similar agencies in other countries (such as the EU Medicines and Food Safety Agencies, the Brazilian Agency for Risk Assessment, and others. [References are listed in the publications section below].

B. Positions and Honors**Positions and Employment**

1972-75 Postdoctoral Fellow, Neurotoxicology: The Johns Hopkins Univ Sch of Public Health (JHSPH), Baltimore, MD
 1975 Assistant Professor: Department of Environmental Medicine, JHSPH
 1975-79 Staff Fellow/Head: Behavioral Neuropharmacology Unit, Experimental Therapeutics Branch, NINCDS, NIH
 1979-81 Chief: Section of Neurotoxicology, NINDS, NIH, Bethesda, MD
 1982-84 Guest Scientist: Reproductive Toxicology Section, Pregnancy Research Branch, NICHD, NIH, Bethesda, MD

1982-91 Chief Toxics Scientist: Environmental Defense, Washington, D.C.
 1987- Adjunct Faculty: Department of Health Policy & Management, JHSPH
 1990-01 Adjunct Professor: Dept of Environmental Health Sciences, JHSPH
 1991-01 Professor: Program in Toxicology, University of Maryland School of Medicine, Baltimore, MD
 1992-01 Professor: Dept of Epidemiology & Preventive Medicine, Univ of Maryland School of Medicine, Baltimore, MD
 1993-98 Senior Consultant/Toxicologist: Environmental Defense Fund, Washington, D.C.
 1996-01 Director: Program in Human Health & the Environment, Univ of Maryland School of Medicine, Baltimore, MD
 2002- Professor, Depts of Environmental Health Sciences, Health Policy and Management, and Epidemiology, JHSPH, Baltimore, MD
 2006 - Guest Investigator, Woods Hole Oceanographic Institution

Other Experience and Professional Memberships relevant to this project

Member, USDEW-FDA Committee to Coordinate Toxicology and Related Programs, 1977-81 (now CCERP-DHHS)
 Expert panelist, NIH Consensus Conferences, 1979, 1982
 Member, U.S. EPA Executive Committee, Science Advisory Board, 1983-89; 1993- 999
 Member, NAS-NRC Board on Toxicology and Environmental Health Hazards, 1983-89; Committee on Exposure Assessment 1989-90; Committee on Biological Markers, 1985-89; Committee on Dioxin, 1987-91; Committee on Neurotoxicology, 1987-91; Committee on Risk Assessment Reviews, 1994; Commission on Geosciences and Environmental Research, 1994-97; NAS-NRC-IOM Committee on Lead Poisoning in the Americas, 1994-1996; Committee on Grand Challenges in Environmental Sciences, 1998-2000; Board on Biotechnology and Agriculture 2000-2005
 Member, NIEHS-NIH Board of Scientific Councillors, National Toxicology Program, 1989-1992
 Member, CDC Advisory Committee to Center for Environmental Health 1997-2002
 Member, Advisory Panel on Lead Screening, CDC, 1997-1999; 2010-

American Public Health Association
 International Society for Environmental Epidemiology
 Society of Toxicology (Metals, Neurotoxicology, Epidemiology and Reproductive Toxicology Sections)
 Member, Public Policy Committee, American Society for Neurochemistry, 1983-84
 Co-Organizer, Women in Neuroscience
 President, Society for Occupational and Environmental Health
 Councillor, Collegium Ramazzini

Honors (Selected)

1967 Graduate: *Summa cum laude* (Vassar College), Phi Beta Kappa
 1967 Leverhulme and Fulbright Fellowships
 1971-72 Rockefeller Foundation Predoctoral Research Fellowship
 1974-75 Joseph P. Kennedy Jr. Fellowship in Neurosciences
 1987 Warner-Lambert Award, Distinguished Women in Science, University of Wisconsin
 1991 Wolman Award, Maryland Public Health Association
 1992 Barsky Award, APHA
 1993 MacArthur Foundation Fellow
 1995 Women Who Make a Difference, Chatham College
 1998 Fellow, International Commission of Occupational Health, WHO
 2005 Global Tox Award, Canadian Society of Toxicology
 2006 Elected to Delta Omega, Johns Hopkins University
 2009 Women Taking the Lead US Library of Congress
 2010 Randall Award for Women in Science, University of Idaho
 2012 Rockefeller Foundation Fellowship, Bellagio

C. Selected Peer-reviewed Publications (from 252 total)

Silbergeld EK: The role of toxicology in causation: A scientific perspective. Courts, Health Science & Law 1:374-385, 1991.

Silbergeld EK: Investing in prevention: Opportunities to reduce health care costs through identifying and reducing environmental contributions to preventable disease. *New Solutions* Fall: 37-51, 1993.

Silbergeld EK, Graham J, and Price LB. Industrial food animal production, antimicrobial resistance, and human health. *Ann Rev Public Health* 29:151-169, 2008.

Silbergeld EK: Understanding risk: The case of dioxin. *Sci Amer Science and Medicine* Nov/Dec: 48-57, 1995.

Silbergeld EK: Preventing lead poisoning in children. *Ann Rev Public Health* 18:187-210, 1997.

Silbergeld EK, Waalkes M, and Rice JM: Lead as a carcinogen: Experimental evidence and mechanisms of action. *Am J Indust Med* 38:316-323, 2000.

Navas-Acien A, Sharrett A R, Silbergeld EK, Nachman K, Burke TA, Schwartz BS, Guallar E. Arsenic exposure and cardiovascular disease: A meta-analysis of the epidemiological evidence. *Amer J Epid* 162: 1037-1049, 2005.

Navas-Acien A, Silbergeld EK, Streefer RA, Clarke JM, Burke TA, Schwartz BS, Guallar E. Arsenic exposure and type 2 diabetes: A systematic review of the experimental and epidemiological evidence. *Environ Health Perspect* 114:641-648, 2006.

Navas Acien A, Guallar E, Silbergeld EK, and Rothenberg SJ. Lead exposure and cardiovascular disease: a systemic review. *Environ Health Perspect* Mar 115(3):472-482, 2007.

Silbergeld EK, Davis M, Leibler JH, and Peterson AE. One reservoir: Redefining the community origins of antimicrobial-resistant infections. *Med. Clin. N Am* 92:1391-1407, 2008.

Silbergeld E. Applying an evidence-based approach: arsenic as a health risk. *Human Exper Toxicol* 28:127-129, 2009.

Mault EA, Ahsan H, Edwards J, Longnecker MP, Navas-Acien A, Pi J, Silbergeld EK, Styblo M, Tseng CH, Thayer KA, Loomis D. Evaluation of the Association between Arsenic and Diabetes: A National Toxicology Program Workshop Review. *Environ Health Perspect* 120: 539-543, 2012.

Silbergeld E and Scherer RW. Evidence-based toxicology: strait is the gate, but the road is worth taking. *ALTEX* 30: 67-73, 2003

D. Ongoing Research Support

Fogarty International Center, NIH Silbergeld (PI) 7/1/10 - 6/30/15
"Environmental Risk Factors for Cardiovascular Disease in Mongolia"

NIEHS, NIH Silbergeld (PI) 9/30/09 – 9/29/14
"Community/Worker Exposures to Pathogens from Industrial Food Animal Production"

NIEHS, NIH Navas Acien, PI 07/01/12-03/31/16
"Arsenic Exposure, Genetic Determinants and Diabetes Risk in a Family Study"

Thrasher Research Foundation Silbergeld (co-PI) 02/01/13-01/31/16
Preventing Community-Associated Methicillin and Multidrug-Resistant *Staphylococcus aureus*

NIEHS, NIH Guallar (PI) 01/15/09-11/30/13
"Lead, Cadmium, Arsenic, and Cardiovascular Risk in Children"

Chairman SCHWEIKERT. Thank you, Dr. Silbergeld.

Our last witness today is Mr. Raymond Keating, Chief Economist at the Small Business & Entrepreneurship Council. Mr. Keating has expertise on a wide range of issues affecting the entrepreneurial sector of the U.S. economy. He has written eight books, hundreds of articles, and writes for the Small Business & Entrepreneurship Council and the Center for Regulatory Solutions' online publication. Mr. Keating is also an Adjunct Professor at the Business School of Dowling College. He received his master's in economics from New York University and an MBA in banking and finance from—is it Hofstra?

Mr. KEATING. Hofstra.

Chairman SCHWEIKERT. Hofstra University. Mr. Keating, five minutes.

**TESTIMONY OF MR. RAYMOND KEATING, CHIEF ECONOMIST,
SMALL BUSINESS & ENTREPRENEURSHIP COUNCIL**

Mr. KEATING. Thank you, Mr. Chairman and Members of the Committee, for holding this important hearing today.

As you mentioned, I am Chief Economist with the Small Business & Entrepreneurship Council and I noticed Representative Johnson left but I wanted to thank her for upgrading me to a doctor. I tried to get away with that because I have two master's degrees, but nobody really lets me, so I have to thank her when I get a chance.

I am going to take a little different tack from my colleagues and look at this issue from the small business perspective and also from the public's point of view of the regulatory process based on a survey that our group did recently. So just a few points that I want to highlight from my written testimony, number one, you know, just to kind of—from a small business perspective, the costs of regulation are very real and significant facts of economic life. Economics 101 tells us that we should expect—what we should expect from increased regulation: higher costs for businesses and consumers, reduced market exchanges, and expanded political control, resources allocated based on political decisions and influences rather than via competition and consumer sovereignty, and that all wind up in the end diminishing economic growth.

Number two, from a small business perspective, the SBA's Office of Advocacy has done a study. Several times I believe they have—I think they have done it three times. They have updated it a couple of times. Just looking at the costs of regulation, the costs of complying with regulation with an eye toward small business, those—just to throw out a few of those numbers, when you look at firms with less than 20 employees on a per-employee basis, the cost of complying with federal regulations are 42 percent higher than firms with 20 to 499 employees and 36 percent higher than firms with 500 or more employees. On the environmental front in terms of environmental regulations, those disparities are even much, much higher.

So the issue of transparency on the science being used to support regulation is not, you know, an esoteric academic or political point. It is very—has very real consequences in terms of the costs imposed on small businesses. And small business owners really want

to know. They need to know what regulations quite frankly are legitimate and which ones that they are dealing with may not be so.

You know, there is a lot going on at the EPA in terms of greenhouse gas regulations and there is more coming. When you look at the industries that are going to be directly affected and are directly affected, again, the majority of those businesses—the vast majority are small firms. When you look at manufacturing firms, manufacturing employer firms with less than 20 workers, that is 76 percent of those businesses. So they are small businesses. When you look at mining, quarry, oil and gas extraction, 85 percent of employer firms have less than 20 workers. So this is a very real issue for small businesses across the board.

Now, the poll that I want to mention we released it last month. It was a poll of American adults under the Center for Regulatory Solutions, our new organization, our new group if you will. And it was interesting what the public had to say on both the process and the cost of the effects of regulation. On the process, three numbers real quick: 68 percent said that government regulations on business are created by out-of-touch people who are trying to push a political agenda, 72 percent said that government regulations are created in a closed, secretive process, 64 percent said that government regulation on business was created in a way that does not consider the real-world impact. So that is the public view of the regulatory process.

In terms of the effects, 53 percent agree that there are too many regulations on business, 61 percent believe that regulations on business are likely to do more harm to the economy by interfering with the market, preventing businesses from growing and hiring new employees and increasing prices for consumers. And small business owners would most assuredly agree with those assessments.

One other one, you know, there is a whole host and I will be happy to get you the results of these—this survey, but 70 percent of Americans said that regulations, they hurt the economy, 66 percent said they mostly hurt entrepreneurs and small businesses. Hurt consumers, 63 percent, mostly hurt American workers, 66 percent. You get the idea. The numbers are overwhelming in terms of how we are viewing—how the American public views this process.

When you look at the economics of regulation, the impact of regulatory costs on small businesses, the views of the public on the regulatory process really should push government officials to be transparent in all aspects of regulation, including how regulations are created, the scientific reasons for regulation, the true cost of regulations. And it matters—you know, it is—you don't want to have a situation where certain agencies or certain political points of view or certain political members are deciding who gets access and who doesn't.

So I think when you look at the Secret Science and Reform Act, I think everybody in Congress on both sides of the aisle should be able to support it.

Thank you.

[The prepared statement of Mr. Keating follows:]



**“The Regulatory Costs for Small Business and Our Economy,
and the Need for Regulatory Transparency”**

Testimony by
Raymond J. Keating
Chief Economist
Small Business & Entrepreneurship Council

On Behalf of the Center for Regulatory Solutions

February 11, 2014

Before the
Committee on Science, Space and Technology

Subcommittee on Environment

United States House of Representatives

The Honorable David Schweikert, Chairman
The Honorable Suzanne Bonamici, Ranking Member

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Protecting small business, promoting entrepreneurship

Chairman Schweikert, thank you for hosting this important hearing today on the need for making the science EPA uses to justify regulatory costs on businesses and the economy, including small enterprises and ultimately consumers, more open and accessible to the public. This will help in holding EPA more accountable to stakeholders of all kinds—most especially the workers who ultimately have to comply with new regulations. Those on both sides of the political aisle and the regulatory debate should support transparency of the underlying data, science and analysis used to justify government regulation. It's certainly an imperative for small businesses, given that regulatory costs disproportionately harm smaller firms.

The Small Business & Entrepreneurship Council (SBE Council) is pleased to submit this testimony on behalf of our Center for Regulatory Solutions.

My name is Raymond Keating, and I am the chief economist for SBE Council, as well as serving as an adjunct professor in the Townsend Business School at Dowling College where I teach a variety of courses in the MBA program; a weekly newspaper columnist for *Long Island Business News*; and author of several books, with the latest being *Unleashing Small Business Through IP: Protecting Intellectual Property, Driving Entrepreneurship*.

SBE Council is a **nonpartisan**, nonprofit advocacy, research and training organization dedicated to protecting **small business** and promoting entrepreneurship. With nearly 100,000 members and 250,000 small **business** activists nationwide, SBE Council is engaged at the local, state, federal and international levels where we collaborate with elected officials, policy experts and business leaders on initiatives and policies that enhance competitiveness and improve the environment for business start-up and growth. The Center for Regulatory Solutions is a project of SBE Council.

The Costs of Regulation

In 1986, President Ronald Reagan declared, "Government's view of the economy could be summed up in a few short phrases: If it moves, tax it. If it keeps moving, regulate it. And if it stops moving, subsidize it." President Reagan had a way with words – in this case, an ability to drive home an **economic** fact of life about the serious costs of various government actions, including regulation – in an amusing way.

The costs of regulations are real and significant facts of economic life about which small business are too often painfully aware. Economics 101 tells us what to expect from increased regulation – that is, **higher** costs for businesses and consumers, reduced market exchanges and expanded political control, resources allocated based on political dictates and influences (such as rent seeking) rather than via competition and consumer sovereignty, and therefore, diminished economic growth.

For example, economists John Dawson at Appalachian State University and John Seater at North Carolina State University recently looked at the impact of federal regulation on economic growth ("Federal Regulation and Aggregate Economic Growth," January 2013). Their findings were striking. They reported:

“Regulation’s overall effect on output’s growth rate is negative and substantial. Federal regulations added over the past fifty years have reduced real output growth by about two percentage points on average over the period 1949-2005. That reduction in the growth rate has led to an accumulated reduction in GDP of about \$38.8 trillion as of the end of 2011. That is, GDP at the end of 2011 would have been \$53.9 trillion instead of \$15.1 trillion if regulation had remained at its 1949 level.” The authors added: “Our results are qualitatively consistent with those obtained from studies using the various cross-country and panel data sets on regulation. Quantitatively, our estimated impact of regulation on aggregate output, large as it is, is similar to or lower than the micro-level impacts estimated in the cross-country and panel data studies. The cross-country and panel data are constructed very differently from our data, covering a subset of total regulations but over an array of countries. It thus seems that regulation has strong and robust negative effects on aggregate output.”

Another look at the state and costs of federal regulations was provided in the twentieth anniversary edition of “Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State,” published in 2013. The author, Clyde Wayne Crews Jr., reported, “For the first time in history, the estimated cost of regulation exceeds half the level of the federal budget itself.” It cost Americans an estimated \$1.806 trillion to comply with federal regulations in 2012. Combine federal spending with these estimated regulatory costs, and “the federal government’s share of the entire economy now reaches 34.4 percent.” That’s a serious drain and drag on the private sector.

How do recent regulatory costs compare to the past? According to Crews, the *Federal Register* serves as government’s “depository of all proposed and final federal rules and regulations,” and its number of pages has long served as a rough measure of the scope of federal regulation. Crews pointed out, “Three of the four all-time high counts have occurred during the Obama administration.”

The Obama years have been particularly troublesome in terms of “economically significant” rules, that is, those that impose an annual cost on the economy of at least \$100 million. As noted in the report, “when it comes to economically significant rules at the completed and active stage ... the current administration is in a class by itself when one looks at the year-end flow.” Economically significant rules have been higher in each year during the Obama administration versus each year during the Bush administration. In fact, the highest annual level under Obama was 24 percent higher than the peak level under Bush.

Crews also broke out regulations by departments of the federal government. He found that the departments of the Treasury, Commerce, the Interior, Agriculture, and Transportation accounted for 1,730 rules, or 42.6 percent of all rules in the agenda pipeline. The Environmental Protection Agency (EPA) came in sixth, and once the EPA’s 223 rules are factored in, those six departments tallied up to 1,953 rules, or 48 percent of all rules in the pipeline.

The Small Business Administration’s Office of Advocacy periodically estimates regulatory costs, obviously with an eye towards the burdens imposed on smaller businesses. In September

2010, the Office of Advocacy published an updated study estimating the costs of complying with federal regulations. The study – “The Impact of Regulatory Costs on Small Firms” by Nicole V. Crain and W. Mark Crain from Lafayette College – provided details regarding the burdens of federal regulatory costs. For example:

- The annual cost of federal regulations registered \$1.75 trillion in 2008.
- For firms with less 20 employees, the per-employee cost registered \$10,585, which was 42% higher than the \$7,454 per employee cost for firms with 20-499 employees, and 36% higher than the \$7,755 for firms with 500 or more employees.
- On the environmental front, per employee regulatory costs for firms with less than 20 employees came in at \$4,101, which topped the \$1,294 cost for firms with 20-499 employees by 217% and the \$883 cost for businesses with 500 or more workers by 364%.
- Small manufacturers get hit particularly hard. Per employee regulatory costs for manufacturers with fewer than 20 employees came in at \$28,316, which was 110% higher than the \$13,504 for manufacturers with 20-499 employees and 125% more than the \$12,586 burden on companies with 500 or more employees. Again, serious cost differentials came in the area of environmental regulation, where per employee costs for manufacturers with fewer than 20 employees came in at \$22,594, which topped the \$7,131 for firms with 20-499 employees by 217% and exceeded the \$4,865 for firms with 500 or more workers by 364%.

Of course, it needs to be pointed out that small and mid-size businesses – that is, those with less than 500 workers – are central to economic growth and job creation. As the SBA’s Office of Advocacy has summed up (“Frequently Asked Questions About Small Business,” September 2012), small businesses account for 46 percent of private-sector output, and 98 percent of firms exporting goods. As for jobs: “Small firms accounted for 64 percent of the net new jobs created between 1993 and 2011 (or 11.8 million of the 18.5 million net new jobs). Since the latest recession, from mid-2009 to 2011, small firms, led by the larger ones in the category (20-499 employees), accounted for 67 percent of the net new jobs.”

Given the formidable costs of regulation, including on small businesses, the need for the regulatory process to be transparent should be supported, again, by both sides of the political aisle, and by both sides of the regulatory debate.

The issue of transparency regarding the science being used to support regulation is not some esoteric academic or political point. It has very real world consequences in terms of costs imposed on small businesses, and the resulting fallout for economic growth and job creation.

Secret Process: Social Cost of Carbon

One of the most glaring cases of regulatory secrecy relates to President Obama’s climate agenda. In a secretive process, several agencies dubbed the “Interagency Working Group” established a highly speculative cost estimate called the “social cost of carbon” (SCC) to measure the benefits of reducing carbon emissions.

As described in a May 2013 document from the White House, “The SCC is an estimate of the monetized damages associated with an incremental increase in carbon emissions in a given year. It is intended to include (but is not limited to) changes in net agricultural productivity, human health, property damages from increased flood risk, and the value of ecosystem services due to climate change.”

From 2010 to 2013, the administration’s SCC estimates, according to various models, jumped markedly, with the four SCC estimates (priced in 2007 dollars per metric ton of CO₂ at various discount rates) for 2020 moving from \$7, \$26, \$42 and \$81 in the 2010 analysis to \$12, \$43, \$65, and \$129 in the latest assessment. That’s quite a leap higher in a short period of time.

In a September 2013 letter, a coalition of business groups pointed out, rightly, that the Administration’s SCC estimates “are the product of an opaque process, are fraught with uncertainties, and any pretensions to their supposed accuracy (and therefore usefulness in policy-making) are unsupportable.” To date, the Administration has not been forthcoming about who specifically participated in the process and whether the IWG adhered to federal guidelines in crafting the SCC estimate. The Administration’s stonewalling prompted two members of Congress to seek a Government Accountability Office investigation to uncover key information related to the IWG process. To be sure, this is not, as the President promised, “the most transparent Administration in history.”

It turns out that the IWG was secretive because they had something to hide, including the fact that models the group used to calculate the SCC estimate are effectively worthless. This is not just my opinion, but that of Professor Robert Pindyck of the Massachusetts Institute of Technology, an expert on these specific models. In a September 3, 2013, *Wall Street Journal* article, it was reported:

“Robert Pindyck, an economics professor at the Massachusetts Institute of Technology, slams the models in a coming paper to be published by the National Bureau of Economic Research, saying they use essentially arbitrary inputs and give a misplaced illusion of scientific certainty. Though his work has given ammunition to skeptics of global-warming science, Mr. Pindyck said his point is really about the difficulty of modeling possible catastrophic impacts of climate change. ‘We know there’s a social cost of carbon, and we know it’s above \$0,’ he said. ‘If anything, the cost of carbon could be higher’ than the administration’s models suggest.”

Pindyck’s point, again, is that this kind of modeling is effectively bogus. It offers nothing scientific – no matter which side of the debate you happen to be on.

This issue of the “social cost of carbon” is critical, given that EPA’s greenhouse gas regime will eventually cover the entire economy, covering a wide array of industries, including pulp and paper, cement, oil and gas, chemicals manufacturing, mining, and many more.

As is the case throughout the U.S. economy, industry after industry in these cases overwhelmingly is about small and midsize firms. For example, 76 percent of U.S. manufacturing employer firms had less than 20 workers in 2010 (latest Census Bureau data), and 98.6 percent had less than 500 workers. Or, consider that within the mining, quarry, and oil and gas extraction sector, 85 percent of employer firms had less than 20 workers, and 98.4 percent less than 500 employees.

When it comes to costly regulations being imposed based in part on faulty, speculative “social costs of carbon” models, small businesses will bear a heavy burden, thereby limiting investment, economic growth, job creation, and competitiveness in the global economy.

Hiding Science at the EPA

In August 2013, the House Science, Space, and Technology Committee Chairman Lamar Smith issued a subpoena to the EPA for the release of the science used as the basis for costly air regulations.

As noted in the accompanying release: “Over the past two years, the Committee has repeatedly requested the data the agency uses to justify virtually every Clean Air Act regulation proposed and finalized by the Obama administration. This was the first congressional subpoena the Science Committee has issued in 21 years.”

It was also reported: “The two data sets in question are used to justify major costly new air regulations. As one example, by its own estimates the EPA’s proposed limits on ozone will cost taxpayers \$90 billion per year, making it the most costly regulation the federal government has ever issued. Some of the data in question is up to 30-years-old.”

Getting the underlying data in question is critical to ensuring that EPA’s upcoming ozone rulemaking—not to mention the entire suite of ambient air quality standards EPA will establish in the coming years—is based on the most rigorous science, and that the public has an objective, accurate assessment of the costs and benefits of this rulemaking.

The U.S. has made enormous progress in cleaning the air over the last 40 years, so much so that we now are talking about reducing very small increments of pollution. Achieving those tiny reductions will no doubt be very costly—as EPA itself admitted when it released its cost analysis for ozone in 2010. The question is: will they be worth it? We won’t know that unless we have the scientific data in front of us, unless scientists from all over the country can attempt to replicate it and determine its validity. Without that, EPA is hiding the ball, and imposing costs without truly knowing what the benefits are. Workers at small firms have the right to know what they’re paying for and complying with. Hopefully, it won’t cost them their jobs.

The Incentives to Regulate

Regulation is economically dangerous because the costs are hidden from the eyes of the average person. People can see the bottom line on taxes, such as smaller take-home pay when income

taxes climb or increased costs at the cash register when sales taxes rise. But the costs of regulation, while just as real and significant as taxes, are not so clear.

Therefore, politicians like to take credit for various initiatives through regulation, while leaving it to business owners and managers to wrestle with the commensurate costs, including, for example, having to raise prices, reduce payroll, rein in or eliminate expansion plans, or even close up shop.

For good measure, keep in mind that both the Congress and the president not only have incentives to issue regulations, but they also have every incentive to pass off the actual rulemaking to unelected bureaucrats. This is a toxic recipe for rising regulatory burdens, reduced accountability, and yes, less transparency.

This incentive structure is another reason why there should be no questions, or secrecy, regarding the data and the science that supposedly justify regulations.

The Public View on Regulation

Interestingly, a poll released in January 2014 by the Small Business & Entrepreneurship Council's Center for Regulatory Solutions revealed notable concerns among American adults regarding government regulation. For example, regarding the process of regulation:

- 68% said that government regulations on business are “created by out-of-touch people who are trying to push a political agenda.”
- 72% said that government regulations are “created in a closed, **secretive process.**”
- 64% said that government regulations on business are “created in a way that does not consider their real-world impact.”
- 61% agreed that government regulations are “administered ineffectively **without rhyme or reason.**”

As for the effects of regulation, consider:

- 53% agreed that there are too many regulations on business, while 19% said there are not enough and 25% said about the right amount.
- 61% believe that government regulations on business are more likely to “harm the economy by interfering with the free market, preventing businesses from growing and hiring new employees, and increasing prices for consumers.”
- As for the overall effect of government regulations on business, it was found that 70% of Americans said that regulation “mostly hurt” the “American economy,” 67% said they mostly hurt “America’s economic competitiveness with the rest of the world,” 66% said they mostly hurt “entrepreneurs and small business,” 63% said they mostly hurt consumers, 64% said

regulation mostly hurt employers, 66% agreed they mostly hurt “American workers,” and 58% said “American companies’ ability to innovate” was mostly hurt by regulation.

These findings on the process and costs of regulation should further push government officials to be transparent in all aspects of regulation, including how regulations are created, the scientific basis for regulation, and the true costs of regulation.

The Need for Transparency and Soundness When Regulating

In President Obama’s Executive Order 13563 titled “Improving Regulation and Regulatory Review,” it was stated:

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.

That’s a sound declaration, and steps obviously need to be taken to shift away from the unfortunate realities of regulation, and closer to this statement.

Clearly, the “Secret Science Reform Act of 2014” would be a straightforward, common-sense reform. As the bill requires, EPA “shall not propose, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action” is “specifically identified” and “publically available in a manner that is sufficient for independent analysis and substantial reproduction of research results.”

That would be a valuable, simple reform measure that all in Congress and in the Obama Administration – based on the President’s own Executive Order – should agree on, and that the American public apparently would embrace given their views on regulatory process and costs. And I can assure you that the members of the Small Business & Entrepreneurship Council embrace this reform, as it would take the scientific information EPA regulators use and send it into the public realm, where it can be properly debated and analyzed. As EPA’s costly ozone rulemaking looms over our stagnant economy, it would be welcome indeed if EPA would be required to make public the all the data it intends to use. What do they have to hide? After all, wouldn’t EPA want to be absolutely certain that a potentially \$90 billion rulemaking is worth it? I know small businesses and their workers certainly would.

Thank you for this opportunity to address the Committee, and I will be glad to answer any questions.

Raymond J. Keating serves as chief economist with the Small Business & Entrepreneurship Council (SBE Council), a nonpartisan, nonprofit small-business advocacy group.

He writes, speaks and testifies on a wide range of issues affecting the entrepreneurial sector of the economy. In addition to policy papers and reports, he pens the weekly SBE Council Cybercolumn, Fact of the Week, Capital & Credit analysis, Technology & IP analysis, and Energy & Entrepreneurs analysis for SBE Council's website www.sbecouncil.org.

Keating also writes a weekly column for *Long Island Business News* and The Dolan Company. Previously, for more than 11 years, he wrote a column for *Newsday* on Long Island.

In addition, Keating is an adjunct professor/lecturer in the business school at Dowling College.

Keating has written eight books – *Unleashing Small Business Through IP: Protecting Intellectual Property*, *Driving Entrepreneurship* (2013), *An Advent for Religious Liberty: A Pastor Stephen Grant Novel* (2012), *Root of All Evil? A Pastor Stephen Grant Novel* (2012), *“Chuck” vs. the Business World: Business Tips on TV* (2011), *Warrior Monk: A Pastor Stephen Grant Novel* (2010), *U.S. by the Numbers: What's Left, Right, and Wrong with America* *State by State* (2000), *New York by the Numbers: State and City in Perpetual Crisis* (1997), and *D.C. by the Numbers: A State of Failure* (1995). He has contributed essays to four other books.

Keating has written hundreds of articles, with pieces published in such periodicals as *The Washington Post*, *The Wall Street Journal*, *The New York Times*, *Boston Globe*, *National Review*, *Investor's Business Daily*, *Chicago Tribune*, *The Washington Times*, *New York Post*, *Daily News*, and many more.

His areas of expertise include taxation; federal, state and city budget issues; monetary policy; regulation; energy policy; supply-side economics; the economics of sports stadiums and arenas; the U.S. economy; trade; and a host of other small-business issues.

Keating holds an MA in economics from New York University, an MBA in banking and finance from Hofstra University, and a BS in business administration and economics from St. Joseph's College.

Chairman SCHWEIKERT. Thank you, Mr. Keating.

One of the joys of getting to sit in this chair, apparently I get to do the first question.

Professor Graham, from what you have heard today and one of my premises is it goes far beyond just sort of us talking about the EPA so that the premise of sort of crowdsourcing of access to data and that the vetting of the confidence within—you know, the statistical confidence. Wouldn't most of the—well, from the regulatory community, the research community, even sort of the armchair statistician, does that really hurt environmental science or research or would it in some ways make it more robust?

Dr. GRAHAM. I certainly don't think it hurts it at all and there are lots of examples where it has helped with a more robust discussion.

I do want to add though and underscore I think a useful distinction that Dr. Silbergeld made between independent studies that draw their own data and whether they verify other studies versus just reanalysis of existing information, and I agree with her that the independent studies sometimes are much more powerful and important. You do need to have a lot of clarity and transparency about how the original study was designed and its protocol in order to do that properly. So a lot of the requirement that is in the bill is necessary to do good independent studies. But I also think reanalysis is oftentimes a very useful type of work that adds new insights. And my example of the automobile safety regulation is one of those.

Chairman SCHWEIKERT. Well, and almost to that premise—and maybe Dr. Cox would be appropriate for this, when looking at others' studies, the ability to take, you know, a study that may be a couple years old and take—you know, and stress it, see what is actually happening with the tails, sometimes bounce it against a more current study, you know, particularly in sort of a peer-reviewed world of—I—and, forgive me, but I don't know how much peer review is reading of the article and seeing if the general statistics work or actually sort of having the ability to look at the underlying data and bounce it against other studies that are around and say do I have a level of confidence? So there are two questions there. Tell me about how far into the raw data you think the peer-review world is going, particularly with government-funded studies, and how important it is to be able to constantly take studies and sort of bounce other models and other data against it.

Dr. COX. The current crisis in non-reproducibility of studies and in publication of results that turn out to be false is solidly grounded in the existing peer-review system. So when we look at papers like why most published research articles are wrong or if we look at last month's editorial on reproducibility in science, what is being referred to specifically is peer-reviewed studies. Typically, peer reviewers don't have the time or the opportunity to dig deeply into the original data. That is not the purpose of peer review. Peer review does add value by saying whether a paper makes sense, whether there are obvious methodological flaws. That is about as far as it usually goes. And again, the very severe problems with trustworthiness of published results and the excess of false

positives in the environmental and medical literature, which has been well documented, are based on peer review.

To your second question, having the opportunity to throw new models at old data I think is critical for making progress. For example, in this world of environmental health that we all care about today, the key question of do exposures cause health effects is one that requires methods that have not traditionally been used. It is a great opportunity but it requires access to data in order for the new methods and better methods to inform public policy.

Chairman SCHWEIKERT. Dr. Graham, just because this is a level of personal curiosity, I am a little bit of a taleb fan, sort of the concept of if it is in the tail, you don't dismiss it because the catastrophic event can't happen. Is making data more egalitarian, will that actually provide us the opportunity to realize there is something, whether it be environmental or in my view of the world, you know, all sorts—to actually be able to identify those risk profiles?

Dr. GRAHAM. It is a good question. The commentary this morning about the Harvard and American Cancer Society procedure where they designate legitimate researchers and say that their data would be made available to legitimate researchers, I just want to make sure that everybody realizes—I say this as a former Harvard faculty member—this is not open access. This is not public access. So some people who may have some very good ideas and could do very good analysis may not look on the face of it like they are legitimate to Harvard or legitimate to the American Cancer Society.

So, yes, it is very important that the principle of open access and public access provide everyone an opportunity to participate and they may find some results that are very unusual, that challenge conventional thinking, and they may never have been judged legitimate when they started that work so it is a very important advantage of true public access.

Chairman SCHWEIKERT. All right. And thank you, Mr. Graham. I know I am over time but I have two others I just wanted to touch. And I don't think I have ever sat on a hearing where, when you look at the CVs of all of you, to quote my little brother, you are all freaky smart. And, forgive me, is it Dr. Silverberg?

Ms. SILBERGELD. Silbergeld.

Chairman SCHWEIKERT. I actually got up very early this morning and actually read your "Evidence-based Toxicology" article, and I have got to compliment you. When a novice like myself could follow it, read it, and actually understand it, you are a terrific writer.

I did want—there was just one thing in your conclusions and I appreciate the concerns so now I sort of want to sort of make the concept sort of move forward sort of public data for public policy. In your first couple paragraphs of your conclusion you actually sort of talk about requiring a framework to accommodate data from numerous types and that that may be sort of like the direction where—I know you were speaking of toxicology research goes. Do you actually see this happening sort of in the toxicology world where more and more data is becoming more and more accessible and a variety of researchers are analyzing it and weighting it and stressing it?

Ms. SILBERGELD. Thank you. If I may first respond to your concept of crowdsourcing science, I am not sure that is such a great

idea and I think, with all due respect to my colleagues on this table, the record of the tobacco industry in—going beyond stressing data—I would say subjecting it to the Spanish Inquisition to twist it to say something that we now know it never said——

Chairman SCHWEIKERT. Well, but——

Ms. SILBERGELD. —is something that is disturbing.

Chairman SCHWEIKERT. But, Doctor, I appreciate that but crowdsourcing of the data is substantially a new phenomenon, not from 20 years ago, and the ability for me to have taken those data sets and said look what is happening—I am sorry. It is not *ceteris paribus*. You are talking two different time frames and two different technologies.

Ms. SILBERGELD. No.

Chairman SCHWEIKERT. Yes, you are.

Ms. SILBERGELD. With respect, sir, that is why I am worried about the notion newly introduced of crowdsourcing because we have experience——

Chairman SCHWEIKERT. Okay.

Ms. SILBERGELD. —of what has happened to access of data.

Chairman SCHWEIKERT. Okay.

Ms. SILBERGELD. That is my comment. With respect to your question, sir, I—and with respect to the comments about peer review, as a journal editor I will take those blows——

Chairman SCHWEIKERT. Well, that——

Ms. SILBERGELD. —and I understand them——

Chairman SCHWEIKERT. —actually wasn't my question.

Ms. SILBERGELD. Yeah.

Chairman SCHWEIKERT. My question was on your conclusion here where you talked about more accessibility to data. I think I am going to have to wait until the next round because I am now 3-1/2 minutes over time already. So let me turn to my Ranking Member. Maybe she can follow up where I was going.

Ms. BONAMICI. Thank you, Mr. Chairman.

And before I begin my questions, I—two brief points. First, I don't want the lack of absence of Members on my side to be indicative of a lack of interest in this issue. There are several hearings and markups happening simultaneously, so please don't consider this as a lack of interest in the topic.

Also, Mr. Chairman, we received and provided you with copies of letters from the American Lung Association, the American Thoracic Society, the Union of Concerned Scientists, the Center for Progressive Reform, and the Natural Resources Defense Council stating opposition to this bill, and I ask unanimous consent that they be submitted to the record.

Chairman SCHWEIKERT. Any objections? So ordered.

[The information appears in Appendix II]

Ms. BONAMICI. Thank you, Mr. Chairman.

Dr. Silbergeld, under current law, because of the need to ensure that protected information like health records remains confidential, there are likely to be data that will not and should not become entirely available to the public. So should the EPA be precluded or any agency for that matter—but for the purposes of this hearing, should the EPA be precluded from considering studies that include health information if the studies are significant to determining the

appropriate course of action? And if not, then how can we independently validate and verify such studies?

Ms. SILBERGELD. Thank you for the question. I think we have a model to go forward here. Which is really the model of evidence-based decision-making that first began in medicine, extended to healthcare, and now I count myself as one of the leaders in moving it into the field of toxicology in which we take the broadest possible look through the available—publicly available data and publications, including government reports, and attempt to synthesize those data using transparent and open processes of data access and evaluation. So I think we should always be committed to extending our view as wide as possible. Do we need to see raw data? I am not convinced that we do. I think in those instances where it has become of interest to do so, we have methods in place to accomplish that.

And perhaps in response to the Chairman's question—and I apologize for using up your valuable time, sir—in fact, journals are increasingly soliciting and accommodating the production of much more extensive data, for example, on statistical models and protocols through the use of appendices. This is a somewhat new process in publication in which my own journal and others now encourage authors to submit this type of information which is publicly accessible through linkages in the paper and in any repository that has that paper that amplifies the kinds of information I think some of my colleagues would find particularly interesting.

I also want to defend my reviewers by saying that they do a very exhaustive job of reviewing. And I agree with Dr. Cox that in fact I think some of the lack of reproducibility has come about through some failures in peer review.

Ms. BONAMICI. Thank you. And I am going to follow up on that because you state that requiring—in your article you state that requiring the disclosure of the raw data from every study that the EPA uses to support its regulatory assessment could actually preclude the EPA from using relevant research if the journal authors don't submit the raw data to the EPA. So could you talk a little bit—I know you touched on that, but could you talk about what would be the impact to the EPA of limiting the scope of those studies if they cannot consider those as part of their scientific review?

Ms. SILBERGELD. Well, for example, unless you can actually resolve the problems of protection of human subjects who appear in studies, this would then eliminate a great deal of the epidemiologic and clinical literature that could be available. And I know that we worry about this because in fact it was the tobacco industry who tried to bust open some repositories of confidential data that would have permitted identification of human subjects, and the rationale given by the industry was they wanted to interview some of those subjects and see if they gave the same answers that were reported in questionnaires used in studies. So this is a very disturbing aspect to the certainly of protection of people's autonomy, confidentiality, and the process of scientific research.

Ms. BONAMICI. Thank you. And I want—time for one question if I may, Mr. Chairman. I understand that the broad scientific community is engaged with the Office of Science and Technology Policy, or OSTP, and what representatives from academia, particularly

the American Association of Universities and the Association of Public and Land-Grant Universities, is calling a thoughtful balanced process to increase public access to the results of federally funded research. And that is a type of government-wide approach to improving public access to federally funded R&D that is preferable to the legislation that specifically targets the EPA, especially in light of the fact the EPA generally relies on studies that are not funded by the Agency but other agencies like NSF and NIH.

So could you please comment on the need to take a government-wide approach to improving public access? And if you could compare the bill we are considering today with OSTP approach and which would strike a better balance between the need for transparency in the regulatory process, balancing the rights of private citizens, and the need for the EPA to use the best science available.

Ms. SILBERGELD. Thank you. I think a comprehensive and consistent approach is certainly to be advocated. The fact, for example, is that a great deal of the evidence that the EPA would find and has found useful was in fact funded by other agencies such as the National Institutes of Health, which has set up an effective and functioning program, speaks to the need for a consistent policy.

But I would like to restate my very great concern that I have a very great interest as a scientist to be able to see industry data and I would like to see industry behind the proactive stance and record of the American Chemical Council and others in terms of opening the doors on their data.

Ms. BONAMICI. Thank you. And my time is expired but I would be interested in hearing from the other witnesses about whether they would support the disclosure of the industry data as well.

Thank you, Mr. Chairman, and I yield back.

Chairman SCHWEIKERT. Thank you, Ranking Member.

And, Mr. Bridenstine.

Mr. BRIDENSTINE. Thank you, Mr. Chairman. And I would like to say I am proud to support your bill, Mr. Schweikert, H.R. 4012, the Secret Science Reform Act.

I would like to bring up a slide if it is possible on the screen.

[Slide]

President Obama's War on the Poor

"So if somebody wants to build a coal-powered plant, they can. It's just that it will bankrupt them."

--- Interview with *San Francisco Chronicle*, November 7, 2008

Mr. BRIDENSTINE. There it is. This is a quote from the President of the United States when he was campaigning. "So if somebody wants to build a coal-fired power plant, they can. It is just that it will bankrupt them." That wasn't based on any kind of scientific data. That is a quote of the President of the United States. It is a campaign promise. He interviewed with the San Francisco Chronicle November 7, 2008. This is a promise that he has followed through with. There are two coal-fired power plants in Oklahoma that are being shut down and the rates on my constituents are going up. The low estimate is 20 percent, some say as high as 40 or 50 percent. Who does that affect? It affects the poor the most. This is President Obama's war on the poor. They spend the biggest part of their budgets on utilities, and so they are the ones being affected the worst.

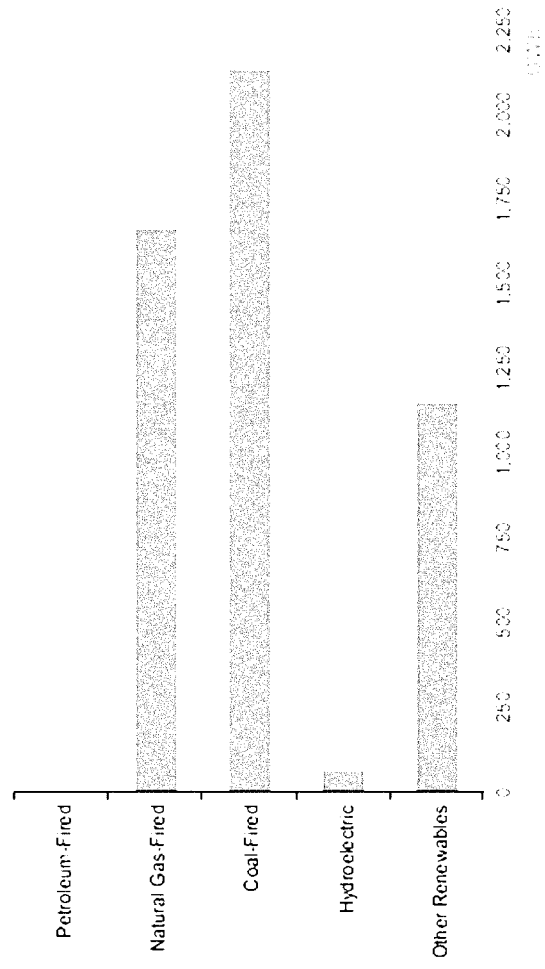
And here is the thing: The transparency of the data that they are using to create the rules and regulations that are shuttering these coal-fired power plants are not transparent. Transparency and verifiability are fundamental principles of any scientific endeavor and should certainly be required in those supported by taxpayers. The EPA continues to violate these principles by preventing independent researchers from examining the data and replicating the studies which "support the Agency's rulemaking." My constituents in Oklahoma's 1st District are paying the price, quite literally paying the price, for the EPA's politicizing the regulatory process and its secret science charade.

Mr. Chairman, I would like to spend a minute explaining how the EPA's secret science and groundless regulations will continue to needlessly harm my constituents and all Oklahomans. According to the Energy Information Administration (EIA), Oklahoma produces four percent of the country's crude oil and eight percent of its marketed natural gas. Oklahoma is leading the fracking revolution to provide cheaper energy to all Americans. Oklahoma is the 5th-largest shale gas-producing State, and 17 of the top 100 natural gas fields are located in Oklahoma. Mr. Chairman, the EPA's newest regulations on fossil fuel production and refining based on this secret science charade threaten my constituents with higher utility bills, less reliable electricity, and fewer jobs in Oklahoma's booming oil and gas industry.

Can we bring up the second slide there?

[Slide]

Oklahoma Net Electricity Generation by Source, Oct. 2013



Mr. BRIDENSTINE. The latest—can we bring up the slide 2?

The latest EIA analysis shows that coal- and natural gas-fired power plants provide about 90 percent, 90 percent of Oklahoma's electricity generation. My district has two petroleum refineries in Tulsa and four natural gas power plants, one in Coweta, one in Tulsa, and two in Jenks. Thanks for bringing up the next slide there.

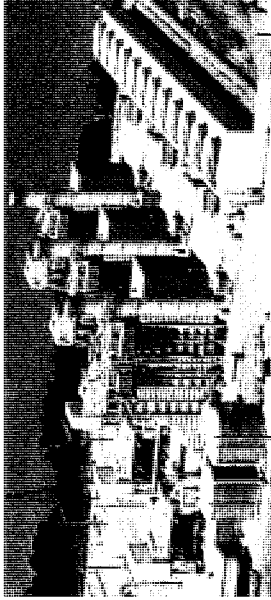
[Slide]

First District of Oklahoma Refineries and Power Plants

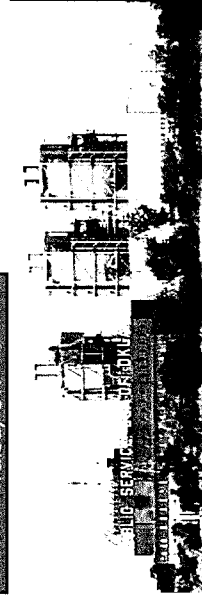
Tulsa Petroleum Refineries
Tulsa, OK



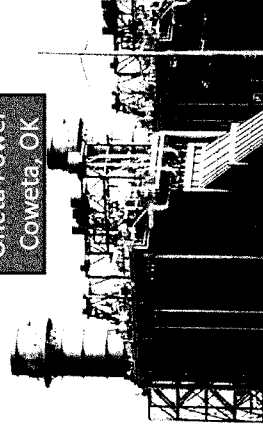
Green Country Energy
Jenks, OK



PSO Tulsa Power Station
Tulsa, OK

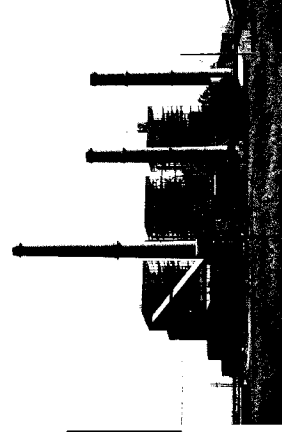


Oneta Power
Coweta, OK



Mr. BRIDENSTINE. We are talking about 155,000 barrels of refining capacity per day and 3,200 megawatts of production capacity. Can we bring up the next slide?
[Slide]

Oklahoma's Coal-Fired Power Plants



OG&E & Georgia-Pacific Plants
Muskogee, OK

Grand River Dam Authority
Chouteau, OK



PSO Northeastern
Gologah, OK



Mr. BRIDENSTINE. My 1st District constituents also use electricity produced by four coal-fired power plants, just—one just outside of my district in Oolagah, Muskogee, and Chouteau. That is another 4,300 megawatts of production that the EPA wants to shut down based on scientific data and models that it will not publicly release.

Can I get the next slide, please?

[Slide]

EPA's Anti-Coal Regulatory Agenda

- CO₂ standards – new units, existing units
- Best Available Control Technology for GHG
- Mercury and Air Toxics Standards (MATS)
- Cross State Air Pollution Rule (CSAPR)
- PM_{2.5} standard (SO₂ & NOx)
- 316(b) rule (cooling water intakes)
- Coal combustion residuals (waste designation)
- Effluent limitation guidelines (surface waters)
- Regional haze (SO₂, NOx, PM 2.5)
- Ozone standard revision (NOx emissions)

Mr. BRIDENSTINE. Mr. Chairman, the EPA has put a bull's-eye on coal-fired power plants, a bull's-eye. This is the regulatory agenda here of the EPA. And once the EPA kills coal, let me be clear. They will come for natural gas. It is just a matter of time and we are already seeing that in the Obama Administration's war on fracking.

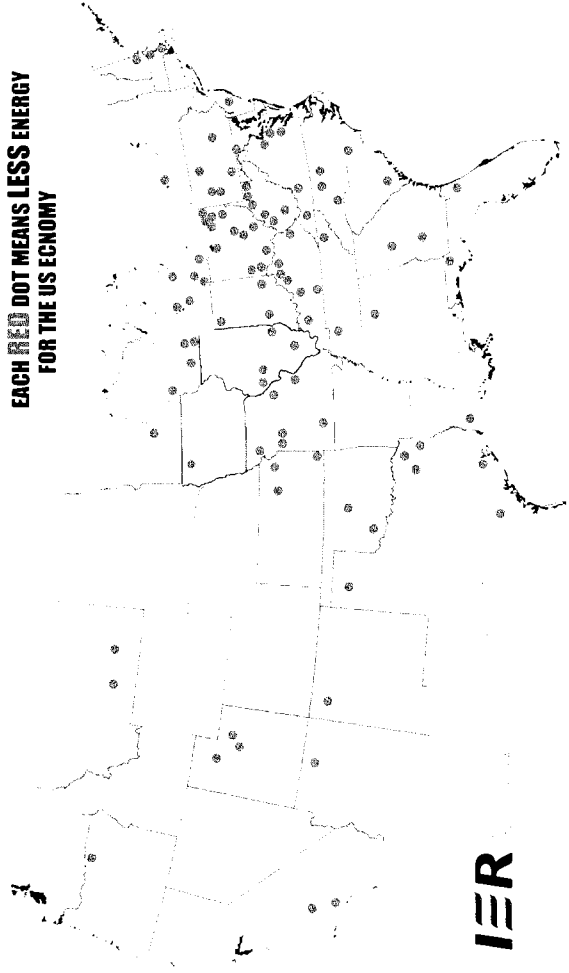
Can we bring up the next slide, please?

[Slide]

POWER PLANTS TO BE CLOSED BY EPA REGULATION

Total MW taken OFFLINE: 33,238

THAT'S NEARLY **10%** OF OUR COAL ENERGY CAPACITY - GONE
EACH **RED** DOT MEANS **LESS ENERGY**
FOR THE US ECONOMY



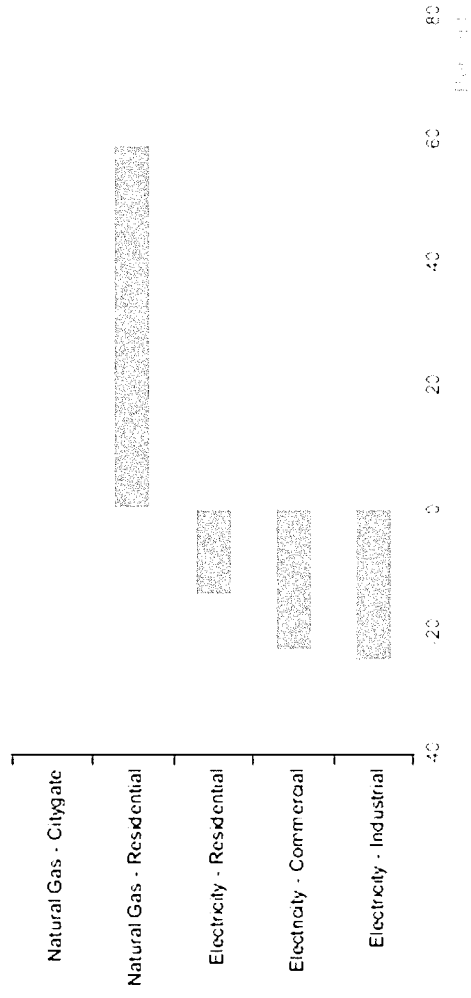
IER

Mr. BRIDENSTINE. In 2012, the Institute for Energy Research estimated that the EPA's MACT and Cross State Air Pollution Rules will take 33 gigawatts of national electricity generation off-line, 33 gigawatts, over twice the EPA's modeling prediction. That is ten percent of our country's coal capacity and also includes closing two natural gas-fired plants in Oklahoma, natural gas-fired plants in Oklahoma, one in Anadarko and one in Oklahoma City. The end result of the EPA's regulatory horror show is higher prices for consumers and industry, less economic growth, and fewer jobs.

Next slide, please.

[Slide]

Oklahoma Price Differences from U.S. Average, Most Recent Monthly



cia

Mr. BRIDENSTINE. According to EIA, Oklahomans pay about 20 percent less for residential, commercial, and industrial electricity than the U.S. average. Killing coal and eventually natural gas production in my State will saddle my constituents already struggling in this sluggish Obama economy with higher utility prices on par with those experienced in heavily regulated States such as California.

Next slide.

[Slide]

Harlan County, KY, Coal Mining Jobs Fell by 48% from 2011 through June, 2013



Paul Swanson, a coal miner laid off since Thanksgiving 2012, waits at the Kentucky Career Center in Harlan in October, 2013. Source/credit: Wall Street Journal, 11-26-13

Mr. BRIDENSTINE. Kentucky has already seen massive layoffs in the coal industry. When EPA uses secret science to justify new regulations, everyone is worse off except for EPA bureaucrats, as well as extreme environmentalists. Let me be clear. The EPA is now saying they are going to come after our woodstoves. Of course, a friend of mine, Thomas Massie from Kentucky, has gotten assurances from the EPA that if you like your woodstove, you can keep it.

Let me ask one question for each of our panelists. Do any of you disagree with the principle that in the case of taxpayer-funded research or studies, the public should have access to the underlying data? Does anybody disagree with that?

Yes, ma'am?

Ms. SILBERGELD. As stated in my testimony for the reasons given, I disagree with that, respectfully.

Mr. BRIDENSTINE. Noted. I yield back.

Chairman SCHWEIKERT. Mr. Smith, Chairman of the full Committee.

Chairman SMITH. Thank you, Mr. Chairman.

Mr. Keating, let me direct my first question to you, and I appreciate the poll that you mentioned earlier. I had not seen those results and they are very, very telling. And let me just highlight a couple of the results that you mentioned: 68 percent said that the government regulations on business are created by out-of-touch people who are trying to push a political agenda; 72 percent said that the government regulations are created in a closed, secretive process; 70 percent of Americans said the regulation mostly hurt the American economy. Those first two poll results that I mentioned and that you cited as well go to the heart of why we need the legislation at hand. And I really don't have a question for you other than to thank you for your testimony. If you want to add anything to your comments about why the legislation will have a positive effect, you are welcome to.

Mr. KEATING. Well, no, and there is a reason why I wanted to bring that here. I mean you talk about people being smart. These folks to my right here are far smarter than I am, but I want to bring the small business perspective and this survey that we had. And it is—you know, when we talk about the egalitarian access to data and the politicization of this process, those are very real things that are having, as the Vice Chair pointed out, very real effects on our economy in terms of jobs, small businesses, economic growth, all the way down the line.

So I am a Madisonian on this. I love checks and balances. And the more checks and balances that we have, the more people we have looking at this, the more scientists, the more economists that we have looking at this, the better it is going to be for everybody because the ultimate point is not to politicize this. It is to get sound public policies. That is the bottom line.

Chairman SMITH. Thank you, Mr. Keating.

Dr. Cox, as you know, some of the data that the EPA is relying upon to make rules and regulations is up to 30 years old. What are the disadvantages of using data that old when it comes to making decisions?

Dr. COX. There are trends and changes in the statistics of public health. Old patterns are not predictive necessarily of current events. More to the point, what regulators want to do is to intervene in the world as it is now to change it and make it better. To do that they often need to understand how the world works now with the current mix of pollutants, with the current configuration of industry. Staring hard into the rearview mirror does not necessarily provide that information. So I think the problem with old data is in part that it is old.

The other thing that I will note is that basically regulations on results that depend on data that are not currently available does indeed allow the Agency to use the best-available information but it also allows Agency to use the worst-available information. Both are part of the published record. Without current access to current data, it is extremely difficult to distinguish between the best and the worst results in the past literature. So rather than looking at dead results and dead literature, I think it is important to keep the data alive and to allow current questions to be informed by current analyses of current data.

Chairman SMITH. Okay. Thank you, Dr. Cox.

And, Dr. Graham, a two-part question, I guess. One, what is the advantage of making this data publicly available, if you can go into some detail; and secondly, is it really difficult to make this data available to the various scientific researchers?

Dr. GRAHAM. I don't think it is difficult. It is already done in most fields of science. The environmental health field is different because of its extensive reliance on some of the patient records we have been talking about, and therefore, there is going to be a meeting next month at the National Academy of Sciences where they discuss not whether these data should be released and shared but how to do so in a way that protects the privacy and confidentiality of those participants. And I have already encouraged the Committee staff to attend and learn from that discussion. And I think what you will find is most of the scientific community with the exception of the mental health field is already on board for this agenda. And so we do have a ways to go persuading the environmental health research community to be involved with the open access issue.

Two other points just to respond to previous questions, this question of industry data, the way I read the Secret Science Reform Act, it applies to industry data. This legislation requires industry data to meet the same standards as academic data or other forms of data. The only thing I can think of that people were referring to is confidential business information, which would be held in the exception that is in the draft legislation. But I can tell you from my experience at OMB, 90, 95 percent of the industry information that they want to bring in is not covered by confidential business information.

Chairman SMITH. Okay.

Dr. GRAHAM. So this bill is going to cover industry data, as it should. Okay. Second point is should we have a government-wide approach, wait for all the agencies to agree that we should do open access or shall we do something that is focused on environmental health research? As I have mentioned, we already have open access

in most fields of science already. You need a targeted approach that goes right at the domain of science where this problem exists and you need a solution obviously to the patient record issue to assure confidentiality. Thank you very much.

Chairman SMITH. Thank you, Dr. Graham. It is very helpful. I yield back.

Chairman SCHWEIKERT. Thank you, Mr. Chairman.

Ms. Edwards.

Ms. EDWARDS. Thank you very much, Mr. Chairman, and I apologize for the shuffling, juggling a little markup in another Committee this morning.

Dr. Silbergeld, as you know, it has been important to protect personal information of individuals participating in epidemiological studies and that there is a strict code of ethics among researchers as it relates to human subjects. As I understand it, researchers such as yourself are working on ways to disclose data from human studies so that individuals are protected but that others can use the data. However, in one of your articles you indicate that there are studies where the removal of all identifying data negates the scientific value of the data set. Can you elaborate on this statement in instances where the identifying data are necessary to the science? And also, can you discuss the importance of protecting the privacy of study participants and concerns that may arise if the potential study participants fear that their information will be exposed to the general public?

Ms. SILBERGELD. Thank you for that question. The clearest example and of greatest relevance to the subject of this Committee's hearing has to do with studies in which we are interested in the location of the subjects. And we have very sophisticated methods of determining this through spatial statistics, the use of GPS, and other data. That data—those data have to be absolutely protected because if those data become available, people can pretty much identify who participates in the studies. And I have conducted several studies in which we collected those data. That information has to be completely de-identified, which then of course means that no one else can exactly take those data and carry out the same analyses.

I just want to reiterate that that to me as a scientist reanalyzing data is an uninteresting approach to science and unlikely to advance our confidence in the results of a specific study. What advances my confidence and should advance the confidence of everyone in this room in the results from one study is really what Dr. Cox alluded to, is whether or not the study can be replicated independently, not whether obtaining the data from the first study can be reanalyzed. That is relatively, frankly, trivial.

And in fact the data that are now being called upon by journals and the NIH will allow one to determine whether protocols are appropriate and statistical models were appropriately selected in studies designed to meet the requirements of hypothesis testing. I also agree that there should be adequate funding given to public and private sector entities so that we can have the updated scientific findings that we all agree are important to us. Thank you.

Ms. EDWARDS. But would you say that there are instances where the identifying data set—that those are very limited instances of

research versus other kinds of research where you can have tons of data that it would be—you know, where it would be important to keep all of the data set available so that you could—I mean perhaps there could be an exclusion or some kind of a waiver or something that isn't the rule for more specialized identifying data sets where people's personal information is identifiable?

Ms. SILBERGELD. I would have to say from my experience and as someone who routinely goes through the rigors of obtaining approval from our Institutional Review Board, I cannot see that I have an ethical—I cannot ethically accept revealing information that would allow personal identification.

I think that the most sophisticated approach to answering your questions and these difficult issues in addition to what Dr. Graham alluded to is really what is going on worldwide, probably first in the European Union because they are confronting it first, but we are looking at it now and that is looking at data from clinical trials. How do we get those data out there to restore the faith that has been pretty badly damaged by drug approval processes around the world and inadequate clinical trials but yet protect the identification of the persons who participate? And I think that is going to be a path forward that will be very informative for all of us.

Ms. EDWARDS. Thank you. And I just have one question as my time is set to expire. Can you explain or describe rather what happens when, as Dr. Graham has said, the scientific culture at EPA is fragile and still in an early stage of development and that the political, legal, and engineering cultures are stronger and more certain than the culture of science and economics? You are the only scientist on this panel and someone who has worked on several expert groups convened by EPA. Do you want to comment on that position?

Ms. SILBERGELD. Thank you. I would like to defend the reputation and international standing of the EPA's scientific staff. They are widely recognized as among the best in the world. I even share the honor of a MacArthur Fellowship with a former EPA scientist. And while I am trained in engineering and I will accept his compliment, I think that the biological, ecological, and human health science at the EPA is extraordinary.

Ms. EDWARDS. Great. Thank you very much.

Thanks, Mr. Chairman.

Chairman SCHWEIKERT. Thank you, Ms. Edwards.

Dr. Broun.

Mr. BROUN. Mr. Chairman, before I start my questioning, I would like to take a point of personal privilege and just say that I am a physician; I am a scientist and we have seen throughout my medical career where there are reports and medical data that are not reproducible and where we have seen researchers promote an agenda and absolutely it is critical for us to have an open access to data so that we can reevaluate existing data of any study, as well as to reevaluate the findings by doing other studies that are likewise trying to study these same issues.

Without having open access of data, it is absolutely impossible for a practicing physician such as myself to make a valid decision on drug use or whatever I am doing as a doctor to try to take care of my patient. So open access to all data is absolutely critical. And

also, in medical research we have avenues of protecting that personal identifiable information and it is absolutely critical that we do so.

So thank you, Mr. Chairman, for giving me access to a few minutes to vent here a little bit. And I appreciate your bringing this bill forward because I think it is absolutely critical.

And we have seen in Georgia, just like Mr. Bridenstine is talking about in Oklahoma, we have seen the EPA bring forth regulations as closing down 15 power plants in the State of Georgia. And we cannot get the data that they have brought forward to really evaluate why they are making the regulatory burden so heavy. And it is going to hurt poor people. This EPA has an agenda that is hurting poor people and it is hurting senior citizens on a limited income. And having open access to the data is absolutely critical for us to be able to evaluate that.

Now, having said that, Dr. Graham, in your view—I hope you will restore some time for me, Mr. Chairman. And, Dr. Graham, in your view does the Freedom of Information Act make this Secret Science Reform Act unnecessary?

Dr. GRAHAM. No, because oftentimes the government doesn't have the possession of the data that is sought.

Mr. BROUN. Well, I agree with that. Dr. Graham, you mentioned that the EPA chemical assessments under IRIS program is an example of the nonregulatory EPA determinations that have significant impacts and should be subject to transparency requirements. The IRIS program has been criticized by the National Academy of Sciences and others. Do you believe greater data access would improve the program?

Dr. GRAHAM. Yes.

Mr. BROUN. Do you think the IRIS program could comply with the provisions of this bill, the Secret Science Reform Act?

Dr. GRAHAM. Yes.

Mr. BROUN. Dr. Graham, the office you previously oversaw at OMB, the Office of Management and Budget, produces a report of cost and benefits of regulations across the federal government. According to the most recent draft of this report to Congress, the vast majority of the benefits for all regulations across the entire federal government, as high as 80 percent, are attributed to EPA Clean Air Act regulations and specifically reduced levels of fine particular matter. In your testimony you noted key uncertainties in EPA's science on this question. Do you find these numbers credible?

Dr. GRAHAM. They have uncertainties, particularly given that the data can only be given to "legitimate researchers." And the people who were sponsoring all this research get to decide who the legitimate researchers are.

Mr. BROUN. And it is just up to them. So it is secret about them deciding who—

Dr. GRAHAM. It reminds me a little bit of the NFL concussion sort of debate we are having right now where the establishment community was saying there is no connection, there is no connection, there is no connection and then sort of the people who were trying to bring other kinds of science involved. If you let the established community have complete control over who the legitimate re-

searchers are, you are not going to get unexpected and new insights.

Mr. BROWN. Mr. Keating, you mentioned forthcoming national EPA regulations on ozone, which could cost \$90 billion per year. What kind of impact will this have on small businesses?

Mr. KEATING. Well, there is an assortment of impacts, first, the ones that you alluded to in terms of—think of a small business owner, small business as a consumer of electricity, power, so on and so on. So you are going to hit on that end in terms of the increased cost. But then as I mentioned in my testimony, all of these industries—and I love telling people this when I go out and speak to the public on all those issues. You know, if you look at the energy industry, pick the pharmaceutical industry, all the ones that people think of as big oil and big pharma and big this and big that. When you actually dig into the numbers, the population is overwhelmingly small firms, less than 20 employees depending on the industry we are talking about, 70, 80 percent. So from a small business perspective, you are getting hit on both sides. You are getting hit as a consumer and you are getting hit as being part of the industry, bottom line.

Mr. BROWN. Mr. Chairman, if I could, I just have another question for Mr. Keating to follow up on that.

This President said that his energy policies will “necessarily skyrocket the cost of energy.” This is what we are talking about as increasing the cost on small businesses. Who gets hurt most there? I believe it is poor people and senior citizens on limited income. Would you agree with that, Mr. Keating?

Mr. KEATING. I would agree with that but I certainly wouldn’t limit it there. When you are talking about an economy that is struggling to create jobs for as long as we have been struggling, who are the job creators? You know, again, when you look at the numbers, small- and medium-sized firms are creating roughly 2/3 of the new jobs. There is a reason why we are suffering these days because—well, I know it could be a long list of things but I think they are all—they all go back to policy. And we look at regulatory issues, it creates an enormous amount of uncertainty for small businesses and it imposes an enormous amount of costs. Those are—you know, it is—again, the consumers—it is the small businesses themselves but it goes well beyond that in terms of people that are just looking to get a job and get back into the labor force.

Mr. BROWN. Thank you, Mr. Keating.

Mr. Chairman, I thank you for your indulgence. I am just very concerned about the attack upon energy, particularly coal-powered energy and fossil fuel energy that this Administration is utilizing the EPA to promote that attack, and it hurts poor people and senior citizens I think the most but it also hurts job creators and hurts our economy. Thank you. I yield back.

Chairman SCHWEIKERT. Thank you, Dr. Broun.

Mr. Weber.

Mr. WEBER. Gosh, I was going to let Dr. Broun keep going. I wasn’t sure of my questions yet. I am just kidding.

Chairman SCHWEIKERT. All right. Thank you, Mr. Weber.

Mr. WEBER. Next witness—

Mr. BROWN. I tried to take your time.

Mr. WEBER. Yeah. Yeah.

I guess this is a question for all the panelists on the risk data, this data that is collected that we are discussing here today. And I will start with you, Dr. Graham. That is—by the EPA, for example, that is a public agency, right?

Dr. GRAHAM. Yes.

Mr. WEBER. Government-funded public agency, we would all agree with that?

Dr. GRAHAM. Yes.

Mr. WEBER. So I guess we would have to agree—anybody that disagrees with that? I guess we would have to agree that the money used to procure that data was public money. No?

Dr. GRAHAM. Well, the—

Mr. WEBER. Dr. Silbergeld, you are saying no.

Dr. GRAHAM. It is a mixture. Some of the studies have a mixture of public and private money.

Mr. WEBER. All right. Do we question the motives of those who provide that private money? We seem to be questioning the motives of those who testify.

Dr. GRAHAM. At this hearing you are in good shape unless you are the tobacco industry.

Mr. WEBER. Well, that is what I am saying. Personally, I think they are blowing smoke but we seem to be questioning people who are involved in this—I am an air-conditioning contractor and—from the State of Texas and we want somebody on that licensing board that understands the industry or somehow is involved. And I understand tobacco was a big lawsuit.

The aim of science is to get to the truth and, Dr. Silbergeld, I was reading your personal statement here where you said, “there is an urgent and important need to adopt an evidence-based approach to improve decision-making and increase public confidence in policy-making and enhancing the scientific basis of toxicology as well as its utility for other domains, including drug regulation,” on and on and on. And then you continue. You say, “through this process I think it is time—it is now appropriate to draw together a workshop of stakeholders.” Well, I would submit that we want people from industry, the energy industry, the coal industry, and we want the data to be accessible so that if—our aim is for the American public’s health and its safety and we want—I mean is it not true that scientists want to get to the truth? Is that a truism? Or is it what Mark Twain said? All scientists are only sure of one thing and that is that every other scientist before them was wrong.

Ms. SILBERGELD. Well, actually, Mark Twain does express a certain tenet in science, which is what we call the falsifiability principle advocated by philosophers, which is that we start by doubting our own hypotheses.

Mr. WEBER. Okay. Well, yeah. Well, that is right. And so I just want to point out that we want those industry ties and we want people to be able to do that. I just find it appalling that we seem to have a disagreement over people in industry have a legitimate reason for getting involved. We question their motive in so many cases. And I think that we have the underlying premise—and you tell me if I am wrong—that somehow government employees are to be trusted more. The EPA, Science Advisory Policy Committee,

whatever, are to be trusted more than those who have a vested interest in the very communities that they live in. And I want us to be open and honest.

And I am going to be supporting your bill, Mr. Chairman, obviously, and I want us to be able to get the open and reviewable science and the methodology that was used. We are dealing on another issue on flood on FEMA where we are questioning their data. But I think that it would be a good thing for all scientists to be able to review the data or am I missing something here? Mr. Keating, I will start with you.

Mr. KEATING. I think you are spot on. And what is interesting about this, this is where public choice economists can help out a little bit here because they are the ones that point out what the incentives are in government, right? What are the political incentives? And free-market people, you know, we still have a certain skepticism, which I like, regarding what government does. So what you want to do when you are talking about science is clear that up as much as you can, dispel the idea that this is all politics, it is all driven by politics—

Mr. WEBER. And I apologize. I am running out of time. If I may go over—

Mr. KEATING. Yes.

Mr. WEBER. —to the good doctor next to you here. Same question. I think it is a good thing if most all of the studies were up for review by all scientists involved, don't you agree?

Ms. SILBERGELD. I think we have that process in place now, sir. And actually, if I may, in response—I am sorry Dr. Broun is not here because in fact his profession has driven what I think to be a model, which is the evidence-based approach. And physicians don't actually usually consult the underlying data. They look at systematic reviews—

Mr. WEBER. And, I am sorry. I need to move on. Dr. Cox?

Dr. COX. I think it is an excellent idea and I don't think that our current systems go far enough in the public interest.

Mr. WEBER. And, Dr. Graham, I think—

Dr. GRAHAM. I agree.

Mr. WEBER. Okay. Well, we want to be very—I know—I believe that all of our colleagues here want to be good stewards of the American tax dollars or taxpayers' money, and so the fact that we want to call in to question some of these policies by the EPA because they are killing jobs; it is just as pure and simple as you can make it. And if the scientific data is not absolutely concrete and 100 percent certain, then I think rather than have a war on coal, rather than have a war on fossil fuels—and I was on the Environmental Reg Committee in the Texas Legislature, and Texas does a good job of cleaning up their air. Now, there are federal government employees would like to think that they have to come in and riot herd on Texas to use an old Texas colloquialism. But leave it to the States for the most part because they do want a clean backyard.

And, Mr. Chairman, I have gone on way too long and I will stop. Thank you very much.

Chairman SCHWEIKERT. Thank you, Mr. Weber.

Ms. Bonamici, do you ever feel that we are just surrounded by Texans on this Committee?

Ms. BONAMICI. Yes, indeed, Mr. Chairman.

Chairman SCHWEIKERT. Would you like to do a closing statement or share some thoughts?

Ms. BONAMICI. Thank you very much, Mr. Chairman. I appreciate the opportunity. And thank you for your courtesy in allowing me to do this. But thank you to all the witnesses for being here today.

Mr. Chairman, I know we share a common goal of transparency and I also—but the issue of course is how do we accomplish that? And I also know that we all want the EPA to be able to use the best science available and I look forward to further discussions about that.

I also want to reiterate the need to hear from the EPA about this proposed legislation to get their input on how this would affect them, their work, their workload, and just to get a sense from them on the record and again working hopefully with the Subcommittee on Science and Technology. So I look forward to—the Subcommittee on Technology and Innovation. I look forward to working with you on this important issue, and as I said, we share the common goal of transparency. Let's figure out if there is a way we can get there. Thank you.

Chairman SCHWEIKERT. Thank you, Ms. Bonamici.

And this was one of those I have a particular personal interest in, so forgive me if sometimes—and I am hoping I get input from everyone, particularly those agencies that would be affected.

There is a running joke in my family, what are the two times in life you think you know everything? When you are 14 years old and the day after you get elected to Congress. It really is actually funny. And my concern is, you know, in part of this discussion, should data that is making regulatory policy, how egalitarian, how much should it be? And, you know, we all have this certain sort of folklore, experience in our lives. When I was a freshman in my statistics class, my professor at that time, she talked about how she had done all this modeling on what—you know, for a couple drug companies on what the different products for ulcers would be, but a couple years later she found out that the ulcers she had were actually caused by bacteria in the lining. So all this study over here on what was the best drug, it turns out they were looking at the wrong thing. They had it wrong.

How often does that happen where the data sets, our current data belief, our current policy we believe today will be dramatically different a decade ago? It was only 10, 12 years ago if you and I sat in this room, we would have been hearing speakers, Members talking about Peak Oil, you know, the next incremental barrel of fossil fuels would be less. We screwed up somewhere the modeling on the understanding of technological curve, where we were at. We got it wrong but yet our tax policy, our environmental policy, our military policy was based on that data. And I am—so part of my embracing of the idea of lots of inputs is I am hoping somewhere there is the brilliance that helps us do what is best, and what is best for our country sometimes may have my ideological leaning and sometimes it might not, but at least it will be fact-based.

So with that, I want to thank the witnesses here and I am very sincere. Having read all your CVs, you are all very, very unique individuals and very bright.

The Members of the Committee will have—if they have additional questions for you, and I am almost sure there will be some coming towards you, we will ask you to respond in writing. The record will remain open for two weeks for additional comments and written questions from Members. And the witnesses are excused. Thank you for giving us some of your valuable time.

[Whereupon, at 11:38 a.m., the Subcommittee was adjourned.]

Appendix I

ANSWERS TO POST-HEARING QUESTIONS

ANSWERS TO POST-HEARING QUESTIONS

Responses by The Honorable John Graham

**U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
Subcommittee on Environment**

**Hearing Questions for the Record
The Honorable David Schweikert**

Ensuring Open Science at EPA

The Honorable John Graham

1. Why do you think “the vast majority of the environmental scientific community should not have difficulty satisfying the public access provision” in the Secret Science Reform Act?

Answer: Once environmental scientists have published their work in the peer-reviewed scientific community, it is already common practice for them to share their data with other scientists who have an interest in their research. The Secret Science Reform Act would simply add EPA scientists to the list of colleagues who may request access to their data. Once EPA scientists obtain the data, they can post it on their web site (barring any legal restrictions).

2. You cite recent recommendations from the Administrative Conference of the U.S. as being supportive of the types of data transparency required in the Secret Science Reform Act. Can you explain what the Conference does and how these recommendations relate to EPA’s approach to open science?

Answer: The Administrative Conference of the United States is a nonpartisan organization chartered and funded by Congress with the mission of improving the transparency and quality of federal rulemaking in the United States. The recommendations made by ACS on data transparency are applicable to all federal agencies, including the EPA.

3. In 2012, the President’s Science Advisor testified that “Absolutely, the data on which regulatory decisions... are based should be made available to the Committee and should be made public.” Also in 2012, the Chair of EPA’s Science Advisory Board testified that EPA’s advisors recommend “that literature and data used by EPA be peer-reviewed and made available to the public.” Do you agree with these statements?

Answer: Yes

4. In analyzing the economic benefits of the Clean Air Act, EPA often cites a study it conducted that finds that the Act achieves \$2 trillion in benefits from 1990 to 2020, with a benefits exceeding costs by a margin of 30-to-1. More than 80 percent of those benefits, though, are derived from studies on fine particulate matter, for which the underlying data has not been made public. Do you find this analysis credible?

Answer: They are not credible without an appropriate indication of uncertainty. They are particularly vulnerable to mistrust among stakeholders because the underlying data have not been made public and thus are not available for verification and sensitivity analysis.

5. You mentioned in your testimony that the data access provisions for the journal *Science* are consistent with the principles in the legislation. Similarly, the journal *Nature* also tells its authors: “An inherent principle of publication is that others should be able to replicate and build upon the authors’ published claims. Therefore, a condition of publications in a *Nature* journal is that authors are required to make materials, data and associated protocols promptly available to readers without undue qualifications.” Do you believe this legislation is consistent with the policies of these journals?

Answer: Yes.

6. You emphasize in your testimony the importance of ensuring transparency and access for assessments and guidance beyond just regulations, stating that “some of the most significant actions taken by EPA are scientific determinations **rather than** regulations per se.” Can you discuss the risks of these types of determinations **and** ways in which openness could improve these EPA products?

Answer: 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.

7. Do you agree that the data transparency policies in the legislation should apply to both data and models, regardless of who funded them?

Answer: Yes.

8. In 2009, you were part of a Bipartisan Policy Center panel that unanimously recommended that “studies used in the formulation of regulation should be subject to data access requirements... regardless of who funded the study.”

- a. Is the Secret Science Reform Act consistent with this recommendation?

Answer: Yes.

- b. Since the legislation applies to any scientific information, regardless of who funded or carried out the research, do you think the bill addresses Dr. Silbergeld's concern that industry fails to disclose critical information for EPA regulations?

Answer: Yes.

- 9. In your testimony on fine particulate matter, you noted some of limitations of the EPA-funded re-analysis of critical data. Do you agree with the National Academy of Sciences' stated that "the Health Effects Institute reanalysis model is... not a substitute for public access to data"?

Answer: Yes.

- 10. During the hearing, Dr. Silbergeld referenced the model of evidence based decision making. In your view, are the transparency principles consistent with evidence based decision making?

Answer: Yes.

- 11. During the hearing, Dr. Silbergeld stated in during the hearing that, "[peer reviewers] do a very exhaustive job of reviewing." In your view, are all peer reviewers provided access to data to ensure reproducibility?

Answer: No.

- 12. In your experience, does EPA's communication of regulatory benefits include all associated uncertainties in their scientific findings?

Answer: No.

Questions for the Record

Submitted by: Full Committee Ranking Member Eddie Bernice Johnson
 Subcommittee on Environment
 Hearing: Ensuring Open Science at EPA – February 11, 2014

Questions for Dr. John D. Graham

- 1) In your testimony you indicate that the “original health data” from the Harvard Six-Cities Study and the American Cancer Society study is not publicly available to researchers through EPA’s website.
 - a. Are you aware the EPA is not the legal custodian of the “original health data?” (Yes/No) No.
 - b. Are you also aware that the rightful owners of the data, the American Cancer Society and Harvard University, have procedures in place to make this data available to legitimate researchers? (Yes/No) Yes.
 - c. You mentioned that HEI conducted a third party examination of the studies and that no major errors were found. It is my understanding that HEI not only validated the results of the original studies, but found a stronger association between air quality and mortality. Do you disagree with HEI, and the way they analyzed their data? (Yes/No) No.

- 2) In October of 1991 you solicited grant monies from Philip Morris for the Harvard Center for Risk Analysis. It should be noted that you addressed your grant solicitation to Philip Morris’ Vice President for Government Affairs, which seems like an odd choice for an academic institution seeking grant support. In 1992 Philip Morris sent the Harvard Center for Risk Analysis a check for \$25,000. However, just a short time later Philip Morris put a stop payment order on the check. In that same year, Kraft General Foods, which was a subsidiary of Philip Morris, sent the Harvard Center for Risk Analysis a check for \$20,000. It should be noted that in that letter several Philip Morris contacts you dealt with during the previous solicitation were cc’d. (Please see attached documents)

Answer: I do not recall the precise events or motives as they occurred more than 15 years ago. However, I believe they are reviewed in the hearing record of my Senate confirmation to the position of OIRA Administrator. See Nominations of Angela B. Styles, Stephen A. Perry and John D. Graham. Hearing Before the Committee on

Governmental Affairs of the United States Senate. First Session. 107th Congress.
Washington, DC. May 17, 2001.

- a. Did you or an employee at the Harvard Center for Risk Analysis request that Philip Morris cancel their grant to the Harvard Center for Risk Analysis?
 - b. Did you or an employee at the Harvard Center for Risk Analysis request that the grant instead come from Philip Morris subsidiary Kraft General Foods?
 - c. Assuming that the money from Philip Morris was refused, as the documentary record shows, was the motive for refusing that funding the perceived stigma of accepting tobacco money? If not, please explain.
- 3) As Dean of the University of Indiana School of Public and Environmental Affairs (SPEA) please describe the kind of ethics training that exists in your program. If any materials describe this training (syllabus, course descriptions, etc.) please provide those to the Committee. Please indicate what has been done in this area since you arrived.

Answer: In our undergraduate and graduate programs, my understanding is that professional ethics are weaved into a variety of courses but we do not rely on any single course in professional ethics to cover this material.

- 4) What rules does the School of Public and Environmental Affairs apply to faculty members in disclosing funding sources for their work when they discuss or publish that research? Please identify changes to those rules that have occurred at SPEA since you arrived.

Answer: There have been no changes in disclosure rules at SPEA since I arrived in 2008. Under sponsored research agreements with outside parties, faculty members are expected to disclose the funding source(s) in their peer-reviewed products.

- 5) The legislation you testified upon, H.R. 4012, proposes measures that would fundamentally change what EPA would have to do with scientific information for any “risk, exposure, or hazard assessment, criteria document, standard, limitation, regulation, regulatory impact analysis, or guidance.” Given that EPA has jurisdiction over pesticides, water, air, surface pollution, superfund clean ups, chemical risk assessments and exposure guidance—just to name some of the issues at the Agency—there are innumerable regulated industries that would have some stake in seeing this measure move forward. You had a rich history of soliciting funding from regulated industry to support your work when you were at the Harvard Center for Risk Assessment. As Dean of the

School of Public and Environmental Affairs, you probably have fund-raising responsibilities in your portfolio.

- a. Please identify all parties (to include third party organizations funded by regulated parties) that you have solicited support from that would have an interest in the changes proposed in H.R. 4012.
- b. Please identify all parties (including third party organizations funded by regulated parties) that have contributed to support the work of the School since 2008 that would have an interest in the changes proposed in H.R. 4012.

Answer: Although I have seen claims in the media and at the hearing about organizations who may favor or oppose H.R. 4012, I am not aware of any specific organizations that would have an “interest” (meaning financial or commercial) in the specific changes proposed by H.R. 4012. Most of my fundraising activity as Dean is directed at individual philanthropists, and I am not aware of any of them who would have an interest in the changes proposed by H.R. 4012.

- 6) H.R. 4012 reflects a tension between the desire to make science and data transparent, and the need to respect existing laws that protect individual interests—for example--patient and study participant privacy, confidential business information and intellectual property protections. On the one hand, EPA is prohibited in the text from using any “scientific and technical information” in a covered action unless that information is specifically identified, and publically available in a manner that is sufficient for independent analysis and substantial reproduction of results. On the other hand, the bill specifies that EPA is not required to engage in public dissemination of information “the disclosure of which is prohibited by law.” It is hard to see how EPA could rely upon most of the major public health research of the last 40 years if they must meet the first set of standards without violating the law by making privacy protected health information publicly available.
 - a. You acknowledged in your oral testimony that the public health research that EPA relies upon is an area where patient sensitive information remains a barrier to full data sharing. However, you seemed to suggest that the issue is not difficult and resides more in the attitudes of the “mental health field” and the “environmental health research community”—by which I assume you meant the public health community—just need to be persuaded to get on board. Please explain in some detail how you believe data can be released in a way that allows for independent analysis and substantial reproducibility but does not violate individual privacy?

Answer: There must be a misunderstanding or a miscommunication on my part. I did not intend to refer in any way to “mental health field”. Disclosures of data can protect privacy by removing identifiers (e.g., names, social security numbers, addresses). The Census Bureau regularly collects data from individuals and makes it

publicly available but does not violate the privacy of individuals. Dr. Cox also described in his testimony a variety of ways that this issue can be addressed, and the March 2014 Institute of Medicine Workshop is devoted precisely to this issue.

- b. Given that participants in health studies are always promised anonymity and privacy is assured by law, what would a “voluntary” breach of that privacy by a Government agency mean for future public health studies?

Answer: I do not know.

- c. In your oral testimony you indicated that Confidential Business Information does not apply to “90, 95 percent of the industry information” that EPA relies upon based on your experience at OIRA. This estimate may have something to do with what OIRA actually reviewed, or what your staff shared with you. A vast range of EPA information has been subject to CBI: pesticide approvals all involve CBI information; costs of compliance often rely on company specific survey data; risk assessment information can include company, even factory-specific submissions about exposures; TSCA reports are full of CBI information and that data may be used in other proposals by the agency that would be a covered action under the bill. For the purposes of meeting the bill’s goal of providing all data necessary for independent analysis and substantial reproducibility, what proportion of the information you were exposed to falls into that category and would be CBI? Please expand in detail on the specific EPA matters that you were able to review that lead you to this estimate.

Answer: You are correct that OIRA reviews of EPA actions are concentrated more in the air and water offices than in the pesticide and toxics offices. However, as an academic I have written extensively on the processes used in pesticides and toxics offices and, even in those offices, much of the data submitted by industry is not confidential business information. For industry data supplied in air and water office rulemakings, very little is confidential business information.

- 7) When you were at OIRA, you brought in a toxicologist, Nancy Beck. Early in the Obama Administration she left OIRA to go to work for the American Chemistry Counsel. Did you serve as a reference for Nancy Beck?

Answer: I do not recall whether I served as a reference for Nancy Beck.

Responses by Cox Dr. Louis Anthony Cox, Jr.

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Rep. David Schweikert
 Chairman
 Environment Subcommittee
 Committee on Science, Space, and Technology
 2321 Rayburn House Office Building
 Washington, D.C. 20515-6301

March 13, 2014

Dear Rep. Schweikert,

I am pleased to provide the following responses to the questions submitted for the record by Members of the Committee, as set forth in the attachment to your letter dated February 27, 2014.

1. Do you agree with the National Research Council, who in 2002, stated that “peer review does not detect fraud, validate factual findings...or substitute for the judgments of the scientific community as a whole?”

Yes, I agree with the National Research Council’s statement. The high prevalence of false-positive results in published studies to which I have alluded, and to which I have provided references in my written testimony, applies to peer-reviewed studies.

2. You have examined the relationship between fine particulate matter and mortality within a publicly available data set, coincidentally run by John Hopkins University.
 - a. Does this data suggest a causal relationship between reducing fine particulate matter and reduced mortality?
 - b. Because the data set you used is public, you suggest that “others will, repeat and improve upon my analysis.” Is that true for the data that EPA relies upon in concluding that there is a causal relationship between fine particulate matter and mortality?

(a) No, the NMMAPS data indicate a clear positive statistical association between PM2.5 levels and levels of mortality risk (e.g., both tend to be high on cold winter days), but they do not suggest any causal relation between reductions in PM2.5 and reductions in mortality risks. After controlling for temperature, month, and city, there is no evidence of any causal relation between PM2.5 levels and mortality risks. This finding is discussed further in the following references: ,

- a. Cox LA Jr, Popken DA, Ricci PF. Warmer is healthier: effects on mortality rates of changes in average fine particulate matter (PM2.5) concentrations and temperatures in 100 U.S. cities. Regul Toxicol Pharmacol. 2013 Aug;66(3):336-46. doi: 10.1016/j.yrtph.2013.05.006. Epub 2013 May 21.
- b. Cox T, Popken D, Ricci PF. Temperature, Not Fine Particulate Matter (PM2.5), is Causally Associated with Short-Term Acute Daily Mortality Rates: Results from One Hundred United States Cities. Dose Response. 2012 Dec 14;11(3):319-43. doi: 10.2203/dose-response.12-034.Cox. eCollection 2012.

3. In 2012, the President's Science Advisor testified that "Absolutely, the data on which regulatory decisions... are based should be made available to the Committee and should be made public." Also in 2012, the Chair of EPA's Science Advisory Board testified that EPA's advisors recommend "that literature and data used by EPA be peer-reviewed and made available to the public." Do you agree with these statements?

Yes, I agree with these statements.

4. In analyzing the economic benefits of the Clean Air Act, EPA often cites a study it conducted that finds that the Act achieves \$2 trillion in benefits from 1990 to 2020, with a benefits exceeding costs by a margin of 30-to-1. More than 80 percent of those benefits, though, are derived from studies on fine particulate matter, for which the underlying data has not been made public. Do you find this analysis credible?

No, I do not find EPA's analysis or resulting estimate of benefits credible. It is based on unproved and scientifically implausible assumptions about concentration-response associations (entirely linear, entirely causal, no threshold, no heterogeneity), incorrect arithmetic for accounting for numbers of "avoided deaths" per year, questionable economic value judgments about the dollar value of "avoided deaths" that do not consider how long deaths are postponed; and an approach to uncertainty analysis that presupposes the answer (use of Weibull uncertainty distributions, which implicitly assume a 100% probability of a positive relation). These points are discussed further in the following reference:

- a. Cox LA Jr. Reassessing the human health benefits from cleaner air. Risk Analysis. 2012 May;32(5):816-29. doi: 10.1111/j.1539-6924.2011.01698.x.

5. You discussed the ability to protect any confidential or individually identifiable information in data sets used by federal regulators. Are these methods cost-effective, and are there examples of government or academic data sets that follow these procedures now?

Yes, cost-effective statistical methods for protecting individual privacy and confidentiality are well developed and have been applied to both government and academic data sets. My written testimony cited methods based on multiple imputation, used at the Census Bureau. A textbook on *Statistical Disclosure Control*, by Hundepool et al., with case studies (<http://www.wiley.com/WileyCDA/WileyTitle/productCd-1119978157.html>) provides further discussion of some of the cost-effective methods that are used to protect confidential data. Financial, medical, and other industries have developed working solutions for protecting confidential or individually identifiable information in data sets used by Federal regulators and others, and such methods have been extended specifically to environmental and health data over the past twenty years (e.g., Cox, LH, Protecting confidentiality in small population health and environmental statistics, Stat Med. 1996 Sep 15-30;15(17-18):1895-905.).

6. You cite the unpredicted results of coal bans in Dublin as evidence of why data access is important. How do these findings relate to US EPA regulations?

The coal-burning bans in Dublin were based on unjustified interpretation of positive statistical associations between exposure levels and mortality risk levels as evidence that reductions in exposures would cause reductions in mortality risks. Dr. Douglas Dockery of the Harvard School of Public Health, a prominent air pollution health effects researcher whose work and opinions about causation have informed US EPA's beliefs and assumptions, championed this misleading causal interpretation of the statistical associations. This interpretation turned out to be unjustified. Yet, precisely such misinterpretation of exposure-response associations as if they were causal relations provides the foundation for the US EPA's assessment of the projected public health benefits from tighter regulation of fine particulate matter and other pollutants. This reasoning was not sound in Dublin, and it is not any sounder in the US. What is particularly frustrating is that is obvious to many methodologists (some of whom I cited in my written testimony) that the types of causal inferences drawn by Dockery and colleagues and the US EPA are not valid, yet it is not easy to correct their calculations using appropriate methods of valid causal analysis and inference because it is not easy to gain access to their data.

7. Can you identify recent developments in scientific journals trending more greater data access policies?

Recent developments in scientific journals toward greater data access include the use of supplemental online information to provide access to original data and analyses; open data access policies; and improvements in public data archiving for scientific research (e.g., <http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.1001779>). For example, as of this month, "[A]ll PLOS journals will require that all manuscripts have an accompanying data availability statement for the data used in that piece of research" (<http://blogs.plos.org/biologue/2014/02/03/opening-up-data-access-not-just-articles/>).

8. Dr. Silbergeld references the model of evidence based decision making. In your view, are the transparency principles in the Secret Science Reform Act consistent with evidence based decision making?

Yes, in my view the transparency principles called for in the Secret Science Reform Act are consistent with, and would facilitate, evidence-based decision making.

9. Dr. Silbergeld stated that, "[peer reviewers] do a very exhaustive job of reviewing." In your view, are all peer reviewers provided access to data to ensure reproducibility?

No, I know from direct experience that peer reviewers are not usually provided access to data and cannot ensure reproducibility. Indeed, prestigious journals such as Science and Nature are in the process of changing their policies and editorial boards to increase reproducibility, due to the crisis of false positives and irreproducible results now being published in top-rated peer reviewed scientific journals.

10. Dr. Silbergeld stated that the bill, “eliminate a great deal of the epidemiologic and clinical literature that could be available,” due to confidentiality concerns. Do you agree with this characterization?

I disagree with Dr. Silbergeld that the bill would eliminate any of the epidemiological and clinical literature. What it would do is to allow the factual basis for claims in the literature to be scrutinized where practicable; for claims that cannot be independently verified to be identified as such; and for future publications and claims to be put on a more trustworthy basis in which both the public and other scientists are more easily able to determine whether and how well opinions and interpretations are actually backed by data, as opposed to being mere personal opinions or interpretations of the authors, masquerading as objective scientific findings.

11. Dr. Silbergeld suggested that studies involving location of subjects could not be de-identified in a way that allows data to be used by other scientists. Do you agree with this characterization?

I disagree with Dr. Silbergeld’s characterization. Techniques such as geomasking are now well developed and inexpensive to apply. They can be used to make spatial data available for analysis while protecting individual confidentiality. The following references provide points of entry to this body of knowledge.

- a. Wieland SC, Cassa CA, Mandl KD, Berger B. Revealing the spatial distribution of a disease while preserving privacy. Proc Natl Acad Sci U S A. 2008 Nov 18;105(46):17608-13. doi: 10.1073/pnas.0801021105.
- b. Hampton KH, Fitch MK, Allshouse WB, Doherty IA, Gesink DC, Leone PA, Serre ML, Miller WC. Mapping health data: improved privacy protection with donut method geomasking. Am J Epidemiol. 2010 Nov 1;172(9):1062-9. doi: 10.1093/aje/kwq248

12. In your experience, does EPA’s communication of regulatory benefits include all associated uncertainties in their scientific findings?

In my experience, EPA’s communication of regulatory benefits conceals, rather than reveals, most of the key uncertainties in their scientific findings. EPA typically communicates regulatory benefits using point estimates (or best estimates) and statistical confidence bands or uncertainty intervals around the estimates. This fails to

communicate major discrete uncertainties, such as about whether the underlying assumptions of the analysis are valid, the probability that there are no benefits at all, the probability that the statistical associations used to estimate benefits are not causal, and the probability that further reductions in air pollution levels will produce few or no benefits because currently permitted levels are already low enough so that they do not cause the adverse health effects attributed to them based on historical data. Further discussion of EPA's approach to quantifying and communicating uncertainty in regulatory benefits estimates, and why it is misleading, is given in Cox LA Jr. Reassessing the human health benefits from cleaner air, Risk Analysis. 2012 May;32(5):816-29. doi: 10.1111/j.1539-6924.2011.01698.x.

Responses by Dr. Ellen Silbergeld

March 4, 2014

RESPONSE TO COMMITTEE LETTER:

Dr Ellen K Silbergeld, Johns Hopkins

Cong. Johnson

1. In your written testimony you mention the need to improve the disclosure of industry data and rightfully point out that the “Secret Science Reform Act of 2014” seems to take a one-sided approach by targeting data from the academic community. You state, “the proposed bill would continue to immunize industry from disclosure while increasing the burden on EPA and, by pass through, on non-industry researchers.”
 - a. Can you please describe the challenges associated with gaining access to industry data?
 - b. How does limited access to industry data effect your ability as a scientist to reach evidence based decisions relevant to human health?

1. (a) challenges associated with gaining access to industry data:

These challenges and adverse impacts of inaccessible industry data are well known and were in fact the driver for the High Production Volume Chemicals project developed by governments, industry, and NGOs in the OECD Environment Program, as discussed in my testimony. There are four types of barriers to accessing industry data: (1) overly expansive definitions of “confidential business information” that preclude accessing information relevant to health and safety [most egregiously with respect to pesticides and biocides test data]; (2) inadequate data disclosures by industry in many MSDS documents [e.g., WV spill] and limited disclosures by industry in the Toxic Release Inventory Program at EPA; (3) deliberate efforts by US industry to block other programs that generate information, such as the CDC biomonitoring program, the Annual Report on Carcinogens by NIH, and US industry lobbying in opposition to the REACH program of chemical regulation in the EU; and (4) lapses in product stewardship (as defined by the American Chemistry Council) such that industry does not adequately test chemical constituents of consumer products, stored materials, and releases.

(b) Impact of limited access

Without information it is not possible to utilize evidence based approaches to decision making in environmental health. Moreover, lack of information constrains inferences about potential harms and risks from exposures to structurally similar classes of compounds (such as flame retardants and endocrine disruptors).

2. Dr. Graham seems to suggest in his testimony that EPA can simply rely on different sources of scientific and technical information for covered actions, if the agency cannot compel the release of data from the scientific community. This is perhaps the clearest language to indicate that the legislation would constrain EPA, limiting the scope of science available to the agency.

- a. Can you please discuss the implications these restrictions would have on researchers and the quality of work conducted by the agency?
- b. How important is it that EPA have the ability to consider the best available science to inform its regulatory actions?

2.

(a) restrictions on EPA use of scientific information

If the EPA is unable to access the peer reviewed literature because raw data are not available as proposed in the "Secret Science" bill, then we move to the dysfunction situation where the EPA will be unable to sustain its decisions because these will be based on inadequate or incomplete science.

(b) Importance of best available science for EPA decision making

It is indeed quite strange why those parties who in the past have criticized the EPA for not relying on "good science" now seek to prevent EPA from utilizing all relevant and "good" science by setting up obstacles to its generation and use.

Cong Bonamici:

1. In your testimony, you discuss the use of third party review as a means of enabling data re-analysis in a non-adversarial way. In fact, as recognized by the other witnesses at the hearing, this type of arrangement was used to re-analyze the data from the Harvard Six Cities Studies and the American Cancer Society Cohort data, the studies often referred to as “secret science.”
 - a) Please discuss the use of third party review and explain why it is an effective model.
 - b) Did the HEI (Health Effects Institute) re-analysis of the Harvard and American Cancer Society studies overturn the conclusions of the original articles?
 - c) In cases where it is impossible to remove all of the identifying data without negating the scientific value of the dataset, is it still appropriate for EPA to use this research to inform its regulatory decision making? If so, why?

1.

(a) third party review of data

When there are supportable reasons for re-analysis of primary data, there are established methods of third party review for accomplishing this goal [note that this differs from demanding universal access to all such data in the absence of any demonstrated need for access or re-analysis]. Third party review by definition involves outside experts with no connection to the original researchers, to the EPA or to any stakeholder demanding such review. Third party review has proven to be effective because of its focus and coherent basis. Such analyses have been designed to evaluate specific issues or findings rather than unfocussed “data dredging”... Because of the limited scope of third party review and the engagement of reputable and non-adversarial reviewers, this method has protected participant confidentiality and other ethical issues.

(b) HEI review of Harvard and ACS studies

A copy of the review summary is attached. To quote the findings of the HEI report:

RESULTS AND IMPLICATIONS

PART I: REPLICATION AND VALIDATION

- An extensive audit of the study population data for both the Six Cities and ACS Studies and of the air quality data in the Six Cities Study revealed the data to be of generally high quality with a few exceptions. In both studies, a few errors were found in the coding and inclusion of certain subjects; when those subjects were included in the analyses, they did not materially change the results as originally reported. Because the air quality data used in the ACS Study could not be audited, a separate air quality database was constructed for the sensitivity analyses described in Part II.
- The Reanalysis Team was able to replicate the original results in both studies using the same data and statistical methods as used by the Original Investigators. The Reanalysis Team confirmed the original point estimates: For the Six

Cities Study, they reported the relative risk of mortality from all causes associated with an increase in fine particles of $18.6 \mu\text{g}/\text{m}^3$ as 1.28, close to the 1.26 reported by the Original Investigators. For the ACS Study, the relative risk of mortality from all causes associated with an increase in fine particles of $24.5 \mu\text{g}/\text{m}^3$ was 1.18 in the reanalysis, close to the 1.17 reported by the Original Investigators.

(c) If EPA cannot remove all identifying data without negating a dataset, is it still appropriate for EPA to utilize a study?

In my opinion (see above) this is not a relevant question. It is rarely the case that access to original study data is necessary for EPA to utilize relevant scientific studies and for the public to have confidence in these studies as bases for regulatory decisions. When such access is needed – which has been relatively rare – then strategies such as third party review can be employed.

2. In your testimony you indicate that even though you support increasing transparency for information used to develop federal regulations, you recognize that the release of raw data associated with human studies could have potential “chilling” effects on “the engagement of the global scientific community in research relevant to the protection of human health and the environment.”
 - a) Please describe the potential repercussions of EPA providing raw data from every study used to support a regulatory assessment.
 - b) In your testimony you mention evidence-based toxicology. What is evidence-based toxicology? How can this improve the science basis for decision making at EPA?
2. (a) repercussions of EPA being forced to provide raw data from every study

This requirement will definitely add to further delay in reaching regulatory decisions by EPA. It will also have a chilling effect on the scientific community as a source of research, as Prof Lynn Goldman and I wrote in our commentary on this topic (paper attached to testimony). Since scientists such as me do not undertake research for the express purpose of or in anticipation of its use in regulatory proceedings, we cannot anticipate that such demands might be imposed upon us as individual researchers or on our institutions. Moreover, prior to such demands, we will have conducted epidemiological studies with

approval of our institutional review boards for human subjects research, and thus may find ourselves in a highly compromised and potentially unethical position of having to abrogate our declaration to participants in our studies that they will be protected from identification or other disclosure.

(b) What is evidence based toxicology?

I appended a copy of my recent paper on this topic to the testimony. In that paper, Dr Roberta Scherer (of the Cochrane Collaboration US Coordinating Center) and I defined evidence based methods as:

Evidence can be defined as the translation of information into accepted practice using methods that reduce bias and increase confidence. As in the law, evidence based methods involve the evaluation of information for its admission into consideration in decision making through the process of applying specified norms and methods. In order to avoid bias, these norms and methods stand apart from the information under consideration and their application is undertaken with complete transparency.

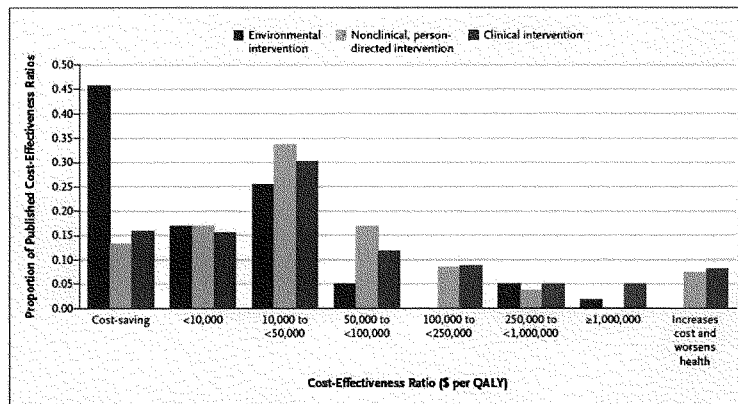
Evidence based methods were first developed in medicine and then expanded to the broad domain of health care, including clinical trials of intervention efficacy, observational epidemiological studies on risk factors for disease, and diagnostic methods. We propose adoption of evidence based methods in toxicology, specifically the norms of transparency and the methodology of systematic reviews, which clearly incorporate the following steps: development and explicit framing of research questions that can be answered by a systematic review, and explicit statement of a publically available protocol for conducting the systematic review. This protocol includes a defined and annotated strategy for locating sources of evidence; a priori conditions for exclusion and inclusion; defined analytic procedures to evaluate study designs and statistical methods; criteria for evaluating selected studies; methods for integrating study results. These rules are based on the assumption that all studies are well intentioned but no study is perfect. The goal is to identify all relevant sources of information in an unbiased manner and then to screen this body of information by identifying aspects of each study that can increase bias or uncertainty and to consider the impact of these aspects on analytic confidence.

Experience over the past decades in application of evidence-based approaches in medicine and health care demonstrates that these methods can enhance decision making by increasing transparency of process and methods, by reducing bias in selecting and evaluating evidence, and by contributing to the improvement of methods used in toxicology and other disciplines to develop information relevant to environmental health and ecosystem decision making.

3. Do you agree with the assertion made by a number of witnesses at the hearing that there is minimal evidence for the economic benefit of EPA regulatory action, particularly actions limiting the emission of air toxins? If not, why?

Evidence for the economic benefits of EPA regulatory particularly with respect to air toxics

I do not agree with this statement on the basis of the evidence. The costs of disease and dysfunctions associated with exposures to toxic chemicals in the environment are very high. The economic benefits for reducing these exposures are also very large and have been empirically demonstrated by a rich area of research and documentation. Overall, an important analysis of the beneficial impacts of air toxics regulation *and enforcement* was published in the NEJM by Choksi and Farley (2012) [copy attached]. As shown below, the overall cost effectiveness of environmental interventions (through regulation) exceeded the combined benefits of all other prevention modalities used in medicine.

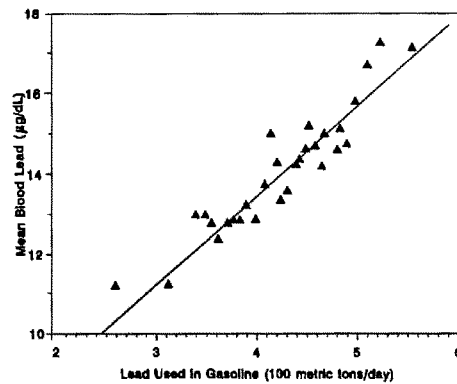


Cost-Effectiveness of Categories of Preventive Interventions.

The authors concluded that “The scientific literature now points to the value of implementing preventive environmental interventions that are cost-saving”.

Dr Richard Morgenstern of Resources for the Future (and formerly a member of the EPA’s Office of Policy Analysis) has also reviewed this topic from the perspective of an economist (for example, Krupnick and Morgenstern 2003, attached).

There is also a large literature on the health and economic benefits of reducing concentrations of lead in ambient air, as well as reductions in ozone, SO_x, and suspended particulate matter. For example, CDC published an analysis of temporal associations between lead in air (related to use of TEL in gasoline) and children’s exposure (blood lead) over the period of EPA mandated reductions in TEL use, as shown below.



These reductions were associated with reduced impacts on children's neurobehavioral development and school performance (Silbergeld 1997, attached). Additional benefits from these regulations continued to accrue through the phase-out of TEL by EPA regulation. Adults in the US have also benefitted from regulated reductions of lead in terms of reduced risks of cardiovascular disease and stroke as air lead levels have decreased.

The benefits of regulated reductions in air pollutants have been analyzed by Correia et al 2013, [paper attached]. There is a significant correlation between these reductions and increased life expectancy over the period from 2002 to 2007. The authors also found that reductions in air pollutants contributed also 20% to the increased life expectancy measured over this same period.

Another approach might be to compare the associations between air pollution and health in China and the US, to utilize a "natural experiment" in lack of environmental regulation.

PREVENTING LEAD POISONING IN CHILDREN

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KEY WORDS: lead poisoning, children's health, environment, prevention

ABSTRACT

Lead poisoning is the most significant and prevalent disease of environmental origin among US children. Despite over 100 years' knowledge of the special hazards of lead exposure for young children, it has taken over a century for effective primary prevention to be adopted. Obstacles to primary prevention have included deliberate campaigns by industry to prevent restrictions upon such uses on lead as plumbing, paints, and gasoline additives; influence of industrial support of biomedical research at major US medical schools; lack of appropriate policy mechanisms to identify and control lead exposures; and opposition to investing resources in lead poisoning prevention. The removal of lead from gasoline, which began in the United States in 1972 and was completed in 1995, has resulted in almost fourfold reductions in median blood lead levels in US children from 1976 to 1991. Increased screening and interventions to identify and abate lead sources, such as lead in housing, also contributed to this major public health success. Nevertheless, lead exposures remain prevalent, although increasingly less generally distributed. Perhaps because of the renewed "ghettoization" of lead, support for lead poisoning prevention has waned. Objections to investing public and private resources in screening and source abatement have challenged the continuing commitment of public health officials to prevention. The demonstrable success and social benefits of preventing lead toxicity are cited in support of continued preventive health policies.

INTRODUCTION

Lead poisoning, for much of this century, has been the most prevalent and serious disease of environmental origin for young children in the United States. Its causes were described accurately by the mid-1920s, but not until the late 1970s were comprehensive and effective actions taken to prevent this disease

by interdicting major uses of lead in consumer products and industry. The fact that over half a century elapsed between knowledge and action indicates that any review of the struggle to prevent lead poisoning in children must attend to the political and economic forces that for 50 years interfered with the implementation of primary prevention policies. The struggle for prevention has involved almost every consumer and environmental protection statute and policy strategy extant in the United States; it has engaged communities, states, and the federal government; it has revealed the nature and scope of injustice in the distribution of environmental risks; it has elicited courageous acts and great mendacity. From the perspective of a century's experience, this review not only describes this history but also provides some insights that may be useful in preventing other environmental diseases, avoiding both the social toll exacted by lead and the political delays involved. Since the author of this review has been personally involved in much of the policy debate on lead poisoning prevention at the local, state, and federal over the past 20 years, this review should be read in light of the strong opinions held and expressed (65).

No small part of the delay in recognizing the nature and scope of lead poisoning and seizing opportunities for disease prevention is due to the actions and expressed opinions of some biomedical researchers considered experts in their day. These scientists and clinicians—among them, Joseph Aub and Cecil Drinker of Harvard and Robert Kehoe of Cincinnati—were retained by the lead industry in its organized campaign to control the discourse on lead poisoning (see 29, 25, 55). For decades, from the late 1920s through the 1970s, the lead industry funded most of the research on lead toxicity at major institutions in the United States, including Harvard, the University of Cincinnati, and Johns Hopkins. Only with the rise of the National Institute of Environmental Health Sciences, under the leadership of David Rall, were other funds available, from a neutral source, and it is not coincidental that with this support a new generation of researchers began to publish new findings on the toxicity and sources of lead in the mid-1970s. Even then, the struggle was neither easy nor pleasant. Attacks on the integrity of researchers reached their nadir when allegations of scientific fraud were raised by consultants to the lead industry against an internationally recognized scientist (64). Although eventually rebutted, these charges were of a piece with earlier personal attacks by the industry and its consultants on Alice Hamilton and Randolph Byers.

The history of lead must induce careful reflection: The natural and laudable bias of scientists toward vigorous skepticism can be exploited to support inaction on the basis of uncertainty. In public health, giving the "benefit of the doubt" to a potentially toxic substance like lead runs the risk of denying a margin of protection to its victims. In the case of lead, the expressed uncertainties about low-level lead exposures (a relative term that changed over the course of this history, as described below) provided not only repeated excuses for inaction

but, more dangerously, justifications for new and expanded uses of this toxic metal. By the time these uncertainties were reduced to a level to support a new consensus on lead's hazards in the early 1980s, thousands of tons of lead had been dispersed into the environment. The responsibility for this catastrophic mistake (to use the terms of Carl Shy) must be shared among industry, government, and academic researchers.

The Nature of Childhood Lead Poisoning

Lead poisoning is an entirely preventable disease, induced by exposures to lead. The toxicity of lead has been recognized for almost as long as this useful metal has been mined, smelted, and used by human societies (34, 42, 48). Rules prohibiting the use of lead additives in beverages were among the earliest food regulations in Europe and the American colonies (18, 75). Although it was recognized as early as the mid-nineteenth century that children might be among the most vulnerable to lead toxicity [for discussion of early opinions and observations, see Reference (50)], specific attention to children as a population at risk was only formalized in the 1920s. Hamilton (26) directed attention to the devastations of occupational and peri-occupational exposures for young children; she recommended that young children be excluded from employment in the lead trades, and that measures be taken to reduce the transport of lead dusts from the workplace to the home. In 1897, the Australian pediatrician Lockhart Gibson reported on cases of young children intoxicated by lead from lead-based paints used on porches and doors (24). The importance of lead paint as a cause of lead toxicity in children was soon reported in the United States, in Baltimore and in Boston [see (54) for a history of the recognition of lead paint poisoning in the United States].

The definition of lead poisoning—that is, at what level of exposure clinical toxicity occurs—has changed markedly over the century. Over this period, medical and public health opinion has shifted dramatically, from assuming that only high-dose, overtly encephalopathic exposures were significant, to the recognition that very low doses, without clear symptom presentation, are associated with measurable neurotoxicity.

Similarly, concepts related to treating lead poisoning have also undergone profound change. Prior to 1940, it was generally assumed that if the child's exposure was promptly reduced, then the effects of lead were reversible unless severe toxicity had been induced (such as coma and convulsions). After the introduction of the chelating agents ethylenediamine tetraacetic acid (EDTA), d-penicillamine, and British anti-Lewisite (BAL) into therapeutic practice in the 1950s and 1960s, drug treatment was added to reduction of exposure as the means of medical management (13). Although there is a large medical literature associating chelation treatment with reductions in blood lead levels and increased excretion of lead in urine, there is much less evidence that treatment

actually affects outcome. Silbergeld & Chisolm (67) reported that children given EDTA showed reductions in blood lead and urinary catecholamine excretion, a potential marker of neurotoxicity; Rosen et al (56) reported that chelation lowered bone lead and improved children's performance on measurements of cognitive function; and David et al (17) reported that chelation reduced hyperactivity in children with past lead exposure. However, these studies involved children with relatively high exposures to lead (in excess of 45 $\mu\text{g}/\text{dL}$).

The reversibility of lead toxicity has been questioned since Byers & Lord (9) suggested in 1943 that lead could induce persistent damage in children, even after their external exposures were reduced and clinical indicators of toxicity were no longer detectable. Needleman and colleagues (45) demonstrated through a careful prospective study that early lead exposure affected children's behavior and intellectual attainment for at least 10 years. Thus it is not clear how much benefit, in terms of reversing toxicity, any postexposure treatments bring. Chelation is undoubtedly valuable to lower high blood levels of and prevent acute neurotoxic effects, such as convulsions, as well as reducing effects of lead on kidney from prolonged high-dose exposure. Extended chelation can reduce overall body burdens of lead as well, including lead in bone (51, 57). Nutrition may play a role in reducing absorption of lead (27), but there is little evidence that essential elements, such as calcium or iron, can counteract the presence of lead at target sites of action once it has been absorbed.

These findings have had profound impacts upon strategies for prevention. It is now the general foundation for public health policy in the United States, France, Australia, and other countries that childhood lead poisoning, or toxicity, is associated with blood lead levels as low as 10 mcg/dL (or 0.5 mmol/L), and that the prevention of toxicity requires prevention of exposure through the identification and control of lead sources in the environment, in air, food, water, and dusts and soils (see 50, 65 for reviews of national policies). The considerable decreases in what have been considered "acceptable" levels of lead exposure for children have driven an expanded consideration of opportunities to prevent exposures through more comprehensive identification and control of potential sources. Thus, the struggle to prevent lead poisoning has been transformed from tertiary/secondary prevention to primary prevention. Nevertheless, current public health policies remain imperfect instruments for achieving progress in primary prevention. In large part, this relates to the complexity of source reduction and to continuing controversies over the value of such strategies as universal screening.

The Demographics of Lead Poisoning

-The prevalence of childhood lead poisoning is largely determined by two factors: age and proximity to environmental sources or media contaminated by

lead. Other factors that have been associated with increased levels of lead in blood—sex, income, race, place of residence—are mostly predictors of exposure. Children's blood (PbB) lead levels are generally highest between 9 and 18 months of age (see 2, 8). This is because children in this age range tend to explore their immediate environments intensively, with a good deal of hand-to-mouth activity (11, 12), and as compared to adults they are also more efficient, by five- to tenfold, at absorbing lead taken in orally (71). Some children have an abnormal pattern of ingesting non-food items, often soils (pica), which, if these soils are contaminated by lead, can result in very high doses of lead. Boys have slightly higher levels of PbB than girls, which is thought to be behavioral, related to a greater frequency of exploratory behaviors in early childhood. Nutrition and genotype play a very slight role in modifying PbB (27, 77).

The variables of income, race, and residence signify the social tragedy of lead poisoning in the United States. The poor and disadvantaged are more likely to live in lead-contaminated environments, especially in dilapidated housing with flagrant lead paint hazards; they are more likely to live in urban neighborhoods where years of traffic have left tons of lead deposits from leaded gasoline; they are more likely to live near point sources of lead, such as smelters, or hazardous waste sites (41).

The fact that lead poisoning is not evenly or randomly distributed among children in the United States continues to raise tremendous obstacles to its prevention. Until the late 1970s, it is fair to say that this disease was "ghettoized", considered to be a risk exclusively to the urban minority poor (35, 43). This assumption was based on very limited data and highly skewed attempts to identify children with elevated blood lead (PbB) levels. Even in Baltimore, the city with the longest history of public health surveillance for lead exposures, few children were tested or evaluated for lead exposure, and hardly any testing was conducted outside the well-defined "lead belt" of inner-city housing, first described by Huntington Williams in the 1930s (78). Concerns for lead poisoning waxed and waned with social concerns for the disadvantaged until the results of the first representative national survey of lead exposures in US children began to be published in 1982 (36). Coupled with the newer experimental and clinical studies demonstrating toxicity at lower levels of lead exposure (42), these national prevalence reports substantially transformed lead poisoning as a public health issue by making it an environmental concern for the general public (for instance, Environmental Defense Fund). Although the median PbB of poor urban black children measured in NHANES II (1976–1980) was the highest of all persons (nonoccupationally exposed), a significant proportion of *all* children had PbB > 15 $\mu\text{g}/\text{dL}$ and the median PbB for affluent white children was 13 $\mu\text{g}/\text{dL}$.

These data prompted efforts to prevent lead poisoning in children on a national scale.

LEAD POISONING PREVENTION FROM 1900 TO 1970

In the absence of national legislation or suitable government institutions, attempts to prevent lead poisoning over the first 70 years of this century (and earlier) were undertaken only by states and cities. Certain uses of lead, such as lead adulterants to cider and wine, were recognized to pose risks of excess exposure, and these were restricted on a local basis in Europe and the American colonies (18, 75). Other proposals—such as banning lead in plumbing, proposed as early as the eighteenth century in England (32)—were resisted by the lead industry, which in 1922 organized itself to fight attempts to restrict its products (55). The Lead Industries Association succeeded for years in stopping many regulations on lead, including blocking the United States from signing the International Labor Organization (ILO) convention prohibiting use of white lead in paint, an international treaty that the United States has never signed (48) (Table 1).

Most attention until 1970 focused, with reason, on occupational lead poisoning. As documented by Hamilton (26), thousands of workers annually were

Table 1 Signatures to White Lead Paint Convention, International Labor Organization^a

1923	Czechoslovakia, Sweden
1924	Austria, Poland, Spain
1925	Bulgaria, Chile, Romania
1926	Belgium, France, Greece
1928	Cuba, Luxembourg
1929	Finland, Norway, Yugoslavia
1933	Columbia, Nicaragua, Uruguay, Venezuela
1936	Argentina
1938	Mexico
1939	Afghanistan, The Netherlands
1952	Italy
1953	Vietnam
1956	Hungary, Morocco, Tunisia
1959	Guinea
1960	Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Gabon, Ivory Coast
1961	Mauritania, Niger
1962	Algeria
1964	Lao People's Democratic Republic
1966	Iraq
1969	Democratic Kampuchea
1970	Panama
1976	Suriname
1978	Comoros, Djibouti
1988	Malta

^aSource: United Nations Environment Programme, 1989 (country names used are those shown in the source cited).

poisoned by lead in industries ranging from ceramics through battery manufacture. She also reported on the poisoning of children through their employment in the lead trades, and through the uncontrolled movement of lead dusts from the workplace to the worker's home, which remains a continuing problem (37). Some children were screened, starting in Baltimore in 1935, with the development of laboratory methods at Johns Hopkins (31). But from 1935 to 1951, fewer than 2000 children were tested with the dithizone method (78).

No actions were taken during this time on lead in environmental media such as air or water, in the absence of any comprehensive environmental legislation. An attempt was made in the 1930s to reduce allowable residues of lead in food (lead arsenate was widely used as a pesticide), but this was defeated by heavy industry lobbying. The production and consumption of lead in the United States continued to grow. Worse, in 1925, a new use of lead was approved, and this was to become the largest single source of lead contamination in history.

The decision to permit the use of alkyl lead additives in automobile fuels represents the greatest single failure in preventing lead poisoning. Described as "the public health catastrophe of the 20th century" (63), this decision caused the release of thousands of metric tons of lead into ambient air, with both long- and short-range impacts. As shown in Figure 1, the greatest increase in human use of lead occurred at this point in time (note log scale on y-axis). This increase was quickly followed by rises in lead concentrations measured in stable ecological indicators, such as Greenland ice (42, 30). How the lead, gasoline, and automobile industries convinced the US Public Health Service to approve lead for gasoline has been eloquently described (58, 47). A sample of the industry propaganda of the time is shown in Figure 2.

Despite the objections of Hamilton and others, a US government commission decided in 1925 to permit tetraethyl lead (TEL) use in gasoline, with a promise to reconsider the issue later (58). Unfortunately for the nation's health, "later" took 50 years to occur.

LEAD POISONING PREVENTION SINCE 1970

This phase of the prevention struggle has been source directed, rather than case oriented. For the first time, dedicated efforts were made to identify and prevent lead exposures prior to exposure of children. These efforts took two forms: setting enforceable standards for environmental media and drinking water, and specific restrictions on certain uses of lead. Such actions were possible because of the creation of new government institutions, the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA). These actions are summarized in Table 2 (50). Sometimes these actions flowed together. For instance, the EPA's review of the National Ambient Air Quality Standard (NAAQS) for lead, begun in 1981 and concluded in 1986 (71), did

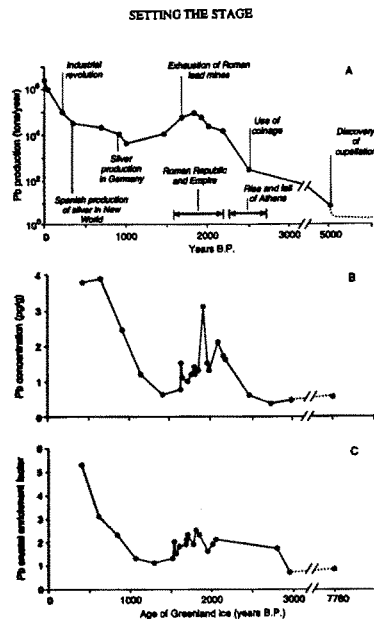


Figure 1 (A) Historical trends in the use of lead; (B) concentrations of lead deposited in Greenland ice; and (C) the relative increase in lead over natural background levels. B.P., before present. Data from NRC 1993.

not result in any change in the NAAQS [although the EPA Science Advisory Board did recommend a reduction from $1.5 \mu\text{g}/\text{m}^3$ to 0.5 or $0.75 \mu\text{g}/\text{m}^3$ (72)]; rather, its four volumes provided substantial weight to public campaigns to ban the use of lead in gasoline, a goal finally achieved in December 1995, after the passage of the Clean Air Act Amendments of 1990. In a similar fashion, the EPA's decision to reduce the drinking water standard for lead from 50 ppb to 5 ppb, in 1986, resulted in bans on use of lead in plumbing solders and fixtures to avoid exceedances due to leaching of lead into drinking water.

These actions to improve environmental standards and to restrict lead uses had major effects on the nature and extent of lead poisoning in US children

Ethylized Gasoline

FOR one year and nine months ethylized gasoline has been on sale. It is now being distributed through about 20,000 filling stations covering one-third of the territory of the United States.

About 200,000,000 gallons have been used by more than one million motorists, with complete safety and satisfaction.

Recently a distressing accident occurred at an experimental plant, where a new process for the manufacture of tetra-ethyl lead, one of the constituents used in ethylizing gasoline, was under development.

Tetra-ethyl lead is a poison, as are many raw materials which enter into the manufacture of harmless compounds. Ethylized gasoline consists of 1,300 parts of ordinary gasoline containing less than one part of tetra-ethyl lead.

This statement is issued to make plain the all-important difference between tetra-ethyl lead, the raw material, and ethylized gasoline, the commercial product.

Ethylized gasoline is more than an improved fuel, giving smoothness to the motor and eliminating knocks; it is a scientific discovery which, in its ultimate development, will contribute largely to the conservation of the world's supply of gasoline.

The dangerous character of tetra-ethyl lead having been recognized from the outset, exhaustive tests have been conducted which have established the safety of ethylized gasoline when used properly as a motor fuel.

These tests have been confirmed by the United States Bureau of Mines, which is making additional studies to determine whether any possible injury can result from continued contact when used for other than motor purposes. Scientific data based on these studies will be submitted to any health commissioner or other public health official on request.

Figure 2 Advertisement placed by the Ethyl Gas Corporation, in the Baltimore Sun, in 1925, in the midst of controversy related to the risks of lead additives to gasoline.

over the 1980s. The reduction in lead used in gasoline (greater than 100-fold, from 1976 to 1986) was associated with average reductions in PbB of over 40%, as shown in Table 3 (66). Controls on lead in other products, such as increased vigilance by the FDA and CPSC over imported foods and toys, also probably contributed to these substantial reductions (2, 53). Use of lead in house paint had been restricted by regulation in 1977, but, for reasons discussed below, this action has had little short- or medium-term impact on lead exposures.

The most dramatic and creative effort at primary prevention was an economic disincentive against lead consumption, introduced as legislation by Congressman Ben Cardin of Maryland in 1993. Inspired by a suggestion

Annu. Rev. Public. Health. 1997.18:187-210. Downloaded from www.annualreviews.org
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Table 2 Action taken by OECD countries to control environmental sources of lead as of 1994

	Environmental media					Environmental sources					Products					Environmental health							
	Drinking water		Surface waters		Ambient air	Air point sources		Water point sources		Sewage sludge	Lead containing wastes		Food-stuffs		Paint	Gasoline	Batteries	Pesticides	Hunting/fishing containers	Food containers	Miscellaneous	Occupational exposures	Child blood lead
	pipes	water	waters	air		soil	air	point sources	water point sources		Dust	or feed	Dust	of feed									
Austria	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Australia	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Canada	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Finland	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Iceland	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Japan	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Mexico	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
New Zealand	x	x	x	x	p	x	x	x	p	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Norway	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	p	x	x	x
Sweden	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	p	x	x	x
Switzerland	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Turkey	x	x	x	x	x	x	x	x	p	x	x	x	x	x	x	x	x	x	x	x	x	x	x
United States	x	x	x	x	x	x	x	x	p	x	x	x	x	x	x	x	x	x	x	x	x	x	x
EC	x	x	x	x	x	x	x	p	x	x	x	x	x	x	x	p	x	x	x	x	x	p	
Belgium	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Denmark	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
France	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Germany	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Greece	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Ireland	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Italy	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Luxembourg	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Netherlands	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Portugal	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Spain	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
United Kingdom	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	

Existing regulation/activity.

p: Proposed regulation/activity.

x: Existing regulation/activity.

p: Proposed regulation/activity.

Table 3 Relationship between lead in gasoline and blood lead levels in the US population*

Year	Lead used in gasoline (10 ⁶ kg)	Median blood lead level (μg/dL)
1976	186.47	14.6
1980	51.59	9.2
1990	0.47	2.8

*Data from References 2, 53.

from the Environmental Defense Fund (21), Cardin proposed a tax on lead, which would serve two purposes: Encourage product substitution by “leveling the playing field” for substitutes for lead, and provide funds dedicated to the screening of children and abatement of past uses of lead, primarily lead paint in housing. This initiative failed in an anti-tax climate, but it represents something of a high-water mark in public health strategies in primary prevention.

Screening is an important aspect of disease prevention, through the early identification of increased exposures and the prompt delivery of therapeutic interventions. Screening not only identifies individuals at risk, but it can also permit health authorities and others to identify sources of lead and reduce or remove them prior to other children being exposed. Screening for lead poisoning involves the measurement of lead in blood, or an appropriately sensitive and specific biomarker of exposure. For lead, the biomarker of erythrocyte protoporphyrin (EP), a biological precursor in the cellular synthesis of heme, was widely used to diagnose lead exposures. This test was highly successful in facilitating screening because it was relatively cheap and, most importantly, with the hematofluorometer, results could be quickly obtained under clinic or field conditions (10, 52). Screening increased in the 1970s in many cities and states until the early 1980s, when screening decreased in the face of efforts to defund public health programs and roll lead screening into underfunded block grants to the states.

When medical consensus caused CDC to lower the guideline defining toxic exposures to lead, first to 25 μg/dl (1985) and then to 10 μg/dl (1991), the EP test was not sufficiently sensitive to identify children with PbBs in excess of these levels. The only recommended methods for screening involved careful collection of blood by venupuncture and lead analysis at a technically competent laboratory (11). The costs increased and logistics become more complicated.

LEAD POISONING PREVENTION IN THE 1990S

The successful regulation of certain lead sources substantially lowered average PbBs in children in the United States, from 1976 to 1991. As shown in Figure 3,

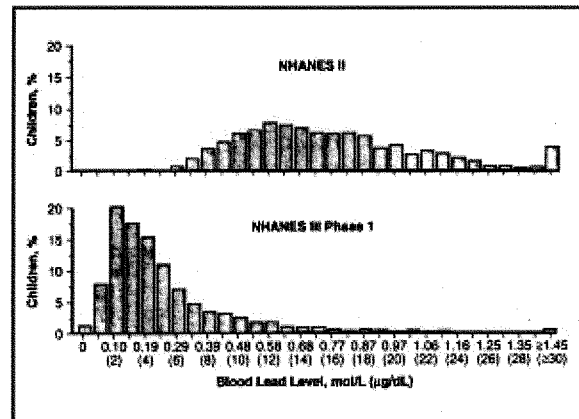


Figure 3 Distribution of blood lead levels in US children (0 to 6 yrs) in 1976-1980 (NHANES II), as compared to that in 1988-1991 (NHANES III). Information on these studies is in Reference 8.

the distribution of PbBs has shifted dramatically. The role of removing lead from gas in this reduction was clear from a trend analysis of the NHANES II data collected from 1976 to 1980, a period that coincided with the first major phasedown of lead in gasoline (Figure 4). While this change must be considered a public health success, this very success has reduced the momentum to fully eliminate lead poisoning. The disease has to a large extent become "re-ghettoized". Now, children with PbB > 10 are much more likely to be black, live in large cities, and to be poor (Table 5) (8). For these children, lead paint is the overwhelming source of exposures (61, 73), followed by exposure to highly contaminated urban soils that contribute to household dusts (39). However, as found by Ashley et al (3) when lead-painted surfaces are present in a home in poor condition, the paint source dominates in house dust and children's blood.

Lead-Based Paint

Lead-based paint in housing has been the most significant source of high-level lead exposure for most of this century. As shown in Table 4, it is the most significant source of lead exposures for young children (1). Despite early recognition, restrictions on the use of lead in paint in the United States were successfully thwarted by the concerted actions of the organized lead industry (55). The city

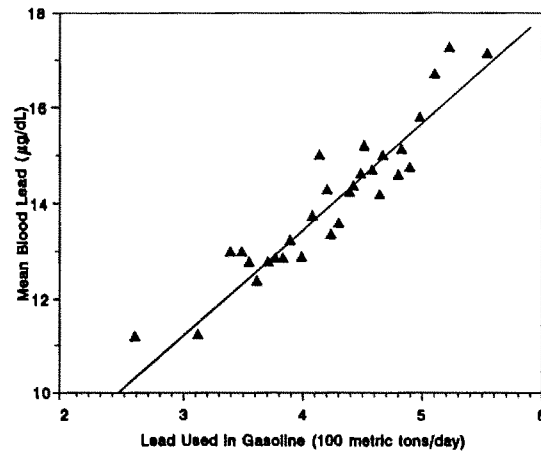


Figure 4 Relationship between lead used in gasoline and median blood lead levels in the US population, 1976–1980 (NHANES II). Although not conducted for this reason, the NHANES survey of national lead exposures serendipitously coincided with the first major reductions in lead usage in gasoline. Later analyses, by Annett and others at CDC, demonstrated a high degree of correlation between monthly lead usage and blood lead (see Reference 2 for details).

of Baltimore, under the inspired leadership of Huntington Williams, banned the use of lead-based paint in public housing, but it was not until 1977 that the US Consumer Product Safety Commission finally issued regulations limiting the concentration of lead in paint to 0.06%. This was a substantial reduction, given that some earlier paint formulations were as much as 45% lead (by weight). However, the regulations covered only paints on *indoor* surfaces of

Table 4 Estimated numbers of children aged less than 7 years residing in unsound and lead-based paint US housing, by age and criteria of deterioration

Category	Construction date	Lead-based paint homes number	Children number
Peeling paint	Pre-1975	1,972,000	567,000
Broken plaster	Pre-1975	1,594,000	458,000
Holes in walls	Pre-1975	2,602,000	747,000
Totals	Pre-1975	6,168,000	1,772,000

Data from HUD.

Table 5 Blood lead levels in the US population, 1988–1991

Population (years)	Blood lead, $\mu\text{cg/dL}$	Percentage above 10 $\mu\text{cg/dL}$ (geometric mean)
<i>Non-Hispanic white</i>		
1–2	3.5	8.5
3–5	2.9	3.7
1–5 low economic status		9.8
high economic status		4.3
<i>Black</i>		
1–2	6.3	21.6
3–5	5.9	20.0
1–5 low economic status		28.4
high economic status		5.8
<i>Mexican-American</i>		
1–2	4.2	10.1
3–5	4.0	6.8
1–5 low economic status		8.8
high economic status		*

*Insufficient numbers for estimation.
Data from Reference 8.

residential structures, and articles (such as toys and furniture) designed for use by children.

More seriously, these steps could not deal with the lead paint that had been used in housing before the 1977 ban. As documented by the Department of Housing and Urban Development, over 40 million residential units in the United States are estimated to contain lead-painted surfaces because they were built before 1960 (Table 4). Of the 42 million units, some 26 million are in dilapidated condition (73), such that lead paint hazards are more likely to present risks of exposure through contamination of house dust and presence of paint flakes and chips (14, 15). Their distribution varies with the age of communities; Massachusetts, Illinois, New York, New Jersey, and Pennsylvania have millions of these units.

Dealing with existing lead paint in housing has proved difficult because of the complex of issues related to poverty, housing, and disease prevention. Housing is an unusual vector of disease: It cannot simply be eradicated without provision of adequate substitutes. When the most dangerous housing is in poor neighborhoods, the social concerns of providing any affordable housing for the poor can come into conflict with preventing disease.

The provision of lead-safe housing has been estimated to require major public or private investments, costing billions of dollars (73). Public policy, where it has existed (usually on the local level), has placed the burden on the private

sector to abate lead hazards when identified. For example, by 1980, Baltimore had developed, on paper, the most rigorous legal standards to require landlords to remove all lead paint from homes where children with elevated PbB were found.

Ford & Gilligan (22) were among the first to document the concerns about the practical problems with this policy. They evaluated the economic resources for private sector lead-paint abatement in Baltimore and concluded that landlords could not recover the costs of adequate abatement from the revenues that could be generated from rental housing in poor neighborhoods. They warned that existing laws, if fully enforced, would result in large-scale abandonment of housing and a loss of affordable housing for the poor. Their analysis was quickly taken up by property owners' organizations to attack lead poisoning prevention programs in Baltimore, New York, and elsewhere. Their concerns were shared, for different motivations, by some advocates for housing and community development, such as the Enterprise Foundation. The controversy was considerably heightened by the success of attorneys for some children and their families in winning large judgments and settlements against property owners.

Despite applied research projects demonstrating that adequate hazard reduction could be achieved for substantially lower costs than first estimated (19, 20), the conflict remained. It came to a head after 1992, when legislation related to lead-paint poisoning prevention had been passed through the efforts of Senators Alan Cranston of California and Paul Sarbanes of Maryland, among others. The Housing Act attacked the lead-paint problem in three ways. First, it closed a loophole in occupational health, whereby abatement and construction workers had not been covered by the 1978 OSHA lead standard (68). Second, it enlisted market forces to encourage abatement by requiring disclosure of lead paint in private real estate transactions. Third, it required HUD to develop policies for dealing with private and public rental housing, particularly for poor and low-income families.

The real estate disclosure program, finally implemented with regulations in 1996, may encourage source reduction, but these are likely to occur only in those housing markets able to sustain the investment required, that is, where the value of property can absorb an abatement "penalty" borne by the seller (either as reduced sale price or investment in abatement prior to sale). The success of disclosure and notification to prevent lead poisoning in children is unknown. Some anecdotal evidence suggests that it has worked in Boston in terms of increasing the amount of abatement (S Pollock, personal communication). But it has served to separate the lead poisoning problem of the affluent from that of the poor. The poor are more likely to be renters than owners, and their housing is in many cases insufficiently valued to absorb the costs of abatement without public subsidy.

The problem of low-income housing was given by HUD to a national task force to resolve. This task force, advisory to HUD, was chaired by two advocates, for housing (C Dolbeare) and lead poisoning prevention (D Ryan). The task force noted the scope of the lead-paint poisoning problem and attempted to resolve the conflicts between housing affordability and lead poisoning prevention by two strategies: lowering the standards for abating lead paint hazards, and inducing property owners to take preventive actions in return for insulation against civil litigation. The Task Force endorsed a policy of managing lead paint in place, rather than requiring actual paint removal or replacement of certain structural elements, such as door and window frames [as recommended by Farfel & Chisolm (20)]. Property owners were to be immunized from litigation if they undertook certain hazard-reduction steps. These recommendations were not universally endorsed. A minority of the Task Force (of which this author was one) rejected the concept of managing hazards in place without an enforceable system of ongoing inspection and maintenance, and they criticized the legal immunity proposal on the ground that it stripped away one of the few protections, admittedly imperfect, available to children at risk.

Several states have adopted this strategy in law or practice. In Maryland, the state legislature passed a law that replaced Maryland's rigorous program with the elements of the HUD Task Force recommendations. Similar proposals have been debated in other states.

Lead-Contaminated Soil

A similar retreat occurred in another arena where the expenses of remediation challenged the ambitious goal of source control. ATSDR had identified lead-contaminated soils as a significant source of lead exposures for children in the United States (1). Under the Superfund hazard ranking system, the presence of lead in soil tended to place a site on EPA's National Priority List based on the assumption that lead in soil was significantly correlated with lead in children's blood. Some 400 sites are on this list because of lead contamination. However, some studies of children living in communities with high soil-lead concentrations did not confirm this association. As reported by Freeman et al (23) and others (see 5), in some communities where the source of lead in soils was related to mining and smelting, no children with PbB above 10 $\mu\text{g}/\text{dL}$ were found. This was in contrast to experience in smelter and mining communities in El Paso, Texas, (33) or Port Pirie, Australia (the site of the world's largest lead mining and smelting operations in the 1960s and 1970s) (38). Once again, an aspect of social class seemed to play a role, as in the housing controversies. When the citizens of Aspen, Colorado, and Park City, Utah, two affluent resort towns in the Rockies, balked at being designated as Superfund sites, one citizen activist in Aspen remarked that "everyone knows that lead poisoning is a disease of poor Black kids and we don't have any of [them] here" (New Yorker).

Studies on the association between urban soil lead and children's PbB have been inconclusive. The EPA sponsored studies in Boston, Baltimore, and Cincinnati to test the effects of reducing soil lead on children's PbB. Relatively small changes were observed (76). The cost of cleaning up lead-contaminated sites was clearly very high, because only soil removal could work. If communities with high soil-lead levels were added to the Superfund list, it was not clear who would or could pay for abatement, since in some cases the source was not an industry but rather the use of lead in gasoline (39).

In the face of this controversy, the primary prevention campaign again faltered. The EPA, charged with issuing standards for lead in soil, retreated to promulgating "advisory" levels that are not enforceable. They were not clearly based on any health-based concept of the potential contribution of lead in soils to lead in blood.

Screening

As the struggle for prevention failed in the case of housing and soils, another element in lead poisoning prevention also came under attack in the 1990s. Screening has always been an element of preventive health policy and early detection of lead exposure can prevent further exposures that result in irreversible toxicity and can also assist in preventing exposures of other children to the same source of lead. But debate has arisen on the meaning of screening, and the reasonableness of measuring lead in blood of all children in the United States.

In 1991, the Centers for Disease Control had recommended that *all* children under the age of two years should be screened at least once by blood lead testing (11). This recommendation was predicated on the NHANES II data that reported widespread prevalence of lead exposures (see Figure 3) and on the inadequacy of postexposure treatment as a means of preventing or reversing toxicity. At the "high-water mark" of screening, in 1990, some 3 million children <6 years were tested. However, for screening to fulfill the purpose for prevention (primary or secondary) it must be part of an integrated program to identify and control the child's lead sources, as well as to manage children with elevated levels. According to a survey conducted by the Association of State and Territorial Health Officials (ASTHO) in 1992, only 21 states had implemented or were planning to implement the 1991 CDC guidelines. Less than half of the 48 states responding had a state system to monitor and follow up children with PbB > 10 µg/dL (4). In *no* state were all children with excess PbB followed up, with identification of exposure sources.

Soon after the 1991 recommendation by CDC, criticisms were expressed from several sources. Physicians in California and Washington criticized the recommendation of *universal* blood lead screening as inflexible and unresponsive to local conditions (6). They argued that lead poisoning was unknown

Table 6 Blood lead levels in Maryland, 1993^a

Area screened	Number screened	Blood lead level, $\mu\text{g/dL}$ (%)				
		1-9	10-14	15-19	20-24	≥ 25
Baltimore City	33,207	21,188 (63.8)	6804 (20.5)	2933 (8.8)	1264 (3.8)	1028 (3.1)
Baltimore County ^b	4772	4140 (86.8)	441 (9.2)	130 (2.7)	36 (0.8)	25 (0.5)
Howard County ^b	339	311 (91.4)	21 (6.2)	4 (1.2)	2 (0.6)	1 (0.2)
Montgomery County ^c	1794	1728 (96.3)	45 (2.5)	15 (0.8)	3 (0.2)	3 (0.2)

^aData from Maryland Lead Poisoning Prevention Program, Maryland Department of the Environment.^bCounties immediately adjacent to Baltimore City.^cMaryland's most affluent county.

in many communities where risk factors were low, and that in these situations requiring universal screening was an unacceptable waste of valuable health resources for the public and private sectors. While some localities reported that increased screening efforts were revealing a greater than expected prevalence of lead exposures in children (for instance, in Rhode Island), others found few if any children with PbB > 10 $\mu\text{g/dL}$ (many of these studies were published in *Pediatrics* ref 1994). The experience of Maryland in 1993 is illustrative. As shown in Table 6, the highest rates of elevated PbB were found in Baltimore City, with the lowest median family income in the state and the highest proportion of minority children, and a preponderance of housing built before 1950. In contrast, in Montgomery County, where median family income is among the highest in the United States, African American children comprise less than 25% of the population, and where the housing stock is newer, the prevalence of PbB > 10 among screened children was less than 1%.

In 1993, the American Academy of Pediatrics endorsed universal screening (16). But in 1994, Birt Harvey, of the Academy, recommended that universal screening should be abandoned (Harvey, 1994). He disputed the benefits of screening for children with PbB < 20 $\mu\text{g/dL}$; he pointed to the fact that in many communities few children were detected with PbB greater than 20 $\mu\text{g/dL}$; and he expressed concerns over laboratory resources and competence.

Under pressure, CDC formally reopened its recommendation for universal screening in 1995. While it is probably true that in some communities, few if any children are exposed to lead such that their PbB exceeds 10 $\mu\text{g/dL}$ (e.g. 7), the practical challenge is to develop a method that accurately defines these communities without missing children who are at risk of lead exposure (69).

Moreover, if such a strategy could be developed and validated, it is not clear that it would save health resources. The costs of blood lead screening can be calculated; the costs of alternate screening methods have not been calculated. Yet the methods proposed by CDC recommend that health care providers administer and interpret an individualized questionnaire, in the context of information on those characteristics of the community that indicate the presence of lead exposure risks. This process has costs in terms of the time required by experienced health care providers and public health officials.

Other criticisms have been leveled against screening of any type, notably by the US Preventive Services Task Force (74). This group concluded that:

There is relatively little convincing evidence that these interventions [screening and environmental or medical interventions based on screening] improve health, however. One issue is that most available studies in asymptomatic children evaluate the effects of various interventions on blood lead levels rather than on clinical outcomes. Second, blood lead levels typically decline with the passage of time. On average, blood lead levels in childhood decrease with age after peaking at about 2 years of age, even without intervention. Longitudinal studies of asymptomatic children with elevated lead levels have shown reductions in blood lead levels after short- and long-term follow-up in the absence of any intervention, a result attributable at least in part to regression to the mean, random variation, and laboratory error.

... Evidence is not available to demonstrate that universal screening for blood lead results in better clinical outcomes than either screening targeted to high-risk persons or individualized testing in response to clinical suspicion. Several older studies reported that, compared to historical results from individualized testing, intensive screening programs targeted to children in high-risk neighborhoods reduced case fatality rates, mortality rates, and proportions of children detected with very high blood lead levels or who developed symptomatic lead poisoning. In the absence of concurrent controls, it is not clear whether the reported reductions in mortality and case fatality rates were due to screening, or to improvements in medical care over time. Reductions in mean lead levels may also have been due to secular trends, changes in screening tests, and to screening greater numbers of children, including many at low risk for severe lead poisoning. Thus, the available evidence regarding the efficacy of screening programs is weak (74).

BENEFITS OF PREVENTING LEAD POISONING

Despite the controversies over how best to prevent lead poisoning, by screening or environmental interventions, several analyses have shown significant net benefits to reducing lead exposures for children. The first of these studies was conducted by Schwartz and colleagues at EPA, in an analysis to support regulating lead in gasoline (See 46 for a review; 62 for the original analysis). As shown in Table 7, a correlation can be drawn between PbB and IQ in children based on several studies conducted worldwide (43). IQ is then correlated

Table 7 Meta-analysis, studies of the lead IQ relationship

References*	Year	n	Effect size	Power to detect small effect	p (lf)
Perino et al (29)	1974	80	0.6	0.2	0.025
Needleman et al (9)	1979	73	0.35	0.47	0.015
Yule et al (30)	1981	82	0.573	0.42	0.021
Winneke et al (31)	1982	26	0.26	0.18	0.15
Smith et al (19)	1983	185	0.17	0.7	0.12
Winneke et al (32)	1983	115	0.351	0.25	0.4
Harvey et al (21)	1984	48		0	
Shapiro & Maracek (33)	1984	193	0.46	0.48	0.025
Lansdown et al (34)	1986	162	0.07	0.48	0.66
Hansen et al (14)	1987	82	0.5	0.34	0.0005
Hawk et al (35)	1986	75	0.64	0.25	0.0004
Schroeder et al (36)	1985	104	0.5	0.33	0.005
Fulton et al (12)	1987	501	0.4	0.52	0.003
Hatzakis et al (13)	1987	509	0.4	0.52	0.00065
					$\sum x = 109.13$
					$p = 2.97 \times 10^{-12}$

*See Reference 45 for original citations.

with academic attainment, from other literature, and academic attainment with lifetime earnings. By these calculations, Schwartz (60) estimated that \$6.9 billion would accrue in benefits if children's PbB were reduced by 1 $\mu\text{g}/\text{dL}$ across the population. Salkever (59) updated these estimates to an increased benefits amount of \$2.5 billion per birth cohort. [The other neurobehavioral sequelae of lead toxicity—antisocial behavior, school dropout, and criminal activity—were not monetized, largely because data are not sufficient to support a marginal analysis associating these outcomes in a dose-response relationship with incremental changes in PbB. Nevertheless, as pointed out by Needleman (43), these costs may be very great.]

Large benefits of lowering blood lead levels were found for reducing lead in gasoline, lowering the drinking water standard, and abating lead paint in housing (60–62). However in some cases net benefits (exceeding costs) were found only when the value of reducing the effects of lead on blood pressure in adults and on materials damage (damage to spark plugs and plumbing) was added into the analyses.

It is more difficult to calculate the benefits of screening. Briss and Schwartz have undertaken several cost benefit analyses, in order to support a rational basis for universal or less than universal screening (CDC, unpublished data).

A major problem lies in the controversy over the role of screening in lowering PbB as discussed above (74).

CONCLUSIONS

The prevention of lead poisoning achieved significant successes in the 1980s when new data on the nature and extent of lead toxicity provided political support for major actions in primary prevention, notably the removal of lead from gasoline. That action undoubtedly reduced environmental levels of lead in soils and air (42) and reduced blood lead levels across the US population (53).

However, the campaign for prevention foundered by the end of the 1980s for three reasons. First, the "easy" tasks of source reduction (removing lead from gasoline, paint, and plumbing) were accomplished [it should be noted that the United States is the only country where these "easy" tasks have been achieved (50).] Second, these accomplishments reduced the urgency of lead poisoning as an issue among the US public as a whole, because lead poisoning, once again, was viewed as a disease affecting only a segment of the population, the disadvantaged of society, in a time when the political climate had largely turned against the "liberalism" of a welfare state. Third, the remaining sources of lead exposures for children—lead in housing and soil—presented daunting economic and technical costs for their solution. Even the relatively small costs of universal screening were considered by some to be too high.

Yet lead poisoning has not disappeared. A disease with a national prevalence of 5% cannot be considered to have been eradicated, as the US government once pledged to eradicate childhood lead poisoning (70). Moreover, a disease with such disparate prevalence, affecting those beset by other conditions of prejudice and disadvantage at a rate of over 25%, or five times more than advantaged children, should not be tolerated in a humane society. The costs of this neglect are born by all, even if the risks of lead poisoning are not equally shared.

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THE FUTURE OF BENEFIT-COST ANALYSES OF THE CLEAN AIR ACT

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Key Words

■ **Abstract** This review examines the first two studies conducted pursuant to a Congressional mandate that the U.S. Environmental Protection Agency analyze the effects of the Clean Air Act on the “public health, economy, and the environment of the United States.” While these studies indicate that overall, the nation received good value for the resources it invested in improving air quality over the past three decades, we don’t know if even higher value could have been obtained by changing or eliminating certain potentially inefficient elements. The review focuses on the critical policy and technical choices made in the analyses, including the selection of the appropriate baseline and the level of disaggregation for the studies. It is proposed that a potential third analysis focus on potential new policies not yet mandated by law or regulation. It is also proposed that the next study fill in key information gaps, expand the benefit categories, and incorporate new research on topics such as mortality and morbidity benefits, cost uncertainties, and others.

INTRODUCTION

Since the Clean Air Act (CAA) was enacted in 1970, critics have repeatedly questioned whether the health and environmental benefits of air pollution control justify the costs incurred by industry, taxpayers, and consumers. Until Congress added Section 812 to the 1990 CAA Amendments, a requirement that the U.S. Environmental Protection Agency (EPA) conduct periodic, scientifically reviewed studies on the effects of the CAA on the “public health, economy, and the environment of the United States,” there was not a specific mandate for the Agency to compare the overall benefits of the CAA with the costs imposed on society. The resulting studies, *The Benefits and Costs of the Clean Air Act: 1970 to 1990* (29) and *The Benefits and Costs of the Clean Air Act, 1990 to 2010* (31), are widely seen as the “gold standard” of benefit-cost studies conducted by government, both in the United States and abroad. Under the auspices of the Advisory Committee for Clean Air Compliance Analysis (ACCACA), operating under the charter of

the EPA's Science Advisory Board, both studies were scrutinized throughout the decade-long preparation by at least three expert committees of outside economists, air quality modelers, epidemiologists, and other health experts. They are probably the most intensive and expensive benefit-cost analyses ever conducted at the EPA.

Notwithstanding the many assumptions needed to address such a broad legislative mandate, the results of the analyses are clear: Overall, the nation has received high returns on its investment in improved air quality over the past three decades. For the early years benefits are estimated to exceed costs by an order of magnitude. Prospectively, benefits still exceed costs, although by a smaller margin.

Particularly because the analyses were conducted at such a highly aggregate level, it is possible that the overall results reflect large gains from only a few programs within the CAA. Indeed, the overall finding of large net benefits may be masking ineffective or inefficient programs or regulations carried out under some titles of the CAA. In addition, many of the technical choices made in these studies involve important methodological issues about which experts differ. Understanding these issues is crucial to interpreting the overall findings. Currently, the EPA and one of its expert committees are meeting to consider the need for and the appropriate focus of a second prospective study. In contrast to the first two studies, the EPA has considerably greater latitude in defining the scope of such an analysis. Arguably, little would be gained by simply updating the existing studies with the same focus and methods used previously.

The overall goal of this review is to elucidate the results of the first two studies, including a critical examination of the policy and technical choices made in the analyses, and to highlight areas for improvement in a potential second prospective study. With this, the reader will develop some perspective on the practice and pitfalls of cost-benefit analysis as practiced by the government, as well as a better understanding of the net benefits to society of the CAA.

This review emphasizes the disaggregation issue and areas where specific methodological choices could make a significant difference to the outcome. One additional attractive option discussed involves focusing the next study on a set of specific policy issues that have the potential to increase the net benefits of the CAA in the decades to come.

The next section describes the basic methods and results of both the prospective and the retrospective studies. Particular attention is paid to the baseline and aggregation issues. The third section considers alternative foci for a new prospective study, including the option of focusing on the key policy challenges likely to be considered in coming years. The fourth section considers a wide range of technical and methodological issues including the need to fill in key information gaps, expand the benefit categories, and incorporate new research on topics such as mortality and morbidity benefits, cost uncertainties, and others. The last section draws overall conclusions and recommendations.

METHODS AND RESULTS OF RETROSPECTIVE AND PROSPECTIVE STUDIES

The EPA's retrospective and prospective studies were designed to examine a specific set of policies that had been enacted by Congress since 1970 and implemented by the EPA. The retrospective analysis focused on air quality policies and regulations put in place from 1970–1990, and the prospective study addressed provisions added in the 1990 CAA Amendments. Both studies were conducted at a highly aggregate, economy-wide level. The retrospective study did not estimate either the benefits or the costs of individual regulations, pollutants, or any subcategories (e.g., stationary versus mobile sources) of the federal air pollution program. The prospective study estimated costs but not benefits by title of the CAA Amendments.

From a policy perspective, an analysis of total benefits and total costs represents a very simple approach to a complex issue. Arguably, few propose abandoning all federal air pollution control. The more policy-relevant question concerns the benefits and costs of individual regulations and, even more relevant, the benefits and costs of marginal changes to individual regulations. The principal rationale offered by the EPA for this highly aggregate analysis is that whereas costs can be reliably attributed to individual regulations or programs, the broad-scale methodology used for the benefits analysis precludes reliable estimation of the benefits by regulation or program, especially because some pollutants, e.g., nitrogen oxides (NO_x), show up in multiple titles. This has been a highly controversial issue throughout these studies and remains so in the design of any new analysis. Indeed, the EPA's own Regulatory Impact Analyses for Ozone and Particulate Matter disaggregates the benefits of controlling these pollutants, although not by CAA Title.¹

In both the retrospective and the prospective studies the EPA analyzed air pollution programs by comparing specific policy and baseline scenarios. The retrospective study contrasted a scenario reflecting historical economic and environmental conditions observed with the CAA in place with a hypothetical scenario that projects the economic and environmental conditions that would have existed assuming that the stringency and effectiveness of air pollution control technologies were frozen at their 1970 levels. In the prospective study all rules promulgated or expected to be promulgated pursuant to the 1990 CAA were contrasted to a scenario that essentially freezes federal, state, and local air pollution controls at the levels of stringency and effectiveness prevailing in 1990. Both studies hold constant the geographic distributions of populations and economic activities across the scenarios.²

¹In addition, work by Smith & Ross (27) contains an analysis in which the Section 812 study results and other information is processed into a title by pollutant cost-benefit analysis.

²Although the scenarios do reflect the basic trends in population and economic growth across the country over the relevant time periods, they do not allow for the possibility that people would respond to pollution by moving away from the dirtiest areas.

The frozen technology assumption—an obvious simplification—is central to the overall results. Arguably, in the absence of new federal regulation, one would expect to see some air pollution abatement activity, owing to state or local regulation or, possibly, on a voluntary basis. As Davies (9) has reported, nonfederal air pollution efforts date back to 1881 when the city of Chicago adopted an ordinance that declared that “the emission of dense smoke from the smokestack of any boat or locomotive or from any chimney anywhere within the city shall be . . . a public nuisance.” More recently, some states have imposed particularly stringent controls in some areas, e.g., California. If one assumed that state and local regulations would have been equivalent to federal regulations, then a benefit-cost analysis of the federal CAA would be a meaningless exercise: Both benefits and costs would equal zero. For both studies, the EPA and the outside experts wrestled with the possibility of developing more realistic baseline scenarios. In the end they decided that any attempt to predict how states’ and localities’ regulations or voluntary efforts would have differed from the CAA is too speculative.

Each of the two (aggregate) scenarios is evaluated by a sequence of economic, emissions, air quality, physical effect, economic valuation, and uncertainty models to measure the differences between the scenarios in economic, human health, and environmental outcomes. Both studies examine the benefits and costs of reducing volatile organic compounds, nitrogen oxides (NO_x), sulphur dioxide (SO₂), carbon monoxide (CO), coarse particulate matter (PM₁₀), and fine particulate matter (PM_{2.5}).³ The retrospective analysis assessed the effect of CAA provisions governing lead in the environment. However, because the 1990 Amendments do not include new provisions for the control of lead, it is not considered in the prospective analysis.

Although both studies attempt broad coverage, there are some notable omissions, largely because of data or modeling limitations. Emissions of hazardous air pollutants are not extensively considered in either study.⁴ Recent revisions to the particulate matter and ozone ambient standards are also omitted from the prospective study, although the EPA analysis indicates that because of similarities in the baseline assumptions, the benefits and costs reported in the Regulatory Impact

³Although the incremental effects of the CAA Amendments on primary particulate matter emissions are relatively small, particulate matter in the atmosphere is comprised of both directly emitted primary particles and particles that form in the atmosphere through secondary processes as a result of emissions of SO₂, NO_x, and organic compounds. These particulate matter species, formed by the conversion of gaseous pollutants emissions, are referred to collectively as secondary particulate matter. Because the CAA, especially the 1990 Amendments, achieved substantial reductions in these gaseous precursor emissions, it has a much larger effect on PM₁₀ and PM_{2.5} than might be apparent if only the changes in directly emitted particles are considered.

⁴Some pilot analyses of hazardous air pollutants were conducted but it was determined that the poor quality of the available information precluded comprehensive quantification of the effects.

Analyses for these pollutants can be considered incremental to the results of the prospective analysis. Estimates for that part of the CAA Amendments regarding stratospheric ozone depletion (Title VI) are developed in the prospective study but they are not fully integrated into the main analysis.

Emissions estimates reflect the expected growth in population, transportation, electric power generation, and other economic activity over the relevant time periods. Different estimation procedures are used for stationary, mobile, and area sources, although the benefit and cost estimates are not disaggregated in that manner. Costs are estimated as increases in expenditures by different entities to meet the additional control requirements of the CAA, including operation and maintenance expenditures plus amortized capital costs (i.e., depreciation plus interest costs associated with the existing capital stock). Changes in employment and prices as well as impacts that might be experienced among customers of the firms that must incur these costs were partially examined in the retrospective analysis but omitted in the prospective study. In limiting consideration of these so-called general equilibrium effects, the EPA reports effectively preclude analysis of the economy-wide costs of imposing additional environmental regulations in the context of existing labor and other (distortionary) taxes.⁵

Although the air quality modeling efforts focused on the full range of pollutants, both studies found that the majority of the total benefits are attributable to changes in particulate matter concentrations. Consistent with current scientific understandings, neither the specific source categories nor the chemical composition of the particles were considered. Thus, secondary particles formed from SO₂, NO_x, and volatile organic compounds were all treated (uniformly) as fine particles. The retrospective study found significant benefits associated with the reductions in lead—principally the phase-down of lead in gasoline. The monetary benefits of air quality improvement include reduced incidence of premature mortality and other human health effects, as well as improvements in visibility and avoided damage to agricultural crops. Despite efforts to characterize the impacts of air pollution on natural systems, the inability to quantify and/or place a monetary value on the damages precluded the development of benefits estimates for ecosystem impacts (except for a supplementary calculation for avoided costs of nitrate reductions; see below). A similar story applies to potential carcinogenic and certain other health effects associated with criteria pollutants.

The monetary benefits reflect interpretations of the available science and economic literature made by the EPA in consultation with its outside experts. As a form of sensitivity analysis, a number of alternative interpretations of the literature were also examined. The quantitatively most important concern the valuation of premature mortality. In both the retrospective and prospective analyses, the EPA developed an alternative scenario based on the loss of life-years approach to reflect

⁵Costs for meeting Title IV through the SO₂ trading program were estimated by a model that allocates emissions reductions cost-effectively in a context of responding to market signals in the electric power and tradable allowance markets.

the greater susceptibility of older individuals to air pollution-induced mortality. In both studies this scenario yielded significantly lower benefits. The prospective study also examined alternative assumptions about the incidence of mortality and the incidence and valuation of chronic bronchitis, as well as certain other effects. Sensitivity analysis was used to examine alternative behavioral responses to stratospheric ozone depletion (Title VI), such as remaining indoors or increasing use of sunscreen or hats.

Table 1 displays the present value of monetary benefits of the CAA by endpoint category, along with comparisons to estimated costs, for 1970–1990. An array of benefit estimates is presented, reflecting the underlying uncertainties. Overall, the present value of total benefits is estimated to range from \$3.5 trillion (5th percentile of the underlying probability distribution) to \$56.3 trillion (95th percentile) over the 20-year period. Comparing the mean benefit estimate (\$22.2 trillion) with the present value point estimate of costs (\$5 trillion), benefits are seen to dwarf costs

TABLE 1 Present value of 1970–1990 costs and monetized benefits by endpoint category for population of continental United States (billions of 1990 dollars, discounted to 1990 at 5%) [from Reference (29)]

Endpoint	Pollutant(s) ^a	Present value		
		5th percentile	Mean	95th percentile
Mortality	PM	\$2,369	\$16,632	\$40,597
Mortality	Pb	\$121	\$1,339	\$3,910
Chronic bronchitis	PM	\$409	\$3,313	\$10,401
IQ (lost IQ pts. + children w/IQ <70)	Pb	\$271	\$399	\$551
Hypertension	Pb	\$77	\$98	\$120
Hospital admissions	PM, O ₃ , Pb, CO	\$27	\$57	\$120
Respiratory-related symptoms, restricted activity, decreased productivity	PM, O ₃ , NO ₂ , SO ₂	\$123	\$182	\$261
Soiling damage	PM	\$6	\$74	\$192
Visibility	particulates	\$38	\$54	\$71
Agriculture (net surplus)	O ₃	\$11	\$23	\$35
Total benefits		\$3,452	\$22,171	\$56,258
Total costs			\$523	
Net benefits (total benefits – total costs)			\$21,648	

^aPM, particulate matter; Pb, lead.

TABLE 2 Alternative mortality benefits' mean estimates for 1970–1990 (in trillions of 1990 dollars, discounted at 5%) [from Reference (29)]

Benefit estimation method	Benefits particulate matter	Total
Statistical life method (\$4.8 million/life)	16.6	18.0
Life-years lost method (\$293,000/year)	9.1	10.1

by a factor of 42:1.⁶ Net benefits amount to \$21.6 trillion. Note that according to the mean estimates particulate matter mortality is estimated to account for 75% of total benefits, followed by chronic bronchitis (15%) and lead mortality (6%). The remaining eight categories comprise the residual 4% of benefits.

Table 2 presents alternative particulate matter mortality benefits when the life-years lost method as opposed to the statistical life approach is used in the calculations. Although the latter approach has historically been used by the EPA in conducting its benefit-cost analyses, some short-term particulate matter exposure studies suggest that a disproportionate share of particulate matter-related premature mortality occurs among persons 65 years of age or older. Thus, at the urging of the outside review committee, the EPA combined standard life expectancy tables with the limited available data on age-specific incidence to develop (crude) approximations of the number of life-years lost by those who die prematurely as a result of exposure to particulate matter. These were presented as alternative estimates. As shown in Table 2, the particulate matter mortality benefits, the largest single benefit category overall, fall by 45% when this alternative valuation method is used. Although use of the life-years lost method does not change the basic conclusion of the retrospective study that the monetized benefits greatly exceed costs over the period 1970–1990, the magnitude of the change demonstrates the importance of answering the question of valuation with greater clarity. As discussed in Updating The Information, below, the life-years lost method is but one of several current issues in the valuation literature.

Table 3, drawn from the prospective study, summarizes the central estimates on a present value basis of the costs and benefits of the Clean Air Act (CAA) for 1990–2010. About 90% of the benefits are associated with avoided mortality, a slightly higher proportion than in the retrospective study. The remainder of the benefits are associated with avoided morbidity and ecological and welfare benefits. On the cost side, the prospective analysis finds that Title I [National Ambient Air Quality Standards (NAAQS)] accounts for almost half of the total cost of the first five titles. Title II (mobile sources) accounts for another third, with the balance distributed among Title III (toxic emissions), Title IV (SO₂ and NO_x from power plants), and Title V (permitting). Because of the long-term nature of the

⁶Note that the costs were treated as if they were certain, when in fact there is much uncertainty about such costs (see Updating The Information, below).

TABLE 3 Summary of quantified primary central estimate benefits and costs of Clean Air Act amendments, 1990–2010 (estimates in millions of 1990 dollars) [from Reference (31)]^a

Cost or benefit category	Annual estimates		
	2000	2010	Present value
Costs:			
Title I	\$8,600	\$14,500	\$85,000
Title II	\$7,400	\$9,000	\$65,000
Title III	\$780	\$840	\$6,600
Title IV	\$2,300	\$2,000	\$18,000
Title V	\$300	\$300	\$2,500
Total costs, Title I–V	\$19,000	\$27,000	\$180,000
Title VI	\$1,400*		\$27,000*
Monetized benefits:			
Avoided mortality	\$63,000	\$100,000	\$610,000
Avoided morbidity	\$5,100	\$7,900	\$49,000
Ecological and welfare effects	\$3,000	\$4,800	\$29,000
Total benefits, Title I–V	\$71,000	\$110,000	\$690,000
Stratospheric ozone	\$25,000*		\$530,000*

^aAnnual estimates for Title VI stratospheric ozone protection provisions are annualized equivalents of the net present value of costs from 1990 to 2075 (for costs) or 1990 to 2165 (for benefits). The difference in time scales for costs and benefits reflects the persistence of ozone depleting substances in the atmosphere, the slow processes of ozone formation and depletion, and the accumulation of physical effects in response to elevated UV-b radiation levels.

benefits of Title VI (stratospheric ozone), its results are not fully integrated into the overall findings. However, the present value benefits of this title exceed costs by a factor of twenty. Overall, while the monetized benefits of the CAA Amendments over the period 1990–2010 still exceed the costs, the ratio of benefits to costs (about 4:1 for Titles I–V) is considerably lower than in the retrospective analysis, suggesting that the “truly low hanging fruit” may have been picked in the early years.⁷

Overall, as the EPA has noted in the prospective study, the conclusion of the Section 812 analysis is clear:

While alternative choices for data, models, modeling assumptions, and valuation paradigms may yield results outside the range projected in our primary analysis, we believe based on the magnitude of the difference between the estimated benefits and costs that it is unlikely that eliminating uncertainties or adopting reasonable alternative assumptions would change the fundamental

⁷In one of the scenarios presented in the prospective study (low benefits), costs actually exceed benefits by \$1 billion per year.

conclusion of . . . [the] study: the Clean Air Act(s') . . . total benefits to society exceed its costs. (31, page v)

Although the findings of these studies have been discussed in the media and, to some extent, on Capitol Hill, it is fair to say they have played only a modest role in the policymaking process. In our judgment, the EPA needs to disaggregate the benefits and costs into those applicable to specific titles, sectors, or regulations in order to have a significant impact on policy decisions. Although the EPA did not do this in the Section 812 study, others have done so for specific titles of the CAA, taking the EPA's aggregate benefit estimate (and cost estimates by title) as given (27). Extensive analysis has also been conducted on the electricity generation sector (Title IV) alone (7, 5). In addition, the EPA was able to develop separate benefit estimates for their new ozone and fine particulate National Ambient Air Quality Standards (30). The findings from these studies are presented in Table 4. This table shows that some titles deliver more net benefits than others and that the new fine particulate NAAQS is likely to be a much better buy for society than the new ambient ozone standard.

TABLE 4 Summary of cost-benefit studies of the 1990 Clean Air Act Amendments for 2010 (estimates in millions of 1990 dollars)

Study	Benefits	Costs
Title IV		
Burtraw et al. (5) ^a	\$25,000	\$800
Chestnut (7)	\$35,277	NA
New NAAQS (30) ^b		
Ozone (8-h), partial attainment	\$400–\$2,100	\$1,100
Ozone (8-h), full attainment	\$1,500–\$8,500	\$9,600
Fine particulates, partial attainment	\$19,000–\$104,000	\$8,600
Fine particulates, full attainment	\$20,000–\$110,000	\$37,000
Clean Air Act Amendments (27) ^c		
Title I	\$26,564	\$14,500
Title II	\$14,968	\$9,000
Title III	\$1,925	\$840
Title IV	\$69,297	\$2,000

^aWhile this estimate is specific to the eastern United States, these benefits are expected to account for 98% of total U.S. benefits.

^bPartial attainment costs are incremental to partial attainment of current standards and reflect partial attainment of promulgated standards. The EPA estimates 17 potential residual nonattainment areas for ozone and 30 potential residual nonattainment areas for fine particulates as of 2010. Full attainment costs, however, are incremental to full attainment of current standards.

^cTotal CAA Amendments benefit estimate (\$110 billion; see Table 2) and cost estimates by title (see Table 2) are from Reference (31).

DESIGN OF A NEW PROSPECTIVE STUDY

The scope of the first two studies was clearly established by Congress based on policies and regulations implemented prior to 1990 or, in the case of the prospective analysis, based on the new provisions of the 1990 CAA Amendments. In contrast, the framework for a second prospective study is less well defined. There have been no revisions to the Act since 1990. Thus, there is not a clear set of Congressionally mandated policies to examine. We believe this absence of specific Congressional direction creates an opportunity for the EPA to establish its own agenda for the second prospective study that enhances the opportunity to further incorporate economic considerations in future policies.

How should the EPA best approach a new Section 812 study? Some might argue for a simple updating of the first prospective study, with the addition of new data and research results. In our judgment, it would be unwise to proceed with such an approach, because the new information generated is unlikely to justify the considerable resource costs involved. Further, the results of such a study would likely have only marginal policy impacts, as most of the regulations considered in such an analysis would have been implemented by the time the study was completed. We believe the new study should focus on critical policy issues likely to be considered by the EPA over the next decade. Specifically, we propose that the EPA use a new Section 812 study as a vehicle for considering how it can improve the net benefits of the CAA in the coming decades. The net benefits framework assures that potential opportunities to increase total benefits as well as those that would decrease total costs are examined. Because the study would likely be completed prior to Congressional and EPA action on these new policies (or alterations of existing policies), there would be a clear opportunity for the analysis to influence policy decisions. If conducted in a timely way, such a study would represent a departure from the first two Section 812 studies, which were conducted after the bulk of the policy decisions were made. Indeed, using the new prospective study in this planning function would show Congress that the EPA is serious about using benefit-cost analysis to inform its regulatory agenda and decision-making.

In contrast to the first two studies, in which the focus was largely on aggregate analyses, a new study aimed at improving the design and implementation of the CAA requires an understanding of how specific elements of the Act are performing. To make decisions on the efficacy and efficiency of specific elements of the CAA requires costs and benefits disaggregated in a useful manner. The disaggregations could include the stringency of air quality standards for ozone and particulate matter (Title I); their implementation through the State Implementation Plan process, including various requirements for mobile source controls (Title II); the provisions for SO₂ allowance trading and reductions in NO_x from power plants (Title IV); and provisions for control of toxic emissions (Title III) and permitting (Title V).

Overall, we believe that the new Section 812 study should also focus on potential new policies not yet part of EPA policy or regulation. The so-called multi-pollutant

bills, which focus on SO₂, NO_x, mercury, and possibly CO₂, would be strong candidates for consideration. It would be particularly useful to consider the benefits and costs of alternative stringency levels for each of the pollutants, as well as the interaction among them. For example, how do the marginal costs (and benefits) of controlling CO₂ vary with alternative stringency levels of SO_x, NO_x, and mercury? The tradeoffs being contemplated between tightening down on these pollutants and loosening or eliminating New Source Review requirements would be particularly illuminating. It would also be useful to examine other initiatives that might be considered to meet new or anticipated NAAQS requirements, e.g., new regulations whose primary goal is to reduce ground-level ozone or those primarily designed to reduce fine particles. When doing this kind of analysis it will be important to note how some regulations (e.g., those dealing with nitrogen oxides and volatile organic compounds in particular) provide benefits in terms of tropospheric ozone, as well as fine particle reductions. Other possible areas of interest include new policies to reduce emissions of hazardous air pollutants, possibly including so-called residual risk standards. For all these policies it would be appropriate to analyze a number of different scenarios that attempted to encompass the bounds of possible new policies.

Consistent with the goal of illuminating issues likely to have particular policy relevance over the next decade, the most important policies to analyze would be those with potentially high costs, whose benefits are uncertain. Examples would be the currently mandated bans on episodic controls currently in the CAA, the current New Source Review process, the Inspection and Maintenance Program, and even the State Implementation Plan conformity process. These represent existing parts of the Act in which alternative approaches may yield significant environmental benefits relative to the costs incurred. It is also possible that selected regulations mandated over the past several years but not yet implemented could be reconsidered in the Section 812 context.

In general, the appropriate level of aggregation depends on the use to which the analysis is to be put. The EPA's review committee has previously urged the EPA to pursue a title-by-title approach (ACCACA 1999). To a limited extent the EPA has done so in the first prospective analysis by estimating the costs of the 1990 amendments on a title-by-title basis. However, because of the difficulty of uniquely attributing individual pollutants to specific titles, it is difficult to break out benefits by title. In the case of SO₂ and NO_x reductions from power plants (Title IV), this is relatively straightforward. However, NO_x controls show up in three separate titles. For future analyses it may be more appropriate from both a methodological and a policy standpoint to distinguish regulations on a broad sectoral basis, e.g., stationary, mobile, and area sources. To the extent feasible, it would also be desirable to seek finer distinctions within these categories, e.g., regulations on electric utilities, petroleum refineries, and other large sources. Individual as opposed to groups of policies should be examined to provide the maximum amount of information to decision makers. Benefits and costs computed by sector can indicate the relative efficiency of controls or other emissions management options aimed at different

pollution source categories. For example, in such a framework it would be possible to compare the net benefits of ozone strategies focusing on emission reductions from stationary sources (e.g., NO_x controls on the electric power industry) with motor vehicle strategies (e.g., enhanced inspection and maintenance programs).

UPDATING THE INFORMATION

The EPA's prospective study was published in 1999, but most of the analyses were completed in 1998. Since then, progress has been made in a number of research areas, including the valuation of health effects and cost analysis. In this section we focus on the new economic research that we believe could and should be incorporated into a second prospective study, and by extension, any cost-benefit analysis of this type of pollution. At the outset, however, we note new developments in the areas of air pollution modeling and in the epidemiological studies used to estimate health effects.

The first prospective study relied on one air quality model to convert SO₂ and NO_x emissions into particulate air pollution and another to convert NO_x and volatile organic compound emissions into ozone. Unfortunately, this approach did not allow the air chemistry underlying these conversions to be addressed in a unified fashion. The newest generation of air quality models addresses both secondary particulate and ozone formation in a single, comprehensive and internally consistent model. Examples of these models include EPA's MODELS3 (32) and the Georgia Tech Model (37). These models are very complex and expensive to set up, so the new analysis probably cannot depend entirely on them. Nevertheless, there is for the first time a capability to examine how the use of a unified air quality model alters the benefit estimates relative to the framework previously used.

Recent epidemiological evidence has led to some new questions and an understanding of the effects of particulate pollution on mortality in adults. Similarly, there is growing evidence of the effect of elevated concentrations of particulate matter on infants—a category that was excluded from both the retrospective and the prospective studies. In the Health Effects Institute-led re-analysis of the long-term study by Pope et al. (24), which was the primary study used by the EPA to estimate mortality effects in their prospective analysis, Krewski et al. (13) clearly reaffirmed the qualitative relationships but found several interesting anomalies.⁸ Other recent studies, both long-term and short-term, came to similar conclusions.

Considering the short-term studies, Samet et al. (25), in their 20 and 90 cities studies, found an aggregate coarse particulate matter (PM₁₀) effect of about half of that estimated by earlier short-term studies. They also found evidence of region-specific variation in mortality effects, most notably in the northeastern United

⁸Long-term studies involve following a cohort of individuals in many cities for years, relating their pollution exposures to the probability of death. Short-term studies involve examining how daily death rates in a given city vary with daily pollution exposures.

States, where mortality effects were estimated to be twice as high as those for the 90 cities overall. Zanobetti & Schwartz (38), in examining potential socioeconomic modifiers of PM_{10} effects, found the mortality effect for females to be approximately one third larger than that for males. Interestingly, adding sulfates (SO_4) and some heavy metals to such models significantly lowers the fine particulate matter ($PM_{2.5}$) effect (4), whereas adding gaseous pollutants generally does not affect the particulate matter coefficients (25). Wichmann et al. (35) finds that the ultra-fine particles (PM_1 or lower) are a significant predictor of mortality, until other pollutants are added.

With respect to the long-term studies, Krewski et al. (13) found slightly larger effects of $PM_{2.5}$ on mortality than that found by Pope et al. (24), but these effects fall dramatically and even become insignificant under some specifications, while SO_2 effects become large and significant. In addition, the mortality effects of fine particles ($PM_{2.5}$) varied with education level, the estimated effect being higher for individuals without a high school education than for those with higher levels of education. Furthermore, Abbey et al. (1) found no relationship of $PM_{2.5}$ for females, and Lipfert et al. (18) in a major study of veterans' mortality and pollution, found no PM effects, whereas they found ozone and NO_2 to be significant predictors of mortality.

At the same time that these new analyses are introducing new questions about mortality effects in adults, several studies around the world have strengthened the case for infant mortality being caused by exposure to particulates. Woodruff et al. (36) found mortality for respiratory causes and sudden infant death syndrome to be positively associated with high PM_{10} exposure for normal birth weight infants but no significant relationship for low birth weight infants. Lipfert et al. (19) replicated the findings of Woodruff et al., though they did not observe differences among categories of birth weights. Also, Bobak & Leon (3), who conducted a matched population-based case-control study covering all births registered in the Czech Republic from 1989 to 1991, found that only particulate matter showed a consistent association with death when all pollutants were entered in one model; these effects were strongest in the postneonatal (rather than the neonatal) period and were specific for respiratory causes.

Filling in Valuation Gaps

A number of key linkages between pollution and endpoints that people value were missing from the prospective study. These include visibility, ecosystem damage, negative benefits (i.e., increased risks of melanomas) to ozone control from added exposure to ultraviolet radiation (UV-B), and effects of toxic exposure. Many of these benefit categories have been examined in recently published literature reviews [e.g., Cropper (8)]. The ACCACA (2) questioned the quality of all the visibility benefits studies, either because of methodological problems or because they had not been peer reviewed. Although the academic interest in valuing visibility benefits may have waned, perhaps from a lack of recent research support, the available

studies suggest that such benefits could comprise a significant fraction of total benefits. In addition, the methods for eliciting values for visibility in a recreational context and in the western United States appear to be reasonably reliable. So few studies are available to set a value for urban visibility benefits that this area must be considered more speculative.

Ecosystem damages were largely ignored in both the retrospective and the prospective EPA studies, for the good reasons that there are no studies suitable for estimating physical ecosystem level benefits from air pollution reduction at the broad regional level (except in very specialized areas, such as the Adirondacks). Also, there are no studies providing a firm basis for valuing such improvements at this broad level, even in places where physical damage might be estimated.

The prospective study attempts to capture some ecosystem damage by counting foregone cleanup costs as a reasonable proxy for losses from nitrification of Chesapeake Bay and other waters associated with NO_x emissions. The expert review committee was adamant that this approach was an unreliable estimate of benefits because, except in special cases, there is no necessary relationship between foregone cleanup costs and the benefits of cleanup.

Finally, both studies were silent on the possible increase in skin cancers associated with increased UV-B radiation, itself associated with ozone reductions. Lutter & Wolz (20) and others have estimated these effects and find them to be nontrivial. The EPA ignored these effects, as it did in the regulatory impact analysis for its recently promulgated new ozone standard. This action was rejected by the Supreme Court (33) and the EPA agreed to consider this effect. Thus, there is no reason why future cost-benefit analyses of the CAA should omit what could be an important perverse effect of reducing ozone air pollution.

Using Better Methods/Newer Studies

The most important valuation number in the report is the value of a statistical life (VSL), which is the average willingness to pay for a given (small) reduction in risk of death divided by that risk reduction. The product of the VSL and the expected number of deaths avoided by the CAA yields an estimate of benefits that represents almost 90% of all benefits calculated in the Section 812 studies. The EPA's VSL estimate of \$6 million was based on a review of 26 of the studies in the literature—21 labor market studies and 5 contingent valuation studies. The analytical methods applied to this review were ad hoc at best, and the reason for choosing the 26 studies was never entirely clear.

We believe that improvements in these estimates could come from two distinct elements of the health valuation literature. The first is a systematic evaluation of this literature. Mrozek & Taylor (22) have performed a meta-analysis of 38 studies contributing 203 VSL estimates. They found that the EPA's best estimate for the VSL (\$6 million in 1998 dollars) is three times too large, i.e., Mrozek & Taylor's best estimate is \$2 million, owing to a number of factors. The most important of these is a false attribution of wage rate differentials to mortality rate differences,

when in fact much of this variation is due to interindustry differences in wage rates that occur for other reasons—a point first raised by Leigh (17).

Just as importantly, there are some new studies in the mortality risk valuation literature [e.g., Hammitt & Graham (11), Krupnick et al. (15), Strand (28), Johannesson & Johannesson (16)] that are specifically designed to reflect the mortality risks associated with air pollution, but using contingent valuation and conjoint analysis approaches. Much of this literature also suggests that the EPA's \$6 million estimate for the VSL is too high, with the appropriate adjustment being quite uncertain, as this literature needs to mature. Nevertheless, some of the literature suggests that the consideration of dread (e.g., with cancer-causing pollution exposures) and altruism (the willingness to pay for health improvements for others) could significantly increase the VSL.

The second most important valuation number in these studies is the value of a case of chronic disease. This is the analogue of the VSL, but for the reduced risk of getting chronic lung or heart disease. The estimate used in the EPA reports (\$266,000) was derived from two small (300 person) pilot conjoint analysis studies (34, 14) that scarcely can support the weight placed upon them. Conjoint analyses and other stated preference techniques have evolved since these studies were done. Unfortunately, no new numbers are available for improving on this estimate. Clearly, this is an important area for future research, if only to do the same studies with a larger sample size.

Estimating Costs

The EPA has a long history of conducting its analyses of the costs of regulations based on engineering abatement cost estimates that are generally "on the shelf." This approach has the advantage of being transparent and easy to defend. One chooses technologies to abate a pollutant from a set of agreed upon technologies, the most cost-effective first.

Unfortunately, this approach is likely to lead to overestimation of control costs for two reasons. First, it does not account for future technological advances that may bring down such costs (or raise effectiveness). This is a particularly important failing when time horizons are long. Second, it often ignores options for reducing costs that are not classified as engineering approaches or do not show up in the approved list of technologies. This applies, in particular, to market or economic incentive approaches to pollution control, which may involve changes in input mix, process changes, product redesign, or others that respond to the need to minimize abatement costs. Recent work by Harrington et al. (12) has found empirical support for the notion that *ex ante* cost estimates tend to overstate true costs. In examining *ex post* information, Morgenstern et al. (21) found that reported environmental expenditures are generally not overstated, although considerable variation exists at the plant level.

The EPA's prospective study, while generally ignoring the cost consequences of incentive approaches, did consider them in the one place where they would be

particularly important, namely for reducing SO₂ from power plants. Title IV of the CAA Amendments of 1990 set up an SO₂ allowance trading system for utilities to substantially reduce their SO₂ emissions through a trading program. The benefits of such a program (forecast out to 2010 estimated from the Integrated Planning Model for the EPA), which accounted for fuel switching, use of lower sulfur coal, new and retiring plants, demand reductions in reaction to higher electricity prices and generation load reallocations as ways of meeting the standard. Several other studies (5, 6, 10) also estimated costs and generally corroborate the EPA's estimates.

An omission in the report, albeit one whose inclusion would significantly raise costs, is the cost to society of imposing environmental regulations in the context of the existing tax structure—the so-called tax interaction effect (23). The tax interaction effect refers to the economy-wide economic losses associated with the imposition of additional environmental (or any other) regulation—losses that tend to be exacerbated by existing labor and other taxes. Aggregate losses are potentially quite large because there are so many people affected.⁹ The tax interaction effect was extensively discussed by the expert review committee and the EPA and is mentioned in the prospective study, but it is not incorporated quantitatively. Clearly, future prospective studies could and should take this effect into account.

Inclusion of Other CBA Studies

Although the EPA studies are quite thorough in referencing the literature underlying key elements of the analysis, they generally omit references to other integrating studies similar in nature to the Section 812 reports. This is in marked contrast to benefit-cost studies in the academic literature, in which one can often find commentary on estimates from similar studies and an attempt at reconciliation of any differences that arise [e.g., Burtraw et al. (5)]. One good example pertains to the EPA's Regulatory Impact Analysis of the Proposed Ozone Standard (30), which is a benefit-cost analysis. The American Petroleum Institute sponsored a study of the costs of meeting the EPA's proposed ozone standard in a multi-state area around the Great Lakes (26). Their estimate was as large as the EPA's estimate for the entire country. No reference was made to the study, nor was any attempt made to reconcile the results. One would hope that future studies would attempt to acquire, analyze, and reconcile results of other major studies addressing relevant parts of future EPA benefit-cost analyses of air quality improvements.

Peer Review

Currently, peer review of the Section 812 studies is performed through unpaid review committees, mostly made up of academics, who meet and participate in conference calls periodically to consider issues that come up in the design,

⁹One committee member estimated that costs of the implemented CAA Amendments could be 30% higher than shown in the report.

implementation, and writing of the review. Because of the necessarily limited attention that such reports can be given by unpaid committees, we recommend that their resources be supplemented by some paid reviewers with expertise in specific areas. This is an approach used by the EPA to do other reviews of agency work under the CAA, such as the reviews conducted of the voluminous *Criteria Documents*, issued periodically to survey the literature relevant to setting new National Ambient Air Quality Standards, under Title I of the Act.

REPRESENTING UNCERTAINTIES ABOUT COSTS AND BENEFITS

Over the years, benefit-cost analyses at the EPA have been getting more sophisticated in terms of their representation of the benefits of environmental improvements. Early analyses either ignored uncertainties, focusing on a best estimate for each of the parameters in the analysis, or identified rather arbitrary "low" and "high" estimates around a "best" estimate and used all the low or high estimates of parameters to create a "super low" and a "super high" benefit estimate, respectively. More recently, as exemplified in both the retrospective and the prospective studies, Monte Carlo simulation techniques were used. Such techniques apply a more logical and rigorous approach to propagating uncertainties in parameters through the various steps of the benefit analysis.¹⁰

No one doubts that costs are uncertain. In fact, costs may be just as uncertain as benefits. However, costs are routinely considered as if they were certain. The same techniques used to analyze uncertainties in benefit estimates should be used to estimate uncertainties in costs. This will not be easy to do. For one thing, the databases containing the engineering data used to estimate costs of reducing air emissions typically offer only "best estimates," with no information provided on the dispersion of such costs across plants. Second, because the cost estimates are engineering-derived rather than statistically based, they come from analyses that do not generate the kind of error distributions found in the statistically based epidemiological and valuation literature.

These points lead to two research strategies. One would be to comb the economics literature for abatement cost functions estimated for various pollutants and sectors and use these instead of the engineering data. Another would be to comb the engineering literature for references to cost distributions across plants and use such information to develop cost ranges.

¹⁰This approach involves first defining probability distributions for each parameter—often based on confidence intervals around estimated regression coefficients—e.g., from the effect of a change in pollution concentration on a health effect. Then simulations are run to draw parameter values from these distributions, computing benefits for each set of trial values drawn. The result is a benefit distribution that truly represents the underlying uncertainties in the parameters.

USE OF COST-EFFECTIVENESS RATHER THAN BENEFIT-COST TECHNIQUES

Up to now we have assumed that future Section 812 studies need to be benefit-cost studies. Yet, under certain reasonable conditions, cost-effectiveness analysis—dividing the cost of a particular regulation by a measure of the effectiveness of that regulation and then comparing various regulations (or regulatory options) according to this cost-per-unit effectiveness measure—may be almost as useful as benefit-cost analysis.

The rationale for this strategy begins by noting that attaching monetary values to health effects is highly controversial, so avoiding doing so has an obvious attraction. Arguably, in the analysis of air pollution policies, in which such a large portion of the benefits are mortality-related and the morbidity benefits tend to move proportionally with changes in mortality, a physical measure of mortality benefits, such as “lives saved” or “life-years saved” may be a good proxy for all health effects. In this case, a cost-per-life-saved measure may be a useful basis for discriminating among various policy initiatives.

There are drawbacks to this approach, however. First, and most importantly, only with benefit-cost analysis can any normative claim be made, i.e., whether the contemplated or already implemented policy makes economic sense. When a benefit-cost analysis of a contemplated action yields negative net benefits, one can make the statement that, on efficiency grounds (and subject to many caveats), society would be made worse off by advancing that particular option. If option A has greater (positive) net benefits than option B, then one can say that both options increase social welfare, but that A is the better option, again, solely from the criterion of efficiency. With only a cost-effectiveness analysis, in contrast, if one finds that option A is more cost-effective than option B (cost per life saved is lower for A than B), one can only conclude that A is preferred to B, not that A is socially beneficial on net.

Second, for a cost-effectiveness analysis to be a reasonable substitute for benefit-cost analysis, one category of benefits (e.g., the mortality benefits) needs to be a large fraction of all benefits. In the context of the CAA, we have argued above that there is some reason to expect that the VSL estimates will be coming down. This means that morbidity benefits may assume a greater share of the total and that, as a consequence, the cost-effectiveness strategy may be less attractive. Further, to the extent that ecological benefits are involved, human mortality benefits may be a poor proxy for them. Certainly, once these as yet poorly understood benefit areas are better understood, the cost-effectiveness strategy will be less compelling as applied to the CAA.

CONDUCT VALUE OF INFORMATION ANALYSIS

Finally, many benefit-cost analyses, including the Section 812 studies, are also useful in helping to set a research agenda. Once one goes to the trouble and expense of conducting such a study, it is not much more complicated to estimate

whether a reduction in the uncertainty of various parameters would materially affect the ultimate conclusions of the analysis. In other words, one can determine which parameters contribute the most to benefit (or cost) uncertainty and would, therefore, be the most important for reducing uncertainty. Implicitly at least, the EPA conducted such a thought process in developing a list of key areas of future research to improve future Section 812 studies. It might be appropriate to formalize that process to get a deeper understanding of the value of proposed new research.

CONCLUDING THOUGHTS

The EPA's Section 812 studies are unique in government. To our knowledge, no other agency provides broad-scope benefit-cost analyses for statutes it implements that are as carefully developed or reviewed. Whereas benefit-cost analyses are now required for all major regulations, the Section 812 analysis serves to integrate such analyses while taking a national and forward-looking perspective on air pollution control.

Subject to some methodological qualifications, the two Section 812 studies already completed indicate that the aggregate benefits of past and ongoing policies to improve air quality have clearly exceeded the costs incurred by industry, taxpayers, and consumers. Whether benefits exceed costs by a factor of 40 or 4 or less, the professional consensus is that, overall, the nation received good value for the resources it invested in improving air quality over the past three decades. Yet we don't know if that value could have been far higher by changing or eliminating certain inefficient elements of the CAA. One of the challenges of a second prospective study is to answer that question.

Another challenge in conducting a new Section 812 study, which is less constrained by Congressional mandate than the first two, is to develop the analysis in such a way as to have the maximum impact on the design and implementation of future air pollution control policies. Specifically, we have recommended the goal of increasing the net benefits of future air quality regulations. We believe the best way to accomplish this is to focus the study on already mandated but not fully implemented policies where significant future costs are anticipated and, particularly, to focus on potential new policies not yet mandated by law or regulation. We have recommended specific candidates for study, but clearly a fuller debate on the issue is appropriate.

We also believe the EPA faces a number of key challenges in incorporating the most recent research in a new Section 812 study and in making the Section 812 study effort a model of how good benefit-cost analyses are designed, performed, and reviewed. The EPA should resist the temptation to sit on its laurels with respect to the positive outcome of the Section 812 studies, recognize the possibility that the CAA can do a better job of delivering benefits to residents of the United States, and endeavor to keep the analysis at the forefront of the rapidly changing social and physical sciences it must draw upon.

Finally, the EPA should take the opportunity afforded by the new Section 812 study to do something it has rarely done before: actually use benefit-cost analysis prospectively as a planning tool to establish priorities for its regulatory and legislative agenda with respect to air pollution issues. Such an action would demonstrate to Congress that the EPA is serious about delivering efficient regulations and other policy initiatives to the American public.

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STATEMENT

Synopsis of the Particle Epidemiology Reanalysis Project

BACKGROUND

Epidemiologic work conducted over several decades has suggested that long-term residence in cities with elevated ambient levels of air pollution from combustion sources is associated with increased mortality. Subsequently, two prospective cohort studies, the Six Cities Study (as reported in Dockery et al 1993) and the American Cancer Society (ACS) Study (as reported in Pope et al 1995) estimated that annual average all-cause mortality increased in association with an increase in fine particles (all particles less than 2.5 μm in median aerodynamic diameter [$\text{PM}_{2.5}$]).

As part of the Six Cities Study, Dockery and colleagues (1993) had prospectively followed a cohort of 8,111 adult subjects in northeast and midwest United States for 14 to 16 years beginning in the mid-1970s. The authors found that higher ambient levels of fine particles and sulfate (SO_4^{2-}) were associated with a 26% increase in mortality from all causes when comparing the most polluted to the least polluted city, and that an increase in fine particles was also associated with increased mortality from cardiopulmonary disease. The relative risks in all-cause mortality were associated with a difference (or range) in ambient fine particle concentrations of 18.6 $\mu\text{g}/\text{m}^3$ and a difference of ambient sulfate concentrations of 8.0 $\mu\text{g}/\text{m}^3$, comparing the least polluted city to the most polluted city.

In the much larger ACS Study, Pope and colleagues (1995) followed 552,138 adult subjects in 154 US cities beginning in 1982 and ending in 1989 (3 cities did not overlap between the 151 and 50 cities studied, resulting in a total of 154 cities). Again, higher ambient levels of fine particles were associated with increased mortality from all causes and from cardiopulmonary disease in the 50 cities for which fine particle data were available (sampled from 1979 to 1983). Higher ambient sulfate levels were associated with increased mortality

from all causes, cardiopulmonary disease, and lung cancer in the 151 cities for which sulfate data were available (sampled from 1980 to 1982). The difference between all-cause mortality in the most-polluted city and the least-polluted city was 17% and 15% for fine particles and sulfate, respectively (with a range of 24.5 $\mu\text{g}/\text{m}^3$ for fine particles and of 19.9 $\mu\text{g}/\text{m}^3$ for sulfate).

Both of these studies came under intense scrutiny in 1997 when the EPA used the results to support new National Ambient Air Quality Standards for fine particles and to maintain the standards for particles less than 10 μm in median aerodynamic diameter (PM_{10}) already in effect. Members of Congress and industry, the scientific community and others interested in regulation of air quality scrutinized the studies' methods and their results. Some insisted that any data generated using federal funding should be made public. Others argued that these data had been gathered with assurances of confidentiality for the individuals who had agreed to participate and that the concept of public access to federally funded data did not take into account the intellectual property rights of the investigators and their supporting institutions. To address the public controversy, Harvard University and the ACS requested that the Health Effects Institute organize an independent reanalysis of the data from these studies. Both institutions agreed to provide access to their data to a team of analysts to be selected by HEI through a competitive process.

APPROACH

To conduct the reanalysis, the HEI Board of Directors, with support from the EPA, industry, Congress, and other stakeholders, appointed an Expert Panel chaired by Dr Arthur Upton from the University of Medicine and Dentistry of New Jersey and former Director of the National Cancer

This Statement, prepared by the Health Effects Institute, is a summary of a research project conducted by the Reanalysis Team, led by Dr Daniel Krewski at the University of Ottawa. The following Special Report contains the detailed Investigators' Report (Summary, Introduction, and Parts I and II), Commentary on the project prepared by a special panel of the Institute's Health Review Committee, and Comments on the Reanalysis Project by the Original Investigators (Drs Douglas W. Dockery, C. Arden Pope III et al).

Particle Epidemiology Reanalysis Project

Institute. The Expert Panel selected competitively a Reanalysis Team—led by Dr Daniel Krewski of the University of Ottawa—and oversaw all aspects of the team's work. They were assisted in their oversight efforts by a broad-based Advisory Board of knowledgeable stakeholders and scientists who, in the project's early stages, provided extensive advice to the Expert Panel on the key questions to be analyzed. The final results of the Reanalysis Team were intensively and independently peer reviewed by a Special Panel of the HEI Health Review Committee, which was chaired by Dr Millicent Higgins of the University of Michigan.

The overall objective of what became the Particle Epidemiology Reanalysis Project was to conduct a rigorous and independent assessment of the findings of the Six Cities and ACS Studies of air pollution and mortality. This objective was met in two parts. In *Part I: Replication and Validation*, the Reanalysis Team sought to replicate the original studies via a quality assurance audit of a sample of the original data and to validate the original numeric results. In *Part II: Sensitivity Analyses*, they tested the robustness of the original analyses to alternate risk models and analytic approaches.

RESULTS AND IMPLICATIONS

PART I: REPLICATION AND VALIDATION

- An extensive audit of the study population data for both the Six Cities and ACS Studies and of the air quality data in the Six Cities Study revealed the data to be of generally high quality with a few exceptions. In both studies, a few errors were found in the coding and inclusion of certain subjects; when those subjects were included in the analyses, they did not materially change the results as originally reported. Because the air quality data used in the ACS Study could not be audited, a separate air quality database was constructed for the sensitivity analyses described in Part II.
- The Reanalysis Team was able to replicate the original results in both studies using the same data and statistical methods as used by the Original Investigators. The Reanalysis Team confirmed the original point estimates: For the Six

Cities Study, they reported the relative risk of mortality from all causes associated with an increase in fine particles of 18.6 $\mu\text{g}/\text{m}^3$ as 1.28, close to the 1.26 reported by the Original Investigators. For the ACS Study, the relative risk of mortality from all causes associated with an increase in fine particles of 24.5 $\mu\text{g}/\text{m}^3$ was 1.18 in the reanalysis, close to the 1.17 reported by the Original Investigators.

PART II: SENSITIVITY ANALYSES

Once the original results of the studies had been validated, the Reanalysis Team sought to test an array of different models and variables to determine whether the original results would remain robust to different analytic assumptions.

- First, the Reanalysis Team used the standard Cox model used by the Original Investigators and included variables in the model for which data were available from both original studies but had not been used in the published analyses (eg, physical activity, lung function, marital status). The Reanalysis Team also designed models to include interactions between variables. None of these alternative models produced results that materially altered the original findings.
- Next, for both the Six Cities and ACS Studies, the Reanalysis Team sought to test the possible effects of fine particles and sulfate on a range of potentially susceptible subgroups of the population. Although different subgroups did show some variation in their estimated effects, the results were not statistically significant with one exception. The estimated effects of fine particles did appear to vary with educational level; the association between an increase in fine particles and mortality tended to be higher for individuals without a high school education than for those who had completed high school or for those with more than a high school education.
- In the ACS study, the Reanalysis Team tested whether the relationship between ambient concentrations and mortality was linear. They found some indications of both linear and nonlinear relationships, depending upon the analytic technique used, suggesting that the

Particle Epidemiology Reanalysis Project

issue of concentration-response relationships deserves additional analysis.

- In the Six Cities Study where data were available, the Reanalysis Team tested whether effect estimates changed when certain key risk factors (smoking, body mass index, and air pollution) were allowed to vary over time. One of the criticisms of both original studies has been that neither analyzed the effects of change in pollutant levels over time. In general, the reanalysis results did not change when smoking and body mass index were allowed to vary over time. The Reanalysis Team did find for the Six Cities Study, however, that when the general decline in fine particle levels over the monitoring period was included as a time-dependent variable, the association between fine particles and all-cause mortality dropped substantially, but the effect continued to be positive and statistically significant.
- Using its own air quality dataset constructed from historical data to test the validity of the original ACS air quality data, the Reanalysis Team found essentially the same results.
- Any future analyses using the sulfate data should take into account the impact of artificial sulfate. Sulfate levels with and without adjustment differed by about 10% for the Six Cities Study. Both the original ACS Study air quality data and the newly constructed dataset contained sulfate levels inflated by approximately 50% due to artificial sulfate. For the Six Cities Study, the relative risks of mortality were essentially unchanged with adjusted or unadjusted sulfate. For the ACS Study, adjusting for artificial sulfate resulted in slightly higher relative risks of mortality from all causes and cardiopulmonary disease compared with unadjusted data. The relative risk of mortality from lung cancer was lower after the data had been adjusted.
- Because of the limited statistical power to conduct most sensitivity analyses for the Six Cities Study, the Reanalysis Team conducted the majority of its sensitivity analyses using only the ACS Study dataset with 154 cities. In that dataset, when a range of city-level (ecologic) variables (eg, population change, measures of income, maximum temperature, number of hospital beds, water hardness) were included in the analyses, the results generally did not change. Two exceptions were that associations for both fine particles and sulfate were reduced when city-level measures of population change or sulfur dioxide were included in the model.
- A major contribution of the Reanalysis Project is the recognition that both pollutant variables and mortality appear to be spatially correlated in the ACS Study dataset. If not identified and modeled correctly, spatial correlation could cause substantial errors in both the regression coefficients and their standard errors. The Reanalysis Team identified several methods for dealing with this, all of which resulted in some reduction in the estimated regression coefficients. The full implications and interpretations of spatial correlations in these analyses have not been resolved and appear to be an important subject for future research.
- When the Reanalysis Team sought to take into account both the underlying variation from city to city (random effects) and the spatial correlation between cities, only sulfur dioxide as a city-level variable continued to decrease the originally reported associations between mortality and fine particles or sulfate. This effect was more pronounced for sulfate.
- When the Reanalysis Team conducted spatial analyses of sulfur dioxide, the association between sulfur dioxide and mortality persisted after adjusting for sulfate, fine particles, and other variables.
- As a result of these extensive analyses, the Reanalysis Team was able to explain much of the variation between cities, but some unexplained city-to-city variation remained.

CONCLUSIONS

The Reanalysis Team designed and implemented an extensive and sophisticated series of analyses that included a set of new variables, all the gaseous copollutants, and the first attempts to apply spatial analytic methods to test the validity of the data and the results from the Six Cities Study and the ACS Study. Overall, the reanalyses assured the quality of the original data, replicated

Particle Epidemiology Reanalysis Project

the original results, and tested those results against alternative risk models and analytic approaches without substantively altering the original findings of an association between indicators of particulate matter air pollution and mortality.

At the same time, the reanalyses did extend and challenge our understanding of the original results in several important ways.

- The Reanalysis Team identified a possible modifying effect of education on the relation between air quality and mortality in that estimated mortality effects increased in the subgroup with less than high school education.
- The use of spatial analytic methods suggested that, when the analyses controlled for correlations among cities located near one another, the associations between mortality and fine particles or sulfate remained but were diminished.
- An association between sulfur dioxide and mortality was observed and persisted when other possible confounding variables were included; furthermore, when sulfur dioxide was included in models with fine particles or sulfate, the associations between these pollutants (fine particles and sulfate) and mortality diminished.

In reviewing these results, the Special Panel of the HEI Health Review Committee identified the following factors to consider when interpreting the results from the Reanalysis Team.

- The inherent limitations of using only six cities, understood by the Original Investigators, should be taken into account when interpreting results of the Six Cities Study.
- The Reanalysis Team did not use data adjusted for artifactual sulfate for most alternative analyses. When they did use adjusted

sulfate data, relative risks of mortality from all causes and cardiopulmonary disease increased. This result suggests that more analyses with adjusted sulfate might result in somewhat higher relative risks associated with sulfate.

- Findings from spatial analyses applied to the ACS Study data need to be interpreted with caution; the spatial adjustment may have overadjusted the estimated effect for regional pollutants such as fine particles and sulfate compared with the effect estimates for more local pollutants such as sulfur dioxide.
- After the Reanalysis Team completed its spatial analyses, residual spatial variation was still noticeable; this finding suggests that additional studies might further refine our understanding of the spatial patterns in both air pollution and mortality.
- No single epidemiologic study can be the basis for determining a causal relation between air pollution and mortality.

In conclusion, the Reanalysis Team interpreted their findings to suggest that increased relative risk of "mortality may be attributed to more than one component of the complex mix of ambient air pollutants in urban areas in the United States". The Review Panel concurs. In the alternative analyses of the ACS Study cohort data, the Reanalysis Team identified relatively robust associations of mortality with fine particles, sulfate, and sulfur dioxide, and they tested these associations in nearly every possible manner within the limitations of the datasets. Future investigations of these issues will enhance our understanding of the effect of combustion-source air pollutants (eg, fine particles, sulfate, and sulfur dioxide) on public health.

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The Cost-Effectiveness of Environmental Approaches to Disease Prevention

Dave A. Chokshi, M.D., and Thomas A. Farley, M.D., M.P.H.

How can society prevent the most disease and deaths per dollar spent? This question arose throughout the debate on U.S. health care reform and will continue to drive decision making as health care funding becomes increasingly constrained. In an atmosphere of austerity, demonstrating the cost-effectiveness of preventive health interventions becomes particularly important.

Although preventive approaches to disease are intuitively appealing — and frequently presented as a way to reduce costs — analyses have suggested that, as a whole, they're no more cost-effective than therapeutic interventions.¹ But are some preventive approaches more cost-effective than others? The National Commission on Prevention Priorities attempted to address this question, ranking clinical preventive services in terms of cost-effectiveness and “clinically preventable burden” of disease.² Yet some preventive services, such as tobacco taxes or water fluoridation, are not delivered in health care settings. Understanding whether certain approaches are more cost-effective than others requires a framework for categorizing preventive interventions.

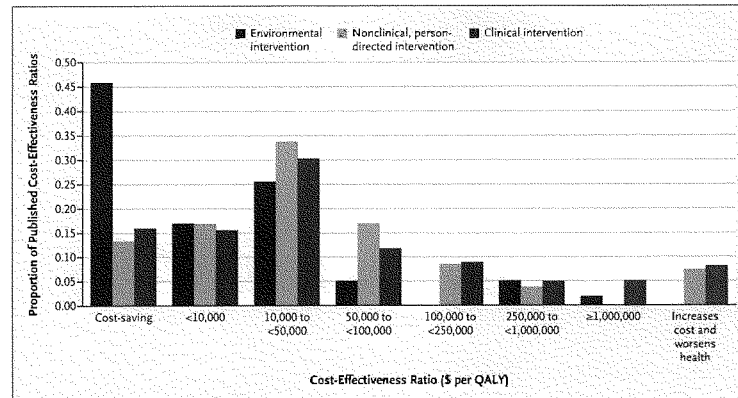
Medicine traditionally classifies

preventive interventions on the basis of disease course; primary prevention aims to prevent new cases of disease; secondary prevention and tertiary prevention mitigate the effects of existing disease. We propose two overlapping dimensions to further characterize primary preventive interventions: environmental versus person-directed, indicating whether the proximate target is an element of the environment or an individual, and clinical versus nonclinical, indicating where an intervention takes place. Separating person-directed from environmental interventions permits the comparison of prevention conducted individual by individual (e.g., cancer screening) with prevention that acts on persons indirectly by altering the physical or social environment (e.g., a ban on trans fats). Whether an intervention takes place within a health care setting or elsewhere has implications for resource allocation, since funding streams for clinical and nonclinical interventions tend to be distinct. Some nonclinical interventions, such as syringe-exchange programs, are person-directed, but all environmental interventions are nonclinical.

Because reaching individuals directly is generally more expensive than changing an environ-

mental element, we hypothesized that unless a person-directed intervention was very effective (like childhood immunization, for example), environmental interventions would generally be more cost-effective. We further hypothesized that it mattered where an intervention was delivered and that nonclinical, person-directed interventions would be more cost-effective than clinical interventions. To test these hypotheses, we conducted a comparative analysis of the cost-effectiveness of environmental, nonclinical but person-directed, and clinical preventive interventions.

We analyzed the contents of the Tufts Medical Center Cost-Effectiveness Analysis (CEA) Registry, which contains information on 2815 cost-effectiveness analyses published through December 2011. Costs per quality-adjusted life-year (QALY, a unit of measure for survival that accounts for the effects of suboptimal health status) are reported after conversion to 2011 U.S. dollars. Only cost-utility analyses — which permit comparison of programs addressing different health problems by converting health outcomes into a common metric — are included in the registry. We excluded studies that didn't report on an intervention meet-



Cost-Effectiveness of Categories of Preventive Interventions.

ing the definition of primary prevention and categorized the remaining studies as environmental, clinical, or nonclinical but person-directed (for complete methods, see the Supplementary Appendix, available with the full text of this article at NEJM.org).

According to our definitions, the CEA Registry contained 401 studies of clinical prevention, with 1259 associated cost-effectiveness ratios; 37 studies of nonclinical, person-directed prevention, with 83 associated cost-effectiveness ratios; and 31 studies of environmental prevention, with 59 associated cost-effectiveness ratios. Environmental interventions were generally more cost-effective than clinical interventions or nonclinical, person-directed interventions (see graph); the proportion that were cost-saving was higher among environmental interventions (46%) than among clinical interventions (16%, $P < 0.001$) or nonclinical, person-directed interventions (13%, $P < 0.001$). The distribution of cost-effectiveness ra-

tios was similar for clinical interventions and nonclinical, person-directed interventions. Twenty-seven of the 59 cost-effectiveness ratios for environmental interventions (46%) indicated that the interventions were cost-saving; an additional 10 environmental interventions (17%) cost less than \$10,000 per QALY, and 15 (25%) cost \$10,000 to \$50,000 per QALY. As a point of reference, \$50,000 to \$100,000 per QALY is often used as the upper limit for favorable cost-effectiveness ratios.

In an environmental model of prevention, people's behavior is influenced by their physical and social environment.³ It can be far less expensive to alter an environmental element to which many people are exposed than to interact with each person directly. Even if the effect of an altered environment on each person is small, the cumulative population effect can be large; cost-effectiveness can be favorable because the cost per person reached is small. For instance, Smith-Spangler et al.

estimated that, as compared with the status quo, a tax on sodium that reduces population sodium intake by 6% would reduce heart disease and stroke incidence, increase QALYs by 1.3 million, and save \$22.4 billion over the lifetime of adults who are currently 40 to 85 years of age.⁴

We were surprised to find that nonclinical, person-directed preventive interventions were not more cost-effective than clinical interventions. Although the absence of a discerned effect may not indicate a true absence of effect, this finding suggests that the "environmental" character of an intervention may be more important than the "non-clinical" character in determining cost-effectiveness. Environmental change may have initial costs followed by lasting effect (e.g., building recreational facilities to promote physical activity), whereas person-directed interventions have continued costs (e.g., exercise programs). Furthermore, many environmental interven-

tions are low-cost because they're implemented by regulation (e.g., smoke-free-air laws) or are executed centrally (e.g., food fortification with folic acid). Some environmental interventions, such as excise taxes, may generate government revenue that can offset costs or be used for health programs.

Our finding that the environmental interventions studied were the most likely to be cost-saving doesn't necessarily mean that all environmental interventions are cost-effective. Some may be expensive to implement and benefit few people — for example, building-safety regulations that prevent extremely rare injuries. The finding suggests, however, that there may be more cost-effective environmental interventions than are currently recognized and that such interventions deserve more attention.

Our analysis could be biased by underreporting of studies of ineffective environmental interventions, leading to an overestimate of favorable cost-effectiveness. On the other hand, published studies are more likely to investigate contentious topics, rather than interventions widely known to be cost-effective. Also, we found significantly fewer studies on environmental and nonclinical, person-directed interventions than on clinical interventions. More generally, cost-effectiveness is predicated on an initial demonstration of effectiveness, which is

often difficult and analytically fraught for preventive interventions, particularly environmental ones. Assessing the value of prevention is more difficult than evaluating treatments for established disease, because the long time horizon for clinical end points introduces considerable uncertainty about benefits.

Our findings have important implications for resource allocation. Environmental prevention is key to addressing the growing disease burden and cost of chronic illnesses. For example, in New York City, an environmental approach to chronic-disease prevention included increased tobacco taxes, a comprehensive smoke-free-air law, mass-media campaigns against smoking and sugar-sweetened beverages, the banning of trans fats from restaurants, and a restaurant calorie-labeling initiative. It has been estimated that the antismoking initiatives alone reduced the number of smokers in the city by 450,000 over a decade and the number of smoking-related deaths by 1500 per year. But increased investment in environmental interventions should not be pitted against person-directed interventions: in most cases, the two work synergistically, as they did in effecting large decreases in mortality from cardiovascular disease in the second half of the 20th century.⁵

The paucity of studies on the cost-effectiveness of environmental preventive interventions im-

pedes their broader adoption. Unlike other forms of economic evaluation, cost-effectiveness studies can demonstrate value through direct comparison of alternative interventions. The scientific literature now points to the value of implementing preventive environmental interventions that are cost-saving and conducting additional cost-effectiveness studies of such interventions.

The views expressed in this article are those of the authors and do not necessarily represent those of the New York City Department of Health and Mental Hygiene.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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The Effect of Air Pollution Control on Life Expectancy in the United States: An Analysis of 545 US counties for the period 2000 to 2007

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Abstract

Background—In recent years (2000 to 2007), ambient levels of fine particulate matter (PM_{2.5}) have continued to decline as a result of interventions, but the decline has been at a slower rate than previous years (1980 to 2000). Whether these more recent and slower declines of PM_{2.5} levels continue to improve life expectancy and whether they benefit all populations equally is unknown.

Methods—We assembled a dataset for 545 U.S. counties consisting of yearly county-specific average PM_{2.5}, yearly county-specific life expectancy, and several potentially confounding variables measuring socioeconomic status, smoking prevalence and demographic characteristics for the years 2000 and 2007. We used regression models to estimate the association between reductions in PM_{2.5} and changes in life expectancy for the period 2000 to 2007.

Results—A decrease of 10 µg/m³ in the concentration of PM_{2.5} was associated with an increase in mean life expectancy of 0.35 years (SD= 0.16 years, p = 0.033). This association was stronger in more urban and densely populated counties.

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Conclusions—Reductions in $PM_{2.5}$ were associated with improvements in life expectancy for the period 2000 to 2007. Air pollution control in the last decade has continued to have a positive impact on public health.

Since the 1970s, enactment of increasingly stringent air quality controls has led to improvements in ambient air quality in the United States at costs that the U.S. Environmental Protection Agency (EPA) has estimated as high as \$25 billion per year.¹ However, even with the well-established link between long-term exposure to air pollution and adverse effects on health,² the extent to which more recent regulatory actions have benefited public health remains in question.

Air pollutant concentrations have been generally decreasing in the U.S., with substantial differences in reductions across metropolitan areas. Levels of fine particulate matter air pollution (particulate matter < 2.5 μm in aerodynamic diameter, $PM_{2.5}$) remain relatively high in some areas. In a 2010 study, the EPA estimated that 62 U.S. counties, accounting for 26% of their total study population, had $PM_{2.5}$ concentrations not in compliance with the National Ambient Air Quality Standards (NAAQS).³

Reductions in particulate matter air pollution are associated with reductions in both cardiopulmonary and overall mortality.² In the mid-1990s, the Harvard Six Cities Study⁴ and the American Cancer Society (ACS) study⁵ reported associations of cardiopulmonary mortality risk with chronic exposure to fine particulate air pollution while controlling for smoking and other individual risk factors. Reanalysis and extended analyses of these studies have confirmed that fine particulate air pollution is an important independent environmental risk factor for cardiopulmonary disease and mortality.^{6–12} Additional cohort studies, population-based studies, and short-term time-series studies have also shown associations between reductions in air pollution and reductions in human mortality.^{13–21} More recently, studies have suggested an association between $PM_{2.5}$ and life expectancy,^{22,23} a well-documented and important measure of overall public health.^{24–26}

As our primary analysis, we estimate the association between changes in $PM_{2.5}$ and in life expectancy in 545 U.S. counties during the period 2000 to 2007. This period is of particular interest, as the EPA restarted wide collection of $PM_{2.5}$ data in 1999–2000, after stopping the nationwide $PM_{2.5}$ monitoring program during the mid-1980s and most of the 1990s. In secondary analyses, we extended to 2007 the data and statistical analysis originally reported by Pope and colleagues²³ for the period 1980–2000, and investigated whether the relationship reported by Pope et al²³ persists in the more recent years.

METHODS

Data

We constructed and analyzed three data sets to estimate the association between changes in life expectancy and changes in $PM_{2.5}$ during the period 2000 to 2007 in 545 counties (Dataset 1), and to investigate whether the association previously reported by Pope et al²³ persists when the data on the same 211 counties are extended to the year 2007 (Datasets 2 and 3).

Dataset 1 included information on 545 U.S. counties for the years 2000 and 2007. These counties include all counties with available matching $PM_{2.5}$ data for 2000 and 2007. Additionally, unlike previous work in which counties were located only in metropolitan areas,²³ Dataset 1 is comprised of counties in both metropolitan and non-metropolitan areas. Figure 1 shows the counties in this dataset shaded according to life expectancy in 2000 and 2007. Variables in this dataset were available at the county level, for both 2000 and 2007.

and included: life expectancy, $PM_{2.5}$, per capita income, population, proportions who were high school graduates, and proportions who were white, black, or Hispanic. Because data on smoking prevalence were not available for all 545 counties, we used age-standardized death rates for lung cancer and chronic obstructive pulmonary disease (COPD) as proxy variables for smoking prevalence.^{27,28} Death rates were calculated in 5-year age groups and age-standardized for the 2000 U.S. population of adults 45 years of age or older. Daily $PM_{2.5}$ data were obtained from the EPA's Air Quality System (AQS - <http://www.epa.gov/ttn/airs/airsaqs/detaildata/downloadaqdata.htm>). Daily $PM_{2.5}$ levels for each county were averaged across monitors within that county using a trimmed mean approach; those daily county-level means were further averaged across days to obtain a county-specific yearly $PM_{2.5}$ average.²⁹

County-level life expectancies were calculated by applying a mixed-effects spatial Poisson model to mortality data from the National Center for Health Statistics (NCHS) and population data from the U.S. Census to obtain robust estimates of the number of deaths in each county.³⁰ These estimated counts were then used to calculate county life expectancies using standard life table techniques, which we discuss in more detail in the eAppendix (Section A).

Socioeconomic and demographic variables were obtained from the U.S. Census and the American Community Survey except per capita income, which was obtained from the Bureau of Economic Analysis. All yearly income variables were adjusted for inflation with 2000 as the base year. Age-standardized death rates for lung cancer and COPD were calculated using mortality data from NCHS using death rates for 2005 to serve as a proxy for 2007 (NCHS data for 2007 was not readily available). Lastly, data on smoking prevalence (proportion of the population who are current smokers) were available from the Behavioral Risk Factor Surveillance System in both 2000 and 2007 for 383 of the 545 counties.

Dataset 2 included data for the year 1980 and the year 2000 for the same 211 U.S. counties included in the 51 metropolitan statistical areas (MSAs) previously analyzed by Pope and colleagues.²³ This dataset is identical to that in the paper by Pope et al.,²³ where it is described in more detail.

Dataset 3 extended Dataset 2 to 2007. All data were available at the county level except for $PM_{2.5}$, which for the year 1980 was available only at the MSA level and for the year 2007 was available at the county level for only 113 of the 211 counties originally included in Pope et al.²³ Thus, for the year 2007, we assigned the same $PM_{2.5}$ values to all the counties that shared an MSA, consistent with the previous analysis.²³ Details and results pertaining to Datasets 2 and 3 are summarized in the eAppendix (Section B1).

Statistical Analysis

Cross-sectional and first-difference linear regression models were fitted to all three datasets. Specifically, we regressed life expectancy versus $PM_{2.5}$ levels across counties separately for the years 1980 (Dataset 2), 2000 (Datasets 1 and 2), and 2007 (Datasets 1 and 3). We then regressed changes in life expectancy over the years 2000 to 2007 (Datasets 1 and 3), 1980 to 2000 (Dataset 2), and 1980 to 2007 (Dataset 3) versus changes in $PM_{2.5}$ over those same periods adjusted for changes in the socioeconomic, demographic, and proxy smoking variables outlined above. Additionally for our largest dataset (Dataset 1: 545 counties, 2000 to 2007), we also performed several stratified and weighted analyses. More specifically, we estimated the effect of changes in $PM_{2.5}$ on life expectancy in models stratified by: 1) percentage of the population with an urban residence in 2000; 2) population density in 2000; 3), land area in 2000; 4) $PM_{2.5}$ levels in 2000; 5) 5-year in-migration in 2000; and 6) change in average yearly temperature over the entire period. These stratified analyses allowed us to

examine whether $PM_{2.5}$ effects on life expectancy were different in counties with particular demographic or weather characteristics. The sensitivity of our results to model specification was further assessed by fitting models weighted by: 1) total population; 2) year 2000 population density; and 3) inverse land area. We included direct measures of the change in prevalence of smoking for the subgroup of counties with matching data on smoking prevalence (383 out of 545), and fit separate models for men and women to determine if effects differed by sex. To account for the correlation due to clustering of counties in the same MSA, robust clustered standard errors were calculated for all models.^{23,31} Specifically, the variance of the vector of estimated regression coefficients, β_{est} , is given by: $Var(\beta_{est}) = (X^T X)^{-1} (X^T V_{est} X) (X^T X)^{-1}$, where V_{est} is a block-diagonal matrix with non-zero blocks $V_{0,j} = (y_j - \mu_{est,j})(y_j - \mu_{est,j})^T$, where j indexes the MSAs. β_{est} is equal to the ordinary least squares estimator. Models were estimated using either REGRESS in STATA version 11.0, `lm()` in R version 2.11.1, or PROC SURVEYREG in SAS version 9.2.

RESULTS

We report the results of our primary analysis, which estimated the cross-sectional relationship between life expectancy and $PM_{2.5}$, and between changes in life expectancy and changes in $PM_{2.5}$, for the period 2000 to 2007 in 545 US counties (Dataset 1). Results of the secondary analyses of the counties studied by Pope et al.²³ using Datasets 2 and 3 are in the eAppendix (Section B; eTables 1a,b and 2a,b). Table 1 lists the summary statistics for the variables in Dataset 1. In 2000, 189 of the 545 counties had a $PM_{2.5}$ level greater than the current 3-year NAAQS level of $15 \mu g/m^3$; by 2007 only 48 of those 189 were not in compliance with the NAAQS. On average, $PM_{2.5}$ levels decreased at a rate of $0.22 \mu g/m^3$ per year, a rate 33% lower than observed in the 211 counties analyzed for the period 1980 to 2000 ($0.33 \mu g/m^3$ per year).²³

Figures 2A and 2B show life expectancies plotted against $PM_{2.5}$ levels for the years 2000 and 2007. Consistent with Pope et al.,²³ cross-sectional regression models showed a negative association between life expectancy and $PM_{2.5}$ in both years. Details are summarized in the eAppendix (Section C).

Figures 2C and 2D show changes in life expectancy plotted against changes in $PM_{2.5}$ levels for 2000 to 2007. We also plotted the estimated regression lines under Models 1 and 3 of Table 2, defined below.

Table 2 summarizes estimated regression coefficients for the association between changes in $PM_{2.5}$ and changes in life expectancy for 545 counties for 2000 to 2007 for selected regression models. When controlling for changes in all available socioeconomic and demographic variables as well as smoking prevalence proxy variables (Model 3), a $10 \mu g/m^3$ decrease in $PM_{2.5}$ was associated with an estimated mean increase in life expectancy of 0.35 years ($SE = 0.16$ years, $p = 0.033$). The estimated effect of $PM_{2.5}$ on life expectancy was consistent across models adjusting for various patterns of potentially confounding variables (e.g. Models 2 – 4). Models 5 – 9 of Table 2 show the results for select stratified and weighted regressions. In counties with a population density greater than 200 people per square mile, a $10 \mu g/m^3$ decrease in $PM_{2.5}$ was associated with an increased life expectancy of 0.72 (0.22 years, $p < 0.01$) (Model 6), compared with -0.31 years (0.22 years, $p = 0.165$) in counties with less than 200 people per square mile (P difference < 0.01). In counties whose proportion of urban residences was greater than 90 percent, a $10 \mu g/m^3$ decrease in $PM_{2.5}$ was associated with an increased life expectancy of 0.95 (0.31, $p < 0.01$) (Model 7), compared with -0.16 (0.16 years, $p = 0.299$) in counties with less than 90% urban residences (P difference < 0.01).

When we re-estimated Model 3 of Table 2 using the square root of population density as the weight (Model 8), the estimated effect of a $10\mu\text{g}/\text{m}^3$ reduction of $\text{PM}_{2.5}$ on life expectancy was more than double that observed in our un-weighted analysis (0.74 [0.24] vs. 0.35 [0.16]). When that same model was weighted by the inverse of county land area (Model 9), the effect was nearly triple that of the un-weighted analysis (0.96 [0.27]). Additional details regarding stratified and weighted analyses are provided in eTables 3 and 4 of the eAppendix.

We conducted similar analyses for the 211-county dataset for 1980 to 2007 and from 2000 to 2007, the results of which are presented in eTables 2a and 2b of the eAppendix, respectively. Results for the period from 1980 to 2000 were identical to those reported by Pope et al.²³

Figure 3 summarizes the point estimate and 95% confidence interval for the effect of a $10\mu\text{g}/\text{m}^3$ decrease in $\text{PM}_{2.5}$ on life expectancy for a select un-weighted and un-stratified regression model in each dataset/time period. Models fitted using Datasets 2 and 3 (left) controlled for changes in income, population, proportion of the population that is black, lung cancer death rate, and COPD death rate, corresponding to Model 4 in eTables 2a,b. Models fitted using Dataset 1 controlled for all available variables and correspond to Model 3 in Table 2. These estimates were fairly consistent, though estimates corresponding to the counties from Pope et al.²³ for the period 2000 to 2007 appeared slightly larger than those from other analyses.

In the analyses stratified by sex, the estimated effect of a $10\mu\text{g}/\text{m}^3$ reduction in $\text{PM}_{2.5}$ for the covariate pattern corresponding to Model 3 of Table 2 was an additional 0.59 (0.17) years of life expectancy for women and 0.08 (0.20) years for men (P difference = 0.027). Differences by sex were also observed in stratified and weighted models, although with less precision. Sex differences were smaller in the most urban counties (urban rate > 90%). Similar results were observed for the period 1980 to 2000 in Dataset 2. (Sex-specific results are presented in eTable 5.)

Effect estimates were not highly sensitive to the inclusion of the estimated change in smoking prevalence. Table 3 summarizes the results for the inclusion/exclusion of the smoking prevalence variable across several models. For example, when Model 3 in Table 2 was re-estimated for the 383 counties with matching smoking prevalence data, a reduction of $10\mu\text{g}/\text{m}^3$ was associated with an increase in life expectancy of 0.49 (0.19) years without including change in smoking prevalence in the model, and 0.47 (0.19) when including those changes. Similar results for smoking were observed in our stratified and weighted models, as well as in our models for men and women separately.

DISCUSSION

Data on air pollution and life expectancy from 545 U.S. counties in 2000 and 2007 show that recent declines in $\text{PM}_{2.5}$ to relatively low levels continue to prolong life expectancy in the US. These benefits are largest among the most urban and densely populated counties. These associations were estimated controlling for socioeconomic and demographic variables as well proxy variables for and direct measures of smoking prevalence.

In previous studies, a $10\mu\text{g}/\text{m}^3$ decrease in $\text{PM}_{2.5}$ has been associated with gains from 0.42 to 1.51 years of life expectancy.^{22,23} Here, a decrease of $10\mu\text{g}/\text{m}^3$ in $\text{PM}_{2.5}$ was associated with an increase in life expectancy of 0.35 (0.16) for 545 counties for the period from 2000 to 2007. An increase in life expectancy of 0.56 (0.19) was estimated for the same 211 counties included in the Pope et al.²³ analysis but extended to the period 1980 to 2007. The estimated effect in those 211 counties from 2000 to 2007 was equal to 1.00 (0.32). Stratified

and weighted analyses within the 545 counties from 2000 to 2007 yielded larger estimates between 0.72(0.22) and 1.12(0.32) – broadly in agreement with those previously reported.

From 2000 to 2007, the average increase in life expectancy across the counties in this study was 0.84 years, and the average decrease in $PM_{2.5}$ in those same counties was $1.56\mu g/m^3$. While $PM_{2.5}$ reductions presumably account for some of the improvements in life expectancy over this period, it is only one of many contributing factors. Other factors may include improvements in the prevention and control of the chronic diseases of adulthood, particularly cardiovascular diseases (CVD) and stroke,^{32,33} and changes in the risk factors associated with them, including medical advances, declines in smoking, and decreases in blood pressure and cholesterol.³³ Given the well-established link between air pollution and CVD mortality,^{5,7-8} and changes in other CVD risk factors, issues of multicausality and competing risk make it difficult to quantify exactly the changes in life expectancy attributable to reductions in $PM_{2.5}$. However, if we consider one of our more conservative effect estimates (Model 3, Table 2) the $1.56\mu g/m^3$ reduction in $PM_{2.5}$ accounts for about 0.055 years (1.56×0.035) of additional life expectancy, or roughly 7% of the increase in life expectancy. Using the estimate from our most urban counties (Model 7, Table 2), the increase in life expectancy attributable to the average reduction in $PM_{2.5}$ was 0.148 years (1.56×0.095), or as much as 18% of the total increase.

An interesting aspect of this study was how pronounced the $PM_{2.5}$ effect was for the original 211 counties from 2000 to 2007. Given that they were originally selected simply on the availability of matching pollution data, what is special about these counties that results in larger estimates of the effect of $PM_{2.5}$ on life expectancy? The stratified and weighted analyses suggest plausible explanations. For instance, the 211 counties were all in metropolitan areas, and the stratified analyses suggest that the effect of $PM_{2.5}$ on life expectancy is greatest in the most urban counties. One possible reason is that the composition of $PM_{2.5}$ is different in urban areas,³⁴ causing $PM_{2.5}$ to have a larger health impact. Another possibility is the “non-metropolitan mortality penalty” – the recent phenomenon in which mortality rates are higher in rural compared with urban areas.³⁵ While it is not clear why the mortality gap between metro and non-metro areas has widened, some hypotheses include greater improvements in standards of care in metro areas, changes in uninsurance rates, changes in disease incidence, and changes in health behaviors.³⁵ These, however, would be valid explanations only if they occurred at different rates in metropolitan areas compared with rural areas. If so, then perhaps failure to include variables that captured one or more of these differences could explain the different estimates of the effect of $PM_{2.5}$ on life expectancy.

Alternatively, metropolitan areas are more densely populated than non-metro areas. Our models that stratified by population density showed that the effect of $PM_{2.5}$ on life expectancy is greatest in the most densely populated study areas (those with a population density of at least 200 people per square mile)—possibly suggesting a role for differential exposure misclassification. That is, in densely populated areas, it is more likely that any two people from the same area are exposed to the same level of $PM_{2.5}$ with perhaps less exposure misclassification. This possibility was supported in our models weighted by the square root of population density and the inverse of land area, which placed more weight on the most densely populated counties and the smallest counties. In these models the effect of a $10\mu g/m^3$ decrease in $PM_{2.5}$ on life expectancy was much larger than the equivalent un-weighted analysis.

Another interesting finding was the difference in the effect of changes in $PM_{2.5}$ on men and women. Findings in the literature regarding the effects of air pollution by sex for long-term exposure have been mixed. Studies using the American Cancer Society and Harvard Six-

Cities cohorts show no significant difference in pollution-related mortality between men and women.^{4-8,10} Studies using a Medicare cohort have reported different effects by age and region, but did not stratify by sex.^{28,36-37} In a study using the Adventist Health cohort, Chen et al.³⁸ reported a large effect of PM_{2.5} on fatal coronary heart disease (CHD) in women but no association in men. Similarly, in separate studies, Lipsett et al.,³⁹ using a cohort of women (California Teachers' Study), reported associations between particulate matter and cardiovascular mortality, while Puett et al.,⁴⁰ using a cohort of men (Male Health Professionals), found no association with all-cause mortality or fatal CHD. For our main analysis using all 545 counties, we find a larger effect of PM_{2.5} on women, suggesting that reductions in PM_{2.5} are more beneficial to gains in life expectancy for women. Models fitted using data for the period from 1980 – 2000 as in Pope et al.²³ showed similar results. Future work should investigate more thoroughly the possibility of different PM_{2.5}-mortality associations for men versus women.

One factor that appeared to play no role in the PM_{2.5} and life expectancy relationship, however, was baseline PM_{2.5} level. This is in agreement with the findings by Pope and colleagues,²³ and implies that, while we may see differences across levels of population density, urban rate, and land area, this is not due to these areas having a higher or lower baseline PM_{2.5} level. Furthermore, this finding suggests that there is no clear threshold below which further reductions in PM_{2.5} levels provide no benefit (eAppendix, eTable 3). The fact that our results were not sensitive to the inclusion of direct measures of change in smoking prevalence suggests that the estimated gains in life expectancy for a 10µg/m³ reduction in PM_{2.5} are not a result of confounding due to changes in smoking prevalence.

Unlike previous cross-sectional analyses,^{16,17} we were able to estimate the association between county-specific temporal changes in PM_{2.5} levels and county-specific temporal changes on life expectancy adjusted by temporal changes in several potential confounding factors. By looking at within-county temporal changes, we reduce the potential bias due to unmeasured confounding. Further, by estimating clustered robust standard errors at the MSA level, we took a conservative approach in accounting for potential spatial correlation between neighboring counties.

Our analysis has the strengths of using some of the largest available datasets, and applying relatively simple analyses. Additionally, we improved on the original analysis by constructing a dataset with PM_{2.5} measured at the county level, in contrast to the more coarse MSA-level readings used in previous studies.^{7,23}

The analysis is limited, however, in its ability to control for all potential unmeasured confounding. Additionally, in comparing selected years, we do not fully exploit potentially informative data between those years. Furthermore, sophisticated analyses of the U.S. Medicare population by Greven et al.³⁶ did not observe associations between "local" trends in PM_{2.5} levels and "local" trends in mortality in 814 zip code level locations in the U.S. for the period 2000 – 2006. "Local" trends were defined as the difference between monitor-specific trends and national trends. The Medicare cohorts, however, consisted only of people age 65 and older, whereas our life expectancy calculations integrate over all ages. Also, other studies using Medicare based cohorts have found significant associations between PM_{2.5} and overall mortality.^{28,37} Future work is needed to investigate whether these differences among studies are due to differences in statistical models, data sources, or populations studied.

It is also worth considering whether life expectancy was the most appropriate outcome to consider in our model. Because life expectancies are calculated from age-specific mortality rates, perhaps a model with age-specific mortality rates as the outcome would be more

appropriate, allowing the age groups most affected by PM_{2.5} exposure to be pinpointed precisely.

In summary, our study reports strong evidence of an association between recent further reductions in fine-particulate air pollution and improvements in life expectancy in the United States, especially in densely populated urban areas.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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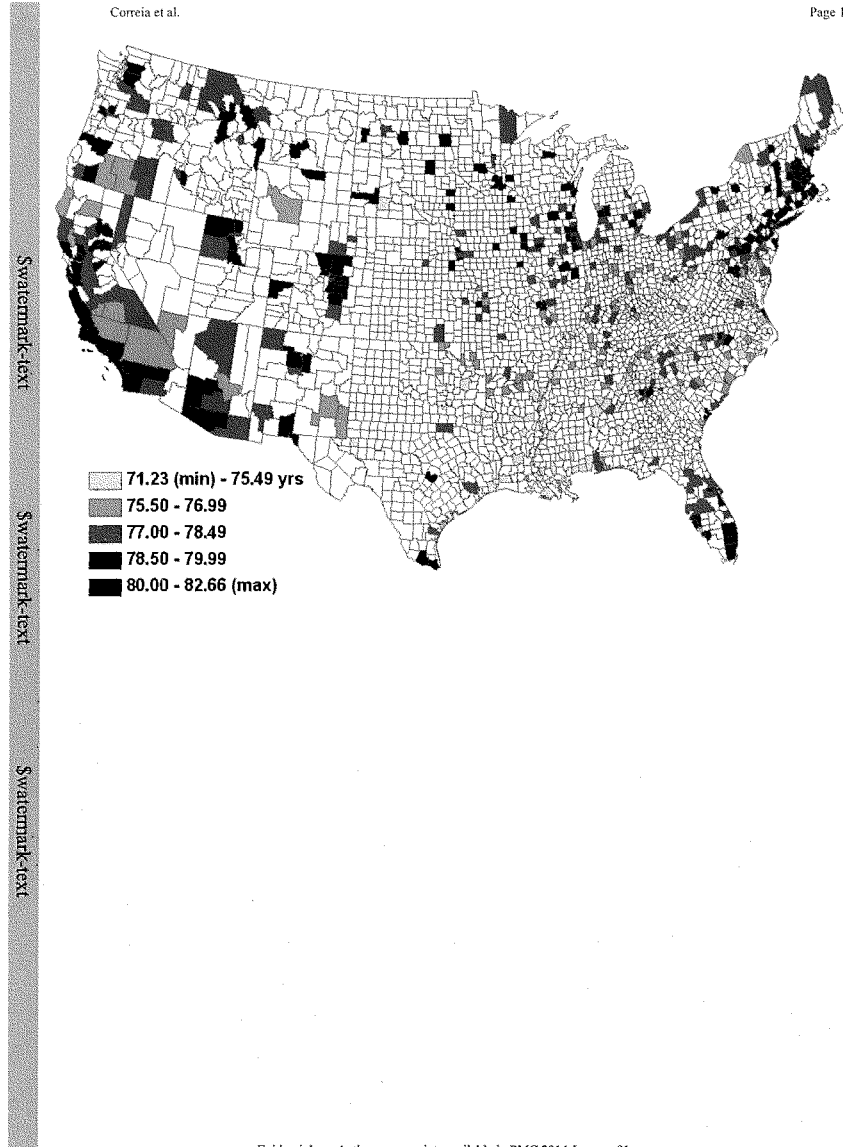
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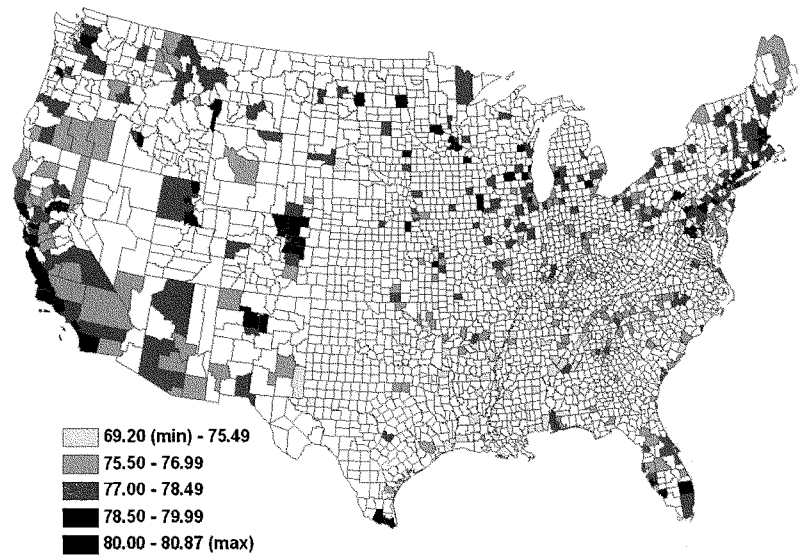


Figure 1.
Map of U.S. with the 545 counties from Dataset 1 shaded according to year (A) 2000 and (B) year 2007 life expectancies.

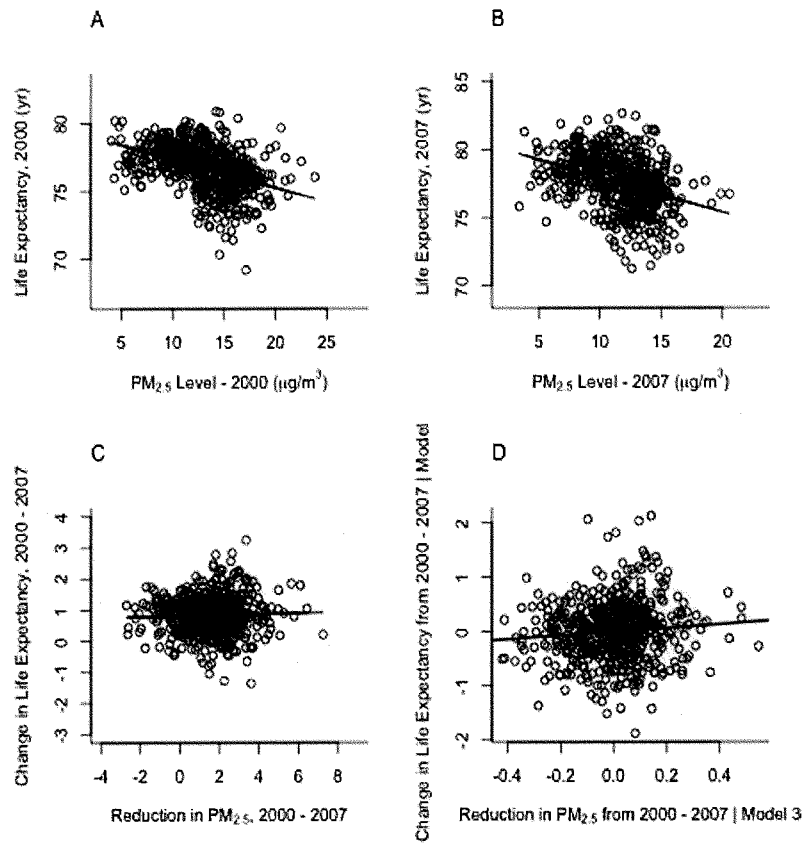
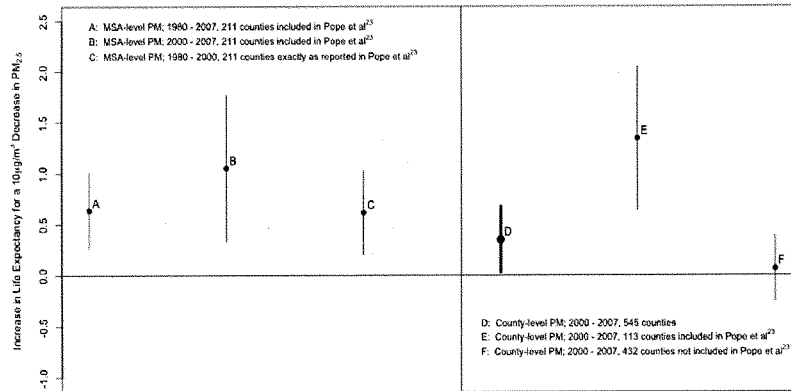


Figure 2.

Cross-sectional life expectancies plotted vs PM_{2.5} levels for (A) 2000 and (B) 2007 in Dataset 1. The slopes of the regression lines correspond to estimates from the simple model: $LE = \text{intercept} + \text{slope} \times PM_{2.5}$ in both the 2000 and 2007 plots. (C) On the left the data are plotted as change in life expectancy vs change in PM_{2.5} over the period 2000–2007. The regression line corresponds to the simple model $\Delta LE = \text{intercept} + \text{slope} \times \Delta PM_{2.5}$ (Model 1 in Table 2). (C) On the right is the added variable plot for PM_{2.5} corresponding to Model 3 in Table 2.

**Figure 3.**

Point estimates (circles) and 95% confidence intervals (vertical lines) for the effect of a $10 \mu\text{g}/\text{m}^3$ decrease in $\text{PM}_{2.5}$ on life expectancy. Estimates A and B were obtained from Dataset 3; Estimate C was obtained from Dataset 2. Estimates A, B, and C were adjusted for changes in income, population, proportion of the population that is black, lung cancer death rate, and COPD death rate (Model 4, eTables 2a,b). Estimates D, E, and F were obtained from Dataset 1, adjusted for changes in income, population, proportion of high school graduates, proportion of the population that is black, proportion of the population that is Hispanic, lung cancer death rate, and COPD death rate (Model 3, Table 2).

Table 1

Summary Characteristics of the 545 Counties Analyzed for the years 2000 and 2007

Variable	Mean (SD)
Life Expectancy (yr)	
2000	76.7 (1.7)
2007	77.5 (2.0)
Change	0.8 (0.6)
PM _{2.5} (µg/m ³)	
2000	13.2 (3.4)
2007	11.6 (2.8)
Reduction	1.6 (1.5)
Per Capita Income (in thousands of \$)	
2000	27.9 (7.4)
2007	30.4 (7.9)
Change	2.5 (2.3)
Population (in hundreds of thousands)	
2000	3.5 (6.3)
2007	3.8 (6.6)
Change	0.3 (0.6)
High School Graduates (prop of population)	
2000	0.81 (0.07)
2007	0.85 (0.06)
Change	0.04 (0.02)
Black Population (prop of population)	
2000	0.115 (0.138)
2007	0.117 (0.139)
Change	0.002 (0.017)
Hispanic Population (prop of population)	
2000	0.119 (0.189)
2007	0.098 (0.135)
Change	-0.021 (0.057)
Deaths from Lung Cancer (no./10,000 pop.) [*]	
2000	16.4 (3.5)
2007	15.5 (3.8)
Change	-0.9 (2.2)
Deaths from COPD (no./10,000 pop.) [*]	
2000	12.8 (3.1)
2007	12.5 (3.5)
Change	-0.3 (2.1)

^{*} 2005 death rates are used as a proxy for 2007 death rates. COPD denotes chronic obstructive pulmonary disease.

Table 2

Results of Selected Regression Models for County-level Analysis, 2000 to 2007. Regression coefficients (SE)

Variable	Model 1 (n=545)	Model 2 (n=545)	Model 3 (n=545)	Model 4 (n=545)	Model 5 ^a (n=257)	Model 6 ^b (n=307)	Model 7 ^c (n=169)	Model 8 ^d (n=545)	Model 9 ^e (n=545)
No. of county units									
Intercept	0.42 (0.04)	1.08 (0.08)	1.00 (0.08)	1.03 (0.07)	0.97 (0.10)	0.91 (0.11)	0.84 (0.15)	0.79 (0.15)	0.67 (0.15)
Reduction in PM _{2.5} (10g/m ³)	0.14 (0.19)	0.35 (0.17)	0.35 (0.16)	0.34 (0.16)	0.39 (0.23)	0.72 (0.22)	0.95 (0.31)	0.74 (0.24)	0.96 (0.28)
Change in income (in thousands of \$)	--	0.013 (0.017)	0.017 (0.018)	--	0.005 (0.018)	0.02 (0.02)	-0.01 (0.03)	0.03 (0.02)	0.05 (0.02)
Change in population (in hundreds of thousands)	--	0.13 (0.05)	0.11 (0.05)	0.11 (0.04)	0.07 (0.05)	0.06 (0.04)	0.02 (0.04)	0.07 (0.06)	0.34 (0.12)
Change in high-school graduates (proportion of population)	--	-9.12 (1.61)	-7.98 (1.56)	-7.83 (1.57)	-7.27 (1.95)	-4.42 (2.60)	4.04 (3.20)	-1.94 (3.35)	-3.30 (3.45)
Change in black population (proportion of population)	--	-6.55 (2.05)	-6.34 (1.97)	6.43 (2.09)	-7.86 (3.07)	-9.02 (2.27)	-12.56 (2.59)	-1.14 (3.00)	-6.21 (2.97)
Change in Hispanic population (proportion of population)	--	-2.16 (0.47)	-2.03 (0.47)	2.13 (0.49)	-2.12 (0.59)	-2.46 (0.68)	-0.95 (0.62)	-3.25 (0.63)	-4.57 (0.75)
Change in lung cancer mortality rate (no./10,000 population)	--	--	-0.02 (0.02)	-0.02 (0.02)	-0.02 (0.02)	-0.05 (0.03)	-0.05 (0.05)	-0.07 (0.02)	-0.07 (0.03)
Change in COPD mortality rate (no./10,000 population)	--	--	-0.05 (0.01)	-0.05 (0.02)	-0.05 (0.02)	-0.06 (0.03)	-0.06 (0.05)	-0.08 (0.02)	-0.06 (0.02)

^aIncluded only counties with the largest year 2000 population in the MSA.^bIncluded only counties with a year 2000 population density > 200 ppl/sq. mile.^cIncluded only counties with a year 2000 urban rate > 90%.^dWeighted by the square root of the year 2000 population density.^eWeighted by the inverse of county land area.

Table 3

Comparison of results of select models for inclusion of smoking variable vs. no inclusion of smoking variable

Selected counties and analysis	No. Counties	Full model, with smoking β (SE, p) for 10 $\mu\text{g}/\text{m}^3$ $\text{PM}_{2.5}$	Full model, no smoking β (SE, p) for 10 $\mu\text{g}/\text{m}^3$ $\text{PM}_{2.5}$
All Counties	383	0.47(0.19, 0.013)	0.49(0.19, 0.011)
2000 population density (persons per square mile)			
>800	110	0.52(0.43, 0.230)	0.53(0.43, 0.221)
>600	139	0.68(0.30, 0.028)	0.68(0.30, 0.027)
>400	187	0.71(0.26, 0.007)	0.70(0.25, 0.007)
>200	272	0.67(0.22, 0.003)	0.65(0.22, 0.004)
< 200	111	-0.50(0.30, 0.100)	-0.39(0.30, 0.193)
2000 urban rate			
>90%	157	0.76(0.28, 0.009)	0.76(0.28, 0.008)
>95%	101	1.01(0.31, 0.002)	0.98(0.32, 0.003)
<90%	226	-0.14(0.20, 0.483)	-0.13(0.20, 0.513)
2000 population density & 2000 urban rate			
>200 & >90%	100	0.95(0.32, 0.004)	0.93(0.32, 0.005)
Regression weighted by square root of 2000 population density (All counties)	383	0.77(0.24, 0.002)	0.76(0.25, 0.003)
Regression weighted by inverse of county land area (All counties)	383	0.81(0.26, 0.002)	0.74(0.27, 0.007)
Sex			
Men	383	0.20(0.23, 0.389)	0.22(0.23, 0.343)
Women	383	0.71(0.20, 0.001)	0.72(0.20, <0.001)

^a Covariates include change in income, change in population, change in high-school graduates, change in proportion of black population, change in proportion of Hispanic population, change in lung cancer mortality rate, change in COPD mortality rate. Analysis used: SAS 9.2, PROC SURVEYREG, clustered by MSA, using the "weight" statement, and STATA 11.0. REGRESS.

Responses by Mr. Raymond Keating

**U.S. House of Representative
Committee on Science, Space and Technology
Subcommittee on Environment**

**Hearing Questions for the Record
The Honorable David Schweikert**

Ensuring Open Science at EPA

**Answers from Raymond J. Keating
Chief Economist
Small Business & Entrepreneurship**

1. In 2012, the President's Science Advisor testified that "Absolutely, the data on which regulatory decisions... are based should be made available to the Committee and should be made public." Also in 2012, the Chair of EPA's Science Advisory Board testified that EPA's advisors recommend "that literature and data used by EPA be peer-reviewed and made available to the public." Do you agree with these statements?

Keating: Yes, I completely agree. When making public policy, it is critical that the process be open and transparent, and that includes the science, models and analysis used to formulate such policy.

2. You testified about the disproportionate impact of federal environmental regulations for small business and small manufacturers, with cost between 100 percent and 400 percent higher than their large counterparts. How does a non-transparent regulatory process particularly hit smaller business?

Keating: The lack of transparency in the regulatory process increases the likelihood that regulations are going to be imposed based on special-interest influences and political preferences rather than according to rigorous, accurate assessments of actual risks, costs and benefits. Regulatory activity based on rent seeking (that is, individuals or groups using government to take wealth from others) and special interests (such as those incentivized to spend heavily in favor of regulation from which they accrue clear benefits, while the wider public, such as consumer or taxpayers, have few incentives to expend the dollars and time to counter the issue given the dispersed nature of the costs) is a constant threat. Non-transparency merely serves to enable the imposition of misguided regulation, and the costs of such regulatory activity falls much more heavily on small firms, as opposed to large businesses.

As a reminder from my written testimony: "The Small Business Administration's Office of Advocacy periodically estimates regulatory costs, obviously with an eye towards the burdens imposed on smaller businesses. In September 2010, the Office of Advocacy published an updated study estimating the costs of complying with federal regulations. The study – 'The Impact of Regulatory Costs on Small Firms' by Nicole V. Crain and W. Mark Crain from

Lafayette College – provided details regarding the burdens of federal regulatory costs... On the environmental front, per employee regulatory costs for firms with less than 20 employees came in at \$4,101, which topped the \$1,294 cost for firms with 20-499 employees by 217% and the \$883 cost for businesses with 500 or more workers by 364%.”

Clearly, excessive regulation resulting from a non-transparent regulatory process not only means increased costs, but also disproportionate burdens on smaller firms.

3. Can you discuss the relationship between the Secret Science Reform Act and existing Administration policy on scientific integrity and transparency, including the President’s Executive Order on “Improving Regulation?”

Keating: Interestingly, the Secret Science Reform Act and President Obama’s Executive Order on “Improving Regulation” appear to be mutually reinforcing. In his Executive Order, the President said, “Our regulatory system ... must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.”

That clearly is reinforced by the Secret Science Reform Act, which requires that the EPA “shall not propose, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action” is “specifically identified” and “publically available in a manner that is sufficient for independent analysis and substantial reproduction of research results.” This legislation clearly aligns with the President’s order to “allow for public participation and an open exchange of ideas,” “promote predictability and reduce uncertainty,” “identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends,” “take into account benefits and costs, both quantitative and qualitative”, and “ensure that regulations are accessible, consistent, written in plain language, and easy to understand.”

Based on this Executive Order, one would expect the Obama administration to be a strong supporter of the Secret Science Reform Act.

4. EPA also develops and justifies regulations on the basis of economic and air quality models that are often not transparent. For example, EPA’s Cross-State Air Pollution Rule and its recent New Source Performance Standard for carbon dioxide were developed through the use of taxpayer-funded, but proprietary model called the “Integrated Planning Model.”
 - a. Do you support ensuring that there is public access to these critical models?

Keating: Quite simply, any model used to formulate public policy – especially those developed with taxpayer funding – must be fully accessible to the public for full assessment and review.

- b. As an economist, how important is it to see the inputs, assumptions, and defaults within a model in order to assess its quality.

Keating: Very early in my career, including during graduate school, two big issues became clear to me about economic or econometric models. First, models could be manipulated to achieve certain results based on the inputs and assumptions used, as well as by those left out. Second, models were limited by a host of factors that were critical, even central to economic growth, for example, yet could not be quantified in an intelligible way to be used in any kind of statistical models. Therefore, it is crucial to see the inputs and assumption underlying any scientific model in order to assess how closely it tracks to the real world, if you will, and how dispassionate or independent the model is.

- 5. In what ways has the development and use of the “social costs of carbon” been inconsistent with the Administration’s commitments to transparency?

Keating: In President Obama’s Executive Order on “Improving Regulation,” it was clearly stated: “Our regulatory system ... must be based on the best available science.” A variety of critics – including, as noted in my written remarks, Robert Pindyck, an economics professor at the Massachusetts Institute of Technology – has made clear that the “science” upon which the “social cost of carbon” estimates are based has little relation to “the best available science.” As noted in the abstract of Pindyck’s paper: “A plethora of integrated assessment models (IAMs) have been constructed and used to estimate the social cost of carbon (SCC) and evaluate alternative abatement policies. These models have crucial flaws that make them close to useless as tools for policy analysis: certain inputs (e.g. the discount rate) are arbitrary, but have huge effects on the SCC estimates the models produce; the models’ descriptions of the impact of climate change are completely ad hoc, with no theoretical or empirical foundation; and the models can tell us nothing about the most important driver of the SCC, the possibility of a catastrophic climate outcome. IAM-based analyses of climate policy create a perception of knowledge and precision, but that perception is illusory and misleading.”

For good measure, there is the matter in which the Obama administration in effect quietly leaked out changes in its “social cost of carbon” guess-timate. As reported in a November 4, 2013, Bloomberg report, “The administration first set a comprehensive price in 2010, and raised it in May of this year after the economic models it used to set the price changed to account for rising seas and other natural changes. That change in May was slipped into a Department of Energy regulation of microwave ovens, a move criticized by Republicans in Congress.”

None of this speaks to a true commitment to transparency and the best available science. Rather, it indicates a regulatory process beholden to a biased, special-interest, and political agenda.

6. A poll last year found that 90 percent of Americans agree with the statement that studies and data used to make federal government decisions should be made public. Do you think small businesses agree with this principle?

Keating: It's encouraging that the general public polled so high in favor of transparency when it comes to governmental decision-making, including regulation. There's no doubt in my mind that small business owners overwhelmingly agree with such sentiments, as they are on the frontlines wrestling with the costs and implementation of regulation.

For good measure, the importance of such transparency for entrepreneurship and small business is widely recognized. For example, in the World Bank's *Doing Business 2014*, it's noted: "Regulations that protect consumers, shareholders and the public without overburdening firms help create an environment where the private sector can thrive. Sound business regulation requires both efficient procedures and strong institutions that establish transparent and enforceable rules." And a bit later: "Where regulation is burdensome and competition limited, success tends to depend on whom one knows. But where regulation is transparent, efficient and implemented in a simple way, it becomes easier for aspiring entrepreneurs to compete on an equal footing and to innovate and expand."

7. During the hearing, you suggested that increases in regulations result in higher costs to consumers and businesses. Can you provide examples that are particularly erroneous for small business?

Keating: When it comes to the "social cost of carbon" regulatory scenario, it's vital to keep in mind that government regulating to limit carbon emissions will necessarily drive up the costs of carbon-based energy, including coal-produced electricity. As noted in a 2012 [report](#) on the impact of energy costs on business, I highlighted just a couple of examples:

Indeed, electricity costs often rank among a firm's biggest expenses. For example, Bob Farber, president of Quality Perforating Inc., a Carbondale manufacturer of pierced coils, sheets and components, in Scranton, PA, was quoted in a May 25, 2010, article in the *Scranton Times-Tribune* observing, "For a business like ours, electricity is probably our biggest fixed cost because all our machines are electric." ...

The particular resources used to generate electricity also will have a clear impact on the cost of electricity. Consider the following from a May 8, 2012, *International Business Times* article written by Todd Westby, who is a small business owner: "Electricity prices are a big concern for me. And on a tight budget, I can only account for so much to go toward the electricity bill before I have to pass this cost onto my customers. Luckily for me, I live in a state where more than 70 percent of the energy is powered by coal. Nebraska's dependence on coal has had tremendous results that businesses and families can appreciate. Our state has the 11th lowest electricity prices in the U.S.... And as I look at coal pricing over the last few decades, I've seen one very important fact: it's stable.

There is little fluctuation in the already affordable cost of coal from year to year. In our uncertain economic times, confidence in low-cost electricity is one fewer obstacle to overcome on the road to recovery.”

For good measure, government mandates, regulations, subsidies and taxes factor into the energy cost equation.

Thank you for your time and attention. Please let me know if there are additional questions.

Appendix II

ADDITIONAL MATERIAL FOR THE RECORD

THE FOLLOWING DOCUMENTS WERE SUBMITTED FOR THE RECORD BY
REPRESENTATIVE SUZANNE BONAMICI



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. 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

**Board of Directors**

John Applegate
 Robert Glicksman
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 Rena Steinzor
 Robert R.M. Verchick

February 11, 2014

The Honorable David Schweikert, Chairman
 The Honorable Suzanne Bonamici, Ranking Member
 House Committee on Science, Space, and Technology
 Subcommittee on the Environment
 Washington, D.C. 20515

Re: Secret Science Reform Act, H.R. 4012

Advisory Council

Patricia Bauman
 Frances Beinecke
 Eula Bingham
 W. Thompson Comerford, Jr.
 Sally Greenberg
 John Passacantando
 Henry Waxman
 Robert Weissman

Dear Chairman Schweikert and Ranking Member Bonamici,

We are professors of environmental and administrative law who specialize in the agencies' use of science in policymaking. We believe that H.R. 4012, the "Secret Science Reform Act," contains a number of significant problems that cumulatively threaten to undermine, rather than enhance the scientific rigor of EPA's decision-making. We urge you to reconsider the need for the bill. At the very least, the bill should be revised significantly before it is considered further by the Committee.

As drafted, H.R. 4012 suffers, at best, from a dangerous lack of clarity. It forbids EPA from relying on scientific and technical information unless that information is both "specifically identified" and "publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results." Neither of the quoted phrases is self-defining. Thus, as it stands, the bill will unnecessarily encourage litigation and could lead to a number of other significant problems that we identify below.

H.R. 4012 threatens to undermine the scientific rigor of EPA's decision-making while leaving the true "secret science" problem untouched. "Secret science" is indeed pervasive in some regulatory programs, yet H.R. 4012 does nothing to address the most serious problems since it inoculates from its reach existing, outdated legal provisions that tolerate the sequestration of research. For example, under Section 10(g) of the Federal Insecticide, Fungicide, and Rodenticide Act, the public and affected parties are not allowed to view the studies underlying EPA's licensing of pesticides until after the agency's registration decision is concluded, and even then the research is available only to

the public under tightly constrained circumstances.¹ Even more problematic, as a result of aggressive trade secret claims, the research on the safety of more than 17,000 chemicals regulated by EPA under the Toxic Substances Control Act is completely insulated from public view by law.² Such impediments to public access undermine independent evaluations of the evidence used by EPA in its regulation, yet they remain untouched by the very bill that promises to expose this secret science.

By contrast, H.R. 4012 targets publicly available research, much of which has been published in peer reviewed journals, as the area in need of heightened transparency. Even more perplexing, the bill tasks EPA -- not the researchers -- with the enormous task of amassing the data underlying each relevant study. If EPA is unable to summon the resources or time to access this underlying information or is otherwise unable to acquire the data, it is apparently prohibited from considering the stud(ies) in its regulatory decision.

This draconian requirement will significantly undermine the scientific integrity of EPA's regulation, rather than enhance it, by placing out of the agency's consideration relevant and material studies when EPA is unable to acquire the underlying information. Such an approach also provides the opportunity for strategic games. For example, under H.R. 4012, sponsors who learn of adverse effects from their products through internal research could attempt to limit EPA's consideration of their findings simply by denying EPA access to their data. Since the data underlying privately-funded research apparently remains the property of private parties, they can control how their research is used by EPA as best suits their interests.

The costs of the requirements in H.R. 4012 are grossly disproportionate to any plausible benefits. Before imposing this new requirement on the thousands of science-intensive projects at EPA, the proponents of such legislative requirements should consider the costs and delays to taxpayers and weigh them against the social benefits. The costs are likely to entail tens of millions of dollars of staff time, years of delay per standard, and the possibility that EPA will either have to bypass considering relevant studies because they cannot make the data available or avoid regulatory action altogether. Consider the bill's requirement as applied to a typical NAAQS science assessment by EPA, for example. In its bibliography for this assessment, EPA cites to hundreds of peer reviewed, published studies that it considered.³ H.R. 4012, as we read it, would require EPA to make the "materials, data, and associated protocols, computer codes and models, and recorded factual materials" underlying each of these hundreds of studies "publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research

¹ A person seeking access to the studies underlying a pesticide registration must certify that he/she will not share the information with manufacturers in other countries. In addition, the pesticide manufacturers must be notified of each person who views their information; the information must be viewed at the agency's office; and the information is available only after a pesticide registration decision is made. 7 U.S.C. § 136a(c)(2)(A).

² See *Declassifying Confidentiality Claims to Increase Access to Chemical Information*, EPA, <http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html> (last visited Apr. 15, 2013) (listing, in Table 4, 17,031 CBI chemicals on TSCA inventory).

³ See EPA's Integrated Science Assessment for Particulate Matter, Dec. 2009, Annex E References, at E-522, available at http://www.epa.gov/ncea/pdfs/partmatt/Dec2009/PM_ISA_full.pdf.

results.” Indeed, aggressive interest groups could even argue that the bill requires EPA to put the raw data into an electronic database to expedite statistical analysis. The costs resulting from such a demand on EPA would be extremely high—a wasteful outcome in an era of budget shortages.

The benefits to regulatory quality – by contrast – seem miniscule. In how many of these agency actions will affected groups actually benefit from this enhanced access to underlying data? And who are the groups with the resources and interest to reanalyze the data or reproduce the study? They certainly are not the groups that are thinly financed. And what is to be gained from the resultant reanalysis? Is the agency equipped to review meta-analyses of data bases that have not been peer reviewed, published, or restricted methodologically? Indeed, as between peer reviewed studies and non-peer reviewed re-analyses of data, is Congress suggesting the latter is preferable or even desirable?⁴

Moreover, while we strongly support extending the Data Access Act to private parties, as has been suggested by the BiPartisan Policy Center, the Administrative Conference of the U.S., and in articles we’ve written, such a requirement should never preclude the agency from using studies when the data is not publicly available.⁵ Imposing such a prohibition on the agencies makes “the perfect the enemy of the good” – limiting the agency’s access to scientific research based on expensive and often fruitless paperwork requirements.

H.R. 4012 facilitates further mechanisms for harassing scientists. There have been repeated, documented incidents of the harassment of researchers whose results produce unwanted results for regulated parties.⁶ In a number of these incidents, the harassing party’s first line of attack begins with subpoena-ing or otherwise acquiring the underlying data and then statistically reanalyzing the data in ends-oriented ways that attempt to cast doubts on the integrity of the researcher.⁷ H.R. 4012 provides still more tools for disgruntled interests to “manufacture doubt.” If Congress seeks to legislate additional opportunities to enable this type of harassment, it should also legislate protections for researchers so that our most talented scientists do not leave the health and environmental science field altogether. As Dr. Donald Kennedy, the former Editor in Chief of *Science*, warns:

I know what many of my fellow scientists are saying to one another They wonder whether the data underlying their findings may be subject to examination

⁴ See generally Sheila Jasanoff, *Transparency in Public Science: Purposes, Reasons, Limits*, 69 LAW AND CONTEMPORARY PROBLEMS, Summer 2006, at 22 (providing an excellent overview of the dangers of hyper-transparency provisions, such as those embodied in the Secret Science Reform Act).

⁵ See, e.g., BiPartisan Policy Center, *Improving the Use of Science in Regulatory Policy* 43 (Aug. 2009); ACUS Recommendation 2013-3; Wendy Wagner and David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls governing the Quality of Public Research to Private Research*, 30 AMERICAN JOURNAL OF LAW & MEDICINE 119 (2004).

⁶ See, e.g., DAVID MICHAELS, DOUBT IS OUR PRODUCT (2008); NAOMI ORESKES & ERIK CONWAY, MERCHANTS OF DOUBT (2009); THOMAS O. MCGARITY & WENDY E. WAGNER, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH (2008).

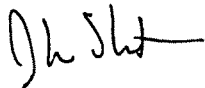
⁷ Herbert L. Needleman, *Salem Comes to the National Institutes of Health: Notes from Inside the Crucible of Scientific Integrity*, 90 PEDIATRICS 977 (1992); Paul M. Fischer, *Science and Subpoenas: When Do the Courts Become Instruments of Manipulation*, 59 L. & Contemp. Problems 159 (1996) (both articles are included as attachments to the letter on file with the Subcommittee).

and reinterpretation, perhaps with some 'spin' supplied by the revisionists. They know that charges of research misconduct could arise from hostile access to their scientific work. They know they are vulnerable to personal attack from those whose interests may be adversely affected by the product of their research.⁸

These are only a few of the many problems we have identified with the bill, but given your upcoming hearing, we believe it is better to share some of them early in the discussions. We are happy to provide a more comprehensive assessment later on, as the legislative drafting progresses.

Thank you for your consideration.

Sincerely,



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Noah M. Sachs
Professor
University of Richmond School of Law



Holly Doremus
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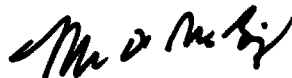
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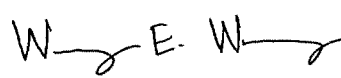
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⁸ Don Kennedy, *Prologue*, at xxiii, in *RESCUING SCIENCE FROM POLITICS* (Wendy Wagner & Rena Steinzor eds. 2006).

Salem Comes to the National Institutes of Health: Notes From Inside the Crucible of Scientific Integrity

Herbert L. Needleman, MD

ABBREVIATIONS. NIH, National Institutes of Health; EPA, Environmental Protection Agency; WISC-R, Wechsler Intelligence Scale for Children-Revised.

Many readers of *Pediatrics* may have only a dim idea of the combative arena in which environmental research is conducted. Probably, very few have had the experience of being investigated for scientific misconduct. My aim in reviewing these two topics is to provide a preventive road map to others and to reveal some inadequacies and inequities in the investigative process. It is necessary, to accomplish this, to be direct and specific. Tact is sacrificed here for the sake of clear instruction.

In 1972 I published 700 words in *Nature* reporting that Philadelphia inner-city children had higher dentine lead levels than suburban children.¹ The paper suggested that the tooth might be a useful marker to estimate body lead burden after exposure had ended. I did not know then that I was taking the first step toward being investigated for scientific misconduct by my university and the National Institutes of Health (NIH) Office of Scientific Integrity.

The Environmental Protection Agency (EPA) asked me to present the 1972 tooth lead paper in Amsterdam at an international meeting on lead. I was unprepared by my past attendance at pediatric meetings for what I encountered there. This was no scholarly debate on the toxicology and epidemiology of lead; this was war. The speakers did not behave like academics hoping to embellish their reputations by parading the results of their last 6 months in the lab. These stakes were much higher.

Arrayed against each other were a small and defensive group of environmentalists and health scientists on one side, and on the other the representatives of the gasoline companies, including such formidable entities as El DuPont, Associated Octel, Dutch Shell, and Ethyl Corporation of America. Any paper suggesting that lead was toxic at lower doses immediately faced a vocal and well-prepared troop that rose in concert to attack the speaker. My 10-minute talk was not spared; giving it marked the beginning of my post-postgraduate education.

This encounter pushed me, on returning to the United States, to look into the history of lead research.

I found that my experience was not new. Two Australians, A. J. Turner and J. L. Gibson, who first described childhood lead poisoning in Brisbane in 1892, were derogated by industry and by a segment of the medical community. When Randolph Byers, one of the earliest pediatric neurologists, first suggested in 1943 that some school dysfunction might be due to undiagnosed lead toxicity, he was threatened with a million dollar lawsuit by Lead Industries Association.² Clair Patterson, the geochemist credited with dating the age of the earth, was publicly vilified as a crank by the industry and had his career threatened when he suggested that civilization had raised everyone's body lead burdens to 1000 times that of our ancient ancestors (personal communication, 1992). All of the early research in lead toxicity was funded by the industry, who had a tight grip on what the public was permitted to know.³

Reading these records vividly brought back an experience I had when I was in medical school. One summer I worked as a laborer at the Deepwater, NJ, DuPont plant, where tetraethyl lead had been synthesized years before. Workers were forbidden to carry matches, and when the smoking whistle blew at 10 AM and 2 PM, we poured out of our buildings by the hundreds to collect at wooden smoking shacks in open areas. There we lined up at two glowing cigar lighters imbedded in the shack wall. While I smoked two cigarettes back-to-back in the 15-minute break, I inspected my coworkers.

Off to the side sat a few older men, obviously slow and clumsy, staring silently into middle space. When they did speak, they seemed remote and out of touch. A veteran worker told me that they were from "The House of Butterflies." They had been poisoned while making tetraethyl lead. Years later, I would read in the *American Journal of Public Health* that during the early stages of tetraethyl lead production at Deepwater,⁴ there had been an outbreak of poisoning among the work force. More than 300 men had been affected, often with full-blown psychotic symptoms; at least 4 had died. Affected workers were frequently seen brushing hallucinated insects off their bodies, hence the name. Production was temporarily stopped by the Public Health Service, but this ban was lifted after a superficial investigation. These damaged men were some of the survivors.

Years later, having satisfied myself that the tooth was a valid marker of past exposure, with Alan Leviton and Bob Reed, I studied a sample of children who were asymptomatic for lead, classifying them by dentine lead levels. The data showed that after con-

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trolling for a number of covariates, children with elevated lead in their teeth scored lower on tests of psychometric IQ, speech and language function, and on measures of attention.⁵ The study seemed to respond to a number of research difficulties that had until then vexed the field, and as a result it received considerable attention. The lead industry, in the form of the International Lead Zinc Research Organization, was uncharacteristically silent for about 6 months. Then they began to call for copies of my original data. I declined. I had seen what had happened to good data when massaged and distorted by industry technicians, and while I was happy to share my data with any bona fide scientist—and did—I was not willing to include the lead industry.

In 1982, the EPA began to rewrite the Air Lead Standard. I was asked to participate. Also invited was Dr Claire Ernhart, a psychologist who had published a paper in 1974⁶ that reported that lead was associated with lower IQ in a group of Long Island black preschoolers. In 1981, she published a paper (in this journal) which criticized my study and said that when followed into the first grade, the lead effect she had previously reported was no longer significant.⁷ Close examination of the paper showed that school-age blood lead levels were in fact significantly related to IQ. Ernhart dismissed this finding as due to chance, and stated that: "If there are, in fact, behavioral and intellectual sequelae of low levels of lead burden... these effects are minimal." Shortly after that paper she became a grantee of the International Lead Zinc Research Organization and began to speak against controlling lead in the environment. When there was a move to put lead back in gasoline, Ernhart appeared in testimony for Lead Industry Associates, asserting that there was no valid health reason to ban its use.⁸

The industry began to raise public questions about the integrity of my studies. In 1983, EPA's Clean Air Scientific Advisory Committee thoroughly reviewed industry-generated charges that my work was flawed. They concluded:

A pioneering general population study was reported by Needleman et al (1979)... Significant effects ($p < .05$) were reported for full scale WISC-R [Wechsler Intelligence Scale for Children-Revised] scores, WISC-R verbal IQ scores, for 9 of 11 classroom behavioral scale items, and several experimental measures of perceptual motor function....

Reanalyses carried out in response to the Committee's recommendations have been reported by Needleman (1984), Needleman et al (1985) and US EPA's Office of Policy Analysis (1984) as confirming the published findings on significant associations between elevated dentine lead levels and decrements in IQ...⁹

I thought that this official statement had finally and permanently sealed the argument. I could have not conceived that these same charges would be resuscitated 7 years later.

In 1990, an attorney from the Department of Justice asked me to participate in what he described to me as a landmark suit brought under the Superfund Act against three lead polluters in Midvale, UT. Among the witnesses for the defense were Dr Ernhart and Dr Sandra Scarr. Scarr had been a member of the government committee that had reviewed my work for EPA. She now appeared in a different role, this time

on behalf of the lead industry, reviving the same charges that had been settled in 1986. They came to my lab for 2 days to examine my raw data in preparation for the trial.

Before going to trial, the case was settled. Sixty-three million dollars was awarded to the federal government to clean up the mine site. After the case was settled, I found out that Scarr and Ernhart had written a lengthy document accusing me of unscientific behavior. They maintained that their conclusions grew out of their examination of my printouts. This document was forwarded to NIH's office of scientific misconduct by David Genesson, an attorney for the Washington, DC, law firm of Hunton and Williams. It was also given to defense lawyers in a number of lead damage cases. I had encountered the name of Hunton and Williams before. This firm had represented Ethyl Corporation of America and El DuPont, contesting the regulation of lead additives in federal court and before the EPA and the Federal Trade Commission. In reading the Scarr/Ernhart document, I found numerous allegations and hints of unscientific behavior.

As I perceived them, their major criticisms of my work were (1) that I did not properly control for confounding; (2) that I selected cases in a biased fashion; and (3) that multiple tests were done, and this could lead to positive associations on the basis of chance.

These kinds of issues are generally considered methodological disagreements and are fought out in the pages of journals; I could not understand why they were defined by my critics as scientific misconduct. Similar criticisms were raised before the EPA in 1982 and dismissed. These facts notwithstanding, in October of 1991, I was notified by the Dean of my medical school that an inquiry into charges of misconduct was being done at the instruction of NIH's Office of Scientific Integrity.

When the proceedings began, I was confident that the printouts would be examined, that I would explain how I analyzed the data, and that like the EPA, the university would rapidly put matters right. I thought this would end this matter quickly and permanently. But the university's behavior seemed odd and troubling. They chose to ignore a number of rather obvious facts that I repeatedly brought to their attention: that the charges were initially raised by two individuals who had been supported by the lead industry; that they had been raised before and dismissed by the Clean Air Science Advisory Committee of the EPA; that my work had been replicated more than 12 times since its publication; and that I had shared my data with other scientists in the past.

Instead, the preliminary Inquiry Panel issued a strange report. The Panel stated that it "found no evidence of fraud, falsification or plagiarism," but inexplicably added that it "is not able at this time to exclude the possibility rule of scientific misconduct in terms of misrepresentation." The report argued that the models I chose were selected to optimize a lead effect, and that I may have selected cases in a biased fashion. The report presented no evidence in support of this assertion, only conjecture.

I rebutted their charges in a letter to the Dean and showed that the charge of misrepresentation was based on false evidence. The Dean declined to review my letter. Instead, he turned it over to the Panel for comment. They also did not respond to any of the facts that I raised in the letter. Instead, they stated that the material I supplied in rebuttal of the report of the Inquiry Panel was "not directly relevant." They recommended a full investigation.

During the time the investigation was being arranged, I requested of the Dean that the Hearing Board he appointed include experts of international standing in the fields of behavioral toxicology and epidemiology. This was denied. I was told that there was no need for this expertise in the two disciplines that my work spanned. I requested that the hearings be open to the university community and the press. Again, this was denied. I asked that two members of the Hearing Board be replaced for possible conflict of interest. One, Dr Robert McCall, was a developmental psychologist whose appointments on many professional committees overlapped with Dr Scarr, and who frequently cited her work in support of his. The second, Dr Herbert Rosenkranz, had been Director of the Environmental Sciences Center at Case Western Reserve University, where Dr Ernhart was a faculty member. This request was also denied.

I began to feel uneasy and increasingly certain that if the case were reviewed *in camera*, I would be found guilty of something. I went before the Faculty Assembly of the university and requested their support in my demand for open hearings. The faculty emphatically supported me. The Assembly passed a unanimous resolution asking the university to open the hearings. At the Faculty Senate, a representative of the administration argued against open hearings, because, he said, it was necessary to "protect the process." The "need to protect the process" was a phrase I was to hear repeated many more times. I argued that the process did not have a nervous system; that it was people who required protection; and that the given reason that hearings were closed was to protect the reputation of the accused. I was in this instance the accused, and I wanted the hearings to be open. The Senate unanimously voted for open hearings.

Pressure began to build on the administration, and I began to receive letters of support from colleagues around the country. Six eminent health scientists, Frank Oski, Arthur Upton, Samuel Epstein, Philip Landrigan, David Bellinger, and Bernard Weiss sponsored a petition to the Chancellor demanding open hearings. It listed almost 400 scientists' signatures. I filed a complaint in federal court asking for open hearings. Reluctantly, for the first time in its history, the university agreed to open hearings.

My accusers, who until then had been quite public and emphatic in their allegations, and who had said that they would willingly come to Pittsburgh to be questioned by me, reversed their field. They were now reluctant to attend. After lengthy negotiations with the administration, they agreed to attend the hearings as witnesses.

The hearing room was filled with scientists, faculty, and members of the local and national press. My

accusers became surprisingly reticent. Dr Scarr, in a lecture at the Massachusetts Mental Health Center,¹⁰ said: "What we have done is to report. . . Dr Needleman to the Office of Scientific Integrity at the NIH, because we feel there are significant deviations from normal scientific practice here and we feel that the data has been massaged, to put it mildly. . . ." Now, in an open hearing, she revised her complaint to say that she merely "had suspicions" that I had consciously manipulated the data to present a false case.

Both witnesses were accompanied by their attorney, Mr David Genesson of Hunton and Williams of Washington, DC. When I asked Dr Ernhart who was paying her legal bills, she refused to answer. She stated that she did not know that Hunton and Williams had represented EI DuPont and Ethyl Corporation of America before the Food and Drug Administration and Federal Trade Commission. In the newspaper the next day, it was reported that there was a "trust fund" established to cover my accusers' legal expenses, but that Scarr and Ernhart did not know who had contributed to it.

During my examination of my accusers, it became clear that a different standard, perhaps an ad hoc standard, was being applied to my work as contrasted to theirs. One of the charges raised by my accusers was that I did not control for age in evaluating the effect of lead on IQ. I pointed out in my cross-examination that the WISC-R IQ was age-adjusted.

DR NEEDLEMAN: Isn't the Wechsler age adjusted?

DR ERNHART: The norming of the Wechsler is age adjusted. . . norming alone is not sufficient to handle age variation. . .

DR NEEDLEMAN: So it would be better to enter age into the model?

DR ERNHART: Yes. . .

DR NEEDLEMAN: In your 1981 paper did you put age into the model?

DR ERNHART: My study is irrelevant to the issues here today.¹¹ [Ernhart had not controlled for age.]

Since Ernhart had raised these criticisms of my work in 1981, and examined my printouts in 1990, I asked her whether it was not true that she had concluded that my study misrepresented the data before she had ever examined my data. Her answer was intriguing.

DR ERNHART: On advice of counsel, I'm not answering that question.

Another claim was that I excluded subjects on the basis of head injury or history of exposure or being non-English speaking *after* I knew their IQ scores, in order to maximize the effect of lead. In the hearing I showed her a piece of computer code from my printout that headed every data analysis. Translated, it said: "Select if lead level equal high or low, and head injury equal 'no,' and plumbism equal 'no' and English is the first and only language in the home." This proved conclusively that the subjects were excluded on criteria that were identified before the study was begun, and that the exclusion was executed by computer without any human judgment. Because Dr Ernhart had spent 2 days with my printouts as part of the Midvale suit, I asked whether she had seen this piece of code.

DR NEEDLEMAN: . . . does this look familiar to you at all?

DR ERNHART: I don't recall having seen this.

This piece of computer code appeared 24 times in the printouts I furnished them. It is difficult to see how it could have been overlooked by anyone looking for problems in case selection.

There was a general retreat by both witness in the degree of certainty with which they indicted me. Scarr, who had been direct and accusatory in a lecture at Harvard, was much less sure about whether I committed scientific misconduct in the public hearing. I asked her about it directly:

DR NEEDLEMAN: Are you certain that you are right when you say I selected the cases consciously knowing the outcome in relation to lead?

DR SCARR: I know you had the opportunity to do that. I don't know what you did.

At the conclusion of the cross-examination, Dr William Cooley, Chairman of the Hearing Board, who had frequently advised my accusers that they were not required to answer my questions, addressed himself to Dr Scarr:

I believe that, if I may ask a clarifying question, it is my impression that you have gone on record here today as essentially indicating that you had ample basis for being suspicious of the scientific work that's under consideration here, but have no specific charges of misconduct.

DR SCARR: Yes, that's correct.

The 2-day hearings were widely reported in the lay press^{12,13} and in *Science*¹⁴ and the *Journal of the National Institutes of Health*. Two months later, on May 20, 1992, the Hearing Board unanimously found no evidence of scientific misconduct.

What is there to be learned from this story? I believe that the spectrum of those behaviors labeled as misconduct in scientific enterprises is disturbingly common and that both the public and the scientific enterprise needs to be protected from inferior or dishonest studies that open the door to procedures or pharmaceuticals of dubious efficacy or that distort our understanding of the way that nature works. I believe that because of the intensely competitive business that science has become, the ethos in which young scientists are socialized and the actual work is conducted has fundamentally changed, and not for the better. Young scientists are regularly exposed to the gap between the professed idealistic standards of practice and the actual, often cynical, conduct of grant getting, data collecting, interpreting, and publishing. There needs to be better policing of our profession.

But the entire tangled process of identifying putative cases of scientific misconduct, and of fairly judging them, is open to abuse at a number of points. If my case illuminates anything, it shows that the federal investigative process can be rather easily exploited by commercial interests to cloud the consensus about a toxicant's dangers, can slow the regulatory pace, can damage an investigator's credibility, and can keep him tied up almost to the exclusion of any scientific output for long stretches of time, while defending himself.

Some way must be found to screen out frivolous or harassing charges of misconduct and shield investigators from this form of tribulation. Once an inquiry

or investigation has begun, it should operate under formal principles of due process. The option as to whether the investigation is open should lie with the accused. If an open hearing is requested, it should be freely granted. One should not be required to fight for this long-honored right. Certainly there is stigma and embarrassment attached to this charge; these are trivial compared with the risks that attend closeted star-chamber proceedings. One can live with embarrassment.

The charges should be given in specific written form to the accused party. They should take the shape of single valued propositions that can be disproven. Vague charges of guilt are out of place in a free society. The accused should have an attorney of his or her choice furnished by the university. The rules of evidence and the burden of proof should be clearly defined. Full and unhindered cross-examination of the accusers should be allowed. Each authority, whether university, hospital, or research institute, should have an ombudsman group with official, not advisory status. At my university, there is a standing committee on academic freedom which serves this role, but it has little official standing. A majority of the members of any investigative panel should be constituted from experts outside the university. Full disclosure to avoid conflicts should be required. These should be chosen in the same fashion as a jury, with challenges for cause allowed.

What can a young investigator do to avoid this unpleasantness? First, be honest. I do not intend this to be facetious. Begin by avoiding work that you believe is clouded by proprietary interests. Avoid contract work to fill out your salary or the department's budget. I say this recognizing that this is a difficult imperative, particularly for young investigators in difficult funding times, but much of this work can carry pressure, even if unstated, to find a certain effect. Recognize the pressure that accompanies the need to produce a publishable study or a given effect. Evaluate what the cost to you might be. In choosing a mentor, select one whose value system places honest science over publishable results.

Discuss with your associates steps to take to minimize bias, conscious or unconscious. Consult a good biometrician or epidemiologist about these questions early in the planning of the project. Record these discussions in a bound book. Remember that years later you may be asked to defend your choices of methods. Keep your data in two secure places, and document the means taken to find, classify and scale subjects and any changes in protocol. In a recent paper, Freedland and Carney¹⁵ polled a group of highly regarded investigators and found that a majority had trouble recalling the methods used to classify patients. Keep minutes of staff meetings, and document discussion of problems. Consult with experts in the difficult methodological areas. Ask them for written comments. Be skeptical of your conclusions. Write up and submit negative studies for publication. Be modest in your claims.

Finally, work to reform the system at every level. Discuss these issues in research conferences, at institutional review board meetings, and at meetings of

scientific societies. Do not avoid difficult areas of investigation. Take risks. If scientists exclusively choose the safe routes, avoid controversial research problems, and play only minor variations of someone else's themes, they voluntarily turn themselves into technicians. Our craft will indeed be in peril. Find and nurture good colleagues who will insist on the best from you, tell you when you are wrong, and stand with you in a difficult time. They are truly treasures, and their friendship will endure and sustain you past all confusion and pain. This article is a deeply felt thank you note to the many valued men and women who did precisely that for me.

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Editor's Note

I asked Dr Needleman to write up his experience with the court system and the National Institutes of Health Office of Scientific Integrity. I tried to follow this case in the press, but I didn't find this very satisfactory. If you're searching for truth you rarely find it in newspapers. Now that I've read Dr Needleman's story I have a clearer idea of his ordeal, but I am confused. Dr Needleman believes he has been found not guilty. The government (Environmental Protection Agency) and other scientists also believe this, but others may not (see page 978, the preliminary report of the Inquiry Panel).

How long must this go on? Has Dr Needleman been victimized over a difference of opinion about the quality of his science?

Editors are exposed daily to conflicting opinions. It has never occurred to me to take such matters to court to be settled! Conflicting opinions are common and very important in science. Truth doesn't emerge easily. Many studies are often needed before one side convinces the other that they are right. Scientific debates can't be settled in courts!

I expect that we will hear the opinions and viewpoints of others about this in our Letters to the Editor column in the next issue of *Pediatrics*.

J. F. L., MD

WRITING AND THINKING

As anyone knows who has ever sat down to write, writing is thinking. The thought not only precedes the word, it follows it too: we do not know what we mean to say until, after many trials and errors, we have found the words. The purpose of writing well is thinking well.

Raimi J. By any other name. *Columbia Magazine*. 1991; (Spring):36-37.

Submitted by Student

SCIENCE AND SUBPOENAS: WHEN DO THE COURTS BECOME INSTRUMENTS OF MANIPULATION?

PAUL M. FISCHER, M.D.*

I

INTRODUCTION

On December 11, 1991, the *Journal of the American Medical Association* ("JAMA") published three studies that examined the effect of the Camel cigarette "Old Joe" advertising campaign on adolescents and children.¹ I was lead author on the study that showed that "Old Joe" was nearly universally recognized by six-year-old children, a level of awareness that matched the logo for the Disney channel. Because cigarette smoking is the leading preventable cause of death and disease in this country, I recognized that this research might play a prominent role in the subsequent debate about tobacco advertising. As a scientist, I naively assumed that this discourse would be conducted in academic journals based upon rigorous research and leading to an improved understanding of whether and how advertising influences adolescent experimentation with cigarettes. To date, most of the subsequent debate has occurred in court.

From the beginning, the tobacco industry attempted to discredit this research and harass the researchers. My experience in confronting the tobacco industry has taught me how easily the courts can become the unwitting accomplices of an industry whose goal is profit, not the identification of scientific truth. In his paper in this issue of *Law and Contemporary Problems*, Michael Traynor states that with "common sense and goodwill in every quarter" there should be few problems due to compelled discovery of scholarly research.² Unfortunately, in some cases, neither common sense nor goodwill prevail. In such cases, the court can become an instrument of abuse.

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1. Joseph R. DiFranza et al., *RJR Nabisco's Cartoon Camel Promotes Camel Cigarettes to Children*, 266 JAMA 3149 (1991); Paul M. Fischer et al., *Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel*, 266 JAMA 3145 (1991); John P. Pierce et al., *Does Tobacco Advertising Target Young People to Start Smoking?*, 266 JAMA 3154 (1991).

2. Michael Traynor, *Countering the Excessive Subpoena for Scholarly Research*, 59 LAW & CONTEMP. PROBS. 119, 148 (Summer 1996).

II

MY INTRODUCTION TO EXCESSIVE SUBPOENAS

A. A Chronology of Events

The "Old Joe" studies were published in a *JAMA* theme issue dealing with tobacco research.³ The American Medical Association also held a press conference in New York to present the findings,⁴ which received wide coverage in the press.⁵

On March 9, 1992, The American Medical Association, the Surgeon General, the American Cancer Society, the American Heart Association, and the American Lung Association called for a ban on "Old Joe" advertising attractive to children.⁶ The following day, James Johnson, C.E.O. of the R.J. Reynolds Tobacco Company ("RJR"), defended "Old Joe" in an interview published on the editorial page of *U.S.A. Today*.⁷ In this interview, he attacked the "Old Joe" studies and its researchers.⁸ Mr. Johnson argued that the "studies are flawed in very serious ways. The scientists who wrote these studies are not unbiased."⁹ He made two specific claims about our research that were not true. He stated that the sample size was twenty three people¹⁰ when in reality it was 229 people. He also claimed that we called the parents of the three- to six-year-old children in our study the night before the data collection and asked them only about cigarette use.¹¹ This statement was a total fabrication. Such a call to the parents would have obviously biased the results.

On March 27, I was served a subpoena duces tecum by RJR.¹² A suit had been filed in California by Janet Mangini against RJR, based on RJR's failure to place health warnings on promotional products such as Camel caps and t-shirts.¹³ I received the subpoena even though my research had not been named in the Mangini complaint, I was not a witness to either side in the case, and my 1991 *JAMA* research had no bearing on the issue of health warnings.

The subpoena ordered me to produce the following: the names and tele-

3. See *supra* note 1.

4. See Stuart Elliott, *Top Health Official Demands Abolition of "Joe Camel" Ads*, N.Y. TIMES, Mar. 10, 1992, at A1.

5. See, e.g., Jane E. Brody, *Smoking Among Children Is Linked to Cartoon Camel in Advertisements*, N.Y. TIMES, Dec. 11, 1991, at D22.

6. Elliott, *supra* note 4.

7. *R.J. Reynolds: Ads Do Not Cause Kids to Smoke*, U.S.A. TODAY, Mar. 10, 1992, at 9A.

8. See *id.*

9. *Id.*

10. See *id.*

11. See *id.*

12. Defendant's Notice of Out of State Deposition on Oral Examination and Request for Production of Documents and Things, *Mangini v. R.J. Reynolds Tobacco Co.*, No. 939359 (Super. Ct., San Francisco Cty., Cal., Mar. 30, 1992).

13. See *Mangini v. R.J. Reynolds Tobacco Co.*, 21 Cal.Rptr.2d 232 (Cal. Ct. App.), *rev. granted & opinion superseded*, 859 P.2d 672 (Cal. 1993), *cert. denied*, 875 P.2d 73 (Cal. 1994) (*en banc*), *cert denied*, 115 S. Ct. 577 (1994).

phone numbers of all of the children who participated in the study; all drafts of the study design; all notes, memos, and videotapes pertaining to the study; the names, addresses, telephone numbers, background information, and occupations of all interviewers; hard copy tabulations and data tapes; originals of all test materials; all correspondence relating to the research; the names, addresses, and background information of all consultants; the names and addresses of all funding sources; and the names and telephone numbers of all respondents who were excluded from the study.

Given the published implications of my research, I had assumed that I might at some point be deposed about this study. I was, however, not prepared to receive a subpoena of this breadth and one that would require turning over the names of three- to six-year-old children. Such disclosure would have violated written confidentiality agreements that I had signed with each parent before conducting the research.

I had also anticipated that the Medical College of Georgia ("MCG"), on whose faculty I was a full professor and under whose auspices the research had been conducted, would provide appropriate legal support for my position. However, Michael Bowers, the Attorney General of the State of Georgia and the official counsel for the medical school, took the position that the prevailing legal issue was not human subject confidentiality, academic freedom, or the reasonableness of the subpoena power, but rather the Georgia Open Records Act, a law designed to permit public access to "official records."¹⁴ Mr. Bowers took this position even though RJR did not, at that time, request the records via the Open Records Act. I refused to comply with the subpoena and MCG refused to provide me with legal assistance.

I contacted my own lawyer, Robert W. Hunter, III, who prepared a motion to quash the RJR subpoena.¹⁵ On April 28, 1992, Chief Superior Court Judge William M. Fleming, Jr., ruled in favor of our motion to quash.¹⁶ RJR immediately appealed the ruling to the Georgia Court of Appeals, but that court, on February 9, 1993, ruled in our favor arguing that the requested documents were beyond the bounds of reasonable discovery.¹⁷

Two weeks later, in an article in a local newspaper, MCG lawyer Clay Stedman stated that the school had not supported my legal efforts because of their position on the Open Records Act.¹⁸ Stedman said that MCG "decline[d] to object to [the] release of this information on the basis that although it was not an Open Records [Act] request, Open Records would have required us to release it."¹⁹ Ironically, RJR attorneys did not know of MCG's position on this

14. Open Records Act, GA. CODE ANN. § 50-18-70 to -76 (Supp. 1996).

15. Motion to Quash, *Fischer v R.J. Reynolds Tobacco Co.*, No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Apr. 16, 1992).

16. See *Fischer v R.J. Reynolds Tobacco Co.*, No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Apr. 28, 1992) (order granting motion to quash).

17. See *R.J. Reynolds Tobacco Co. v Fischer*, 207 Ga. App. 292 (1993).

18. Kathleen Donahue, *Researcher Has Hefty Legal Fees*, THE AUGUSTA CHRONICLE, Feb. 27, 1993, at 17A.

19. *Id.*

issue and had previously admitted in their Court of Appeals brief that they believed the records were not accessible to them under the Open Records Act because the research had not been supported by state funds.²⁰

One week after the publication of this article, James R. Johnson, legal counsel for RJR sent a letter to H. Dean Propst, Chancellor of the University System of Georgia, and subsequently to Francis Tedesco, President of MCG, requesting that my research records be released to RJR under the Open Records Act.²¹ I was given forty-eight hours to turn over all of the previously described records with the exception of the children's names. Clay Stedman, as MCG legal counsel, indicated that I would be suspended if I did not turn over the documents. Francis Tedesco, M.D., President of MCG, indicated that the Attorney General would have me arrested if I did not comply with the request.

At the advice of my lawyer, I turned all of the documents over to the court for protection until such time as the legal issues relating to the Open Records Act, academic freedom, and human subject confidentiality could be resolved. The court accepted the documents and approved a temporary restraining order against the Open Records request.²²

One month later, RJR petitioned the court to assist MCG and the Attorney General in the action against me.²³ Both the Attorney General's Office and MCG supported RJR's compelled disclosure motion.²⁴ Ironically, this action united the medical school and a tobacco company against one of the school's own faculty members.

On August 12, 1993, I received a nine-page letter listing documents and data requested by RJR through the Open Records Act.²⁵ It stated that RJR wanted all documentation related to the study regardless of when it was generated or by whom.²⁶ In response to a 1993 change in the Open Records Act which excluded release of the names of research participants, RJR did request that the subject names be redacted from the submitted documents.

On December 1, 1993, I resigned from the faculty of MCG and entered private practice in Augusta. On July 20, 1994, Judge John H. Ruffin signed an RJR request to release all of the records held by the court. The records were released to an RJR lawyer before we were notified of the decision, making an appeal of this decision moot.

20. Petitioner's Brief, *R.J. Reynolds Tobacco v. Fischer*, 207 Ga. App. 292 (1993).

21. Letter from James R. Johnson, Legal Counsel, RJR, to Francis J. Tedesco, President, MCG (Mar. 10, 1993) (on file with author).

22. Motion for Temporary Restraining Order, *Fischer*, No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Mar. 12, 1993).

23. See James R. Johnson's Motion to Intervene as a Defendant, *Fischer*, No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Apr. 22, 1993).

24. Letter from David M. Monde, Attorney, Jones Day, Reavis & Pogue, to Kathryn L. Allen, Senior Assistant Attorney General (Apr. 20, 1993) (on file with author).

25. Letter from RJR to author (Aug. 12, 1993) (on file with author).

26. See *id.*

B. Lessons Learned

Every day in every academic institution, people request information from scientists. Most of the time this is done by fellow scientists in the process of scientific research. For example, after the publication of the "Old Joe" study, I received requests from other researchers for specific information about our study and how it was done. Such requests are usually limited to information that would permit replication of the research. Successful replication is essential to establish scientific validity, and therefore scientists are usually pleased to share information.

Scientists do not use subpoenas to seek scientific truth! Thus, the subpoena of a researcher's files is evidence that the process has moved outside of the realm of scientific inquiry. As the cases cited in this paper illustrate, a subpoena usually means that the research in question has commercial implications and that a company has decided that its lawyers, rather than its scientists, are in the best position to protect the company's interests.

Nevertheless, many subpoenas for research are routine. For example, a medical researcher might discover and report a series of side-effects in patients taking a new drug. The pharmaceutical company that manufactures the drug may then subpoena the records to see if there is an alternative explanation for the patients' symptoms. Other than concerns about patient confidentiality, such a subpoena would be handled in a routine fashion.

However, not all compelled disclosure is routine. In the extreme, subpoenas can be unwittingly used in a manner that is damaging to the researcher, the scientific process, and the greater public good.

III

DAMAGING EFFECTS OF EXTREME SUBPOENAS

A. Discredit the Research. Discredit the Researcher.

It was clear from the *U.S.A. Today* interview that RJR wanted to discredit me and my research.²⁷ Furthermore, this refutation would not follow the usual "rules" of science.

The standards for a published scientific paper require that the report include sufficient detail about the scientific methods utilized so that another individual in the field could duplicate the study. This was precisely what *Advertising Age* did after initially expressing reservations about the "Old Joe" research. They commissioned research that was published five months later and showed that the Camel campaign was indeed highly effective in reaching young people, especially children younger than age thirteen.²⁸ The president of the research company said, "I was blown away by the number of smaller kids who could

27. See R.J. Reynolds, *supra* note 6.

28. See Gary Levin, *Poll: Camel Ads Effective with Kids*, *ADVERTISING AGE*, Apr. 27, 1992, at 12.

name cigarettes."²⁹ Had RJR been concerned about the veracity of our findings, they could have duplicated our research in several weeks for a few thousand dollars. Instead, they spent two and a half years, and a great deal more money, in an attempt to access every page in my files.

Why would RJR be interested in every scrap of paper in a research file? The answer to this question became clear from the experience of Dr. Joseph DiFranza, the lead author of one of the "Old Joe" studies.³⁰ His research showed that Camel cigarettes' share of the youth market increased from a mere 0.5% to a substantial 32.8% following the "Old Joe" advertising campaign.³¹ Dr. DiFranza received a similar subpoena and turned over his records to RJR. In one of the letters to a colleague that was included in the disclosed documents, Dr. DiFranza wrote, "I have an idea for a project that will give us a couple of smoking guns to bring to the national media."³² RJR released this letter to the press and claimed that it proved that the researchers were biased and that the research was fraudulent.³³

It is easy to characterize any scientist as being biased. The public assumes that scientists enter into research without a point of view. Nothing could be further from the truth. Science is impossible to do without passion about an idea. Scientists are not without opinions, but they agree to subject these opinions to objective experiments to see if they are true. In every researcher's files, there are notes that could be taken out of context and characterized as proving bias.

In addition, every research study represents a series of methodological decisions about how data are collected and analyzed. These decisions require expert judgment and each of these judgments, when viewed in isolation, could be challenged. It is precisely because of this, that the final published paper becomes the record of the research. In the published manuscript, the researcher must describe the findings, discuss their meaning, and most importantly, identify the study's limitations.

The broad subpoena filed by RJR is akin to requiring a Supreme Court Justice to report every private note made and every comment spoken in considering a case, rather than merely being responsible for the contents of the final opinion. It would be quite easy to discredit the decisions of even the best judges if their private notes and thoughts were publicly open on demand.

B. Human Subject Confidentiality

The conduct of research on human subjects requires that the public have confidence that its best interests will be protected and that its confidentiality will be preserved. In the case of our research, RJR requested the names and

29. *Id.*

30. DiFranza, *supra* note 1.

31. *See id.*

32. *See* Maria Mallory, *That's One Angry Camel*, BUS. WK., Mar. 7, 1994, at 94.

33. *See id.*

addresses of 239 three- to six-year-old children whose parents had signed agreements in which we promised complete confidentiality. According to Peggy Carter, an RJR spokesperson, the company intended to use this information to contact the research subjects.³⁴ Her reason for requesting this breach of confidentiality was that "[t]here have been a number of stories that have come up in recent years where scientists claimed to have produced research that ... was never done at all."³⁵ While this reasoning is paranoid at best, it would not be necessary for RJR to knock on children's doors at night to prove that the data in question were collected, rather than fabricated.

The issue of subject confidentiality took an interesting legal turn in my case. MCG initially acknowledged the potential for abuse. In a letter from Carol Huston, one of the school's attorneys, to the Attorney General's office, she stated that

[Fischer's] concern, which I believe is well founded, is that Reynolds is attempting to harass him (and other researchers) through tactics such as this in order to discourage future research, the results of which may not be favorable to the tobacco industry.... We also believe if [RJR] obtains the names of the respondents, it seems very likely that [it] may contact them and attempt to harass them. This, in turn, may discourage other individuals from participating in future research projects.

Despite these observations by an MCG lawyer, the Attorney General's position prevailed, and the school insisted that all names be released.

As a general matter, institutions that participate in federally funded medical research must sign agreements with the Department of Health and Human Services ("DHHS"), by which they agree to conduct research according to federally-established guidelines. Human subject confidentiality is well-protected by these standards. My study, however, was not federally funded and was subject to these guidelines only because of contractual agreements between DHHS and MCG.

On September 8, 1992, I was contacted by the acting chief of the Office of Protection from Research Risks of the National Institutes of Health. He had heard of my case and wanted information about any breach of human subject protection. He subsequently sent a letter to the school alleging noncompliance with their DHHS contract because of the school's position requiring release of my subjects' names. The school responded that the federal regulations could be avoided because my research was not federally funded. DHHS and MCG subsequently signed a revised contract in which only federally funded research was governed by federal regulations regarding subject confidentiality.

C. Harassment

The tobacco industry approach to litigation has been described by Lawton M. Chiles, Jr., Governor of the State of Florida, as "designed to confuse the medical evidence, stone-wall, delay, refuse reasonably to settle claims, and to

34. See Marcia Barinaga, *Who Controls a Researcher's Files? Tobacco Company R.J. Reynolds Subpoenas Research Study Data*, 1256 SCL 1620 (1992).

35. *Id.*

run up plaintiffs' attorneys' fees in a war of attrition."³⁶ He cites a memo written by J. Michael Jordan, an attorney for RJR:

The aggressive posture we have taken regarding depositions and discovery in general continues to make these cases extremely burdensome and expensive for plaintiffs' lawyers, particularly sole practitioners. To paraphrase General Patton, the way we won these cases was not by spending all of Reynolds' money, but by making the other son of a bitch spend all his.³⁷

This same approach was used to wear down my resources, including my time, attention, and money. The ultimate goal is to make the process sufficiently painful so that the researcher cannot complete further research and so that other scientists are discouraged from conducting similar studies.

Scientists are perfect subjects for harassment by litigation. They often have little knowledge of the law and little patience for the slow and subtle workings of the legal system. The distraction and anxiety caused by depositions, legal costs, and court appearances can easily put an abrupt end to a promising line of research or a research career.

It should be noted that RJR did not limit its harassment efforts to the use of the press and the courts. It also attempted to conscript the institution at which I worked. Bernard Wagner, M.D., Professor at the New York University School of Medicine and paid consultant to RJR, contacted my research colleagues and the President of MCG with accusations of scientific fraud.³⁸ A similar letter was sent to the University of Massachusetts regarding Dr. DiFranza's "Old Joe" study.³⁹ While MCG did not respond, the University of Massachusetts used these baseless accusations to initiate scientific misconduct hearings against Dr. DiFranza. He was eventually found innocent of these charges.⁴⁰

IV

SUGGESTIONS

As a researcher who has been through the experience of compelled disclosure, many of the suggestions outlined in this paper do not appear to be viable solutions to the problem that I faced. I would not argue that scientists deserve special protection under the law in the same way that lawyers, priests, or journalists have claimed the need for protection of their relationships with clients, parishioners, and confidential sources. Science, after all, is based on a shared and open search for truth. I am not, however, so naive as to believe that most subpoenas for research records are based on goodwill, public interests, or the search for truth. I offer the following thoughts:

36. Complaint, *Florida v. American Tobacco Co. et al.*, No. CL-1466A0 (Circuit Ct., 15th Circuit, Palm Beach, Fla., Apr. 18, 1995).

37. *Id.* at 28-29 (memorandum from J. Michael Jordan, legal counsel, RJR).

38. Letter from Bernard Wagner to Tina Rojar (Mar. 29, 1993) (on file with author).

39. Based on the author's conversations with Dr. DiFranza.

40. *Id.*

First, if a request for compelled disclosure has been made, realize that the process has moved outside of the normal exchange between scientists. It is likely that a commercial entity and its profits are at stake. It is also likely that the company will have greater legal resources and experience than the scientist, who may have never stepped foot inside a courtroom.

Second, despite institutional affiliation and responsibilities to protect academic freedom, universities may provide poor legal counseling to scientists facing compelled disclosure. This problem may become greater due to the increased reliance of universities on corporate support. We might expect to see university presidents siding with corporate contributors rather than their academic faculty.

Next, if a subpoena is requested by an industry, consider the industry's past record in dealing with the scientific community. Consider whether the industry has used the legal system to discourage good science in the past.

Also, consider the breadth of the request. If it goes far beyond what a reasonable scientist would require to duplicate the research, then there may be other ways that the company could validate the research findings without violating the privacy of the scientist's records.

Ask the scientist to identify specifically how compelled discovery could impede his research. It is impossible for the court to balance the rights of the company with those of the scientist unless it understands the implications of the legal process on the scientist's time, attention, and financial resources.

Finally, human subject confidentiality, promised as part of the research process, must be protected at all costs. There are excellent ways to identify scientific fraud without violating anonymity, such as the use of an independent review panel of scientists.

V

CONCLUSION

The uneasy relationship between law and science is likely to continue regarding disclosure of scientific research materials. Law and science are worlds apart in terms of values that they hold and the rules that they follow. Whether it be DNA evidence or silicone breast implants, it appears that these two worlds will collide with ever-increasing frequency. This inevitable collision will require that scientists have a better understanding of the legal implications of their research and that judges have a better understanding of the impact of their decisions on the progress of science.



NATURAL RESOURCES DEFENSE COUNCIL

February 11, 2014

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Committee on Science, Space, and Technology
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Honorable Eddie Bernice Johnson, Ranking Member
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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,¹ 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."² 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

¹ For other examples of proprietary models employed by EPA, see 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, 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.

² <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 (SO₂), nitrogen oxides (NO_x), carbon dioxide (CO₂), 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.³ 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.⁴

³ 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_addendum.pdf; & <http://www.epa.gov/clearskies/clearskiessummary04-11.pdf>.

⁴ See, e.g., <http://yosemite.epa.gov/opa/advpress.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."⁵ 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_{2.5}) 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.⁶ 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

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://georgewbush-whitehouse.archives.gov/news/releases/2002/02/20020214-5.html>.

⁵ <http://cfpub.epa.gov/ncea/cfm/recorddisplay.cfm?deid=135427>.

⁶ Rep. Lame Smith, "The EPA's Game of Secret Science," The Wall Street Journal (July 29, 2013). http://online.wsj.com/news/articles/SB10001424127887323829104578624562008231682?mg=r_cno64-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.⁷

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."⁸ This too is incorrect.

In December 2012, a seminal report entitled the 2010 Global Burden of Disease⁹ "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 release¹⁰ 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 report¹¹ 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

⁷ 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).

⁸ *Supra* note 6.

⁹ [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).

¹⁰ <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.

¹¹ <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 Assessment¹² for the PM_{2.5} 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_{2.5} 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_{2.5}.”

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.¹³

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

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

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

reductions deemed achievable by state-of-the-art technology.¹⁴ 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.¹⁵ The most recent list of section 8(e) studies from April 2013 shows just how pervasive these industry CBI claims are.¹⁶

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

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

¹⁵ 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/>.

¹⁶ <http://www.epa.gov/oppt/tsca8e/pubs/8monthlyreports/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
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February 11, 2014

The Hon. Lamar Smith
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The Hon. Eddie Bernice Johnson
 Ranking Member, Committee on Science, Space,
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The Hon. Suzanne Bonamici
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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."

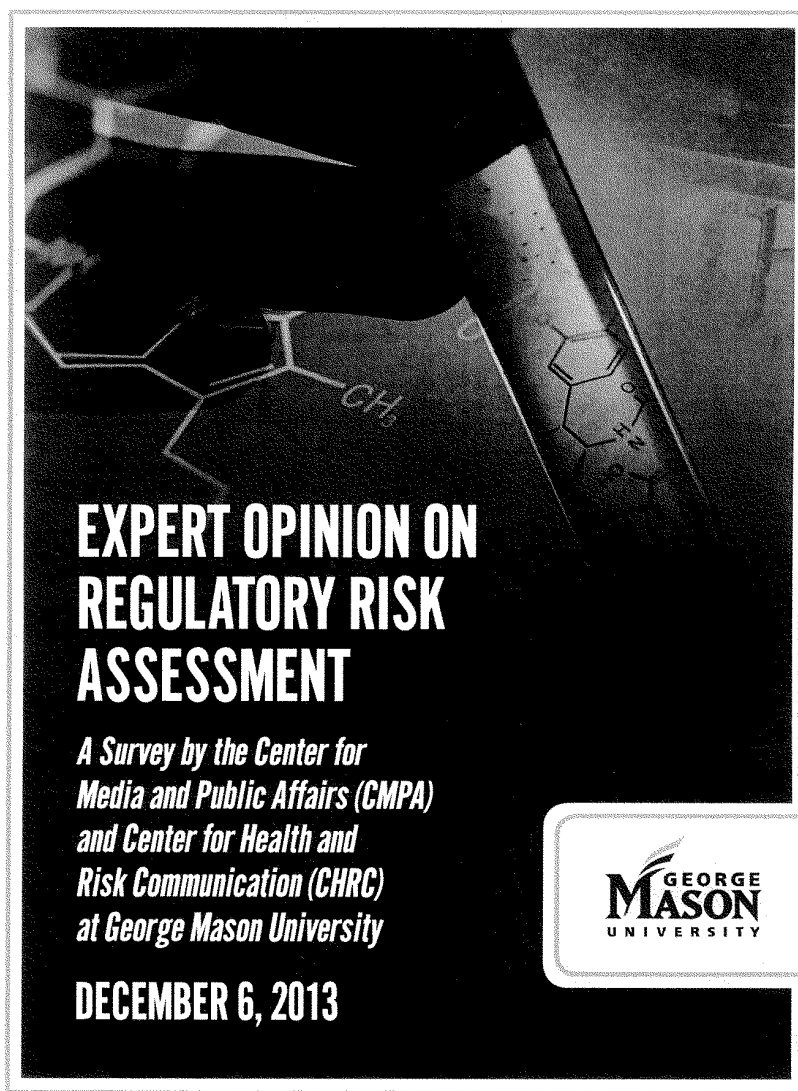
I strongly urge you to oppose the Secret Science Reform Act of 2014. The proposed bill would inhibit the EPA's ability to carry out its science-based mission to protect human health and the environment

Sincerely,



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

THE FOLLOWING DOCUMENTS WERE SUBMITTED FOR THE RECORD BY
REPRESENTATIVE DAVID SCHWEIKERT





George Mason University Survey: Expert Opinion on Regulatory Risk Assessment

Introduction

The challenges of assessing and regulating potential health risks to the public and the environment from chemical exposures have drawn much debate and growing interest from the expert community and Congress in recent years. The process and science behind how risk assessments are conducted is opaque to many people, because it involves assessing complex information from toxicology, pharmacokinetics, epidemiology, biostatistics and other areas. In addition, public controversy regarding the utility and quality of assessments increasingly accompanies decisions on the safety of individual chemicals as well as broader health assessment frameworks, such as the EPA's IRIS process.

Public debates on these matters typically involve representatives of industry and environmental groups, public officials, and individual scientists from a variety of institutions whose work bears on these issues. But there is no mechanism to tap into the collective opinion of the experts in these fields to capture their uniquely valuable insight. Moreover, members of the media sometimes focus attention on the loudest or most discordant voices, which may not be representative of informed opinion.

It would be easier for the public and regulators alike to make informed decisions if they had some way of knowing the opinions of the broader expert community. The survey by the Center for Media and Public Affairs (CMPA) and Center for Health and Risk Communication (CHRC) at George Mason University described below was conducted to advance the current discussion over the role of risk assessment in government regulatory decisions by bringing the collective voice of the expert community into the public arena.

To capture the viewpoint of the scientific community, we surveyed members of three professional organizations whose memberships represent repositories of knowledge and experience in regulatory risk assessment. They are the Risk Assessment Specialty Section of the Society of Toxicology (SOT-RASS), the Dose Response Section of the Society for Risk Analysis (SRA-DRS), and the International Society for Regulatory Toxicology and Pharmacology (ISRTP).

Results

The survey results outline the preferences of scientific experts for the conduct of regulatory risk assessments, as well as their valuations of how well current procedures are working. We find general agreement on how elements of regulatory risk assessments should work, coupled with concern over how well they are working in practice.

There is widespread endorsement of commencing assessments with problem formulations and analysis plans that are peer reviewed; data acquisition that includes access to raw data and the use of inclusion/exclusion criteria; applying data evaluation that uses the same criteria for evaluating studies regardless of institutional origin; implementing weight of evidence methodology that incorporates the use of non-linear (threshold) models; and establishing procedures insuring the independence and effectiveness of external peer review.

By contrast, there is widespread concern over the current application of these procedures. Fewer than one in three scientists say that, in their experience, problem formulations are often conducted. Fewer than one in three affirm that raw data from critical studies are often made available to assessors or peer reviewers. Only one in four say that standardized search protocols are often used for collecting data. Fewer than half say that all relevant and reliable studies are often selected for evaluation, and only one in four say consistent and transparent criteria are often used to evaluate studies.

Fewer than half affirm that weight of evidence methodology is often used, or that mode of action information is applied well for characterizing human risk. Only about one in four say that current peer review procedures provide sufficient input from stakeholders.

Finally, respondents criticize the weighting of various factors in risk management. As they perceive current practices, too little attention is being given to scientific factors and economic costs and benefits, and too much attention is given to environmental groups, the precautionary principle, media coverage, and political concerns.

The following is a summary of some of the key findings from the survey that touch on critical areas of developing assessments:

Problem Formulation/Analysis Plans

Over two thirds of the experts (68 percent) believe it is “very important” to complete a problem formulation evaluation and have an analysis plan in place prior to conducting a regulatory risk assessment. However, fewer than half as many (30 percent) say that, in their experience, prior problem formulations were conducted. In addition, almost all respondents believe that analysis plans should be peer reviewed. Most (65 percent) regard an internal review as acceptable, while 34 percent think an external review is necessary. Only five percent say that no peer review of analysis plans is necessary.

Data Acquisition

A major element of risk assessments involves acquiring and evaluating evidence from studies that bear on the assessment. Most respondents (69 percent) regard it as “very important” for assessors to have access to underlying raw data for the most critical studies in order to independently analyze their results.

However, only 31 percent report that, in their experience, such underlying raw data are “often” or “always” made available to assessors, while nearly as many (27 percent) say the data are “rarely” or “never” made available. (The remaining 42 percent say that the data are “sometimes” made available.)

A somewhat smaller majority (59 percent) see it as very important for peer reviewers as well to have access to underlying raw data from critical studies. In this case, only 16 percent report that this is done often or always, compared to 42 percent who say it is done rarely or never.

One area in which there is almost universal agreement among these scientists concerns the use of inclusion/exclusion criteria for selecting the studies to be reviewed. Ninety-four percent support the use of such criteria, compared to only six percent who do not.

However, only 24 percent report that, in their experience, standardized search protocols are often or always used and described for collecting all available study data. This is fewer than the 35 percent who say this was rarely or never done.

Data Evaluation

Respondents are less than sanguine with regard to the existing data evaluation process. While 44 percent say that the goal of using all relevant and reliable studies has often or always been met in risk assessments they are familiar with, 42 percent say this goal is met only sometimes, and 13 percent say it is met rarely or never.

Similarly, fewer than one out of four respondents (24 percent) report that consistent and transparent criteria are often or always used to evaluate the quality and reliability of studies. Only 29 percent reported that such criteria are rarely or never used.

Finally, there is widespread agreement (by 82 to 18 percent) that the same criteria should be used to evaluate the quality and reliability of all studies, regardless of their origin in academia, government, industry, contract labs, etc.

Weight of Evidence

We asked several questions regarding various aspects of the weight of evidence methods used to integrate various types of data in making an overall judgment on risk. Most respondents (89 percent) believe that weight of evidence methodology should be used, described, and documented for all risk assessments.

However, when asked how often, in their experience, weight of evidence methodology was applied in regulatory risk assessments, fewer than half (45 percent) replied that this was often or always used. Thirty-nine percent said it was sometimes done, and 16 percent report that it was rarely or never used.

When this methodology is used, only one out of four (24 percent) describe it as often or always consistent and transparent. About the same number (23 percent) describe it as rarely or never consistent and transparent. A slight majority (53 percent) say that it sometimes meets these criteria.

When asked how well mode of action information is applied in characterizing risk to humans, only 39 percent replied that it is done well, compared to 61 percent who said it is done poorly.

There was far greater agreement on the use of non-linear models and thresholds. When a non-mutagenic mode of action is indicated, 88 percent believe that non-linear (threshold) models should be used to estimate human risk from substances that cause cancer at high doses in lab animal studies. The same proportion would consider non-linear thresholds in mutagenic carcinogenesis as well.

Similarly, when a threshold event is responsible for cancer effects, 82 percent would proceed with a linear low dose extrapolation, and nearly as many (75 percent) would do so in the absence of multiple tumor sites.

Peer Review

As with weight of evidence methodology, there is widespread agreement on the importance of external peer review in regulatory risk assessment. Seventy-three percent see external scientific peer review as very important and 24 percent see it as somewhat important.

In addition, 78 percent believe the peer review process should be conducted independently of the office or program that develops a risk assessment. A smaller but still substantial majority (65 percent) would create an independent entity that insures authors would respond to peer review comments.

In contrast to the agreement on the need for strong external peer review procedures, opinion is split over current practices. Only one out of four (25 percent) believe that current procedures often or always provide sufficient opportunity for input from stakeholders, compared to 31 percent who say this rarely or never happens. Even fewer (21 percent) say current processes assure that stakeholder input is thoroughly considered by peer reviewers, compared to 38 percent who say this happens rarely or never.

Risk Management

Two out of three respondents say they have taken part in formal discussions or reviews of risk management documents, and most are critical of the priorities and practices of risk management. Only 41 percent believe risk management decisions are adequately based on our current knowledge and understanding of biology and toxicology. In addition, they would change the relative weight they see risk managers as giving to various elements embedded in risk management decision-making.

Given a list of eight factors to choose from, respondents believe that risk managers currently give the greatest weight to the legal implications of regulatory decisions, followed closely by political concerns. These are followed by some closely clustered factors—the precautionary principle, environmental group concerns, scientific factors, media coverage, and economic costs and benefits. Industry concerns are perceived as receiving the lowest weight.

By contrast, when respondents are asked how these same factors should be weighted, scientific factors far outpace all others. Economic costs and benefits finish a clear second, and legal implications an equally clear third. Then three factors are closely grouped together—industry concerns, environmental group concerns, and the precautionary principle. Lowest on the list are political concerns and media coverage, in that order.

Methodology

We created an online questionnaire with the assistance of Harris Interactive, a leading survey and market research firm and an industry leader in online polling.

In February 2013, each organization sent a letter to its members inviting them to participate by accessing a link provided by Harris. A total of 186 respondents completed the questionnaire. This group included 167 members of SOT-RASS, 40 members of SRA-DRS, and 27 members of IS RTP. (These numbers reflect membership in more than one organization by some individuals.) Response rates were 23 percent for SOT-RASS, 28 percent for SRA-DRS, and 27 percent for IS RTP.

The questionnaire addressed attitudes toward several important aspects of regulatory risk assessment. These include the use of problem formulation and accompanying analysis plans, the acquisition and evaluation of data, the application of weight of evidence methodology, the role of peer review, and the use of/adherence to guidance documents.

In addition, we asked respondents for their opinions about factors involved in risk management decisions. (Most reported taking part in formal risk management reviews as well as in risk assessments.) Finally, we inquired about various background factors, such as their occupation, discipline, certification, experience, and area of expertise. These sample characteristics are listed as an addendum below.

Addendum: Sample Characteristics

The sample is 58 percent male and 42 percent female and averages 54 years of age. Over 80 percent have a PhD, and 58 percent possess a professional certification, led by 45 percent who are certified by the American Board of Toxicology.

The sample is relatively diverse in occupations and expertise. Respondents' primary area of expertise is spread among 31 percent who are primarily expert in risk characterization, 28 percent in hazard

identification, 24 percent in dose-response assessment, and 10 percent in exposure assessment. Thirty-one percent work in industry, 30 percent are consultants, 25 percent are employed by government entities, and 13 percent are based in academia or non-profit organizations.

Respondents also report considerable and diverse experience in areas of concern. Over 80 percent have worked on industrial chemicals, over 60 percent on pesticides and water contaminants, over 50 percent on consumer products and occupational risks, over 40 percent on air pollution, hazardous waste, and food products, and over 30 percent on pharmaceuticals. In addition, over two-thirds say they have worked in their field for 20 years or more.

This group also has widespread experience with risk assessment. Just under half (49 percent) have developed risk assessments for government agencies, and 77 percent have contributed to or reviewed government risk assessments. In addition, nearly two-thirds (65 percent) have developed risk assessments and 75 percent have contributed to or reviewed risk assessments for non-government entities.

In view of the qualifications and experience reported by respondents, it seems appropriate to regard them as representing an expert community with regard to risk assessment.

For more information on the professional organizations referred to, please see:

The Society of Toxicology: www.toxicology.org

The Society for Risk Analysis: www.sra.org

The International Society of Regulatory Toxicology & Pharmacology: www.isrtp.org

The American Board of Toxicology: www.abtox.org/HomePage.aspx

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**Center for Media and Public Affairs &
The Statistical Assessment Service
George Mason University**

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Overview: CMPA Regulatory Risk Assessment Survey

Problem Formulation/Analysis Plans	Percent
Problem formulation/analysis plan very important	68
Problem formulation always/often conducted	30
Analysis plan should be peer reviewed	95
External review necessary	34

Data Acquisition	Percent
Access to raw data by assessors very important	69
Raw data made available to assessors often/always	31
Access to data by peer reviewers very important	59
Raw data made available to peer reviewers often/always	16
Inclusion/exclusion criteria should be used	94
Standardized search protocols are used often/always	24

Data Evaluation	Percent
Goal of using all relevant and reliable studies is met always/often	44
Consistent/transparent criteria are used to evaluate studies always/often	24
Same criteria should be used to evaluate studies of all origins	82

Weight of Evidence	Percent
Should use weight of evidence method for all risk assessments	89
Weight of evidence methodology used often/always	45
Weight of evidence approach consistent/transparent often/always	24
Mode of action info applied somewhat/very well	39
Should use non-linear model to estimate human risk from animal studies	88
Non-linear thresholds should be considered	88
When threshold event responsible for cancer, next step is:	
If multiple tumors, use non-linear low dose extrapolation	75
If absence of multiple tumors, use non-linear low dose extrapolation	82

External Input	Percent
External peer review is very important	73
Review should be independent of office/program that developed the assessment	78
Should create independent entity to ensure authors respond to review	65
Process often/always provides opportunity for stakeholder input	25
Input from experts, public thoroughly considered often/always	21

Guidance Documents	Percent
Served as peer reviewer for regulatory risk assessment	53
If so, very knowledgeable about guidance documents used	63
Government agencies follow own guidance documents often/always	51

Risk Management Factors

- Risk management decisions are based on current knowledge of biology and toxicology very/somewhat well. 41%

How much weight do risk managers *currently* give to:

Risk Management Factors	Great Deal of Weight (%) *	Mean Score (1-5)
Legal implications	72	3.9
Political concerns	66	3.8
Precautionary principle	52	3.4
Environmental groups	49	3.4
Science	47	3.5
Media coverage	43	3.3
Economic costs/benefits	41	3.2
Industry	28	2.9

How much weight *should* risk managers give to:

Risk Management Factors	Great Deal (%)*	Mean Score (1-5)
Science	98	4.8
Economic costs/benefits	67	3.9
Legal implications	48	3.5
Industry	20	3.0
Precautionary principle	19	2.5
Environmental groups	16	2.8
Political concerns	8	2.1
Media coverage	4	1.8

* 4 or 5 on scale from 1=none to 5=great deal Mean score on 1 to 5 scale from 1=none to 5=great deal

Respondent Profile

Background	Percent
Male	58
Average age	54
Ph.D.	82
Years in field 20+	68

Field	Percent
Toxicology/pharmacology	65
Enviro Health	8
Cell/molecular biology	5

Certification	Percent
American Board of Toxicology	45
Academy of Toxicological Sciences	13

Occupation	Percent
Industry	31
Consulting	30
Government	25
Academic/non-profit	13

Primary RA expertise	Percent
Risk characterization	31
Hazard identification	28
Dose-response assessment	24
Exposure assessment	10

Areas worked in	Percent
Industrial chemicals	83
Pesticides	63
Water contaminants	60
Consumer products	53
Occupational	52
Air pollution	47
Hazardous waste	46
Food	42
Pharmaceuticals	31

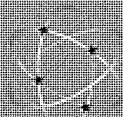
Risk Assessment Experience	Percent
Developed gov't RA's	49
Developed non-gov't RA's	65
Contributed to/reviewed gov't RA's	77
Contributed to/reviewed non-gov't RA's	75
Took part in formal risk management reviews	66

FINAL REPORT | August 5, 2009



Improving the Use of Science in Regulatory Policy





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We would like to express our appreciation for the support and vision of the funders who made this

project possible: the David and Lucile Packard Foundation, the ExxonMobil Foundation, and the William and Flora Hewlett Foundation.

The findings and recommendations in this report are solely those of the Science for Policy Project panel and do not necessarily reflect the views or opinions of the Bipartisan Policy Center, its Advisory Board, or its Board of Directors.

Executive Summary

The use of science in the formulation of regulatory policy – by both the Executive Branch and the Congress – has been a political flashpoint in recent decades.¹ Policy makers often claim that particular regulatory decisions have been driven by, or even required by science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being “politicized” and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.

The question is not whether scientific results should be used in developing regulatory policy, but how they should be used. This report is structured around three sets of questions that are at the heart of the debate over the use of science in regulatory policy. Those questions are:

- What kinds of activities or decision-making amount to “politicizing” science? How and to what extent can one differentiate between the aspects of regulatory policy that involve scientific judgments and those that involve making policy recommendations (which are inherently political)?
- When and how should Federal agencies empanel advisory committees? How should members be selected? How should conflicts of interest and biases of potential members be handled? What is scientific balance and how can it be achieved? How can the independence and integrity of committees’ deliberations be assured?
- What studies should agencies and advisory committees review in formulating regulatory policy? How should they be weighed? What role should peer review play and how might peer review be modified and strengthened?

Implementing our panel’s answers to these questions would result, we believe, in a more candid, transparent, and rigorous use of science in regulatory policy making and a more honest and thoughtful debate about regulatory proposals.²

¹ In this report, “science” refers to the natural and physical sciences and engineering.

² The primary focus of this report is the systemic problems affecting the role of science in regulatory policymaking, such as conflating science questions and policy questions, as they are fundamental longstanding and often overlooked. Other forms of misuse or abuse of science in government are also unacceptable, as reflected by this panel’s clear admonition in Chapter 1 that “political decision-makers should never dictate what scientific studies should conclude.” However, those issues have been discussed elsewhere, and are not the primary subject of this report. Even if every potential abuse of science were avoided, regulatory policy would still get mired in avoidable debates unless the issues discussed in this report were addressed.

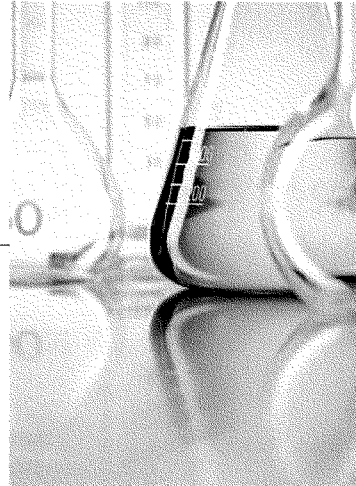
Recommendations

Each chapter of the report makes an overarching recommendation (those numbered below) and then elaborates on how to implement it. Those more detailed recommendations, listed below, are generally in bold in the text of the report.

- **RECOMMENDATION ONE: The Administration needs to promulgate guidelines (through executive orders or other instruments) to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.**

Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the "politicization" of science actually arise over differences about policy choices that science can inform, but not determine.

The Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy. At a minimum, the Administration should require that a section of the *Federal Register* notice for any proposed guidance or rule that is informed by scientific studies describe the primary scientific questions and the primary policy questions that needed to be answered in drafting the rule.



An additional approach to clarifying this distinction would be to also require the *Federal Register* notice to include answers to such questions as: What additional science would change the debate over a proposed regulatory policy and in what ways would the debate change? Another possible approach would be to require federal agencies to spell out genuine alternative regulatory policies when proposing guidance or a rule.

The first impulse of those concerned with regulatory policy should not be to claim "the science made me do it" or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making.

■ **RECOMMENDATION TWO: *The Administration should promulgate guidelines (through executive orders or other instruments) directing agencies to follow the policies described below on: when to consult advisory panels on scientific questions, how to appoint them (including how to deal with conflicts of interest and biases), and how they should operate. Congress should pass, and the President should sign into law, any statutory changes needed to implement these policies.***

Federal agencies should use scientific advisory committees to the maximum extent possible to review the science behind regulatory policies.

TYPES OF ADVISORY PANELS

Advisory committees that are to exclusively address science questions (referred to in this report as “scientific advisory committees”) should generally consist only of members with relevant scientific expertise.

All non-government members of scientific advisory committees should be appointed as Special Government Employees.

In general, scientific advisory panels should not be asked to recommend specific regulatory policies.

*The remainder of the recommendations are concerned exclusively with procedures related to **scientific advisory panels**.*

TRANSPARENCY IN THE SELECTION PROCESS

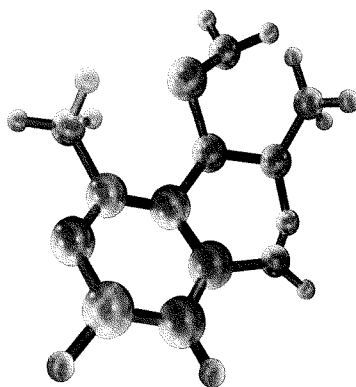
The process of naming advisory committee members should be made more transparent. Options for achieving greater transparency include: seeking recommendations for members on the Web and/or through contacts with relevant groups; publicly announcing on the Web the criteria for membership (such as the range of scientific disciplines that need to be included); and announcing proposed members on the Web to solicit public comment.

FACTORS IN SELECTING ADVISORY COMMITTEE MEMBERS

The primary purpose in appointing a committee is to gather a group of eminently qualified individuals who can have an open, engaged and comprehensive discussion of the issues before them. Appointing a committee capable of comprehensive discussion involves, among other things, achieving balance among the applicable scientific disciplines. Moreover, agencies should avoid turning repeatedly to the same scientists for service on advisory committees. And agencies should periodically turn over the staff that is assigned to select panelists.

DISCLOSURE OF QUALIFICATIONS, FINANCES AND ACTIVITIES

Members of federal scientific advisory committees should be required to disclose to the government information on relevant financial relationships and professional activities (such as giving talks at conferences and testifying in court) going back five years. Members should also be asked to disclose, to the best of their ability, any relevant professional activities that occurred more than five years prior to their committee service.



Federal agency disclosure forms should be as clear and uniform as possible. Developing a single form that draws on the different forms used now by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) would be a good start.

For financial disclosure, the categories of information the National Academy of Sciences views as relevant for its panelists are also appropriate for federal agencies.

To build public trust through transparency, much more information on federal advisory committee members needs to be available than is now the case. One possibility would be for federal agencies to make publicly available all the information on a panelist's disclosure form *except* the precise dollar amounts of their stock holdings or compensation and any information on the finances of their spouse or dependent children. At the same time, the agency would disclose the member's educational background and scientific credentials.

DETERMINING CONFLICTS OF INTEREST

For conflict of interest, there must be a clearer federal policy with bright lines that leaves as little doubt as possible as to who would be considered to have a conflict if they served on a particular advisory committee. The definition should be as uniform across agencies as possible and, at the very least, should set a minimum standard for all agencies. The general principles that the National Academy of Sciences uses to define conflict of interest apply equally well to the government. The question to be asked in defining a conflict of interest is whether a particular financial relationship would tend to constrain a generic individual's point of view. Such relationships need to be defined as conflicts regardless of the source of the funding.

When considering whether a conflict of interest exists, federal agencies should look back two years rather than just considering current relationships as is now the case. *Two members of our panel dissented from the recommendation in this paragraph for reasons described on page 22.*

DEALING WITH CONFLICTS OF INTEREST

The desired norm for federal agencies should be to appoint advisory committees whose members are free of conflicts of interest. There will be instances, though, when scientists with conflicts of interest may be needed for a panel because of their expertise.

The standard for allowing someone with a conflict of interest to serve on an advisory committee should be changed to the clearer and arguably more stringent policy of the National Academy of Sciences under which a conflicted expert can serve only in a situation where having a conflicted panel member is "unavoidable." (The current standard is whether the need for the conflicted member's services "outweighs the potential for a conflict of interest posed by the financial interest involved.")

Appointment of an individual with a conflict of interest should require a formal waiver from the appointing official. When a waiver is granted, the agency should publicly state that the appointee has a conflict and should provide enough information that the public and the other committee members understand what kinds of efforts were made to find a non-conflicted individual, how and why the appointed individual was considered to be conflicted, and why the individual was appointed nonetheless, as well as disclosing who signed off on the waiver.

Agencies should not appoint anyone with a conflict to serve as the chair or co-chair of a committee. And agencies should limit the issuance of conflict waivers.

DETERMINING AND DEALING WITH BIAS

The federal government should follow the National Academy's lead and distinguish clearly between conflict of interest and bias.

The goal should generally be to assemble committees of individuals who are as impartial (i.e., fair-minded) as possible and to ensure that the overall committee is balanced. Agencies should not shy away from including scientists on a panel who are considered "outliers" on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream.

MANAGING ADVISORY COMMITTEES

Once the final members of a committee have been named, federal agencies need to defend their choices of appointees and stand by their panel if it comes under attack.

Committee members need to know of each other's financial relationships and viewpoints. Moreover, the appropriate agency official needs to take an active role in supporting the committee's work, which includes managing any conflicts for the duration of the panel.

Federal agencies should not be able to circumvent the processes discussed above by contracting out the appointment or operation of advisory committees.

The Administration and the Congress should carefully think through the benefits and disadvantages of requiring all meetings to be open. It might be worth considering, for example, whether some scientific advisory committees could be allowed to hold some closed meetings if the selection process for committee membership were more open than it generally is today (as recommended above).

The recommendations of a committee, though, must always be made public (assuming no classified information is involved), and indeed committees should be required to explain fully their methodology and the rationale for their conclusions. In the *Federal Register* notice for any rule for which a scientific advisory committee was convened, the federal agency should be required to state whether it differed with any conclusions of a scientific advisory committee and if so, why, and should be required to explain how the new regulatory policy is consistent with the conclusions that were accepted.

-
- **RECOMMENDATION THREE: Agencies and their scientific advisory committees should cast a wide net in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent.**

TRANSPARENCY

The process of conducting literature reviews should become more transparent. Agencies and their scientific advisory committees should be explicit about the criteria they are using to determine which scientific papers to review and how those papers are being evaluated. Once an agency has opened a docket on a rule or guidance that will draw on scientific studies, it should make available on the Web a list of the studies it is reviewing and should regularly update the list.

CRITERIA

In general, papers in high impact, peer reviewed journals should be given great weight, and papers that have not been peer reviewed should be treated with skepticism. But agencies and scientific advisory committees need to extend their inquiry beyond simply ascertaining whether a paper was peer reviewed; peer review is a necessary but not sufficient determinant of quality. Conversely, studies that have not been peer reviewed should not be summarily rejected if they appear to contribute to the inquiry.

In general, agencies and scientific advisory committees should be wary of studies when it is unclear who funded the study or whether the principal investigator(s) had any conflicts of interest.

Agencies and scientific advisory committees should be extremely skeptical of a scientific study unless they are sure that the principal investigator(s) (as opposed to the sponsor or funder) had ultimate control over the design and publication of the study.

In fields where a public registry of studies exists (such as the registry established by the Food and Drug Administration Modernization Act of 1997), agencies and scientific advisory committees should consider the relevant registered studies and should be wary of studies that met the criteria for the registry, but were not registered.

DATA AVAILABILITY

Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act (Shelby Amendment) and its implementing circular regardless of who funded the study.

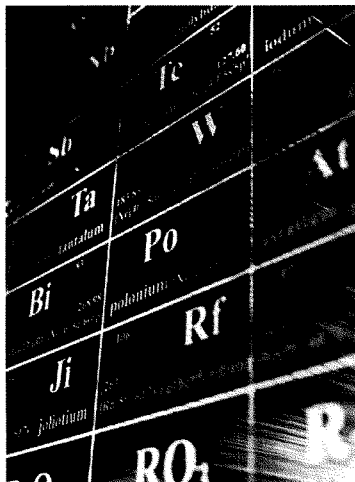
Confidential Business Information (CBI) is a legitimate and needed designation for information submitted to the federal government, but it appears to be overused today. The Administration and the Congress should gather data on the extent and nature of CBI claims. The Administration and Congress should consider requiring each new CBI claim to include a brief, but substantive justification for the claim.

ADDITIONAL STUDIES

Agencies should experiment with a variety of additional approaches that would enable them to commission studies and literature reviews related to pending regulatory decisions that would be widely seen as unbiased.

PRESENTING CONCLUSIONS

In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty. Policy makers should be wary of conclusions about risk that are expressed as a single number.



■ **RECOMMENDATION FOUR:** *The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest.*

PEER REVIEW

Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review, particularly peer review of draft manuscripts. Universities should do more to make service as a peer reviewer an expected and appreciated aspect of a scientist's career. Scientific journals should improve the quality control of peer review and should experiment with different ways of conducting peer reviews. *The report lists a number of specific approaches that could be tried by the government, universities and journals.*

INFORMATION ON SCIENTIFIC STUDIES

Federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies.

Federal agencies should determine whether the idea of research registries, which today is focused on research related to pharmaceuticals, can be expanded to other fields.

CONFLICT OF INTEREST

Journals should have clear, publicly accessible conflict-of-interest policies and should require full disclosure of how studies were funded and of any and all conflicts of interest they determine an author has. Editors should also disclose any of their own conflicts of interest. In addition, journals should consider requiring authors to certify that they had ultimate control over the design and publication of the study being described in a paper.

Federal agencies need to consider promulgating rules that would sanction scientists who run afoul of federal, university or journal requirements concerning disclosure, conflict of interest or ultimate sponsor control.

Introduction

The use of science in the formulation of regulatory policy – by both the Executive Branch and the Congress – has been a political flashpoint in recent decades.¹ Policy makers often claim that particular regulatory decisions have been driven by, or even required by science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being “politicized” and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.

These problems are largely systemic; they will not magically vanish with a change of Administrations or a shift in the composition of the Congress.² But the advent of a new Administration and a new Congress is an opportune time to take stock of the situation and to try to devise ways to get beyond the predictable battles that would otherwise lie ahead. The use of science in regulatory policy is another area in which government needs to get beyond the stale debates

and false dichotomies of the past. The question is not whether scientific results should be used in developing regulatory policy, but how they should be used.

New governmental processes are needed – approaches that will be seen as legitimate by stakeholders on all sides of issues and that will make policy making more transparent. A critical goal of any new procedures for establishing regulatory policy must be to clarify which

A tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today.

aspects of a regulatory issue are matters of science and which are matters of policy (e.g., economics or ethics). A tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today.

To come up with new approaches, the Bipartisan Policy Center established the Science for Policy Project. To carry out the project, the Center assembled a diverse panel of experts to develop recommendations for both the Executive Branch and the Congress on how to improve the way science is used in making regulatory policy

¹ In this report, “science” refers to the natural and physical sciences and engineering.

² The primary focus of this report is the systemic problems affecting the role of science in regulatory policymaking, such as conflating science questions and policy questions, as they are fundamental, longstanding and often overlooked. Other forms of misuse or abuse of science in government are also unacceptable, as reflected by this panel’s clear admonition in Chapter 1 that “political decision-makers should never dictate what scientific studies should conclude.” However, those issues have been discussed elsewhere, and are not the primary subject of this report. Even if every potential abuse of science were avoided, regulatory policy would still get mired in avoidable debates unless the issues discussed in this report were addressed.

across the government's areas of responsibility. The panel includes liberals and conservatives, Republicans and Democrats, scientists and policy experts, and leaders with experience in government, industry, academia and non-governmental organizations.

This report is structured around three sets of questions that are at the heart of the debate over the use of science in regulatory policy. (By "regulatory policy," we mean not only specific rules, but all regulatory statements and guidance issued by Administration officials, and statements, hearings and legislation from the Congress.) Those questions are:

- What kinds of activities or decision-making amount to "politicizing" science? How and to what extent can one differentiate between the aspects of regulatory policy that involve scientific judgments and those that involve making policy recommendations (which are inherently political)?
- When and how should Federal agencies empanel advisory committees? How should members be selected? How should conflicts of interest and biases of potential members be handled? What is scientific balance and how can it be achieved? How can the independence and integrity of committees' deliberations be assured?
- What studies should agencies and advisory committees review in formulating regulatory policy? How should they be weighed? What role should peer review play and how might peer review be modified and strengthened?

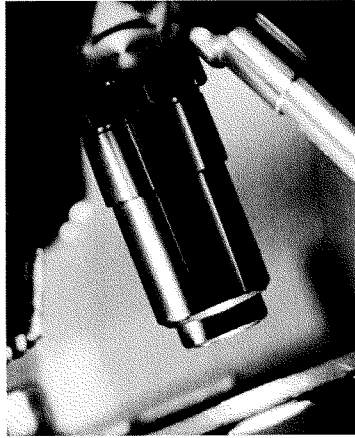
Implementing our panel's answers to these questions would result, we believe, in a more candid, transparent, and rigorous use of science in regulatory policy making and a more honest and thoughtful debate about regulatory proposals.

With those results in mind, our hope is that this report will help shape, among other things, the implementation of the President's scientific integrity memorandum, which raises questions similar to those above.³

Like the Presidential memorandum, this report does not focus on any particular area of regulatory policy. Instead, we recommend principles and procedures that we believe should improve regulatory policymaking and debate across the board. Our recommendations are focused on the procedures used by the regulatory agencies.

But while our only specific recommendation for Congress is to make any statutory changes needed to implement our proposals regarding scientific advisory committees (see Chapter 2), this report has additional implications for the Legislative Branch. Like the Executive Branch, Congress needs to take to heart, and find ways to implement, the principles and processes the report recommends. More specifically, Congress needs to find ways to distinguish the aspects of regulatory policy that involve scientific judgments from those that involve making policy recommendations in its debates, in the questioning of its witnesses, and in its parsing of the arguments brought to it by the Administration and lobbyists on all sides of regulatory issues. In addition, Congress should consider codifying the principles and procedures recommended in this report to make them less likely to change from Administration to Administration. Congress could consider passing general legislation on the issues in this report and/or including provisions in legislation as relevant

³ Memorandum for the Heads of Executive Departments and Agencies, March 9, 2009. <http://edocket.access.gpo.gov/2009/pdf/E9-5443.pdf>. It should be noted that our study was initiated in the spring of 2008 – in the midst of the Presidential primary season – so it was not created to inform the Memorandum.



programs are reauthorized. In doing so, however, Congress should avoid becoming overly prescriptive.

Again, our firmest and most fervent hope is that this report will help point the Administration, the Congress, the media, interest groups and the courts to think more carefully and to speak more precisely about what is truly at issue when regulatory proposals are being debated.

This report proposes specific procedures that we believe can inaugurate a new era – an era in which the science behind regulatory proposals will emerge

from a more transparent and credible process that fully acknowledges the complexities of reaching scientific conclusions; and in which the disagreements over political ideology, economics and values that are at the heart of many regulatory disputes will be debated openly and fully, not transmogrified into a political battle waged through science.

This new era will not come into being, and certainly will not be sustained, merely by public officials claiming to mean well or trying to do their best. Change requires institutionalizing specific procedures that will inculcate and direct this new way of thinking. This report recommends just such procedures.

If our recommendations are implemented and succeed as we hope, science will be better protected and political values will be more fully debated, enhancing the process of regulatory policy making, and ultimately, democracy itself. The result should be better regulatory policy that protects the public both from needless regulations and from needless dangers.

1

Chapter One

RECOMMENDATION ONE: The Administration needs to promulgate guidelines (through executive orders or other instruments) to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.

Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the “politicization” of science actually arise over differences about policy choices that science can inform, but not determine. For example, decisions about how much risk society should tolerate or what actions should be taken in the face of scientific uncertainty are not science questions, rather they concern policies and values. Matters such as risk and uncertainty need to be informed by scientific results, but science cannot tell policy makers how to act. True, distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on science.

It would also help policy makers determine which experts to turn to for advice on regulatory questions, and what kinds of questions they should be expected to answer.

The Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy. That distinction also needs to be spelled out in regulatory documents. At a minimum, **the Administration should require that a section of the *Federal Register* notice for any proposed guidance or rule that is informed by scientific studies describe the primary scientific questions and the primary policy questions that needed to be answered in drafting the rule.** For example, for a clean air rule, the scientific questions might include how many excess deaths or hospital admissions would be expected to result from different atmospheric concentrations of the pollutant. The policy questions would include how to decide what level of concentration to allow, given the scientific information. The *Federal Register* notice would go on to describe

the answers to the listed questions and their rationale. (Chapters 2 and 3 discuss how federal agencies should obtain and characterize answers to scientific questions.)

One approach that could help clarify the often problematic distinction would be to also **require the Federal Register notice to include answers to such questions as: What additional science would change**

Unless clarifying science and policy issues becomes a central aspect of regulatory policy discussions, it will be very difficult to get beyond the finger-pointing and misleading debates that have been a barrier to sensible policy making for so long.

the debate over a proposed regulatory policy and in what ways would the debate change? This both would help pinpoint the nature and extent of scientific uncertainty and would highlight which aspects of a regulatory issue are not primarily about science.

Another possible approach would be to require federal agencies to spell out genuine alternative regulatory policies when proposing guidance or a rule. Although this approach is embodied in some federal decision processes (e.g., those under the National Environmental Policy Act), the approach is not uniformly applied, and the alternatives proposed can be less than genuine. The idea would be to make clear the range of policy options that were available, given the science and the requirements of law. For example, agencies could be required to describe alternatives of different levels of stringency (or cost, when allowed by statute) that would be in keeping with the science and would comply with statutory mandates.

Many additional options for implementing Recommendation One might be developed, but the goal should be to change the conversation about regulation and to inculcate new habits of thought. **The first impulse of those concerned with regulatory policy should not be to claim “the science made me do it” or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making.**

No system for clarifying the roles of science and policy questions in regulatory decision making will be air tight or completely immune from abuse. But that is not a reason to adhere to the status quo. Unless clarifying science and policy issues becomes a central aspect of regulatory policy discussions, it will be very difficult to get beyond the finger-pointing and misleading debates that have been a barrier to sensible policy making for so long. In short, there must be clarity and transparency about the roles of policy and science in regulatory decisions for science to be appropriately integrated in regulatory policy.

Chapter Two

RECOMMENDATION TWO: The Administration should promulgate guidelines (through executive orders or other instruments) directing agencies to follow the policies described below on: when to consult advisory panels on scientific questions, how to appoint them (including how to deal with conflicts of interest and biases), and how they should operate. Congress should pass, and the President should sign into law, any statutory changes needed to implement these policies.

Federal agencies should use scientific advisory committees to the maximum extent possible to review the science behind regulatory policies. (At the same time, agencies should be working to strengthen the internal capabilities of their staffs, including their scientists.) Public officials should not delegate their ultimate responsibility to set policy to advisory committees. But scientific advisory committees can help ensure that policies are based on a range of scientific knowledge and perspectives, and they can make the regulatory process more transparent. As a result, the proper use of advisory committees can make it easier to adopt and more difficult to overturn good regulations.

Types of advisory panels

The first question for an agency establishing an advisory committee should be whether the committee's charge will be to handle science questions or policy questions (or perhaps both). Agencies should ensure that science and policy questions are distinguished as clearly as

possible in charges to advisory panels. **Advisory committees that are to exclusively address science questions (referred to in this report as "scientific advisory committees") should generally consist only of members with relevant scientific expertise.** Advisory committees that are to address policy questions that are informed by science should include members with relevant scientific expertise along with policy specialists and stakeholders.

All non-government members of scientific advisory committees should be appointed as Special Government Employees to ensure they comply with the appropriate ethics guidelines and requirements.

In general, scientific advisory panels should not be asked to recommend specific regulatory policies.²

¹ Agencies may want to empanel advisory committees to provide recommendations on how to strengthen their internal expertise, but this report deals only with advisory committees charged with answering questions pertaining to regulatory policy.

² Our panel is not arguing that scientists should never be consulted on policy questions. As noted above, scientists should be included on policy panels when regulations that are informed by science are being considered. And agencies should always feel free to create avenues for individual scientists to give their views on regulatory policy. When scientists use such avenues, they should make clear they are talking about matters of policy, not science. But for the reasons described in Chapter 1, scientific advisory committees should not recommend specific regulatory policies. For example, a scientific advisory committee might draw conclusions about the cancer risks posed by a particular substance, but should not recommend what an agency should do in response.

Rather, they should be empaneled to reach conclusions about the science that would help guide a regulatory policy decision. They might also be charged with evaluating a regulatory option or options developed by federal officials in light of current scientific understanding. For example, a scientific advisory committee might be asked to determine if a proposed standard was consistent with achieving a level of risk prescribed by federal officials.³

*PLEASE NOTE: the remainder of this chapter is concerned exclusively with procedures related to **scientific advisory panels**.*

Transparency in the selection process

The process of naming advisory committees should be made more transparent. Options for achieving greater transparency include: seeking recommendations for members on the Web and/or through contacts with relevant groups;⁴ publicly announcing on the Web the criteria for membership (such as the range of scientific disciplines that need to be included); and announcing proposed members on the Web (along with their disclosure forms, to the extent discussed below) to solicit public comment. Agencies would then respond to the comments

³ There are some cases in which a scientific determination automatically triggers a policy outcome under a statute. Examples include whether a plant or animal is an endangered species under the Endangered Species Act and whether a substance endangers public health under the Clean Air Act. In such instances, agencies need to take special care to distinguish science and policy questions. On a panel concerning an endangered species designation, for example, arguments over whether to designate a species (i.e., applying the Act) should be distinguished from arguments about whether the Act is needed or whether the current state of the law imposes the correct standards for designation. And in both the Endangered Species and Clean Air Act examples, the determination that a species or substance requires regulation still leaves open questions about how the species or substance should be regulated. Questions about how to regulate have scientific and policy aspects that often can be distinguished, and a separate scientific advisory committee could be empaneled to address the science questions involved.

⁴ Agencies need to ensure that they seek advice from a balanced selection of groups, not favoring groups on a particular side of an issue or with a specific area of expertise. Groups might include scientific societies or relevant departments in universities.

when the final panel was announced. While some agencies use some of these techniques some of the time today, greater transparency needs to become the norm, and the processes for assembling advisory committees need to become more standardized. Merely announcing committees in the *Federal Register* is not sufficient.

In addition, each time an advisory committee is appointed, an agency should publicly release the names of the key officials responsible for appointing the advisory committee and briefly describe the roles they played in the process.

Factors in selecting advisory committee members

The primary purpose in appointing a committee is to gather a group of eminently qualified individuals who can have an open, engaged and comprehensive discussion of the issues before them. As the National Academy of Sciences puts it in describing its own policy for selecting panels, "All [committee members] must be highly qualified in terms of knowledge, training and experience...to properly address the tasks assigned to the committee."⁵

Appointing a committee capable of comprehensive discussion involves, among other things, achieving balance among the applicable scientific disciplines. This is more essential than is commonly understood. Such balance not only ensures that the full range of science will inform a decision, but also guards against advice being unconsciously biased by the

⁵ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, May 12, 2003, Page 2. Available at: <https://www.nationalacademies.org/doi/10.17226/10000>, pdf. In this report, the term "National Academy of Sciences" is used to refer to the entire Academy complex: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine and their operating arm, the National Research Council.



perspectives, values, norms or techniques that may be inherent in particular fields.

Agencies should also strive to include on committees scientists at different points in their careers. Young, mid-career and senior scientists may have different perspectives and strengths to bring to a committee.

It is also critical to identify a chair who is widely respected, has a reputation for considering all perspectives, and can manage a committee so as to encourage debate and discussion yet produce results on schedule.

Moreover, agencies should avoid turning repeatedly to the same scientists for service on advisory committees. Instead, they should seek to continually expand the circle of relevant experts to whom they turn for advice. One way to do this is to think more broadly about what expertise is applicable to the question before the advisory committee. Someone whose work is focused on questions at the periphery of a field or subfield, for example, may have sufficient expertise to understand a question and could bring a fresh perspective to it.

Agencies should be alert to their own biases in selecting advisory committee members. For example, staff who work on an issue to be reviewed by an advisory committee should not select the members of that committee, although they should be permitted to recommend panelists' names to the official making the committee appointments. **And agencies should**

periodically turn over the staff that is assigned to select panelists.

Finally, agencies need to consider what conflicts of interest or biases potential committee members may bring to the table. To determine whether conflicts or biases (as defined below) exist and have been properly handled, both agencies and the public need to have more information than is currently available concerning the members of scientific advisory committees.

Disclosure of qualifications, finances and activities

Members of federal scientific advisory committees should be required to disclose to the government information on relevant financial relationships and professional activities (such as giving talks at conferences and testifying in court) going back five years. Members should also be asked to disclose, to the best of their ability, any relevant professional activities that occurred more than five years prior to their committee service. Any reporting period is inherently arbitrary, but the current disclosure periods need to be extended to get a fuller picture of a member's experience and possible conflicts and biases.

Federal agency disclosure forms should be as clear and uniform as possible; panelists should have no doubts about what the government needs to know. Developing a single form that draws on the different forms used now by the Environmental Protection Agency (EPA)⁶ and the Food and Drug Administration (FDA)⁷ would be a good start. For example, the FDA form asks about speaking and writing, while the EPA form does not. The EPA form includes general questions on bias that are not on the FDA form. The

⁶ EPA Form 3110-48: Confidential Financial Disclosure Form for Environmental Protection Agency Special Government Employees.

⁷ FDA Form 3410: Confidential Financial Disclosure Report for Special Government Employees.

EPA form asks solely about compensated testimony, but uncompensated testimony is also relevant in assessing bias; the FDA form is unclear about whether uncompensated testimony should be listed.⁸

For financial disclosure, the categories of information the National Academy of Sciences views as relevant for its panelists are also appropriate for federal agencies: “employment relationships (including private and public sector employment and self-employment); consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships and serving as an expert witness in litigation); stocks, bonds and other financial instruments and investments including partnerships; real estate investments; patents, copyrights and other intellectual property interests; commercial business ownership and investment interests; services provided in exchange for honorariums and travel expense reimbursements; research funding and other forms of research support.”⁹ Also, like the Academy, financial disclosure should cover not only the individual committee member, but “the individual’s spouse and minor children, the individual’s employer, the individual’s business partners, and others with whom the individual has substantial common financial interests... and the interests of those for whom one is acting in a fiduciary or similar capacity.”¹⁰ As noted above, the government should require this information for the previous five

years. The Academy seeks only current information about finances.¹¹

Not only the government, but also the public needs more information to determine whether a conflict or bias exists and has been appropriately handled.

To build public trust through transparency, much more information on federal advisory committee members needs to be available than is now the case.

To build public trust through transparency, much more information on federal advisory committee members needs to be available than is now the case.

Obviously, a balance must be struck between the value of public information and privacy concerns. And public disclosure must not be so extensive that it greatly reduces the number of scientists willing to serve on committees. Federal agencies should monitor whether new requirements are making it harder to attract committee members. But disclosure is becoming more routine – in scientific journals and at universities, for example – and the government should not be a last bastion of secrecy.

One possibility would be for federal agencies to make publicly available all the information on a panelist’s disclosure form except the precise dollar amounts of their stock holdings or compensation and any information on the finances of their spouse or dependent children. At the same time, the

⁸ While agency disclosure requirements should be as uniform as possible, some agencies may need to add specific questions that reflect conflict concerns particular to a specific inquiry. One goal of uniformity is to make it easier for scientists to comply with disclosure requirements by enabling them to provide the same standard information for all advisory committee service. But there is no point in making the standard form longer or more complicated than need be to accommodate questions that would only be relevant to a few committees.

⁹ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, May 12, 2003, Page 5.

¹⁰ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, May 12, 2003, Page 4.

¹¹ Committee members should also be expected to disclose any conflict that might not be covered by these standard categories. For example, they should disclose if they have an adult child in a position that they know could be materially affected by the conclusions of the committee.

agency would disclose the member's educational background and scientific credentials. Ideally, all of this information would be released when committee members' names were put up on the Web for public comment (per our recommendation above).

An eventual goal would be to make it standard practice for scientists to have a public curriculum vitae (CV) that included all their relevant employment, research support, publications, speaking, testimony, etc. Such a CV would provide much of the information sought on government disclosure forms. Many scientists already post their CV on their websites, and standardizing and expanding this practice would be part of creating a culture of disclosure that would be responsive to, and relevant for more than requirements for service on government committees.

Regardless of whether they have such a CV, scientists should be far more attentive to the need to disclose financial relationships and professional activities, including the need to disclose any that develop during service on an advisory committee. But federal agencies must also do their own research on potential committee members; they should not rely exclusively on self-disclosure.

Determining conflicts of interest

While it is the duty of a scientist to fully disclose the information needed to determine whether a conflict of interest or bias would impinge on service on an advisory committee, it is the government that must define conflict and bias and decide how they will be handled. (Bias is dealt with later in this chapter.) **For conflict of interest, there must be a clearer policy with bright lines that leaves as little doubt as possible as to who would be considered to have a conflict if they served on a particular advisory committee.** The definition should be as uniform across

agencies as possible and, at the very least, should set a minimum standard for all agencies. Differences among agencies lead, among other things, to public confusion, and can leave advisory committee members open to the charge that a different agency would have considered them to have had a conflict of interest. Differences among agencies may be acceptable if the agencies draw on different scientific fields with different norms for conflict, but in such cases agencies should be required to explain publicly any departures from the standard government definition. (As discussed below, defining a conflict is a separate matter from – if related to – deciding what to do when someone is determined to have a conflict.)

The general principles that the National Academy of Sciences uses to define conflict of interest apply equally well to the government: "The term 'conflict of interest' means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization....[Conflict] means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of the committee. Conflict of interest requirements are objective and prophylactic. They are not an assessment of one's actual behavior or character....[For regulatory issues], *the focus of the regulatory inquiry is on the identification...of any interests that may be directly affected by the use of such reports in the regulatory process.*"¹² (Italics in the original.)

Our panel did not reach agreement on a complete set of circumstances that should be considered to constitute a

¹² The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Pages 4, 9.

conflict of interest. This again underscores the need for clear definitions and illustrative cases in federal policy as the definition is not obvious. (See the Appendices of this chapter for a list of the circumstances our panel considered, and for a comparison of conflict policies used by a variety of institutions.)

Our panel did agree that certain relationships should be considered a conflict. For example, an employee of a company that has a product under review, or a scientist funded by that company to research or defend that particular product should be considered to have a conflict of interest vis-à-vis an advisory committee reviewing the environmental or health impacts of that product. The same would be true of someone with the same links to a competing product.

The panel also agreed that the question to be asked in defining a conflict of interest is whether a particular financial relationship would tend to constrain a generic individual's point of view. Such relationships need to be defined as conflicts regardless of the source of the funding. Definitions of conflict should not single out scientists based on their affiliation or funding source (i.e., industry, academia, government, non-governmental organization); rather, conflict policies should treat all paid work in an even-handed manner, that is, according to the same principles. An example would be a conflict policy that was defining situations in which a scientist could fear losing a job or funding if he or she reached a particular conclusion. In that case, the task in setting policy would be to examine whether each type of employment or funding could be construed to pose such a threat. In short, it is the relationship between the funding source and the scientist, not the funding source itself, that is critical.

Whatever the definition of conflict, **when considering whether a conflict of interest exists, federal agencies should look back two years rather than just considering current relationships as is now the case.**

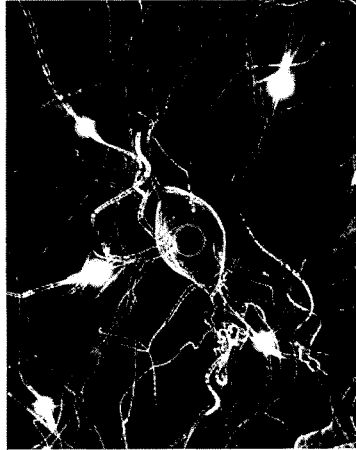
Any time period is going to be arbitrary, but financial relationships in the immediate past can be a relevant consideration. *Two members of our panel dissent from this recommendation for reasons explained below.*¹³

Agencies should ensure that the theory they use to classify particular relationships as conflicts of interest (e.g., because such relationships could lead a panel member to fear losing future funding) is consistent with the notion of considering past, and not just current relationships.

Dealing with conflicts of interest

The desired norm for federal agencies should be to appoint advisory committees whose members are free of conflicts of interest. (Relevant experts who have conflicts could still make presentations to a panel.) There will be instances, though, when scientists with conflicts of interest may be needed for a panel because of their expertise. This may be especially true in novel

¹³ The text of the dissent is: "Two members dissent from the two-year look-back period because they believe the Committee is confusing the two key concepts, conflict and bias. When a scientist is engaged in a current activity that creates a conflict (e.g., acting as a paid expert witness in an ongoing trial concerning issues closely related to the panel's work), the presumption is that the scientist may be compromised in reaching a determination during the panel's work that is inconsistent with his or her paid testimony. That is a conflict. However, if that testimony occurred 18 months prior to the panel's work and the relevant legal proceedings are finished, there is no conflict. By definition, a conflict cannot be historical. It is possible, however, that a scientist with a history of expert testimony on a key issue may be judged to have a bias (e.g., if he is perceived as inflexible in his views, even in the face of new evidence) and that is why it is essential to understand a scientist's history as an expert witness and his or her openness to new evidence and insights. In the presence of such a bias, the scientist might be excluded from the panel or might be counter-balanced with one or more other experts who possess differing views or biases. The best solution to the bias depends on the pool of available experts. The same distinction – between conflict and bias – is important when assessing whether commercial relationships create a conflict. If a scientist has a direct commercial interest (e.g., through stock holdings or an employment relationship) in the outcome of a panel's deliberations (e.g., the scientist owns an Airbnb supplier or is Chief Executive Officer of an Airbnb supplier when the panel's work concerns the future of Airbnb), there is a conflict. A commercial interest that existed 18 months ago, and no longer exists, cannot – by definition – be a conflict. A bias, however, may or may not exist. Given this line of reasoning, it should be apparent why the National Academy of Sciences and the federal government do not currently use a two-year look-back period when assessing whether science advisors have conflicts.



areas of technology in which most funding may come from those interested in producing new products.

Currently, experts with conflicts of interest can be appointed as Special Government Employees to serve on an advisory committee if the need for their services "outweighs the potential for a conflict of interest posed by the financial interest involved."¹⁴ **The standard should be changed to the clearer and arguably more stringent policy of the National Academy of Sciences under which a conflicted expert can serve only in a situation where having a conflicted panel member is "unavoidable."** The Academy considers a conflict to be unavoidable "if, for example, the individual's qualifications, knowledge and experience are particularly valuable to the work of the committee and if the [Academy] is unable to identify another individual with comparable qualifications, knowledge and experience who does not also have a conflict of interest."¹⁵ The Academy's description of how to determine when a waiver is permissible, or one similar to it, could be adopted by the federal government even if the current statutory language remained unchanged.

Appointment of an individual with a conflict of interest should require a formal waiver from the appointing

official. **When a waiver is granted, the agency should publicly state that the appointee has a conflict and should provide enough information that the public and the other committee members understand what kinds of efforts were made to find a non-conflicted individual,¹⁶ how and why the appointed individual was considered to be conflicted, and why the individual was appointed nonetheless, as well as disclosing who signed off on the waiver.** (If the disclosure procedures proposed in this chapter were in place, the agency would still need to specify which aspect of the individual's background was considered a conflict.) If proposed advisory committee membership were placed on the Web for public comment, as recommended earlier, that would be the point at which a waiver would be announced.

Agencies should not appoint anyone with a conflict to serve as the chair or co-chair of a committee. And agencies should limit the issuing of conflict waivers to ensure that individuals with conflicts do not generally constitute more than a small percentage of the membership of a committee.

Determining and dealing with bias

The federal government should follow the National Academy's lead and distinguish clearly between conflict of interest and bias. The Academy's view of bias should guide federal policymakers: "Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular

¹⁴ 18 U.S.C. § 208(b)(3)

¹⁵ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Page 8.

¹⁶ This does not require releasing the names of individuals who were considered for appointment or who were asked and declined, nor does it require releasing the name of every group that was consulted. But it does require describing the kinds of steps that were taken to seek non-conflicted individuals. Following the recommendations in this chapter for soliciting public comment on potential committee members should help agencies gather names of qualified, non-conflicted individuals.

group. Potential sources of bias are not necessarily disqualifying for purposes of committee service.¹⁷

Bias is an inherently murky concept, and every individual has biases. But **the goal should generally be to assemble committees of individuals who are as impartial (i.e., fair-minded) as possible.** This is not the same as saying that a committee should (or could) be made up of individuals with no views on the matter at hand; the goal is to pull together a committee that can act in good faith.

Agencies should not shy away from including scientists on a panel who are considered “outliers” on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream.

The approach to bias will depend on the precise question(s) being posed to the committee. Generally, strong biases in committee members should be avoided. But in some cases, an agency may want to appoint some members with strong and even fixed views on an issue because they need such individuals' expertise or because they want to ensure that those scientific views are fully represented on the committee. In such instances, **the goal should be to ensure that the overall committee is balanced.**

Agencies should not shy away from including scientists on a panel who are considered “outliers” on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream. Minority reports should be allowed on advisory committees, although consensus should be the goal.¹⁸ Outliers who are willing to engage the issues can play a useful function by sharpening discussion within a committee, even if they decide not to sign on to the committee's final report.

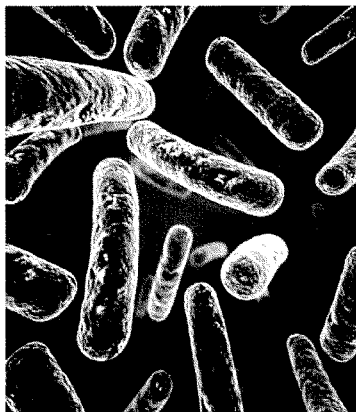
Unlike conflict of interest, there is no way to come up with a litmus test for bias or to establish clearly delineated categories. Rather, in handling bias, federal agencies need to carefully consider the full picture of an individual's activities that emerges from his or her disclosure forms as well as getting a sense of the individual's personality and reputation in the field. For example, for academic scientists, receiving funding from a variety of sources can be a sign of fair-mindedness. Similarly, responding to critics, publishing in a variety of journals, and speaking at a variety of invited conferences can be indicators of openness. On the other hand, testifying repeatedly on one side of an issue before Congress or in the courts can be taken as indications of a point of view that may need to be balanced in putting together a panel.

Managing advisory committees

Once the final members of a committee have been named, **federal agencies need to defend their**

¹⁷ “Consensus” itself can be a tricky word. A useful definition appears in *Building United Judgment: A Handbook for Consensus Decision Making*. “The goal of consensus is a decision that is consented to by all group members. Of course, full consent does not mean that everyone must be completely satisfied with the final outcome—in fact, total satisfaction is rare. The decision must be acceptable enough, however, that all will agree to support the group in choosing it.” (M. Avery, B.J. Strehel, B. Auvine, Madison, WI: Center for Conflict Resolution, 1981.)

¹⁸ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, May 12, 2003, Page 3.



choices of appointees and stand by their panel if it comes under attack. (This assumes, of course, that no new information comes to light that should have been disclosed by a scientist or uncovered by an agency. Seeking public comment on committee members, as recommended earlier, should help prevent such situations.)

Committee members need to know of each other's financial relationships and viewpoints. At their first meeting, and periodically thereafter, National Academy panel members are expected to discuss their relationships and previously stated views with fellow panel members in a closed session. Federal agencies may want to adopt this practice (although under current law it would have to be in open session), or may want to experiment with other means of ensuring that a panel has a collective understanding of its membership's commitments and interests. At a minimum, advisory committee members should be given copies of all the members' public disclosure forms prior to the first meeting.

Moreover, the appropriate agency official needs to take an active role in supporting the committee's work, which includes managing any conflicts for the duration of the panel. An official may need to remind panel members of member interests. Also, an official may need to seek recusal of a member or otherwise manage conflicts, if they develop.¹⁹ New conflicts that

develop or relevant new activities that are undertaken during service on a committee must be disclosed and handled in the same manner they would have been in advance of service on a panel.

Federal agencies should not be able to circumvent the processes discussed above by contracting out the appointment or operation of advisory committees. The Administration should limit the extent to which federal agencies can use outside contractors to establish advisory committees, and federal agencies should be alert to any conflicts of interest those firms may pose. Moreover, committees chosen by contractors should be subject to the same rules and procedures as a similar committee established directly by an agency, particularly on the matters of conflict, bias and disclosure discussed above.

It is also vital for the federal government to establish and maintain an internal tracking system on the process of recruiting scientific advisors, the numbers and types of conflicts and biases encountered and the degree to which increased disclosure inhibits the recruitment of a full range of qualified experts. In addition, the public database on advisory committees needs significant improvement. It should provide easy access to the names and backgrounds of all individuals serving on advisory committees and information on the conflict of interest waivers that have been granted.

The Administration and the Congress should carefully think through the benefits and disadvantages of requiring all meetings to be open. **It might be worth considering, for example, whether some scientific advisory committees could be allowed to hold some closed meetings if the selection process for committee membership were more open than it generally is today (as recommended above).** Transparency is an essential principle of democratic governance, but some deliberations can benefit from a modicum of private discussion to enable committee members to think and

¹⁹ New conflicts can develop because the committee discussion takes an unanticipated turn, but they are far more likely to arise because of new activities undertaken by committee members.

speaking more freely and open-mindedly. Allowing the closure of meetings would require changes in statute, and any such changes should limit the use of closed meetings and be very specific about when closure is permissible.

The recommendations of a committee, though, must always be made public (assuming no classified information is involved), and indeed committees should be required to explain fully their methodology and the rationale for their conclusions. In the *Federal Register* notice for any rule for which a scientific advisory committee was convened, the federal agency should be required to state whether it differed with any conclusions of a scientific

advisory committee and if so, why, and should be required to explain how the new regulatory policy is consistent with the conclusions that were accepted.

Finally, federal officials must give advisory committees clear, definite and realistic deadlines for reporting and clear information on when a committee report will be released and how it will be used.

One way the Administration might approach some of the issues raised here would be to review the guidance that the Office of Management and Budget and the Office of Science and Technology Policy issued in 2005 to see how it might be improved.²⁰

²⁰ Office of Management and Budget, January 14, 2005, Final Information Quality Bulletin for Peer Review, *Federal Register*, 70: 2664–2677.

APPENDIX 1

Hypotheticals for consideration in setting rules for conflict of interest

As noted in the text, our panel did not reach agreement on a complete set of circumstances that should be considered to constitute a conflict of interest. But we did have a detailed discussion about the circumstances that might constitute a conflict. To structure that discussion, we debated the hypothetical cases described below. (Some of the hypotheticals are based on actual cases.)

Our panel did not agree on whether to define these cases as examples of conflict of interest or bias, or on whether to exclude the individual described in the case. Notably, though, these were two separate questions. For example, there were a number of members of our group who would describe these cases as “bias” but would nonetheless generally exclude the person with the bias (rather than just balancing their presence). The cases are described below because they should be thought through by any official deciding how to define and handle conflict and bias.

- An individual is a board member, employee or significant stock holder of the company whose product is being reviewed by an advisory committee – or has a similar interest in a competing company. How should company be defined for these cases? Would the limitation be the same if the byproduct of a company's production was being reviewed, esp. if that byproduct was produced by many companies or even industries?
- An individual has received funding from the company to study the particular product under review.
- An individual has received funding to study the particular product under review from a philanthropic entity set up by the company (and that maintains close ties with the company).
- An individual has received research funding from a company that has a direct interest in the results of an advisory committee, but on a different subject – maybe even from a different division of the company. Should that person be excluded? Should it depend on whether the individual has also received funding from the government or others? Should it depend on whether the individual's work has generally or always supported the company's point of view?
- An individual is a board member, employee or stockholder of a company that would be part of a general class of companies affected by a regulation – say, a clean air rule. Should the disqualification still be automatic? Should it matter what division of a company the person is associated with (if an employee)?
- An individual is an employee of a non-governmental organization (NGO) that has taken a position on the issue before the committee.
- An individual is president of a professional society that espouses a position on the issue that is under review.
- An individual is an unpaid board member of an NGO that has taken a position on the issue before the committee. What if the individual is a board member of an environmental group on an issue on which other environmental groups have weighed in?
- An individual is an employee of an NGO and that individual has publicly testified on the matter under review by the committee. Would it make a difference if that testimony occurred during service on the committee?

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- An individual runs a university center that has received funding from a company with a direct interest in the matter under review. Would the same decision apply to someone who was a dean of a college or president of a university that received that funding? Would the same decision apply to a gift from an individual with a clearly held view – either on the specific issue or ideologically? [Do such items even require disclosure?]
 - An individual is affiliated with (but does not head) a university center that has received funding from a company with a direct interest in the matter under review. What if the person were a professor in a college or university that received such funding?
 - An individual received funding from a federal agency that has an interest in the outcome of a review (as a regulated entity).
 - An individual has consulted for a company that has a direct interest in the matter under review. How close does the consultation have to be related to the matter at hand? Does it matter if the consultation was arranged through a contractor that was helping to defend a company's product?
 - An individual has a consulting contract with a firm whose other clients include a company with a matter under review by an advisory committee.
 - An individual was paid for lectures by a company with a product under review. Does it matter how directly the lectures promoted the product?
 - An individual is a member of a political or policy advocacy group that has taken a strong stand on the issue in question.

APPENDIX 2

Comparison of conflict of interest policies – selected institutions¹

	National Endowment for Democracy Founded 1983/84	International Democracy Foundation 1990/91	Open Society Foundations 1990/91	Open Society Foundations 1990/91	Open Society Foundations 1990/91
Conflict of interest policy	"The National Endowment for Democracy (NED) is a non-profit organization that provides financial support to democratic movements and institutions in newly democratic states. NED's mission is to promote democracy and human rights around the world. NED's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The International Democracy Foundation (IDF) is a non-profit organization that provides financial support to democratic movements and institutions in newly democratic states. IDF's mission is to promote democracy and human rights around the world. IDF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The Open Society Foundations (OSF) are a group of non-profit organizations that provide financial support to democratic movements and institutions in newly democratic states. OSF's mission is to promote democracy and human rights around the world. OSF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The Open Society Foundations (OSF) are a group of non-profit organizations that provide financial support to democratic movements and institutions in newly democratic states. OSF's mission is to promote democracy and human rights around the world. OSF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The Open Society Foundations (OSF) are a group of non-profit organizations that provide financial support to democratic movements and institutions in newly democratic states. OSF's mission is to promote democracy and human rights around the world. OSF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."
Conflict of interest policy	"The National Endowment for Democracy (NED) is a non-profit organization that provides financial support to democratic movements and institutions in newly democratic states. NED's mission is to promote democracy and human rights around the world. NED's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The International Democracy Foundation (IDF) is a non-profit organization that provides financial support to democratic movements and institutions in newly democratic states. IDF's mission is to promote democracy and human rights around the world. IDF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The Open Society Foundations (OSF) are a group of non-profit organizations that provide financial support to democratic movements and institutions in newly democratic states. OSF's mission is to promote democracy and human rights around the world. OSF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The Open Society Foundations (OSF) are a group of non-profit organizations that provide financial support to democratic movements and institutions in newly democratic states. OSF's mission is to promote democracy and human rights around the world. OSF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."	"The Open Society Foundations (OSF) are a group of non-profit organizations that provide financial support to democratic movements and institutions in newly democratic states. OSF's mission is to promote democracy and human rights around the world. OSF's policies are designed to ensure that its funds are used for the benefit of the people of the countries it supports, and that its staff and board members do not have any conflicts of interest that could compromise the integrity of its work."

¹ This table was created by the project staff in January, 2008 to assist the panel in its discussions of disclosure, conflict of interest, and bias.

Part of Business Description	Harvest/Admission Wards (2013)	International Agency for Protection of Cancer (IARC) (2013)	Food and Drug Administration (FDA) (2013)	Environmental Protection Agency (EPA) (2013)	National Institute of Health (NIH) (2013)
Part of Business Description		<p>Respiratory system cancer, including lung cancer, is the leading cause of cancer death in the United States. The incidence of lung cancer has increased significantly in the past few decades, and is expected to continue to rise. The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p> <p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>Any agent or activity that is known to cause cancer is classified as a "known human carcinogen." The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p> <p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>Respiratory system cancer, including lung cancer, is the leading cause of cancer death in the United States. The incidence of lung cancer has increased significantly in the past few decades, and is expected to continue to rise. The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p>
Part of Business Description		<p>Respiratory system cancer, including lung cancer, is the leading cause of cancer death in the United States. The incidence of lung cancer has increased significantly in the past few decades, and is expected to continue to rise. The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p> <p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>Any agent or activity that is known to cause cancer is classified as a "known human carcinogen." The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p> <p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>Respiratory system cancer, including lung cancer, is the leading cause of cancer death in the United States. The incidence of lung cancer has increased significantly in the past few decades, and is expected to continue to rise. The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p>
Part of Business Description		<p>Respiratory system cancer, including lung cancer, is the leading cause of cancer death in the United States. The incidence of lung cancer has increased significantly in the past few decades, and is expected to continue to rise. The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p> <p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>Any agent or activity that is known to cause cancer is classified as a "known human carcinogen." The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p> <p>The leading cause of death from lung cancer is respiratory failure. Other causes of death include heart disease, stroke, and infection. Lung cancer is a leading cause of death among men and women in the United States.</p>	<p>Respiratory system cancer, including lung cancer, is the leading cause of cancer death in the United States. The incidence of lung cancer has increased significantly in the past few decades, and is expected to continue to rise. The leading cause of lung cancer is cigarette smoking, which accounts for about 85% of all cases. Other causes include radon exposure, air pollution, and asbestos exposure.</p>

[illegible]

National Institute of Health Office of Biomedical Research (NIBR)	Department of Population Agency for International Development (USAID)	Food and Drug Administration (FDA)	International Agency for Cancer Research (IARC)	National Institutes of Health (NIH)
<p>The purpose of this report is to provide information to the public regarding the progress of research on the causes of cancer and the potential for prevention and control. The report is intended to be a general overview of the current state of knowledge and to provide information on the progress of research in this field. The report is not intended to provide a detailed review of the literature or to provide information on the progress of research in this field.</p>	<p>The purpose of this report is to provide information to the public regarding the progress of research on the causes of cancer and the potential for prevention and control. The report is intended to be a general overview of the current state of knowledge and to provide information on the progress of research in this field. The report is not intended to provide a detailed review of the literature or to provide information on the progress of research in this field.</p>	<p>The purpose of this report is to provide information to the public regarding the progress of research on the causes of cancer and the potential for prevention and control. The report is intended to be a general overview of the current state of knowledge and to provide information on the progress of research in this field. The report is not intended to provide a detailed review of the literature or to provide information on the progress of research in this field.</p>	<p>The purpose of this report is to provide information to the public regarding the progress of research on the causes of cancer and the potential for prevention and control. The report is intended to be a general overview of the current state of knowledge and to provide information on the progress of research in this field. The report is not intended to provide a detailed review of the literature or to provide information on the progress of research in this field.</p>	<p>The purpose of this report is to provide information to the public regarding the progress of research on the causes of cancer and the potential for prevention and control. The report is intended to be a general overview of the current state of knowledge and to provide information on the progress of research in this field. The report is not intended to provide a detailed review of the literature or to provide information on the progress of research in this field.</p>

National Institutes of Health Office of Extramural Research CIRRI	Food and Drug Administration FDA Center for Drug Evaluation and Research CDER	Environmental Protection Agency EPA Office of Research and Development ORD	National Science Foundation NSF Division of Biological Sciences DBS	Department of Energy DOE Office of Biological and Environmental Research BER
<p>Research on the molecular basis of human disease, including the identification of genes and proteins involved in disease, and the development of new drugs and therapies to treat disease.</p>	<p>Research on the molecular basis of human disease, including the identification of genes and proteins involved in disease, and the development of new drugs and therapies to treat disease.</p>	<p>Research on the molecular basis of human disease, including the identification of genes and proteins involved in disease, and the development of new drugs and therapies to treat disease.</p>	<p>Research on the molecular basis of human disease, including the identification of genes and proteins involved in disease, and the development of new drugs and therapies to treat disease.</p>	<p>Research on the molecular basis of human disease, including the identification of genes and proteins involved in disease, and the development of new drugs and therapies to treat disease.</p>

Comparison of conflict of interest policies – selected journals*¹

* The Journals participating in ICMJE include JAMA, BMJ, and New England Journal of Medicine.
 † This table was created by project staff in January, 2009 to assist the panel in its discussions of disclosure, conflict of interest, and bias.

Journal of Clinical Investigation	Abstract of the Association Abstracts	Summary	How Reported Amount of Discharge (days)	Actual or Estimated (days)	Association of Discharge with (days)
<p>Abstract The role of physical medicine in clinical practice is being re-evaluated. The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>
<p>Abstract The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>	<p>The purpose of this study was to determine the role of physical medicine in the management of patients with chronic conditions. The study was conducted in a tertiary care hospital. The results of the study are presented in this abstract.</p> <p>Keywords: Physical medicine, chronic conditions, tertiary care hospital.</p>

Journal of Clinical Pharmacology (1980-1985)	Journal of the American Medical Association (1986-1990)	Pharmaceutical Research (1991-1995)	Pharmaceutical Research (1996-2000)	Pharmaceutical Research (2001-2005)	Pharmaceutical Research (2006-2010)	Pharmaceutical Research (2011-2015)	Pharmaceutical Research (2016-2020)	Pharmaceutical Research (2021-2025)	Pharmaceutical Research (2026-2030)
<p>The Journal of Clinical Pharmacology is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>The Journal of the American Medical Association (JAMA) is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical medicine. It is published by the American Medical Association (AMA).</p> <p>JAMA is one of the most influential medical journals in the world. It is read by a wide range of clinicians and researchers and is a leading journal in the field of clinical medicine.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>	<p>Pharmaceutical Research is a peer-reviewed journal that publishes original research, clinical trials, and reviews of clinical pharmacology. It is published by the American College of Clinical Pharmacology (ACCP).</p> <p>The journal is known for its high-quality research and its focus on clinical pharmacology. It is a leading journal in the field and is read by a wide range of clinicians and researchers.</p>

3

Chapter Three

RECOMMENDATION THREE: Agencies and their scientific advisory committees should cast a wide net in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent.

It is a commonplace to argue that regulation should be based on the “best available science,” but determining what constitutes the best available science in any specific instance is no easy task. Assembling and evaluating the relevant scientific literature is a complex undertaking, not subject to any single, simple formula. That said, some basic principles should guide agencies and their scientific advisory committees as they sift the scientific literature. It should be Administration policy that agencies adhere to these principles.

Transparency

First, **the process of conducting literature reviews should become more transparent.** Agencies and their scientific advisory committees should be explicit about the criteria they are using to determine which scientific papers to review and how those papers are being evaluated. Those criteria should be open for public comment either as part of the comment period on a proposed rule or, when possible, earlier in the rulemaking process.

In addition, once an agency has opened a docket on a rule or guidance that will draw on scientific studies, it should make available on the Web a list of the studies it is reviewing and should regularly

update the list.¹ The list should be open for public comment both to help evaluate the studies on the list and to help identify any relevant studies that are being omitted. When a rule based on scientific studies is proposed, agencies should make clear in the *Federal Register* notice which studies were particularly influential and why.² Agencies should require their scientific advisory committees to do the same in their final reports.

Criteria

While the specific criteria an agency or scientific advisory committee uses to evaluate scientific studies may vary from issue to issue, the criteria should always be consistent with the principles below.

In general, papers in high impact, peer reviewed journals should be given great weight, and papers that have not been peer reviewed should be treated with skepticism. However, the quality of peer review varies widely, and journal rankings and impact factors do not guarantee that peer review of

¹ Agencies should monitor the impact of making this information available to see if it is improving the regulatory process.

² In some cases, the influential studies will be cited and discussed in a supporting technical document such as a risk assessment or an engineering study. Even in such instances, the *Federal Register* notice should cite the key studies.

a specific paper was performed adequately. **Agencies and scientific advisory committees need to extend their inquiry beyond simply ascertaining whether a paper was peer reviewed; peer review is a necessary but not sufficient determinant of quality.** That further inquiry might explore how the peer review was conducted, how the paper fits into the larger body of literature under review, and perhaps most important, the methodology behind the conclusions described in the paper (for example, how a cohort to study was chosen in an epidemiological study).

In general, agencies and scientific advisory committees should be wary of studies when it is unclear who funded the study or whether the principal investigator(s) had any conflicts of interest.

Conversely, studies that have not been peer reviewed should not be summarily rejected if they appear to contribute to the inquiry. Agencies and scientific advisory committees should be able to commission their own peer reviews (or in some cases, the scientific advisory committee itself might be assigned, or take on peer review of a study as a formal task). Agencies need sufficient funding and need to set realistic schedules to allow for such reviews.

(Chapter 4 discusses ways in which the federal government, as well as scientists and scientific journals could improve the peer review process.)

In general, agencies and scientific advisory committees should be wary of studies when it is unclear who funded the study or whether the principal investigator(s) had any conflicts of

interest.³ Agencies and scientific advisory committees can seek this information if it is not made public as part of the paper itself.⁴ Agencies and scientific advisory committees should consider sources of funding and any conflicts of interest as they review the reasons why a study may have been undertaken, the way a study was framed and carried out, and how the study results have been interpreted and discussed. In general, no studies should be excluded *a priori* because of the type of funding behind them.⁵ The focus should be on the study itself.

Beyond general concerns about funding and conflicts of interest, **agencies and scientific advisory committees should be extremely skeptical of a scientific study unless they are sure that the principal investigator(s) (as opposed to the sponsor or funder) had ultimate control over the design and publication of the study.**

In fields where a public registry of studies exists (such as the registry established by the Food and Drug Administration Modernization Act of 1997), agencies and scientific advisory committees should consider the relevant registered studies and should be wary of studies that met the criteria for the registry, but were not registered. Among the reasons to consult a registry is that a registry is more likely than the published literature to include reports of negative results (i.e., of instances where a study failed to confirm

³ Our panel did not discuss how to define "conflict of interest" for the authors of scientific papers. More thought needs to be given as to whether definitions of "conflict of interest" for service on scientific advisory committees (including those used by the National Academy of Sciences) would be fully relevant and complete if applied to authors of original scientific papers and review papers.

⁴ For studies performed years or decades in the past, it may be difficult to obtain information about the funding of a study and to discern whether conflicts existed. In the future, if the disclosure practices this report recommends become more widespread, agencies and scientific advisory committees will be better able to identify conflicts.

⁵ Eliminating whole categories of studies raises practical as well as philosophical issues. For example, for questions involving new types of technologies or materials (e.g., nanotechnology), most of the available studies are likely to have been funded by the industries that are developing new products.

an expected effect). Negative results need to be taken into account even when they are not peer reviewed (with the cautions mentioned above); they are less likely to be peer reviewed because journals are often reluctant to publish such studies.

There is no simple way to lay out generic rules for literature reviews – every body of literature and every field has its idiosyncrasies – but the principles above should offer some overarching guidance. In short, a good literature review strives to develop a sense of the entire body of relevant literature; evaluates the methods that were used in studies; digs, when necessary, beyond the published material, to get a better sense of methods and data; and is aware of the sources of funding and the extent of sponsor control over studies. Or, put another way, a good literature review is an exercise in comparing studies, looking first at the thrust of a body of literature and how broadly and well founded its conclusions are, then examining any well done studies that may be taking issue with the literature, and then reviewing what might be categorized as exploratory studies – studies that may relate to the question under consideration but were not carried out for that purpose.

Data availability

As noted above, literature reviews are enhanced when more information is available on the methods and data on which studies' conclusions are based. Scientists themselves and scientific journals could take steps to facilitate access to methods and data, as will be discussed in the next chapter. But the government also could increase the availability of information on methods and data.⁶

Studies used in the formulation of regulation should be subject to data access requirements

equivalent to those under the Data Access Act (Shelby Amendment)⁷ and its implementing circular⁸ regardless of who funded the study. If a study is used by an agency to inform the development of a regulation, then the same kinds of information about that study should be available upon request, regardless of whether the study was funded by the federal government, industry, or some other entity.

Confidential Business Information (CBI) claims can also make it difficult for the interested public to evaluate studies that contribute to regulatory policy.

CBI is a legitimate and needed designation for information submitted to the federal government, but it appears to be overused today. There is great incentive for companies to claim CBI (i.e., why not err on the side of caution and secrecy?) even though that may be counter-balanced by a desire to earn the trust of regulators by being open about their scientific data. **The Administration and the Congress should gather data on the extent and nature of CBI claims. The Administration and Congress should consider requiring each new CBI claim to include a brief, but substantive justification for the claim.** Congress should also review the CBI provisions of specific statutes as they come up for reauthorization.

Additional studies

The recommendations in this report thus far, though, may not always be enough to resolve a regulatory question or to gain public faith in a regulatory process. Sometimes, a literature review will make clear the need for additional studies to address a dispute, but an agency will be seen as having too great a stake in the outcome to commission such work itself. Or sometimes an agency may not be trusted to appoint a balanced scientific

⁶ Our panel did not discuss the Information Quality Act (P.L. 106–554, Section 515) or the regulations issued pursuant to it.

⁷ P.L. 105–277.

⁸ OMB Circular A-110.

advisory committee, or the complexity of doing so might strain its resources. In the latter case, an agency could turn to the National Academy of Sciences, but agencies may want to consider creating other avenues, especially if settling a controversy requires additional studies, not just a review of the existing literature.

In the area of clean air policy, the Health Effects Institute (HEI), established in 1980 and jointly funded by industry and government, has established a reputation as an honest broker with trusted scientific expertise to help the Environmental Protection Agency when it runs into the kinds of issues mentioned in the previous paragraph. HEI has clear and strict procedures for commissioning and reviewing studies that have enabled it to be seen by all sides in clean air disputes as an unbiased authority.³

Agencies should experiment with a variety of additional approaches that would enable them to commission studies and literature reviews related to pending regulatory decisions that would be widely seen as unbiased. For example, agencies might want to consider setting up their own equivalents of HEI, or they might want to consider giving either standing or *ad hoc* scientific advisory committees the ability (and the budget) to commission additional studies. They might also turn to another federal entity that would not be considered to have a stake in the outcome of the issue. Regulatory agencies have sometimes turned to the National Institute of Environmental Health Sciences for this purpose, for example.

Agencies should also encourage creative mechanisms by which scientists from industry, government, academia and non-governmental organizations can design experiments, collaborate on studies, and co-author scientific papers for publication in the open literature. In addition to advancing scientific knowledge, these multi-sector collaborations may work to build trust.

Presenting conclusions

In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty. Deciding how much risk and what kinds of risk society should tolerate is a policy decision, as is determining whether and how to act in the face of scientific uncertainty. Those values questions need to be debated fully and openly. What agency scientists and scientific advisory committees need to do to inform that debate is provide clear scientific information about what the risks appear to be and how definitive the current scientific literature is about the existence and levels of those risks.

Policy makers should be wary of conclusions about risk that are expressed as a single number. Rather, risk should be expressed as a range, with different scenarios and assumptions for different risk levels, including their relative likelihoods, spelled out. The population distribution of risks should be spelled out when such information is available and relevant. Also, terms that are applied to levels of risk (e.g., "probable" or "possible") need to be defined precisely, i.e. quantitatively. Legal terms need to be translated into scientific ranges and vice-versa. The same is true for the terminology used to describe uncertainty.

If agency scientists or a scientific advisory panel concludes that a range of concentrations is safe for humans, animals or plants, it should be clear about the levels of uncertainty and risk at different levels within that range.

³ More information on HEI can be seen at www.healtheffects.org. Daniel Greenbaum, the president of HEI, is a member of this panel, but did not originate the proposals concerning HEI. HEI is often cited in the policy literature as a model for resolving scientific issues related to regulatory policy. See, for example, John D. Graham (ed.), *Harnessing Science for Environmental Regulation* (Westport, NC: Praeger, 1991) and Sheila Jasanoff, *The Fifth Branch* (Cambridge: Harvard University Press, 1990).

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Chapter Four

RECOMMENDATION FOUR: The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest.

This report has focused on steps the federal government needs to take to clarify and improve its own processes for injecting science into the regulatory process. But the federal regulatory process draws on the larger ecology (and economy) of the scientific enterprise and can only improve to the extent that the overall enterprise is functioning well. It will be more difficult for the federal government to achieve the improvements called for in our earlier chapters unless the other actors in the scientific enterprise also rise to the occasion.

Peer review

Peer review is the primary guarantor of integrity in the scientific system. It has inherent limitations, as do all human processes, but without it, the scientific enterprise would have diminished quality and credibility. In recent years, there has been growing concern that the peer review system may be eroding. Scientists may feel too burdened to review their colleagues' papers or may do so with insufficient care. Peer review is no longer assumed to be a professional obligation, and the institutions that rely on peer review mostly do too little to underscore its value. Moreover,

there has been little experimentation or empirical study about how to make it more effective.

Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review, particularly peer review of draft manuscripts. Possible steps that could be tried run the gamut from paying scientific advisory committee members a nominal fee to participate to requiring federal grantees to participate in a minimum number of peer reviews over the life of their grant to qualify for future funding. A middle-ground might be requiring grant applicants to list peer review service on their applications. The government could also encourage or require universities that receive federal grants to demonstrate that they were creating incentives for their faculty to participate as peer reviewers. It might help even just to have top federal science officials make clear in their speeches and writings that service as a peer reviewer is an expected aspect of a scientific career. Agencies should also ensure that their own scientists serve as peer reviewers. The Office of Science and Technology Policy could direct federal agencies to experiment with ways to increase participation in peer review, and then evaluate which experiments turn out to be most successful.

Universities should do more to make service as a peer reviewer an expected and appreciated aspect of a scientist's career. Faculty should be encouraged to participate in peer review by both their colleagues and administrators. Service as a peer reviewer should

Peer review is the primary guarantor of integrity in the scientific system.

be rewarded in tenure, promotion and salary decisions. Graduate students, post-doctoral researchers, and even faculty, particularly junior faculty, should be mentored on how to conduct a creditable peer review.

Scientific journals should improve the quality control of peer review and should experiment with different ways of conducting peer reviews. Journals should try to expand their circle of peer reviewers and should encourage more thorough peer reviews, perhaps by publicly acknowledging top-notch peer reviewers. Journals should give peer reviewers feedback (perhaps from the scientists whose work they reviewed) on the quality of their peer reviews. Journals should consider experiments to determine what produces the best (and in some cases, most transparent) peer reviews, such as publishing peer reviews (with or without the name of the peer reviewer) on the Web or along with the paper being reviewed, publishing lists of peer reviewers annually or in each issue, using open rather than anonymous peer reviews, or going in the other direction and using double-blind peer reviews. Journals should require their peer reviewers to disclose to the journal the information the editors need to determine whether any conflicts of interest exist, and the journal should consider disclosing that information to the article author

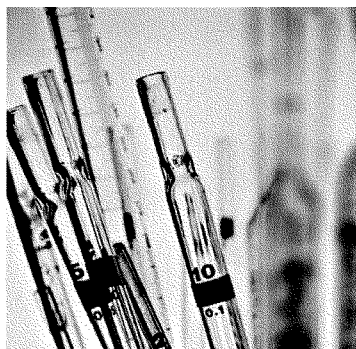
and/or the readership.¹ Also, journals could consider nominally compensating reviewers.

Information on scientific studies

As noted in Chapter 3, to evaluate a study fairly and completely, one needs a full sense of the data generated and the methods employed in the study. Yet this information is often difficult to obtain. That may have been understandable when paper journals were the basic means to communicate scientific information, but in the electronic age, the primary limitation on providing more information is a lack of will. **Federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies.** The extent to which data and methods should be made public will vary by field, as each field has different standards as to what information a scientist can hold close to protect their intellectual property or future work. But enough information should be published on-line in conjunction with journal publication that an interested scientist could fairly evaluate the study results and replicate them, if so desired. Scientists need to understand that if they wish their studies to be relied upon by federal regulators, those studies must have a high degree of transparency about data and analytic methods.

Also as noted in Chapter 3, registries can help make information on a field of research more complete and accessible. **Federal agencies should determine whether the idea of research registries, which today is focused on research related to pharmaceuticals, can be expanded to other fields.** The nature of clinical trial research and its link to federal regulation may well be unique, but there may be other fields

¹ As noted in Chapter 3, more thought needs to be given to how conflict of interest should be defined for authors of papers.



with enough similarities to experiment with variations on registries. At the very least, agencies could make it easier to find the results of any study that was federally funded by, for example, having a searchable database of reports on what research was performed with grant money. A model might be the EPA STAR (Science to Achieve Results) grant program, which maintains on-line versions of the regularly submitted progress reports from projects it is funding, providing a broader inventory of the work underway than is available through the peer reviewed literature. Ideally, such a database would also include intramural research, that is, research that was carried out by federal agencies themselves rather than by grantees.

Conflict of interest

As noted in Chapter 3, the quality of literature reviews depends, in part, on having complete and accurate information on the funding of scientific studies and on any possible conflicts of interest that the scientists conducting a study may have had. Given the value placed on peer review and on the reputations of scientific journals, it is also vital that any conflicts editors may have be disclosed as well. Many journals have tightened their conflict of interest rules in recent years, and they have made some efforts to coordinate their policies. But more could be done. **Journals should have clear, publicly accessible conflict-of-interest policies and should require full disclosure of how studies were funded and of any and all conflicts of interest they determine an author has. Editors should also disclose any of their own conflicts of interest. In addition, journals should consider requiring authors to certify that they had ultimate**

control over the design and publication of the study being described in a paper.

As noted in Chapter 2, universities have also begun to put in place tighter and more consistent rules concerning conflict of interest. Universities need to help create a culture of transparency about funding and need to have clear, accessible and enforced policies on conflict of interest and on ultimate sponsor control. Violating university policies should have real consequences.

Similarly, **federal agencies need to consider promulgating rules that would sanction scientists who run afoul of federal, university or journal requirements concerning disclosure of conflict of interest or ultimate sponsor control.**

Scientists

The recommendations above are directed at institutions both to help create a culture of participation and transparency and to ensure that bad actors are discovered and reprimanded. But a truly healthy scientific enterprise relies on the individual actions and the decisions of each scientist. Scientists themselves, regardless of where they work, need to understand that the future health and credibility of the scientific enterprise depend on individual scientists addressing the concerns raised in this chapter. They need to ensure that they and their colleagues are participating as actively and openly as possible in the entire scientific process from research through publication and are open to involving themselves in the policy process. They should work as well to ensure that their professional societies regularly host sessions at their annual meetings on the importance and conduct of peer review, and consider the establishment of annual awards for particularly significant contributors to peer review in their fields. Scientists cannot expect regulatory policies to be based on the best available science unless they conduct, review, and evaluate that science in a way that garners public trust.

Afterword

Our report does not, and was not intended to deal with every issue that bedevils regulatory policy making, or even the use of science in it. Our panel focused on what we saw as perhaps the most fundamental and least discussed problems in regulatory policy making – the conflation of science and policy questions, and the need for greater transparency in analyzing the science behind policy making.

Among the many questions we did not discuss, but want to acknowledge are: how to strengthen the internal scientific capacity of federal agencies, how to protect whistleblowers, the extent to which the White House (and in particular, the Office of Information and Regulatory Affairs) should review specific regulatory decisions, and what kind of access individual federal scientists should have to the media. These and other questions are important, but other groups have weighed in on them, and we put these matters beyond the purview of our report.

There are two matters, though, that we want to point out that should draw attention from those both inside and outside the government who might wish to follow up on this report.

First, as noted in the report, there is remarkably little empirical data and relatively little discussion in the policy literature of the issues the report covers. Data and research are greatly needed on such questions as: Who is getting appointed to federal advisory committees and how? How many advisory committee members have conflicts of interest (however

defined) and what impact do those conflicts have on committee proceedings? What kinds of committees give the best advice? What kinds of literature reviews are most “successful”? How often do peer reviewed papers prove to have faulty methodologies and how can that be prevented? What peer review systems work best? And so on. More work is also needed on questions related to the central theme of this report – the need to distinguish between scientific and policy questions. How can that be done in specific cases? Where has it been done successfully? What is the impact? What other, broader changes to the political system might enhance the debate about science and regulation? Our panel drew on the considerable and varied personal experience of our members and the policy literature that does exist to develop recommendations that we believe will make a difference. But that old saw of scientific reports is especially valid here: more research is needed. In this case, the research should include monitoring the extent to which our recommendations are implemented and their impact.

Second, this report did not deal directly with one fundamental problem at the intersection of science and policy: the inherent disconnect between the pace at which scientific understanding changes and at which policy action takes place. Sometimes the policy apparatus cannot keep up with the speed of scientific change; in other cases, policy makers seek scientific answers before the research to provide them is ripe. Deeper thinking is needed on the question of how to

continually refresh the scientific understanding that underlies regulatory policy, and how to periodically update that policy as a result – without building in so much instability that industries cannot plan, or so much constant debate that the rulemaking apparatus simply seizes up entirely.

Science and politics are both dynamic systems, and this report will hardly be the last word on the intersection of science and regulatory policy. But we believe it is an important start. We look forward to working with the Administration and the Congress to implement our recommendations.

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Panel Member and Staff Biographies

Members

SHERWOOD BOEHLERT (CO-CHAIR)

Former Congressman Sherwood Boehlert (R-NY) represented Central New York State in the U.S. House of Representatives for 12 terms, ending in 2006. He served on the House Science Committee for his entire Congressional career and in 2001 was elected its Chairman. In addition, he was third-ranking member of the House Transportation and Infrastructure Committee. From 1995 to 2000 he served as Chairman of the Subcommittee on Water Resources and Environment. Boehlert was also a long-time member of the House Permanent Select Committee on Intelligence and a founding member of the House Select Committee on Homeland Security. *Congressional Quarterly* named him one of the 50 Most Effective Lawmakers on Capitol Hill; *National Journal* dubbed the long-time environmental leader "The Green Hornet," and *Time* magazine cited him as a go-to "power center" in the House. In 2007, Boehlert joined The Accord Group, where he is Of Counsel. Additionally, the former lawmaker serves with former Rep. Martin Sabo, former Sen. Slade Gordon, and former Detroit Mayor Dennis Archer as Co-chair of the Bipartisan Policy Center's Transportation Project for the 21st century. Boehlert is a Board Member of a number of national organizations, including the Alliance for Climate Protection; the Heinz Center for Science, Economics and the Environment; the League of Conservation Voters; the Health Effects Institute and the Natural Resources Defense Council Action Fund.

DONALD KENNEDY (CO-CHAIR)

Donald Kennedy is the former editor-in-chief of *Science*, the journal of the American Association for the Advancement of Science, and a senior fellow of the Woods Institute for the Environment at Stanford University. His present research program entails policy on such trans-boundary environmental problems as: major land-use changes; economically-driven alterations in agricultural practice; global climate change; and the development of regulatory policies. Dr. Kennedy has served on the faculty of Stanford University since 1960. From 1980 to 1992 he served as President of Stanford University. He was Commissioner of the U.S. Food and Drug Administration from 1977-79. Previously at Stanford, he was Director of the Program in Human Biology from 1973-77 and Chair of the Department of Biology from 1964-72. Kennedy is a member of the National Academy of Sciences, the American Academy of Arts and Sciences, and the American Philosophical Society. He served on the National Commission for Public Service and the Carnegie Commission on Science, Technology and Government, and as a founding Director of the Health Effects Institute. He currently serves as a Director of the Carnegie Endowment for International Peace, and as Co-chair of the National Academies' Project on Science, Technology and Law.

ARTHUR CAPLAN

Arthur Caplan is the Emanuel and Robert Hart Professor of Bioethics, Chair of the Department of Medical Ethics and the Director of the Center for Bioethics at the

University of Pennsylvania. Prior to coming to Penn in 1994, Dr. Caplan taught at the University of Minnesota, the University of Pittsburgh, and Columbia University. He was the Associate Director of the Hastings Center from 1984-87. Dr. Caplan is the author or editor of 25 books and over 500 papers in refereed journals of medicine, science, philosophy, bioethics and health policy. His most recent book is *Smart Mice Not So Smart People* (Rowman Littlefield, 2006). He has served on many national and international committees including as the Chair of the National Cancer Institute Biobanking Ethics Working Group, the Chair of the Advisory Committee to the United Nations on Human Cloning, the Chair of the Advisory Committee to the Department of Health and Human Services on Blood Safety and Availability, and a member of the Presidential Advisory Committee on Gulf War Illnesses. He is a member of the Board of Directors of The Keystone Center, Tengion, the National Center for Policy Research on Women and Families, Octagon, the Iron Disorders Foundation, and the National Disease Research Interchange. He writes a regular column on bioethics for MSNBC.com. Dr. Caplan is the recipient of many awards and honors including the McGovern Medal of the American Medical Writers Association, Person of the Year-2001 from *USA Today*, one of the 50 most influential people in American health care by *Modern Health Care* magazine, one of the 10 most influential people in America in biotechnology by the *National Journal* and one of the ten most influential people in the ethics of biotechnology over the past ten years by the editors of the journal *Nature Biotechnology*.

LINDA J. FISHER

Linda J. Fisher is Vice President and Chief Sustainability Officer at E. I. du Pont de Nemours and Company. She has responsibility for advancing DuPont's progress in achieving sustainable growth, DuPont's environmental and health programs, the company's product stewardship programs, global regulatory

affairs, and government affairs. She joined DuPont in 2004. Prior to that, Fisher served in a number of key leadership positions in government and industry including: Deputy Administrator of the Environmental Protection Agency (EPA) from 2001-03; EPA Assistant Administrator - Office of Prevention, Pesticides and Toxic Substances; EPA Assistant Administrator - Office of Policy, Planning and Evaluation; and Chief of Staff to the EPA Administrator. Fisher, an attorney, was also Vice President of Government Affairs for Monsanto and was Of Counsel with the law firm Latham & Watkins. She is a member of the DuPont Health Advisory Board and the DuPont Biotechnology Advisory Panel and serves as liaison to the Environmental Policy Committee of the DuPont Board of Directors. Fisher serves on the Board of Directors of the Environmental Law Institute, on the Board of Trustees of The National Parks Foundation, on the Board of Directors of Resources for the Future, and on the Board of Covanta Holdings.

LYNN R. GOLDMAN

Lynn R. Goldman, a pediatrician and epidemiologist, is Professor in the Department of Environmental Health Sciences at the Johns Hopkins University Bloomberg School of Public Health. Her areas of focus are public health practice, children's environmental health, disaster preparedness, and chemical and pesticide regulatory policy. Dr. Goldman is Principal Investigator for the Hopkins National Children's Study Center and co-PI of the Center for Preparedness and Catastrophic Event Response (PACER). As Assistant Administrator for Toxic Substances at EPA, she directed the Office of Prevention, Pesticides and Toxic Substances from 1993 through 1998. Prior to joining EPA, Dr. Goldman served as Chief of the Division of Environmental and Occupational Disease Control of the California Department of Health Services. Dr. Goldman has served on numerous boards and expert committees, including the Committee on Environmental Health of

the American Academy of Pediatrics and the Centers for Disease Control Lead Poisoning Prevention Advisory Committee. Dr. Goldman is a member of the Institute of Medicine, Vice Chairman of the Institute of Medicine Roundtable on Environmental Health Sciences, and a member of the National Academy of Sciences Standing Committee on Risk Analysis Issues and Reviews.

JOHN D. GRAHAM

John D. Graham is Dean of the Indiana University School of Public and Environmental Affairs (SPEA). His research interests include government reform, energy and the environment, and the future of the automobile in both developed and developing countries. He came to SPEA after serving as Dean of the Frederick Pardee RAND Graduate School at the RAND Corporation in California. Prior to joining RAND, Dr. Graham served in the White House Office of Management and Budget (OMB) from 2001-06. As the Senate-confirmed Administrator of the Office of Information and Regulatory Affairs, he led a staff of 50 career policy analysts who reviewed major regulatory proposals from Cabinet agencies. Prior to his role at OMB, Dr. Graham was a Professor of Policy and Decision Sciences at the Harvard School of Public Health. From 1990 to 2001, Dr. Graham founded and led the Harvard Center for Risk Analysis. In 1995, he was elected President of the Society for Risk Analysis, an international membership organization of 2,400 scientists and engineers.

DANIEL GREENBAUM

Dan Greenbaum joined the Health Effects Institute (HEI) as its President and Chief Executive Officer in 1994. In that role, Greenbaum leads HEI's efforts, supported jointly by the EPA and industry, with additional funding from the Department of Energy, Federal Highway Administration, U.S. Agency for International Development, the Asian Development

Bank, and foundations, to provide public and private decision makers with high quality, impartial, relevant and credible science about the health effects of air pollution. Greenbaum has focused HEI's efforts on providing timely and critical research and reanalysis on particulate matter, air toxics, diesel exhaust and alternative technologies and fuels. Greenbaum currently serves on the U.S. National Research Council (NRC) Committee on Health, Environmental, and Other External Costs and Benefits of Energy Production and Consumption. He has been a member of the NRC Board of Environmental Studies and Toxicology and Vice Chair of its Committee for Air Quality Management in the United States. Greenbaum also chaired the EPA Blue Ribbon Panel on Oxygenates in Gasoline, which issued the report "Achieving Clean Air and Clean Water" and EPA's Clean Diesel Independent Review Panel, which reviewed technology progress in implementing the 2007 Highway Diesel Rule. Before coming to HEI, he was Commissioner of Environmental Protection in Massachusetts.

MICHAEL P. HOLSAPPLE

Michael P. Holsapple is the Executive Director of the International Life Sciences Institute's Health and Environmental Sciences Institute (HESI) in Washington, D.C. Dr. Holsapple has published over 150 manuscripts and chapters. After completing two years of postdoctoral work at the Medical College of Virginia/Virginia Commonwealth University, he was appointed an Assistant Professor in the Department of Pharmacology and Toxicology. He was tenured and promoted to Associate Professor in 1989. Dr. Holsapple served as the Director of his department's graduate program from 1987 until 1991, and he received the "Professor of the Year Award" in his department in 1989. Dr. Holsapple joined the Toxicology, Environmental Research and Consulting Laboratories at the Dow Chemical Company in 1994 and was promoted to

Scientist in 2000. His responsibilities included serving as the Technical Leader of both the Immunotoxicology and the Respiratory Toxicology Groups. Dr. Holsapple left Dow in 2002 to join the HESI staff. Dr. Holsapple is currently an Adjunct Professor in the Department of Pharmacology and Toxicology at Michigan State University. He is a member of the American College of Toxicology and the Society of Toxicology (SOT). He is a charter member of the Immunotoxicology Specialty Section in the SOT. In recognition of his contributions to toxicology, Dr. Holsapple received the SOT Achievement Award in 1992. Dr. Holsapple became the Vice President-elect of SOT in 2008.

KEVIN KNOBLOCH

Kevin Knobloch is the President of the Union of Concerned Scientists (UCS). Knobloch first worked at UCS from 1989 to 1992 as Legislative Director for Arms Control and National Security. He returned in January 2000 and was named President in December 2003. He oversees the organization's research, public education, and legislative programs. Knobloch recently served as Chair of the Green Group, a coalition of the CEOs of 34 national environmental organizations, and currently serves as Co-chair of the Green Group Climate and Energy Committee. He led UCS delegations to the United Nations International Climate negotiations in Montreal in 2005 and in Bali in 2007. In addition to his positions at UCS, he served as Director of Conservation Programs for the Appalachian Mountain Club in Boston. During six years on Capitol Hill, he was the Legislative Director for U.S. Senator Timothy Wirth (D-CO) and Legislative Assistant and Press Secretary for U.S. Representative Ted Weiss (D-NY). He began his career as an award-winning newspaper journalist, writing for several Massachusetts publications. He recently completed eight years on the Board of Directors of the Coalition for Environmentally Responsible Economies and serves on the Environmental League of

Massachusetts Board of Directors. He is also co-founder and former President of the Arlington (MA) Land Trust.

KENNETH OLDEN

Kenneth Olden has been the Founding and Acting Dean of the proposed School of Public Health at the City University of New York since 2008. Dr. Olden is a cell biologist and biochemist by training, and has been active in cancer research for over three decades. From 1979 to 1991, Dr. Olden worked at Howard University in several roles, ultimately as Director of the Howard University Cancer Center and Chairman of the Department of Oncology. From 1991 to 2005, Dr. Olden was Director of the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program, with a concurrent scientific post as Chief of the Metastasis Section of the NIEHS Environmental Carcinogenesis Program. Dr. Olden has maintained his research interests throughout his administrative career. Much of his work has focused on the role of glycoproteins in cancer. Working with Ken Yamada and others at the National Cancer Institute, he studied the glycoprotein fibronectin, and its possible role in inhibiting metastasis.

ROGER A. PIELKE, JR.

Roger A. Pielke, Jr. has been on the faculty of the University of Colorado since 2001 and is a Professor in the Environmental Studies Program and a Fellow of the Cooperative Institute for Research in Environmental Sciences (CIRES). At CIRES, Dr. Pielke served as the Director of the Center for Science and Technology Policy Research from 2001-07. His research focuses on the intersection of science and technology and decision making. In 2006, Dr. Pielke received the Eduard Brückner Prize in Munich, Germany for outstanding achievement in interdisciplinary climate research. Before joining the University of Colorado, from 1993-

2001, he was a Scientist at the National Center for Atmospheric Research. Dr. Pielke is an Associate Fellow of the James Martin Institute for Science and Civilization at Oxford University's Said Business School. He is also a 2008 Fellow of the Breakthrough Institute. He is also author, co-author or co-editor of five books. His most recent book is *The Honest Broker: Making Sense of Science in Policy and Politics*.

SHERRI K. STUEWER

Sherri Stuewer is Vice President – Safety, Health and Environment for Exxon Mobil Corporation. In that role she is responsible for developing, reviewing, and coordinating Exxon Mobil's worldwide efforts concerning the environment, safety, and health. Prior to her current position, Stuewer was Strategic Planning Manager for Exxon Mobil, General Manager of the Exxon Company U.S.A. supply department, and Manager of the Exxon refinery in Baytown, Texas. Over her 33-year career with Exxon Mobil, she has held a variety of technical and managerial positions in refining, planning, and logistics. Stuewer is a member of the Board of Trustees and the Engineering College Council at Cornell University. She is also a Board Member of the YMCA of Metropolitan Dallas and the Bermuda Institute of Ocean Sciences. She is a past Chair of the Industry Advisory Board to the International Energy Agency.

WENDY E. WAGNER

Wendy E. Wagner is the Joe A. Worsham Centennial Professor at the University of Texas School of Law and recently joined the Case Law School faculty as a Professor through a joint, half-time arrangement with the University of Texas. Prior to joining the University of Texas Law faculty, Wagner was a Professor at the Case Western Reserve University School of Law and School of Management, and was a Visiting Professor at the Columbia Law School and the Vanderbilt Law School.

She writes primarily in the area of environmental law and science, exploring the ways that science is used and misused in decision-making by the courts, Congress, and the agencies. Wagner has participated as an officer or committee member in a number of professional societies, including several sections of the American Bar Association, the Society for Risk Analysis, the National Conference of Lawyers and Scientists, and has served on several National Academy of Sciences committees. Wagner began her legal career in 1987, when she served as a law clerk for the Honorable Albert Engel, the Chief Judge of the U.S. Court of Appeals, Sixth Circuit, in Grand Rapids, Michigan. She then served as an Honors Attorney at the Environmental Enforcement Section of the Environment Division at the Department of Justice in Washington, D.C. Wagner then moved to the General Counsel Office of the Department of Agriculture (USDA) in 1991 where she served as the Pollution Control Coordinator and established a central office, with six satellite legal offices, to manage and advise USDA agencies on compliance under the pollution control laws.

Staff

DAVID GOLDSTON

David Goldston served as Chief of Staff of the House Committee on Science from 2001 through 2006, the culmination of more than 20 years on Capitol Hill working primarily on science policy and environmental policy. Since retiring from the Congressional staff, Goldston has been a Visiting Lecturer at Princeton University's Woodrow Wilson School of Public and International Affairs and at the Harvard University Center for the Environment. He writes a monthly column for *Nature* on science policy titled "Party of One." He serves on the National Academy of Sciences' Aeronautics and Space Engineering Board and on a panel of the Academy's Committee on National

Statistics. He Co-chaired an American Physical Society study on energy efficiency and has served on panels producing reports under the auspices of the American Academy of Arts and Sciences and OMB Watch.

JOSH TRAPANI

Josh Trapani joined the staff of the Bipartisan Policy Center in 2008. Previously, he was an American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellow on the Policy Analysis staff within the Research & Development Deputy Area, U.S. Forest Service, where his work focused on climate change adaptation and mitigation. Prior to that, Dr. Trapani was the American Geophysical Union's Congressional Fellow, working for Senator Dianne Feinstein (D-CA) on public lands, climate change, and other science issues. Dr. Trapani also holds a Research Collaborator position with the Department of Paleobiology at the Smithsonian Institution. Trained as a geoscientist, his research took him to sites throughout the United States as well as to Coahuila, Mexico and the Omo Valley of Ethiopia. He has published a dozen peer-reviewed papers, as well as essays on science and policy.



BPC Science for Policy Interim Report: Improving the Use of Science in Regulatory Policy March 10, 2009

The use of science in the formulation of regulatory policy – by both the Executive Branch and the Congress – has become a political flashpoint in recent decades. Policy makers often claim that particular regulatory decisions have been driven by, or even required by, science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being “politicized” and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.

These problems are largely systemic; they will not magically vanish with a change of Administrations or a shift in the composition of the Congress. But the advent of a new Administration and a new Congress is an opportune time to take stock of the situation and to try to devise ways to get beyond the predictable battles that would otherwise be ahead. The use of science in regulatory policy is another area in which government needs to get beyond the stale debates and false dichotomies of the past. The question is not whether scientific results should be used in developing regulatory policy, but how they should be used.

New processes are needed – approaches that will be seen as legitimate by most stakeholders on all sides of issues and that will make policy making more transparent. A critical goal of any new procedures for establishing regulatory policy must be to clarify which

aspects of a regulatory issue are matters of science and which are matters of policy (e.g., economics or ethical). The tendency, on all sides, to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and animosity all too present in the regulatory system today.

To come up with new approaches, the Bipartisan Policy Center assembled a diverse panel of experts to develop recommendations for both the Executive Branch and the Congress on how to improve the way science is used in making regulatory policy across the government’s areas of responsibility. The panel includes liberals and conservatives, Republicans and Democrats, scientists and policy experts, and leaders with experience in government, industry, academia and non-governmental organizations.

The goal of the panel is to issue a report this summer with specific recommendations for both the Executive Branch and Congress. That report will be designed to answer three sets of questions concerning regulatory policy. By “regulatory policy,” we mean not only specific rules, but all regulatory statements and guidance issued by Administration officials, and statements, hearings and legislation from the Congress. Those questions are:

- What kinds of activities or decision-making amount to “politicizing” science? How and to what extent can one differentiate between the aspects of regulatory policy that involve scientific judgments and those that involve making policy recommendations (which are inherently political)?

- When and how should Federal agencies empower advisory committees? How should members be selected? How should conflicts of interest and biases of potential members be handled? What is scientific balance and how can it be achieved? How can the independence and integrity of committees' deliberations be assured?
- What studies should agencies and advisory committees review in formulating regulatory policy? How should they be weighed? What role should peer review play and how might peer review be modified and strengthened?

The panel met for the first time in January and therefore still has much work to do to formulate specific policies and procedures that respond to these questions, but the panel did get far enough to lay out some initial general guidance for the new Administration. Again, the final report will provide recommendations for the Congress as well as expanding on suggestions for the Administration.) Note that in the recommendations below, "science" refers to the natural and physical sciences and engineering. The panel's ultimate recommendations may also deal with the social sciences.

- **RECOMMENDATION ONE: The Administration needs to develop ways, when developing regulatory policies, to explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.**

Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the "politicization" of science actually arise over differences about policy choices that science can

inform, but not determine. For example, decisions about how much risk society should tolerate or what actions should be taken in the face of scientific uncertainty are not science questions, rather they concern policies and values. Matters such as risk and uncertainty need to be informed by scientific results, but science cannot tell policy makers how to act. True, distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debates would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. The transparency would both help force values debates into the open and could limit spurious claims about, and attacks on, science. It would also help policy makers determine which experts to turn to for advice on regulatory questions, and what kinds of questions they should be expected to answer.

The Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy. That distinction also needs to be spelled out in regulatory documents. One approach that could help clarify the often problematic distinction would be to require policymakers to answer questions such as: What additional science would change the debate over a proposed regulatory policy and in what ways would the debate change? This both would help to pinpoint the nature and extent of scientific uncertainty and would highlight which aspects of a regulatory issue are not permeable about science.

Another possible approach would be to require federal agencies to spell out genuine alternative regulatory policies when proposing guidance or a rule. The idea

would be to make clear the range of policy options that were available, given the science and the requirements of law. For example, agencies could be required to describe alternatives of different levels of stringency for cost, when allowed by statute that would be in keeping with the science and would comply with statutory mandates.

Many additional options for implementing Recommendation One might be developed, but the goal should be to change the conversation about regulation and to inculcate new habits of thought. The first impulse of those concerned with regulatory policy should not be to claim "the science made me do it" or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making.

No system for clarifying the roles of science and policy questions in regulatory decision making will be on tight or completely immune from abuse, but that is not a reason to adhere to the status quo. Unless clarifying science and policy issues becomes a central aspect of regulatory policy discussions, it will be very difficult to get beyond the finger-pointing and misleading debates that have been a barrier to sensible policy making for so long. In short, there must be clarity and transparency about the roles of policy and science in regulatory decisions for science to be appropriately integrated in regulatory policy.

★ **RECOMMENDATION TWO: The Administration needs to develop guidelines on when to consult advisory panels on scientific questions, how to appoint them, how they should operate, and how to deal with conflicts of interest.**

Federal agencies should use advisory committees to the maximum extent possible to review the science behind regulatory policies that are under consideration. At the same time, agencies should be working to strengthen

the internal capabilities of their staff, including their scientists. Public officials should not delegate their ultimate responsibility to set policy. But scientific advisory committees can help ensure that policies are based on a range of knowledge and opinions, and they can make the regulatory process more transparent. As a result, the proper use of advisory committees can make it easier to adopt and more difficult to overturn good regulations once promulgated.

The first question in establishing an advisory committee should be whether the group will handle science questions or policy questions (or perhaps both). Science and policy questions should be as clearly distinguished as possible in charges to advisory panels. Advisory committees that are exclusively addressing science questions should generally consist only of members with relevant scientific expertise. Advisory committees that are addressing policy questions that are informed by science should include members with relevant scientific expertise among their members.

In general, scientific advisory panels should not be asked to recommend specific policies. Rather, they should be empowered to reach conclusions about the science that would guide a policy decision. They might also be charged with evaluating a regulatory option or custom developed by federal officials in light of scientific understanding. For example, a scientific advisory panel might be asked to determine if a proposed standard was consistent with achieving a level of risk prescribed by federal officials.

The remainder of this section is concerned exclusively with procedures related to scientific advisory panels.

The process of naming advisory committees should be made more transparent. Options for accomplishing this include: seeking recommendations for members on the Web or through contacts with relevant groups; publicly announcing on the Web the criteria for membership

such as the range of scientific disciplines that need to be included, and announcing proposed members on the Web to allow for public comment. While some agencies use some of these techniques some of the time today, greater transparency needs to become the norm, and processes need to become more uniform.

Achieving balance among scientific disciplines is more essential than is commonly understood. Such balance not only ensures that the full range of science will inform a decision, but also guards against advice being unconsciously biased by the perspectives, values or techniques that may be inherent in particular fields. It is also critical to identify a chair who is widely respected, has a reputation for considering all perspectives, and can manage a committee so as to encourage debate and discussion yet produce results on schedule.

Publishing proposed committee members is also a way to learn of possible conflicts of interest. Our panel is still considering how agencies should handle such conflicts. We run the gamut from allowing anyone with a conflict to serve on an advisory panel as long as the conflict is disclosed to banning anyone with a conflict from an advisory panel (while allowing the panel to hear and evaluate that person's views). We hope our final report can offer more specific guidance on how to assess and handle conflicts.

Without question, though, the Administration should set a clear, rigorous, uniform government policy on conflict of interest and create a standard form for disclosure that could be used by all advisory committees and in all agencies (at that, at the very least, would set a minimum standard for all agencies). The Administration should narrow the range of conflict policies used by federal agencies, scientific journals and international scientific bodies in developing its policy. Any policy should clearly define what constitutes a conflict of interest that must be disclosed (including the time period covered, any monetary thresholds, and what family

members and professional associates are included), what conflicts would be disclosed to the public as well as the government, and what conflicts, if any, would disqualify an individual from serving on an advisory committee.

Agencies need to check more effectively for conflicts on the part of advisory committee members. Scientists should be far more sensitive to the need to disclose conflicts, but federal agencies should not be relying exclusively on self-disclosure to ensure that federal guidelines on disclosure are being followed.

Federal officials who select members of scientific advisory committees should consider biases in addition to financial conflicts of interest. The policies of the National Academy of Sciences helpfully distinguish between conflicts and biases, which arise, for example, when a potential advisory committee member has a record of taking sides on an issue. Having published views on a matter should not, in and of itself, be a barrier to participating on a selected advisory committee. Rather, advisory committees should have a diversity of perspectives, and members should be expected to be open-minded, regardless of their previous work.

The Administration should also carefully think through efforts to ensure open meetings of advisory committees. It might be worth considering, for example, whether some scientific advisory committees could be allowed to hold some closed meetings if the selection process for committee membership were more open than it generally is today (as recommended above). Transparency is an essential principle of democratic governance, but some deliberations can benefit from a modicum of private discussion to enable committee members to think and speak more freely and open-mindedly. Allowing the closure of meetings would require changes in statute, and any such changes should limit the use of closed meetings and be very specific about when closure is permissible.

The *major* recommendations of a committee, though, must always be made public (assuming no classified information is involved), and indeed committees should be required to explain fully their methodology and the rationale for their conclusions. Federal officials should be required to explain how a committee's conclusions or recommendations are embodied in a new regulatory policy or why they are not.

Finally, federal officials must give advisory committees clear, definite and realistic deadlines for reporting and clear information on what a committee report will be released and how it will be used.

One way the Administration might approach some of the issues raised here is to review the guidance from the Office of Management and Budget and the Office of Science and Technology Policy issued in 2003 to see how it might be improved.

■ **RECOMMENDATION THREE: Agencies and advisory committees should cast a wide net in reviewing studies relevant to regulatory policy and must improve their methods of filtering and evaluating those studies.**

Our panel is just beginning to discuss how to flesh out this recommendation. However, a few general principles have emerged.

Not all studies should be given equal weight in surveying a field. To the extent possible, agencies and advisory committees should set out criteria in advance for reviewing the quality and relevance of individual studies and then should apply those criteria systematically in evaluating and synthesizing the research. Among the factors that need to be considered are: when a study was published, the quality of the peer review it underwent, any conflicts of interest the scientists conducting the study may have had and whether such conflicts were disclosed, and the extent

to which a study's findings are supported by other work, and whether such work was published in peer-reviewed journals.

Policy makers should be wary of conclusions about risk that are expressed as a single number. Rather, risk should be expressed as a range, with different scenarios and assumptions for different risk levels spelled out. Reviews of a body of scientific literature should always express levels of uncertainty as clearly and fully as possible so that policymakers can then discuss their response to that uncertainty.



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Bipartisan Policy Center. The Science for Policy Project. "Improving the Use of Science in Regulatory Policy." August 5, 2009.

<http://bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fml.pdf>



ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Administrative Conference Recommendation 2013-3

Science in the Administrative Process

Adopted June 14, 2013

Over the last three decades, several authorities made recommendations for improving transparency in the use of science¹ in the administrative process.² Partially in response to these recommendations, the executive branch and Congress have made a number of reforms to the scientific process undergirding agency decisionmaking. In 2009, President Obama issued a memorandum directing 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."³ "Each agency should [also] have appropriate rules and procedures to ensure the integrity of the scientific process within the agency."⁴ The Office of Science and Technology Policy (OSTP) elaborated upon this memorandum in 2010, instructing agencies to "communicate scientific and technological findings by including a clear explication of underlying

¹ The scope of this recommendation is limited to the "natural sciences" (e.g., chemistry, physics, medical science, geology, etc.), mathematics, statistics, computer science, and other allied fields. It is based upon a report that deals with agency research and decisionmaking related to the natural sciences. WENDY WAGNER, SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES (Feb. 18, 2013), *available at* http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf.

² See e.g. NAT'L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011); COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994); NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983); BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 16, 41-42 (2009) [hereinafter "BPC REPORT"]; see also CTR. FOR EFFECTIVE GOV'T, ADVANCING THE PUBLIC INTEREST THROUGH REGULATORY REFORM: RECOMMENDATIONS FOR PRESIDENT-ELECT OBAMA AND THE 111TH CONGRESS 26, 34, 47 (2008).

³ Memorandum from the Admin. of Barack H. Obama for the Heads of Executive Departments and Agencies on Scientific Integrity, DAILY COMP. PRES. DOCS., 2009 DCPD No. 00137 (Mar. 9, 2009) [hereinafter "Obama Scientific Integrity Memo"], *available at* <http://www.gpo.gov/fdsys/pkg/DCPD-200900137/pdf/DCPD-200900137.pdf>.

⁴ *Id.*



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assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic projections.”⁵

At base, these initiatives demand heightened transparency of agencies’ use of science as a central means of ensuring the basic accountability of agency regulation. If an agency identifies the role that scientific information plays in its ultimate decision and explains how it ensured that its scientific analysis was rigorous, then the public has a basis against which it can evaluate both the scientific and policy judgments underlying the agency’s decision. This transparency allows those outside the agency to assess whether the agency’s policy decision comports with the authorizing law and the scientific record. A transparent decisionmaking process also advances other institutional and scientific goals, such as identifying promising areas for future research and serving as a bulwark against misuse of science for political ends.⁶

Despite these important initiatives, a study commissioned by the Administrative Conference⁷ (and public meetings that considered questions it raised) revealed that agency decisionmaking processes would benefit from further improvements. Drawing on this learning, the recommendation offers several proposals for enhancing the transparency of agencies’ use of science. At the same time, the Conference recognizes that agencies’ abilities to implement this recommendation may be affected by resource limitations.

First, the recommendation highlights a number of innovative practices undertaken by different federal agencies to enhance the transparency of their scientific decisionmaking processes. As a general matter, agencies should articulate the specific questions to be informed by scientific information, specify study designs for new research, and establish criteria

⁵ Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies on Scientific Integrity (Dec. 17, 2010), *available at* <http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf>. To effectuate this and a number of other responsibilities, agencies were asked to report back to OSTP on the actions taken to develop and implement their scientific integrity policies by April 2011.

⁶ BPC REPORT, *supra* note 2, at 3.

⁷ WAGNER, *supra* note 1.



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for weighing existing studies.⁸ Agencies should identify scientific reports or data upon which they relied and material literature that they considered, but upon which they did not rely, to the extent practicable and permitted by law.⁹ Agencies should establish checkpoints (i.e., times for closing off consideration of additional research or debate prior to making a final regulatory decision) and policies for reopening that consideration. Agencies should also consider extending attribution to individual staff who participate in the preparation of scientific reports and taking other steps to promote robust debate among agency scientists.¹⁰ In addition, agencies should share best practices with other agencies and should recommend the removal

⁸ In so doing, agencies should endeavor to explain the relationship between scientific research and the policy decisions the research is intended to inform. NAT'L RESEARCH COUNCIL, COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* 7 (1983).

⁹ See Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 Fed. Reg. 48,789, 48,789 (Aug. 9, 2011); see also Exec. Order. No. 13,642, *Making Open and Machine Readable the New Default for Government Information*, 78 Fed. Reg. 28,111 (May 14, 2013); Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies on Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (calling for agency plans to permit public access to research papers funded in whole or in part with federal monies). As a general matter, the agency should make publicly available any scientific literature it considered, including literature it reviewed but upon which it ultimately did not rely. For purposes of the recommendation, literature that an agency "considered" includes not only any study an agency official relied upon but also any study an agency official reviewed but ultimately determined not to rely upon (because it was deemed to be outside the scope of the scientific study at hand, was not considered sufficiently reliable, or was otherwise rejected by the agency official). Cf. Administrative Conference of the United States, Recommendation 2013-4, *The Administrative Record in Informal Rulemaking*, ___ Fed. Reg. ___ (providing a similar definition of "consider" in the context of the administrative record in informal rulemaking). If an agency official merely had access to a study but did not specifically analyze it to determine its relevance, that study has not been "considered" within the meaning of the recommendation for purposes of making such literature publicly available.

¹⁰ In response to President Obama's call for agencies to develop "appropriate rules and procedures to ensure the integrity of the scientific process," Obama Scientific Integrity Memo, *supra* note 3, a number of agencies have promulgated integrity policies to promote open debate among agency scientists. See, e.g., ENVTL. PROT. AGENCY, SCIENTIFIC INTEGRITY POLICY (Feb. 2012), available at http://epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf; FOOD AND DRUG ADMIN., SCIENTIFIC INTEGRITY AT FDA, FDA STAFF MANUAL GUIDES, VOLUME IV-AGENCY PROGRAM DIRECTIVES 2 (2012), available at <http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm306446.htm>; NAT'L OCEANIC AND ATMOSPHERIC ADMIN., SCIENTIFIC INTEGRITY (Dec. 7, 2011), available at http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/202-735-D.pdf; NUCLEAR REGULATORY COMM'N, COLLABORATIVE WORK ENVIRONMENT PROGRAM, <http://www.nrc.gov/about-nrc/values.html#open> (last updated May 4, 2012); see also Francesca T. Grifo, *Federal Agency Scientific Integrity Policies: A Comparative Analysis* (Mar. 2013), http://www.ucsusa.org/assets/documents/scientific_integrity/SI-policies-comparative-analysis.pdf.



of any legal impediments to promoting transparency in decisions in which science is an important element.¹¹

Second, the recommendation offers a series of proposals to bring greater congruity to the treatment of publicly and privately funded scientific research. Specifically, it encourages the disclosure of data underlying scientific research, including both privately funded and federally funded research, that an agency is considering (to the extent practicable and permitted by law).¹² Similarly, it recommends extending conflict of interest disclosure norms to private parties who submit studies used by an agency.

RECOMMENDATION

Suggested Agency Practices Regarding the Use of Science in the Administrative Process

1. *Explaining Agency Scientific Decisionmaking.* Agencies should explain in proposed and final decision documents how they ensured rigorous review of the scientific information underlying each science-intensive regulatory project. This includes a statement of how each agency evaluated the scientific information used in its analysis; how the agency made that information available to reviewers and the public; how the analysis was reviewed by experts and interested parties; and how the agency ensured that the final decision was supported by the scientific record.

2. *Assuring Transparent Assessments.* At an early stage in their decisionmaking processes, agencies should identify the specific policy questions that may be informed by science; describe the design of the assessments needed to characterize risks and inform policy decisions; and describe the criteria to be used in reviewing and weighing existing studies. When completed, assessments should: identify other appropriate analytical choices and explain

¹¹ See WAGNER, *supra* note 1, at 135–38 (identifying a number of external legal impediments to promoting transparency, including short statutory deadlines, limits on dissemination of scientific studies, resource limitations, and caps on the number of discretionary advisory committees agencies can constitute).

¹² Legal restrictions that may limit agencies' ability to provide such disclosures include, among other things, protections for personal privacy, trade secrets, and confidential business information.



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why they were not chosen; provide a synthesis of the available evidence and relevant literature guided by the assessment design or criteria; identify significant assumptions and choices of analytical techniques; provide a statement of remaining uncertainties; and discuss how different plausible choices might change the results of the assessment. Where possible, agencies should also explain the relationship between their scientific findings and the final policy choice. Agencies should strive to communicate this information in a manner that is clear to the general public.

3. *Disclosing Underlying Studies and Data.* To the extent practicable and permitted by law and applicable policies, each agency should identify and make publicly available (on the agency website or some other widely available forum) references to the scientific literature, underlying data, models, and research results that it considered. In so doing, the agency should list all information upon which it relied in reaching its conclusions, as well as any information material to the scientific analysis that it considered but upon which it ultimately did not rely. Consistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines, each agency should ensure that members of the public have access to the information necessary to reproduce or assess the agency's technical or scientific conclusions.

4. *Checkpoints and Explanations.* Agencies should consider establishing explicit checkpoints for regulatory projects, defining both the conditions under which they intend to close their consideration of research or debate in order to reach a decision and when they might reopen that consideration, particularly in cases when they are not bound by judicially enforceable deadlines. In any case, agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors.

5. *Identifying Future Projects.* For science-intensive projects, agencies should identify specific types of future research that may be needed to reduce significant uncertainties in order to advance understanding of the issues.



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6. *Attribution for Agency Personnel.* Agency personnel play an important role in producing their respective agencies' scientific analyses. Agencies should consider providing their personnel with some form of consensual attribution for reports or analyses to which they contribute in a significant way. If appropriate, such attributions should be made for personnel who contributed in a significant way to a technical or scientific report, including not only scientists but also economists, lawyers, and other contributors. Reviewers and other contributors could be identified by name and general contribution.

7. *Encouraging Debate.* Agencies should encourage vigorous debate among agency scientists and should explore ways of incorporating the diversity of that debate in any resulting work product. Agency employees should be encouraged to publish their scientific work in the peer reviewed literature, provided that they follow applicable agency procedures and that confidential governmental deliberations are not compromised. Dissenting staff members should be protected from reprisals.

8. *Sharing of Agency Best Practices.* Agencies should identify and publicize the innovations they have developed for transparently incorporating science into their regulatory decisions. OSTP, an interagency group headed by OSTP, or another body should consider occasionally convening agency representatives to discuss and share best practices.

9. *Addressing Legal Obstacles to Transparent Decisionmaking.* Agencies should identify legal obstacles that may impede otherwise appropriate public access to the scientific information underlying agency analyses or that may prevent the agencies' development of scientifically robust decisionmaking processes. Agencies should recommend appropriate actions to eliminate such impediments, including revisions in existing law, to the Executive Office of the President.

Agency Disclosures to Enhance the Transparency of Research

10. *Data Disclosure.* To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research, including both privately and federally funded



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research being considered by the agencies. Where practicable, such information should be disclosed in machine-readable format. Where such data are not subject to legal or other protections, and the data's owners nonetheless will not provide such access, agencies should note that fact and explain why they used the results if they chose to do so. Agencies should review their confidential business information policies to ensure that they include appropriate mechanisms to prevent over-claiming.

11. *Conflict of Interest Disclosure.* Agencies should require conflict of interest disclosures on all scientific research submitted to inform an agency's licensing, regulatory, or other decisionmaking processes. This disclosure should be similar to the conflict of interest disclosure required by some scientific journals, such as that used by the International Committee of Medical Journal Editors. The regulatory conflict of interest disclosure should also, where permitted by law, identify whether the experimenter or author had the legal right without approval of the sponsor of the research to: design the research; collect the data; interpret the data; and author, publish or otherwise disseminate the resulting report or full dataset. To the extent that a party other than the principal investigator (e.g., the study sponsor or funder) had control over the design or publication of the study, agencies should disclose this fact and specify the nature of the control such an entity exercised.

Recruiting Researchers Through Facebook

To the Editor:

We have read with considerable interest Dr. Richiardi's communication regarding the use of Facebook to recruit participants in the NINFEA study.¹ As previous initiatives report, Facebook provides a positive virtual environment in which study participants can be enrolled and followed.^{1,2} As a widely used online social network, Facebook may be useful for other research purposes. We would like to share our experience in recruiting researchers through this website.

In June 2011, our Collaborative Working Group for the Research of Human Resources for Health, Red-LIRHUS (Grupo Colaborativo Latinoamericano para la Investigación de Recursos Humanos en Salud), designed a multicenter study to explore the profile and professional expectations of Latin American medical students, with questions on topics such as emigration intention and primary-care labor perspectives.

This study was conceived as a continent-wide evaluation, using a pilot tested³ self-administered survey. To gather these data, we decided to start the fieldwork by enrolling researchers from various countries in Latin America via Facebook. Given that medical students were the potential study subjects, we decided to involve them also as the local principal investigators.

In October 2011, the project was approved by the Ethical Committee of the Instituto Nacional de Salud del Perú. We started with a limited number of universities, but this situation was insufficient to achieve our objective. We, therefore, implemented a new recruiting strategy by posting an invitation on the "wall" of the local organizations' Facebook pages (by country or university) of the Medical Students' Scientific Societies (Sociedades Científicas de Estudiantes de Medicina)⁴ and similar groups, such as the International Federation of Medical Students' Associations.

Overall, 80 researchers agreed to take part in this project; they represented 80 universities from 15 Latin American countries. Approximately half of these researchers were recruited by Facebook. Also, in October 2011, we created a Facebook "Closed Group," called Red-LIRHUS, to connect all participant researchers (including those who were contacted using Facebook and those who were not). This group provided responses to common questions and included 95% of the participant researchers in their local universities.

As our experience suggests, Facebook can be helpful in recruiting and communicating with a research team, even in a multinational context.

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Benefits of Publicly Available Data

To the Editor:

The National Morbidity, Mortality, and Air Pollution Study (NMMAPS) was designed to examine the health effects of air pollution in the United States. The primary question was whether particulate matter was responsible for the associations between air pollution and daily mortality. Secondary questions concerned measurement error in air pollution and mortality displacement.

Since then, NMMAPS has been used to answer many important questions in environmental epidemiology.

The data from 108 US cities for the years 1987–2000 comprise daily observations of mortality counts in 3 age groups, air pollutants (including particulate matter and ozone), and weather (including temperature).

The data were made publicly available first via the Web (<http://www.ihapss.jhsph.edu/data/data.htm>), and then via R.² They were removed from public availability in 2011 due to privacy concerns.

We used a systematic review to find peer-reviewed papers or reports that used the NMMAPS data. There were 67 papers or reports in total (see the eAppendix [<http://links.lww.com/EDE/A575>] for the methods and a complete list). Thirty-three publications (49%) were based on the publicly available data (Table). The most common application was methodology (33 publications). The first authors came from 5 countries.

Sixty-seven publications are a substantial research output from one study, reflecting the originality and scope of the data. The data have been used to answer questions on the health effects of air pollution and temperature in the United States, and to answer methodological questions. Such applications also create benefits outside the United States, as new and refined methods can be used in other countries.

NMMAPS has been used to examine deaths during heat waves and to predict future heat-wave deaths due to climate change. Examining climate change was not an original goal of NMMAPS, but these data (which cover a wide range of climates over a

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TABLE. Number of NMMAPS Publications by Their Dependence on Public Availability, Application, and Country of First Author, Ordered by Frequency (n = 67)

	Publications No. (%) ^a
Arising from NMMAPS' public availability ^b	
No	34 (51)
Yes	33 (49)
Application	
Methodology	33 (49)
Air pollution	19 (28)
Temperature	5 (7)
Air pollution and methodology	5 (7)
Air pollution and temperature	4 (6)
Air pollution and season	1 (1)
Country of first author	
United States of America	39 (58)
Australia	18 (27)
United Kingdom	8 (12)
Italy	1 (1)
Greece	1 (1)

^aPercent do not always add to 100% because of rounding.

^b"Yes" if none of the authors were from the US NMMAPS team authors.

long time) are an excellent resource for investigating this critically important question.

Research from NMMAPS has been used by US Environmental Protection Agency for regulatory impact statements on particulates³ and ozone, and by reports on climate change.⁴ It has influenced policy outside the United States, being cited in a UK government report on particulate matter⁵ and a World Health Organization report on air pollution.⁶

The easy availability of NMMAPS meant that researchers could write papers without the time and costs of data collection and ethics applications. The study has benefited the research careers of statisticians and epidemiologists around the world. This creates a virtuous circle, as researchers are more likely to stay in the field, produce more research outputs, and win grants. If this pattern is to continue, more researchers need to make their data publicly available.

US investigators who worked to make NMMAPS publicly available

should be applauded. More formal rewards for providing access to data are difficult, which may be one reason why more data sets are not made freely available.⁷

A key obstacle to data-sharing is the ethics of sharing medical data, with the major concern being whether risks outweigh benefits. The number and influence of publications from NMMAPS outweigh (in our opinion) data-security concerns, particularly as the NMMAPS health data are aggregated and anonymized. Nonetheless, data-security concerns caused these data to be removed from public availability in 2011—a backward step for reproducible research.⁸ Thanks to NMMAPS, the United States has an improved understanding of the health effects of air pollution and heat waves. Furthermore, the utility of these data is not diminishing—9 papers were published in 2010, 7 in 2011, and additional papers are currently under review.

ACKNOWLEDGMENTS

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On Influencing Population Means

To the Editor:

Possible temporal trends in sperm concentration at the population level have been used to discuss the role of environmental factors (including endocrine disruptors) on male fertility. An assumption sometimes made¹ is that temporal trends in biologic parameters, such as sperm concentration, will parallel temporal trends in their risk factors. As we illustrate later in the text, this assumption is simplistic, outside the (probably rare) situation where a single common environmental factor has a major impact on the biologic parameter of interest.

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February 10, 2014

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

Re: Secret Science Reform Act of 2014 (H.R.4012)

Dear Chairman Smith:

The Halogenated Solvents Industry Alliance, Inc. ("HSIA"), an association of producers and users of chlorinated solvents, supports your Committee's efforts to stop EPA from proposing regulations and adopting risk assessments based on science that is not transparent or reproducible. I write to bring to your attention a particularly egregious example of such EPA action involving trichloroethylene ("TCE"), a solvent that is often found at contaminated waste sites as a result of its legacy use by the electronics and manufacturing industries and by the Armed Services to clean aircraft, tanks, and ships.

In September 2011, EPA issued its long-awaited "Toxicological Review of Trichloroethylene (CAS No. 79-01-6) in Support of Summary Information on the Integrated Risk Information System (IRIS)." This IRIS Assessment contains a reference concentration ("RfC") of 0.0004 ppm (0.4 ppb or 2 $\mu\text{g}/\text{m}^3$) for TCE, a value considered by EPA to be protective for all non-cancer critical effects.

In 2012, EPA Region IX began issuing action levels of 9 $\mu\text{g}/\text{m}^3$ (commercial and industrial) and 2 $\mu\text{g}/\text{m}^3$ (residential) for short-term exposure to TCE at sites under its jurisdiction such as the Middlefield-Ellis-Whisman Superfund Site in Mountain View, California.¹ Because these levels are intended to protect against fetal cardiac malformations, they have raised a great deal of public concern at the Mountain View site (home to a new Google campus) and other places where they have been applied. Indeed, other EPA regions have applied comparable action levels to require evacuation of Naval facilities and other buildings. Compliance is problematic, as 2 $\mu\text{g}/\text{m}^3$ is within the range of background concentrations of TCE in urban air.

¹ A December 13, 2013 letter to Stephen Hill of the California Regional Water Quality Control Board outlines and reaffirms the Region IX position:
[http://yosemite.epa.gov/r9/sfund/r9sfdocw.nsf/3dc283e6c5d6056f88257426007417a2/a9da00560074ea6688257c3800762812/\\$FILE/93538641.pdf/EPA%20Region%209%20South%20Bay%20VI%20Letter%2012-3-13.pdf](http://yosemite.epa.gov/r9/sfund/r9sfdocw.nsf/3dc283e6c5d6056f88257426007417a2/a9da00560074ea6688257c3800762812/$FILE/93538641.pdf/EPA%20Region%209%20South%20Bay%20VI%20Letter%2012-3-13.pdf)

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The action levels are all based on the IRIS RfC, which in turn is derived largely from a study by Johnson *et al.* entitled Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat, Environmental Health Perspectives 111: 289-92 (March 2003). The problem is that this study was not conducted according to EPA's Good Laboratory Practices ("GLP") and is not reproducible, as noted in the August 2013 peer review of a recent EPA "TSCA Chemicals Work Plan" assessment of TCE which was highly critical of EPA's reliance on Johnson *et al.*: "One of the fundamental tenets in science is the reliability and reproducibility of results of scientific investigations."² The peer reviewers noted:

- At least two GLP-compliant studies conducted under both EPA and Organization for Economic Coordination and Development ("OECD") guidelines have been unable to reproduce the effect seen by Johnson *et al.*, despite the participation in one of the studies by Johnson herself.
- The dose-response relationship reported in Johnson *et al.* for doses spanning an extreme range of experimental dose levels is considered by many to be improbable, and has not been replicated by any other laboratory. This has been the subject of a series of articles in the scientific press.³
- The congenital heart defect incidence in *control* animals in Johnson *et al.* was 86 times the *historical* control incidence in the rat strain they used.

As California EPA noted in declining to rely upon Johnson *et al.*: "These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits. The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin et al., 2004)."⁴

HSIA's attempts to see the raw data which formed the basis of the Johnson paper have been unsuccessful. The data supplied to EPA by Johnson were inadequate to validate or refute the paper's conclusions. A direct appeal to Johnson has not made the data available for public scrutiny. And a Freedom of Information Act request (pursuant to the Shelby Amendment) has been denied by the National Institutes of Health, and is now on appeal.

² http://www.scgcorp.com/tcl2013/pdfs/090613_TCE_FINAL_All%20Reviewers%20Comments.docx

³ Hardin, B, et al., Trichloroethylene and Cardiac Malformations, Environ. Health Perspect. 112: A607-8 (2004): "Johnson et al. (2003) provided no rationale for designing their study with a concurrent control five times larger than the treatment groups, which leads us to ask whether the control group reported here is, in fact, a composite of controls from multiple, perhaps five, different studies.. The immediate impact of this large control group is that the very cardiac 'abnormalities' at the 1.5 ppm dose that did not differ significantly from controls in 1993 become statistically significant in 2003."

⁴ California EPA Public Health Goal for Trichloroethylene in Drinking Water (July 2009), at 21.

The Honorable Lamar Smith
February 10, 2014
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In sum, the RfC in the 2011 IRIS TCE assessment is based on a flawed and irreproducible study, but it is being given the effect of law by EPA. The action levels developed by Region IX were referred to EPA headquarters, and the question of setting short-term TCE exposure limits has resulted in significant ongoing disagreement among the EPA regions, as documented in the enclosed Inside EPA report of December 31, 2013 and numerous other articles in the trade press.⁵ Thus, the proper interpretation and use of this non-GLP study in risk assessment is a question of the highest priority to EPA's Superfund program.

There is a scientifically supportable way for EPA to resolve the controversy caused by its reliance on the Johnson *et al.* study. HSIA has offered, under a voluntary testing agreement in place with the Agency for Toxic Substances and Disease Registry ("ATSDR"), to fund a definitive study on the relationship between TCE and cardiac malformations that would be designed by a panel including representatives of ATSDR and EPA. Our letter of April 23, 2013 on this subject is enclosed. Although such a study, if accepted, could have been conducted and reported by now, neither ATSDR nor EPA has responded to our offer.

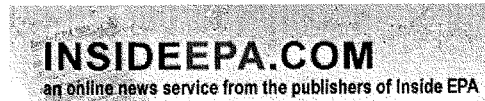
I hope this is helpful to your Committee. Please do not hesitate to let me know if we can provide further input.

Very truly yours,


Faye Graul
Executive Director

Enclosures

⁵ See, e.g., DOD Uses New TSCA Assessment to Criticize Trichloroethylene IRIS Value, Inside EPA (June 3, 2013); Exposure Uncertainties May Hamper EPA Effort To Assess TCE's Risks, Inside EPA (April 25, 2013); Amidst Review, EPA Scientists Defend Finding on TCE's Heart-Defect Risks, Inside EPA (February 15, 2013); Massachusetts Adds to Scrutiny of EPA TCE Risk Assessment's Adequacy, Inside EPA (February 11, 2013); New Jersey Short-Term TCE Limits Add to Growing Array of Approaches, Inside EPA (February 6, 2013); Regions Split Over Short-Term TCE Limit, Highlighting Need for EPA Guide, Region X TCE Guidance, Inside EPA (January 2, 2013).



Risk Policy Report - 12/31/2013

Region IX Short-Term Limits For TCE Exposure May Guide National Policy

Posted: December 30, 2013

EPA Region IX is urging California state regulators to implement strict action levels and strengthened sampling strategies at certain Superfund sites in the San Francisco Bay area to protect against short-term exposures to the solvent trichloroethylene (TCE), measures that likely indicate how EPA will address TCE's short-term risks nationwide, according to an informed source.

Since late 2012, EPA officials have said agency headquarters is seeking a consistent nationwide policy for assessing and mitigating the risk of fetal cardiac malformations, a novel risk from short-term *in utero* exposures to TCE. The agency has yet to produce a document for dealing with the risk calculation for the birth defect, which first appeared in the September 2011 Integrated Risk Information System (IRIS) TCE assessment. Since then, states, EPA regional officials and industry have been struggling to account for it in cleanup plans at contaminated sites.

In a Dec. 3 letter, EPA Region IX urges the California Regional Water Quality Control Board (CRWQCB) to follow a program for assessing risks from short-term exposures to TCE that includes stringent prompt response action levels. The letter also asks the Golden State regulators to adopt sampling strategies consistent with EPA's recent draft guidance for assessing and mitigating vapor intrusion risks from chlorinated solvents. Vapor intrusion occurs when toxic vapors rise into buildings from underground contamination. *The letter is available on InsideEPA.com. (Doc ID: 2456809)*

In the letter, Kathleen Salyer, assistant director of the Superfund Division of Region IX's California Site Cleanup Branch, recommends mitigation measures for when prompt response action levels are exceeded. The limits and stricter sampling strategies are intended to reduce *in utero* exposures at nine sites contaminated with chlorinated solvents.

In an attachment to the Dec. 3 letter, Region IX urges California water quality regulators to adopt a prompt response action level of 9 micrograms per cubic meter (ug/m³) to protect workers at commercial and industrial facilities during an 8-hour work day, and of 7 ug/m³ for a 10-hour workday. Additionally, Region IX recommends a prompt action level of 2 ug/m³ to protect against residential exposures.

When indoor air limits are reached, the memo recommends interim measures to mitigate short-term risks. These measures include fans or ventilation to increase building pressurization, installing subslab and or crawlspace depressurization systems, or a soil vapor extraction system. Region IX also suggests evacuation to eliminate exposures, especially when immediate response levels are exceeded.

"In reviewing the multiple lines of evidence that have been collected for the South Bay Sites, EPA Region 9 has identified data gaps that must be filled to fully evaluate the potential for vapor intrusion into buildings overlying the South Bay Sites contamination," Salyer writes to Stephen Hill, Chief of CRWQCB's Toxics Cleanup Division.

A source familiar with the thinking of some EPA officials says the Region IX plan could prompt EPA headquarters to issue a very similar policy for assessing and mitigating risks to pregnant women from short-term exposures to TCE in the near future.

"This may force the hand of headquarters to get something out" to address risks from short-term exposures to TCE, the source says. "It's really a sign, not just for the levels, but for sampling practices, that this is a direction where EPA as a whole is heading."

In addition, the source says headquarters has not objected to Region IX's approach, and that the delay in creating a nationwide policy to protect against short-term exposures to TCE likely stems from debate over whether EPA's Office of Solid Waste and Emergency Response (OSWER), which recently crafted draft vapor intrusion guidance, or the agency's Office of Research and

Development, which includes the IRIS program that addresses chemical-specific challenges, should issue the policy.

The substance of a future national policy will likely be similar to those outlined in the recent Region IX memo and the limit Region X set to protect against short-term exposures late last year, the source says. "I haven't heard anyone at EPA questioning the general approach that Region IX or Region X have taken with setting numbers."

In response to a request for an interview or comment on the Region IX letter, an EPA spokeswoman said the agency is working with its regional officials to address vapor intrusion risks at sites contaminated with TCE and that specific action levels to protect against short-term exposures are not part of the OSWER guidance for assessing and mitigating vapor intrusion from chlorinated solvents.

Since the publication of the IRIS assessment for TCE, the Defense Department (DOD) and industry officials have criticized the science supporting the fetal cardiac risk as too uncertain for use in regulation, and said limits derived to protect against short-term exposures are based on conservative assumptions. In comments submitted on EPA's vapor intrusion guidance, DOD has urged the agency to create "defensible procedures" for setting limits to protect against short-term exposures and for responding to them at military facilities.

EPA Region IX has been a leader in efforts to protect against the birth defects risk at contaminated sites, and in early 2012 proposed a removal action level (RAL) of 15 ug/m³ to protect workers at the Middlefield-Ellis-Whisman (MEW) Superfund site in Mountain View, CA, from short-term exposures to TCE. That limit as well as the recent prompt response action levels are derived from the IRIS assessment for TCE, which set a reference concentration (RfC) – the amount of a substance EPA believes can be inhaled daily over a lifetime without adverse effects – of 2 ug/m³.

The RfC, which protects against chronic exposures, was based in part on a 2003 toxicology study by Paula D. Johnson that showed fetal cardiac malformations in lab rats exposed to TCE. EPA said the study indicated the birth defects could occur from inhaling the substance during pregnancy, implying risk from short-term exposure. Several peer review panels backed EPA's use of the study and the birth defects risk.

Region IX's new prompt action levels are based on a hazard quotient (HQ) of 1, though the letter states that similar levels indicating a need for an immediate response may be derived using an HQ of 3, per a 2008 OSWER policy memo for calculating RALs. The HQ represents the ratio of the exposure level to a calculated 'safe' dose.

The levels are similar to Region IX's proposed 2012 RAL for the MEW site of 15 ug/m³, using an HQ of 3. The Region IX prompt response action level is also similar to a level that Region X recommended last year of 8.4 ug/m³ in indoor air at commercial and industrial sites, and identical to Region X's limit of 2 ug/m³ to protect against exposures in homes.

But in a Dec. 13, 2012, memo, Region X described its limits as "not-to-be-exceeded concentrations, as averaged over any 21-day period of time," noting that current science is unclear on whether shorter spikes in indoor air contamination during a 21-day period cause birth defects.

Region IX limits use a different exposure duration than Region X, as the RAL assumes a single daily exposure above 15 ug/m³ for pregnant women could result in fetal cardiac defects, while the prompt response action levels are averaged over an eight or 10-hour workday.

The source says the question of exposure duration remains a challenge for EPA in part because current technology that can measure variability in indoor air levels over extended durations is not cost-effective. In the Dec. 3 memo, Region IX requires sampling practices included in OSWER's draft vapor intrusion guidance for assessing and mitigating risks from vapor intrusion that was released for public comment in April, saying the document's multiple lines of evidence approach must be followed "to fully evaluate the potential for vapor intrusion into buildings overlying" the nine contaminated sites.

Region IX requires multiple rounds of sampling from multiple locations, and also says sampling should be conducted in crawlspaces and basements. In addition, the letter calls for sampling in cold weather months when some sites contaminated with TCE in the San Francisco Bay area have been found to have contamination levels in indoor air two to three times higher than in other seasons.

A state regulator criticized some assessment approaches backed in the letter, saying recommendations including sampling when the air conditioning systems are not running are not technically defensible or are excessively conservative and will lead to unnecessary precautions at some homes and buildings. The source declined to comment on the response action levels for TCE, citing scientific uncertainty surrounding that issue. -- *Dave Reynolds*

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April 23, 2013

Dr. Edward Murray
Acting Director
Division of Toxicology and Human Health Sciences
Agency for Toxic Substances & Disease Registry
1600 Clifton Road NE, MS F-57
Atlanta, GA 30333

Re: Proposal for Trichloroethylene (TCE) Developmental Toxicity Study

Dear Dr. Murray:

When we met with you in October regarding the protocol for the developmental neurotoxicity study that the Halogenated Solvents Industry Alliance, Inc. (HSIA) is conducting pursuant to its agreement with the Agency for Toxic Substances and Disease Registry (ATSDR) to fill certain priority data needs identified by ATSDR, there was some discussion as to whether it might be possible to expand that study to include a developmental toxicity component that would address whether and to what extent TCE might play a role in causing cardiac anomalies in pups of exposed animals. As you are aware, this is a subject of some controversy in the scientific literature, with serious regulatory implications for the evaluation of short-term human exposures arising from vapor intrusion at contaminated sites.

There was a consensus among the scientists we consulted that expanding the developmental neurotoxicity study would not be practical. Given our shared interest in clarifying whether TCE is a developmental toxicant, we approached you to see if ATSDR would have an interest in expanding our agreement to include a study intended to address the cardiac endpoint. During a conference call on March 6, it was agreed that we would provide you a description or skeleton protocol for the kind of study we have in mind to see whether ATSDR and the other Tri-agency Superfund Applied Research Committee (TASARC) members believe that such a study could help resolve this important issue.

1. Rationale for Study

Johnson *et al.* (2003) reported cardiac effects in rats from research carried out at the University of Arizona and originally published ten years earlier by the same authors.¹ In the earlier-published study, there was no difference in the percentage of cardiac abnormalities in

¹ Johnson, P, *et al.*, Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat, *Environ. Health Perspect.* 111: 289-92 (2003). Dawson, B, *et al.*, Cardiac teratogenesis of halogenated hydrocarbon-contaminated drinking water, *J. Am. Coll. Cardiol.* 21: 1466-72 (1993).

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rats dosed during both pre-mating and pregnancy at drinking water exposures of 1100 ppm (9.2%) and 1.5 ppm (8.2%), even though there was a 733-fold difference in the concentrations. The authors reported that the effects seen at these exposures were statistically higher than the percent abnormalities in controls (3%). For animals dosed only during pregnancy, the abnormalities in rats dosed at 1100 ppm (10.4%) were statistically higher than at 1.5 ppm (5.5%), but those dosed at 1.5 ppm were not statistically different from the controls. Thus, no meaningful dose-response relationship was observed in either treatment group.

In 2003, Johnson *et al.* republished data from the 1.5 and 1100 ppm dose groups published by Dawson *et al.* in 1993 and pooled control data from other studies, an inappropriate statistical practice. When compared against the pooled control group, statistically significant increased rates of abnormalities were reported for the 250 ppb and 1100 ppm groups but not for the intermediate 1.5 ppm group. The authors concluded that rats exposed to levels of TCE greater than 250 ppb during pregnancy have increased incidences of cardiac malformations in their fetuses.

Johnson *et al.* has been heavily criticized in the published literature,² and the University of Arizona studies were expressly rejected as the basis for a public health goal (PHG) by the California Office of Environmental Health Hazard Assessment (OEHHA)³ and minimal risk levels (MRLs) by the ATSDR.⁴ Moreover, the Johnson *et al.* findings have not been reproduced by any other investigators. In one study conducted by Fisher *et al.*,

² Hardin, B, *et al.*, Trichloroethylene and cardiac malformations, Environ. Health Perspect. 112: A607-8 (2004); Watson, R., *et al.*, Trichloroethylene-contaminated drinking water and congenital heart defects: a critical analysis of the literature, Repro. Toxicol. 21: 117-47 (2006).

³ "Johnson *et al.* (2003) reported a dose-related increased incidence of abnormal hearts in offspring of Sprague Dawley rats treated during pregnancy with 0, 2.5 ppb, 250 ppb, 1.5 ppm, and 1,100 ppm TCE in drinking water (0, 0.00045, 0.048, 0.218, and 128.52 mg/kg-day, respectively). The NOAEL for the Johnson study was reported to be 2.5 ppb (0.00045 mg/kg-day) in this short exposure (22 days) study. The percentage of abnormal hearts in the control group was 2.2 percent, and in the treated groups was 0 percent (low dose), 4.5 percent (mid dose 1), 5.0 percent (mid dose 2), and 10.5 percent (high dose). The number of litters with fetuses with abnormal hearts was 16.4 percent, 0 percent, 44 percent, 38 percent, and 67 percent for the control, low, mid 1, mid 2, and high dose, respectively. The reported NOAEL is separated by 100-fold from the next higher dose level. The data for this study were not used to calculate a public-health protective concentration since a meaningful or interpretable dose-response relationship was not observed. These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits: The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin *et al.*, 2004)." California EPA Public Health Goal for Trichloroethylene in Drinking Water (July 2009), p. 21.

⁴ ATSDR concluded that "[t]he study is limited in that only two widely spaced exposure concentrations were used and that a significant dose-response was not observed for several exposure scenarios." Toxicological Profile for Trichloroethylene Update (September 1997), p. 88. More recently, however, following publication by EPA in 2010 of its TCE IRIS Assessment, ATSDR issued an Addendum that bases both chronic and intermediate-duration MRLs on the EPA RfD/RfC values (0.0005 mg/kg/day /0.0004 ppm (2 µg/m³)), which in turn are based in part on Johnson *et al.* Addendum to Toxicological Profile for Trichloroethylene (January 2013).

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pregnant rats were administered a daily dose of 500 mg TCE/kg by gavage on gestational days 6 through 15 and despite employing an improved method for assessing cardiac defects and the participation of Johnson herself in the study, the heart malformation incidence for fetuses from TCE-treated dams did not differ from control values on either a per fetus or per litter basis.⁵

No increase in cardiac malformations was observed in a second guideline, GLP-quality inhalation study reported by Carney *et al.*,⁶ despite high exposure concentrations (i.e., 0, 50, 150 and 600 ppm TCE for 6 hours/day and 7 days/week from gestational days 6 through 20) and techniques capable of detecting most of the malformation types reported by Johnson *et al.* Carney *et al.* concluded that the no observed effect concentration (NOEC) for fetal effects was 600 ppm. Carney *et al.* is the published report of the developmental toxicity study H5IA sponsored under our voluntary agreement with ATSDR to fill certain priority data needs for TCE.

In summary, based on a critical evaluation of these studies, the dose-response relationship reported in Johnson *et al.* for doses spanning an extreme range of experimental dose levels is considered by many to be improbable.⁷ Johnson *et al.* remains a poor basis for assigning human hazard, and no mechanistic or other studies provide information that bridges the gap to support the Johnson *et al.* conclusions.

2. Proposal

We propose to sponsor a definitive study to confirm the developmental effects of TCE in rats claimed by Johnson *et al.* and subsequently used by EPA in its 2011 development of an RfD and RfC. As a GLP inhalation developmental toxicology study has already been conducted under a protocol approved by TASARC, it would seem most appropriate that the proposed study focus on oral ingestion, as did Johnson *et al.* There are many variables associated with study design (i.e., dosing range, dosing vehicle, dissection methods, etc.) so the actual protocol for this study should be adopted by consensus under the guidance of an expert panel, which would include an author from each of the earlier, conflicting studies as well as recognized academic or consulting experts in developmental toxicity. In order for the study to have credibility with the regulatory community, ATSDR and the other TASARC agencies would need to be represented on the panel and approve the protocol.

⁵ Fisher, J, *et al.*, Trichloroethylene, trichloroacetic acid, and dichloroacetic acid: do they affect fetal rat heart development? *Int. J. Toxicol.* 20: 257-67 (2001).

⁶ Carney, E, *et al.*, Developmental toxicity studies in CrI:Cd (SD) rats following inhalation exposure to trichloroethylene and perchloroethylene, *Birth Defects Research (Part B)* 77: 405-412 (2006).

⁷ "Johnson and Dawson, with their collaborators, are alone in reporting that TCE is a 'specific' cardiac teratogen." Hardin, B, *et al.*, Trichloroethylene and cardiac malformations, *Environ. Health Perspect.* 112: A607-8 (2004).

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Under the guidance of the panel, the proposed study would be put out for bid to reputable test laboratories with the appropriate expertise in developmental toxicity. If dose-related cardiac malformations are, in fact, observed, agency reliance on the University of Arizona studies would be confirmed. However, if the Johnson *et al.* results are not confirmed, it would be accepted that those studies should not be used as the basis for the RfD, RfC, MRLs, or other such guidance values for TCE. HSIA would expect that the results from the existing inhalation study and the proposed oral study, both conducted as part of ATSDR's voluntary program to fill priority data needs, would be accepted as the appropriate basis for the development of inhalation and oral non-cancer hazard values.

HSIA appreciates being given the opportunity to contribute to the resolution of this controversial issue and hopes that the members of TASARC share our commitment to application of the best science to the development of regulatory decisions. We look forward to hearing your thoughts on this proposal and would certainly be available to discuss it in greater detail at your convenience. I can be reached by phone at either (703) 875-0684 (office) or (202) 286-6464 (cell) or by email at jbelle@hsia.org.

Sincerely,



John U. Bell, Ph.D., DABT
Director of Scientific Programs