ELEVATION OF THE ENVIRONMENTAL PROTECTION AGENCY TO DEPARTMENT LEVEL STATUS: H.R. 37 AND H.R. 2138

HEARINGS

BEFORE THE

SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

ON

H.R. 37

TO ELEVATE THE ENVIRONMENTAL PROTECTION AGENCY TO CABINET-LEVEL STATUS AND REDESIGNATE SUCH AGENCY AS THE DEPARTMENT OF ENVIRONMENTAL PROTECTION

AND ON

H.R. 2138

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ELEVATION OF THE ENVIRONMENTAL PROTECTION AGENCY TO DEPARTMENT LEVEL STATUS: H.R. 37 AND H.R. 2138

FRIDAY, JUNE 6, 2003

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Doug Ose (chairman of the subcommittee) presiding.

Present: Representatives Ose and Davis (ex officio).

Staff present: Dan Skopec, staff director; Barbara Kahlow, deputy staff director; Danielle Hallcom, professional staff member; Melanie Tory, jr. professional staff member; Yier Shi, press secretary; Alexandra Teitz, minority counsel; and Cecelia Morton, minority office manager.

Mr. OSE. Good morning. Welcome to this morning's Energy Policy, Natural Resources and Regulatory Affairs Subcommittee hearing.

Today we welcome the full committee chairman. Good morning.

As this Nation faces a new generation of environmental challenges, the issue of the elevation of the Environmental Protection Agency [EPA], is more important than ever. The United States is one of the few industrial nations that does not place environmental protection in a Cabinet-level position. I believe that environmental protection is as important as other Cabinet functions and is critical to the health and well-being of this Nation's environment and its people.

Since its creation in 1970, EPA has grown from a small agency to one with about 18,000 employees and a budget of $7.7 billion. Over the last 30 years, 11 major environmental laws expanded EPA's jurisdiction and delegated most implementation activities to the States. EPA now faces new environmental challenges originating from nonpoint sources that are difficult to regulate. To meet these future challenges, many experts have stated that EPA needs to be reformed.

During the last Congress, this subcommittee held three hearings addressing EPA elevation bills introduced by Congressman Sherwood Boehlert and former Congressman Steve Horn. Several experts, industry representatives, EPA and other administration and State officials testified to the merits of the elevation and current

organizational problems at EPA that hinder effective environmental protection. Today's hearing will examine two new EPA elevation bills referred to this subcommittee. H.R. 37, introduced by Congressman Sherwood Boehlert, is identical to H.R. 2438, as introduced in the 107th Congress. H.R. 37 would restrict itself to elevating EPA to department-level status.

Based on the expert testimony from our previous three hearings, I introduced H.R. 2138 on May 15, 2003. My bill would make significant organizational and institutional changes to EPA. It reorganizes EPA into three Under Secretaries, the first being for Policy, Planning, and Innovation; the second for Science and Information; and the third for Compliance, Implementation, and Enforcement. The Under Secretary for Policy, Planning, and Innovation would have authority over all program offices, regulations, and policy development. The Under Secretary for Implementation, Compliance, and Enforcement would supervise the regional offices.

Responding to the overwhelming criticism over the lack of sound science at EPA, my bill creates an Under Secretary for Science and Information. This section mirrors legislative language from H.R. 64, known as the Strengthening Science at the EPA Act, introduced by Congressman Vernon Ehlers, which passed the House in the last Congress. Finally, my bill creates an independent Bureau of Environmental Statistics to collect, analyze, and report on environmental and human health conditions. We have a chart on the right for everyone to take a look at.

Currently, each EPA regional office, program office, and division reports directly to EPA's Administrator and Deputy Administrator as reflected on the chart on the left. The subcommittee heard testimony during the last Congress that this stovepipe organization results in EPA's inability to effectively address cross-media environmental protection. I believe that EPA's structure, as it currently exists, lacks adequate oversight and coordination of its offices to ensure that science, policy and implementation are integrated throughout EPA.

The subcommittee also heard testimony during the last Congress that EPA lacks scientific leadership, critical science for decisionmaking, intra-agency dissemination of information, and coordinated efforts between the Office of Research and Development and the program offices. The lack of coordination between the Water and Air program offices that resulted in the MTBE contamination of our groundwater, particularly in California, must never happen again. I believe all science at EPA needs to be consolidated into a centralized division headed by strong leadership that will advance environmental protection by conducting peer-reviewed scientific studies of the highest caliber.

One of the most serious deficiencies at EPA is the unavailability of reliable and measurable environmental outcome data, such as cleaner water and fewer illnesses. Several other departments have their own statistical agencies to provide independent and reliable data for decisionmaking and analysis. By creating a Bureau of Environmental Statistics, we can ensure that the policies EPA advances are actually cleaning the environment and protecting the health of our citizens.

EPA, as it exists today, does not have the institutional ability to meet the environmental challenges of the 21st century. By reorganizing the EPA and providing the statistical tools to understand our changing environment, we have the opportunity to create an executive department that does a better job of protecting the environment than it currently does as an independent Federal agency.

I look forward to the testimony of our distinguished panel here today.

I am sorry to report that we have heard from one of our witnesses, Janice Mazurek, Director for Innovation and the Environment at the Progressive Policy Institute, that she will be unable to participate today due to an unexpected situation. I ask unanimous consent that her full written statement be included in the record. Hearing no objection, so ordered.

Our panel of witnesses with us today includes Dr. Paul Portney, president of Resources for the Future; Dr. George Gray, acting director, Center for Risk Analysis at Harvard School of Public Health; Dr. Steven Hayward, F.K. Weyerhaeuser fellow at the American Enterprise Institute; Wesley Warren, senior fellow for environmental economics at the Natural Resources Defense Council; and Rena Steinzor, professor, University of Maryland School of Law, and board member for the Center for Progressive Regulation.

Thank you all for coming.

[The prepared statement of Hon. Doug Ose and the texts of H.R. 37 and H.R. 2138 follow:]

Chairman Doug Ose
Opening Statement
Elevation of the Environmental Protection Agency to Department Level Status:
H.R. 37 and H.R. 2138
June 6, 2003

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I look forward to the testimony of our distinguished panel here today. The panel of witnesses includes: Dr. Paul Portney, President, Resources for the Future; Janice Mazurek, Director for Innovation and the Environment, Progressive Policy Institute; Dr. George Gray, Deputy Director, Center for Risk Analysis, Harvard School of Public Health; Dr. Steven Hayward, F.K. Weyerhaeuser Fellow, American Enterprise Institute; Wesley Warren, Senior Fellow for Environmental Economics, Natural Resources Defense Council; and, Rena U. Steinzor, Professor, University of Maryland School of Law and Board Member, Center for Progressive Regulation.

TESTIMONY OF JANICE MAZUREK
DIRECTOR, CENTER FOR INNOVATION & THE ENVIRONMENT
PROGRESSIVE POLICY INSTITUTE
BEFORE THE SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS OF THE COMMITTEE ON GOVERNMENT REFORM U.S. HOUSE OF REPRESENTATIVES

JUNE 6, 2003

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to appear before you once again to represent the Progressive Policy Institute's views on elevating the U.S. Environmental Protection Agency (EPA) to cabinet level status.

My involvement in this question and related matters dates back to the publication in 1995 of the National Academy of Public Administration report, *Setting Priorities, Getting Results: A New Direction for EPA*. I had the pleasure of serving as a staff researcher on that study, which was commissioned by the Congress to determine whether EPA was allocating resources to meet the most pressing environmental concerns. After that report was published, I joined J. Clarence (Terry) Davies at Resources for the Future, where we published a book that evaluates pollution control policy in the United States.

I currently direct PPI's Center of Innovation and the Environment. Over the past eight years, PPI has promoted performance-based, market-oriented, and community friendly strategies to help solve today's environmental programs and to sustain improvements into the future that the American people demand. We call these "second generation" environmental policies to distinguish them from the first generation of landmark environmental laws and regulations set in place by Congress in the 1960s and 1970s.

In that context, my message today is two fold: PPI strongly supports elevation of EPA to Cabinet status as provided for in H.R. 37, introduced by Congressman Sherwood Boehlert and H.R. 2138, introduced by Congressman Doug Ose. Conferring Cabinet status on EPA would put the organization on equal footing with other departments and send a strong signal internationally that the United States takes the threat of global warming as well as emerging new threats such as those related to chemical or biological attacks and protecting the Nation's water supply seriously. But our view is that elevation alone is insufficient to reorient the agency towards such important new challenges of the 21st century.

As I have stated to you before, an EPA Cabinet bill represents an important opportunity to do even more than serve as a symbolic gesture: it represents an opportunity to provide EPA with the tools to enhance environmental performance.

H.R. 2138 begins to do so in three important ways: 1) the bill promotes better functional integration of what for 30 years has been a deeply fragmented and fractured organization; 2) it promotes the development of science and research to better help identify environmental problems earlier; and 3) it puts in place a process to begin to provide to the public data and statistics to better illustrate the condition of the environment. And because PPI supports the axiom that bigger does not necessary equate with better, we support the bill's aim to make EPA more strategic without significantly increasing the organization's funding levels.

In moving forward with these modifications, I would urge the Subcommittee to also consider providing EPA with the "legal space" to develop more flexible, innovative tools to better allocate scarce resources to meet the most pressing environmental concerns. The Second Generation of Environmental Improvement Act (H.R. 3448) introduced by Reps. Greenwood, Dooley and Tauscher in the 106th Congress provides an excellent blueprint to provide EPA with the authority and resources to pursue more innovative environmental management strategies.

The Modernization Imperative

H.R. 3448 reflects what Karl Hausker has described as a "remarkable convergence of ideas" about how the country could improve the existing system created by Congress 30 years ago to manage and control pollution.[1] Independent researchers and bi-partisan panels during the late 1980s and 1990s have published at least 18 major studies that endorse the idea of making EPA and the statutes it administers more modern (**Table 1**).

Congress, by "overwhelming majorities" in the 1960s and 1970s, passed the current first generation set of environmental protection laws in response to public outrage over highly publicized, highly visible crises such as burning rivers and "killer" smog.[2] In doing so, legislators replaced a patchwork of state laws and local ordinances with a more uniform system of federal standards to protect Americans across the country (**Table 2**). Although the standards are uniform, it is important to note that the laws to address pollution are nonetheless extraordinarily *piecemeal*, passed by Congress to control problems as they occur by environmental medium (air, water, and land). To administer this system, President Nixon created EPA.

During their 30-year history, these first generation environmental laws have achieved some astonishing successes. The laws sharply reduced industrial pollution and urban smog, even as population and cars grew apace.[3] They constructed a national grid to treat and control sewage and the industrial pollution that once set rivers such as the Cuyahoga afire. And the first generation laws—which delegate authority for their implementation to states that demonstrate institutional capacity to administer and enforce them—have helped transform many states from environmental laggards to environmental leaders.

But as a number of studies have demonstrated, the current piecemeal set of pollution control laws only crudely reflects how pollution really behaves. In some cases, the system merely serves to move pollution around. For instance, scientists now understand that up to 35 percent of nitrogen in the Chesapeake Bay originates from car and truck exhaust that blows from the Washington area.[4]

Compounding the problem is the fact that EPA (and most state environmental agencies) is structured according to these piecemeal laws. That is, EPA's air office combats air pollution and its water office tackles water pollution. And although pollution in real life seldom stays confined to such narrow boundaries, when it comes to EPA's separate offices, the twain seldom meet.

As a result of this "stovepipe" bureaucratic structure, high-risk problems sometimes slip through the administrative cracks. The most notable case is MTBE (methyl tertiary butyl ether). For more than ten years, California has mandated MTBE's

addition to gasoline to reduce emissions of smog-causing contaminants. But while the chemical has indeed decreased polluting air emissions in California, it also has leaked from underground storage tanks—and is now a serious source of groundwater pollution that will be costly to clean up.

Unfortunately, at the time of its introduction as a fuel additive, California had no mechanism to allow state agencies responsible for air and water pollution to conduct cross-media reviews of MTBE's potential health risks. The state's experience with MTBE illustrates that pollution cannot be satisfactorily managed within the administrative boundaries of individual statutes.

To improve how their environmental protection agencies set priorities, states such as California have examined how to better integrate their environmental protection agencies but have stopped short of doing so in part out of concerns that their newly-reorganized agencies would no longer comport well with EPA's current medium-specific structure.[5]

Better Integration

By reorganizing EPA from its current medium-specific structure into three major divisions, Representative Ose's bill will help the new Department and states that seek to undertake a similar reorganization to better identify high environmental risks to humans and to the environment and prevent them from 'slipping through the regulatory cracks.'

Although reorganizing the new Department into functional divisions is a promising start, it ultimately will be necessary for Congress to undertake a through review of the existing environmental statutes. I believe that for now, it is prudent for Representative Ose's bill to stop short of revising the current set of environmental statutes. However, the Subcommittee should reconsider Dr. Davies' suggestion, offered at a hearing on this subject almost two years ago, of establishing a Congressional or blue ribbon commission under Congressional auspices to undertake a review of the current statues and recommend how they can be better aligned to promote environmental protection.[6]

Better Data

Reorganizing the new Department into function divisions will help to make EPA more strategic. But EPA cannot manage what it does not measure. Although our monitoring networks are better than they were during the 1970s they are still inadequate to support more performance-based, market-oriented environmental management approaches. In fact, as Terry and I found in our evaluation of the pollution control system some data networks are too sparse to help support first generation approaches. The point is underscored by EPA Inspector General Report released last week. The report found that the agency's computerized database to track water pollution is plagued with problems and may become effectively useless unless the agency takes dramatic steps to fix the system.

Fortunately, Dr. Portney, President of Resources for the Future years ago developed a way to address the data deficit, a solution that is largely reflected in the Chairman's bill – the creation of a Bureau of Environmental Statistics.

The Bureau would provide timely, focused, and comprehensible performance measures – measures that in turn would help to make EPA more strategic by helping to better set the public's sights on environmental results. Better data also has the potential to open the door to more flexible, market-based means that allow the regulated entity to exceed, rather than merely meet, existing national environmental standards.

H.R. 2138, while an important step in the right direction, largely focuses on how EPA collects and reports to the public environmental information. While it may be beyond the jurisdiction of this Subcommittee, it is also imperative that we restructure and streamline how regulated entities report environmental information.

H.R. 3448 contains such provisions. H.R. 3448 is designed to improve not only the quality of data collected and reported by EPA, but also to streamline reporting and recordkeeping requirements by eliminating any redundant or unnecessary requirements and by adding any requirements needed to fill data gaps. I encourage the Subcommittee to consider H.R. 3448's provisions to overhaul how the regulated community currently reports data to EPA.

Strong Science

Much of EPA's 30-year progress has been achieved through the development and application of science to inform and to coordinate regulatory decisions. Yet the agency has never had a top science official, which has left EPA vulnerable to accusations that its science is weak and lacks credibility. Such claims can undermine the agency's regulatory decisions and fuel controversy.

As the scientific complexity of EPA's decisions increases, it is now the time to fix this structural weakness in the agency's operations. Three years ago, the National Academy of Sciences (NAS) put forth a strong and unambiguous set of recommendations for improving science at EPA.[7] The NAS found that science must play a stronger role at EPA in order to tackle today's increasingly complex problems.

PPI for several years has supported the implementation of the NAS recommendations. In 2001, we championed a proposal advanced by Senator Tom Carper (D-DE) and Senator George Voinovich (R-OH), the "Environmental Research Enhancement Act of 2001" (S 1176) to create a new position of Deputy Administrator for Science and Technology at EPA. We also supported counterpart legislation in the House (H.R. 64) by Representative Vernon J. Ehlers (R-MI). Both bills propose to make EPA's science deputy responsible and accountable for the scientific and technical foundations of agency decisions.

Consistent with our position on this issue, we support the Chairman's efforts to strengthen science at EPA, contained in the Department of Environmental Protection Act. The bill endeavors to consolidate what currently are disparate scientific activities scattered throughout the agency into a coherent division and creates an Undersecretary for Science and Information charged with the new division's oversight. Such measures will help to ensure that the Department is better able to identify and address risks to humans and to the environment earlier and more effectively.

Promote Innovation

Strengthening science at EPA will help to identify new threats earlier but EPA also requires innovative new strategies to solve such emerging problems. As mentioned, EPA has done a commendable job in making progress on the environmental problems that command and control laws were designed to fix – smog from smokestacks and sewage. But now we are faced with a new set of environmental challenges, different from those we first recognized in the 1970s. Consider that while two fifths of smog-causing nitrogen oxides come from factories and power plants, the rest comes from cars, railroads, airplanes and other miscellaneous, non-industrial sources whose actual emissions are difficult to control under the Clean Air Act.

Similarly, greenhouse gas emissions remain totally unregulated under the Clean Air Act and run-off from agricultural lands and urban development remains – not discharges from permitted sources under the Clean Water Act – are now the most pervasive form of water pollution, affecting 70 percent of rivers and streams that fail to meet water quality standards.

First generation pollution control laws have been rewritten and updated about as far as they can go; little gain is possible now by major rewrites. Now, progress can only be made in small increments until a broader public consensus is reached in new ways to tackle the big problems.

The first Bush Administration and the Clinton Administration made some notable progress in this direction through a series of voluntary initiatives designed to provide regulated entities with greater flexibility in exchange for better environmental results. Some of these voluntary 'reinvention' initiatives (Energy Star, Green Lights, 33/50) have helped to reduce emissions, save energy and save money. But, for the most part, EPA's voluntary initiatives have served to underscore the need for legislative backing.[8]

To meet pressing new challenges in a manner that is effective and efficient, EPA must be provided with the legal space to design, implement, and evaluate more innovative environmental management practices. H.R. 3448 does just that.

The Department of Environmental Protection Act provides EPA with the management and scientific tools to better meet the environmental challenges of the 21st century. But this Subcommittee may also want to consider additional language such as that contained in H.R. 3448 that provides EPA with the authority to pursue a broad array of experiments to better manage and solve environmental problems.

Conclusion

Terry Davies and I in our book published several years ago found that the fragmented [pollution control] system is in serious trouble.[9] Although it has achieved some important successes, the current system is inadequate to make Americans safer and more prosperous in the future. EPA has made some notable attempts to improve environmental management. But Terry and I concluded that only Congress could effectively remedy EPA's problems. Ultimately, it will be necessary for Congress to revisit the current set of fragmented statutes that EPA administers. The Chairman's

Cabinet elevation bill rightfully refrains from modifying these statutes now but begins to take a few important steps toward making EPA more integrated, data rich, and strategic.

Thank you for inviting me to provide PPI's perspective. I welcome any questions you may have.

Table 1. Second Generation studies and reports

Title	Year	Organization
Unfinished Business: A Comparative Assessment of Environmental Problems	1987	U.S. Environmental Protection Agency. Office of Policy Analysis
Reducing Risk: Setting Priorities and Strategies for Environmental Protection	1990	U.S. Environmental Protection Agency. Science Advisory Board
Setting Priorities, Getting Results: A New Direction for the EPA	1995	National Academy of Public Administration (NAPA)
White House Policy on Reinventing Environmental Regulation	1995	Clinton, William J. and Al Gore
Reinventing the Wheel for Environmental Management.	1995	National Environmental Policy Institute (NEPI)
Sustainable America: A New Consensus for Prosperity, Opportunity and a Healthy Environment for the Future	1996	President's Council on Sustainable Development
Building Partnerships for Accountable Devolution	1996	National Environmental Policy Institute (NEPI)
Integrating Environmental Policy	1996	National Environmental Policy Institute (NEPI)
Industry Incentives for Environmental Improvement: Evaluation of U.S. Federal Initiatives	1996	Global Environmental Management Initiative
Environmental Goals and Priorities: Four Building Blocks for Change	1997	National Environmental Policy Institute (NEPI)
Risk Management. Framework for Environmental Health Risk Management, Volume 1, 2	1997	Presidential/Congressional Commission on Risk Assessment
Resolving the Paradox of Environmental Protection	1997	National Academy of Public Administration (NAPA)
Thinking Ecologically	1997	Esty, Dan C. and Marian R. Chertow, eds., Yale University
The Environmental Protection System in Transition: Toward a More Desirable Future	1998	Enterprise for the Environment
Pollution Control in the U.S.: Evaluating the System	1998	Resources for the Future
Second Generation of Environmental Stewardship: Improve Environmental Results and Broaden Civic Engagement	1999	Progressive Policy Institute
Towards a Sustainable America: Advancing Prosperity, Opportunity, and a Healthy Environment for the 21st Century	1999	President's Council on Sustainable Development
Environment.gov: Transforming Environmental Protection for the 21st Century Vol. 1-III	2000	National Academy of Public Administration (NAPA)

Source: Adapted from Hausker, Karl. "The Convergence of Ideas on Improving the Environmental Protection System." The Center for Strategic and International Studies (CSIS) web report, 1999. Available at: http://www.csis.org/pubs/wr_EnvironPS.pdf

Table 2. Federal environmental protection laws

Law	Year Authorized
Clean Air Act	1970
Endangered Species Act	1973
National Environmental Policy Act	1970
Clean Water Act	1972
Safe Drinking Water Act	1974
Resource Conservation and Recovery Act	1976
Toxic Substances and Control Act	1976
Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)	1980

Source: Adapted from Davies, J.Clarence and Jan Mazurek. *Pollution Control in the U.S.: Evaluating the System.* Washington, D.C.: Resources for the Future. 1998.

[1] Hausker, Karl. "The Convergence of Ideas on Improving the Environmental Protection System." The Center for Strategic and International Studies (CSIS) web report, 1999. Available at: http://www.csis.org/pubs/wr_EnvironPS.pdf

[2] Lazarus, Richard. "A Different Kind of Republican Moment in Environmental Law." Draft. January, 8. 2003.

[3] Davies, J.Clarence and Jan Mazurek. *Pollution Control in the U.S.: Evaluating the System.* Washington, D.C.: Resources for the Future. 1998.

[4] Davies, J.Clarence and Jan Mazurek. *Pollution Control in the U.S.: Evaluating the System.* Washington, D.C.: Resources for the Future. 1998.

[5] California Unified Statute Commission. 1997. *Unifying Environmental Protection in California. Final Report.* Sacramento, CA.

[6] Testimony of J. Clarence (Terry) Davies, Senior Fellow, Resources for the Future before the U.S. House of Representatives, Committee on Government Reform, Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs.

[7] National Academy of Sciences. Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices. Commission on Life Sciences (CLS), Commission on Geosciences, Environment and Resources (CGER). 2000.

[8] Mazurek, Jan. *Back to the Future: How to Put Environmental Modernization Back on Track.* Washington, D.C. Progressive Policy Institute: April 2003.

[9] Davies, J.Clarence and Jan Mazurek. *Pollution Control in the U.S.: Evaluating the System.* Washington, D.C.: Resources for the Future. 1998.

May 30, 2003

MEMORANDUM FOR MEMBERS OF THE GOVERNMENT REFORM SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS

FROM: Doug Ose

SUBJECT: Briefing Memorandum for June 6, 2003 Hearing, "Elevation of the Environmental Protection Agency to Departmental Level Status: H.R. 37 and H.R. 2138"

On Friday, June 6, 2003, at 10:00 a.m., in Room 2154 Rayburn House Office Building, the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs will hold a legislative hearing on two bills seeking to elevate the Environmental Protection Agency (EPA) to department level status. The hearing is entitled "Elevation of the Environmental Protection Agency to Departmental Level Status: H.R. 37 and H.R. 2138."

In the last Congress, the Subcommittee explored EPA elevation at three hearings held on September 9, 2001, March 21, 2002, and July 16, 2002. At the time, two EPA elevation bills were referred to the Subcommittee: H.R. 2438 introduced by Congressman Sherwood Boehlert and H.R. 2694 introduced by former Congressman Stephen Horn. Several experts, representatives of the regulated community, State representatives, and EPA and other Administration officials testified to both the merits of elevating EPA to department level status and the various problems at EPA that hinder effective environmental protection. During the 107th Congress, the Subcommittee did not markup either EPA elevation bill.

The current hearing will examine two new EPA elevation bills that were referred to the House Government Reform Committee. H.R. 37, introduced by Congressman Sherwood Boehlert, is identical to H.R. 2438, as introduced in the 107th Congress. H.R. 37 simply elevates EPA to department level status.

H.R. 2138, introduced by Congressman Doug Ose, provides for elevation while instituting structural changes to EPA's organization and provides for a Bureau of

Environmental Statistics[1]. Specifically, H.R. 2138 would reorganize EPA into three Under Secretaries: (1) Policy, Planning, and Innovation; (2) Science and Information; and, (3) Compliance, Implementation, and Enforcement (see Chart A). The Under Secretary for Policy, Planning, and Innovation would have authority over all program offices, regulations and policy development. The Under Secretary for Implementation, Compliance, and Enforcement would supervise the Regional offices. The bill also provides for an Under Secretary for Science and Information in order to centralize scientific activities and ensure dissemination throughout the Department. Finally, the bill creates a Bureau of Environmental Statistics to collect, analyze and report on environmental and human health conditions, also supervised by the Under Secretary for Science and Information.

Unlike many Federal departments, EPA does not gather and analyze statistical data on environmental conditions to determine the success of EPA activities. Indeed, many Federal departments utilize statistical agencies to provide independent and reliable data for decisionmaking and program evaluation. Instead, EPA primarily uses output measurements (such as the number of permits and enforcement actions) instead of outcome measurements (such as cleaner water, fewer illnesses, and less days off from school or work) to determine whether EPA is reaching its goals.

Both H.R. 37 and H.R. 2138 redesignate EPA as the Department of Environmental Protection. In the main, Congress previously reorganized existing departments when creating new departments, such as the recently-enacted Homeland Security Act of 2003 (Pub. Law 107-296), Department of Education in 1979 (Pub. Law 96-98), and Department of Energy in 1977 (Pub. Law 95-91) (see Chart B). A question to be addressed at the hearing is whether Congress should include management and organizational changes in conjunction with the elevation of an existing Agency.

Under the current regime, EPA made great progress in the cleanup of the large industrial and municipal wastes that served as the impetus for EPA's establishment by President Nixon over 30 years ago. However, this nation faces a new generation of environmental challenges that stem not from major point source pollution, but from sources, such as agricultural and urban runoff, dry cleaners and mobile sources. The Subcommittee learned from the last Congress' hearings that, in the face of these new challenges, the current fragmented structure and culture of EPA may hinder the Agency's ability to efficiently and effectively protect the environment and human health in the future.

Originally, the first EPA Administrator created a relatively small Agency with 4,084 employees, three Assistant Administrators, ten Regional offices, and five environmental commissioners. In the subsequent 30 years, EPA has grown to over 18,000 employees. Despite this expansion, EPA is organized into ten Regional offices,

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[1] Several departments have independent statistical agencies, including the Commerce Department's Bureau of the Census, the Education Department's National Center for Education Statistics, the Energy Department's Energy Information Administration, Health and Human Services's National Center for Health Statistics, and the Labor Department's Bureau of Labor Statistics.

nine Assistant Administrators (program offices), and numerous other offices each of which still reports directly the Administrator and Deputy Administrator (see Chart C). In addition, since EPA's inception, Congress has passed 11 major environmental statutes based on environmental media or pollution source, each expanding EPA's jurisdiction. Hearing witnesses testified that this "stovepipe" structure hinders the dissemination of scientific data, innovative programs, and cross-media analysis. Witnesses reported that the lack of coordination and information sharing between program offices is particularly detrimental to successful policymaking.

Moreover, as a practical matter, scientific research is conducted in the program offices and the Office of Research and Development. During the Subcommittee's hearings, several witnesses testified that EPA's scientific decentralization requires policymakers to search for data in multiple locations, facilitates incompatibility of databases, results in inefficient research planning, prevents adequate peer review, and fosters an uncooperative "fiefdom" culture within the program offices that stymies thorough scientific review.

Importantly, States play an increasingly vital role in the implementation of our environmental protection laws. Most States develop their own policies, regulations, and enforcement mechanisms based on the delegated authority of Federal environmental statutes. According to The Environmental Council of the States (ECOS), States spent $13.6 billion in Fiscal Year 2000 on environmental protection, a 64.8 percent increase since 1986. Moreover, States reportedly collect 94 percent of the environmental data found in EPA's databases; yet, all States do not collect data in a uniform manner, leaving EPA with an incomplete picture of the state of the environment.

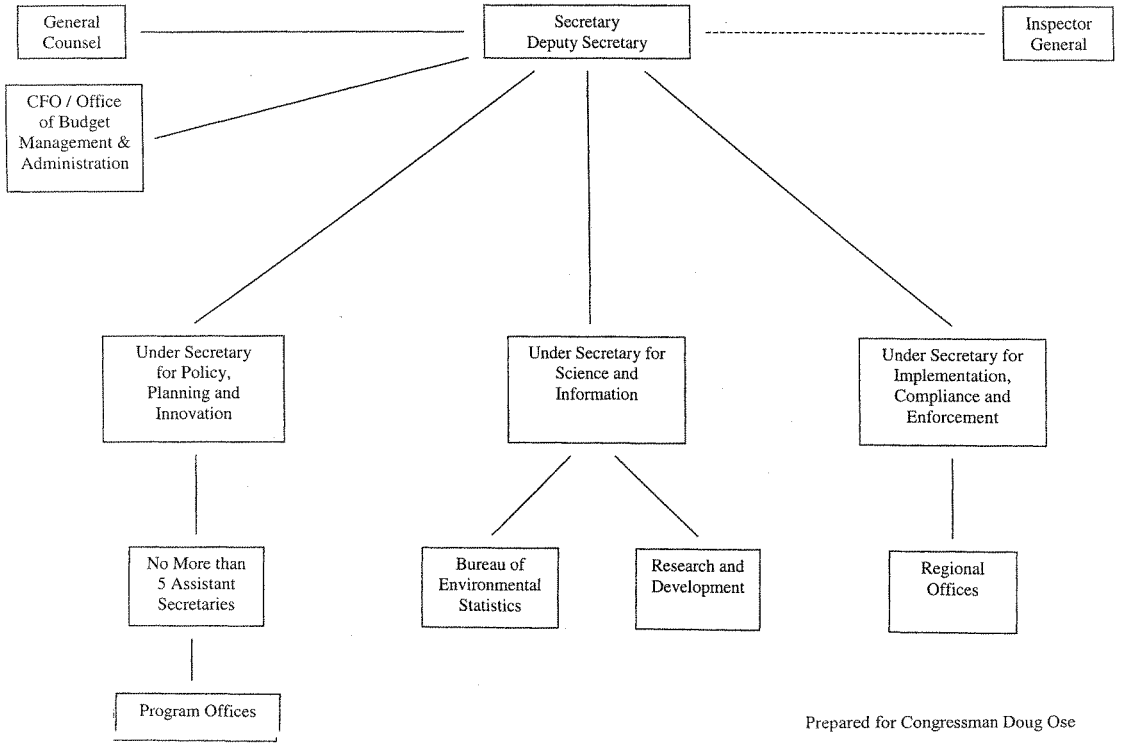
EPA is charged with one of the most important tasks in government: protecting this Nation's environment and human health. Every President since President George H.W. Bush has asked the Administrator of EPA to sit on the Cabinet without formal designation as an executive department. In most industrialized nations, the leading environmental official is a formal member of the Cabinet or its equivalent.

The invited witnesses for the hearing are: Dr. Paul Portney, President, Resources for the Future; Jan Mazurek, Director for Innovation and the Environment, Progressive Policy Institute; Dr. George Gray, Deputy Director, Harvard Center for Risk Analysis, Harvard School of Public Health; Dr. Steven Hayward, F.K. Weyerhaeuser Fellow, American Enterprise Institute; Wesley Warren, Senior Fellow for Environmental Economics, Natural Resources Defense Council; and, Center for Progressive Regulation.

Attachments

Chart A

DEPARTMENT OF ENVIRONMENTAL PROTECTION (H.R. 2138)



Prepared for Congressman Doug Ose

Chart B

LAST SIX CABINET ELEVATIONS

Department	Date	Law	Agency Transfers of Power
HUD	9/9/1965	PL 89-174	All of the functions, powers, & duties of the Community Facilities Administration, Federal Housing Administration, Federal National Mortgage Association (Fannie Mae), Housing & Home Finance Agency, Public Housing Administration, & Urban Renewal Administration
Transportation	10/15/1966	PL 89-670	**DOC** (Bureau of Public Roads, Nat'l Traffic Safety Agency/Nat'l Highway Safety Agency, Office of High Speed Ground Transportation, & Great Lakes Pilotage Administration), **DOI** (Alaska Railroad), **Treasury** (Bureau of Customs' vessel documentation functions & Coast Guard), Civil Aeronautics Board, Federal Aviation Agency, Interstate Commerce Commission, & St. Lawrence Seaway Development Corporation
Energy	8/4/1977	PL 95-91	All functions of **DOC** (Office of Energy Programs), **DOD** Navy (various), **HUD** (various), **DOI** (functions relating to electric power & 4 power marketing agencies - Bonneville, Southwestern, Southeastern, Alaska - & certain functions of Bureau of Mines), the Energy Research & Development Administration, Federal Energy Administration, & the Federal Power Commission
Education	10/17/1979	PL 96-88	Transfers from **DOD** (administration and operation of overseas dependents schools); **HEW** (Advisory Council on Education Statistics, Education Division, Federal Education Data Acquisition Council, Institute of Museum Services, Office for Civil Rights, & offices implementing the Rehabilitation Act of 1973); **HUD** (all functions relating to college housing loans); **DOJ** (all functions of the Attorney General & the Law Enforcement Assistance Administration with regard to the student loan & grant programs known as the law enforcement education & the law enforcement intern program); **DOL** (functions relating to programs for the education of migrant & seasonal farm workers); National Science Foundation (science education)
Veterans Affairs	10/25/1988	PL 100-527	Veterans' Administration (establishment & redesignation as a Department)

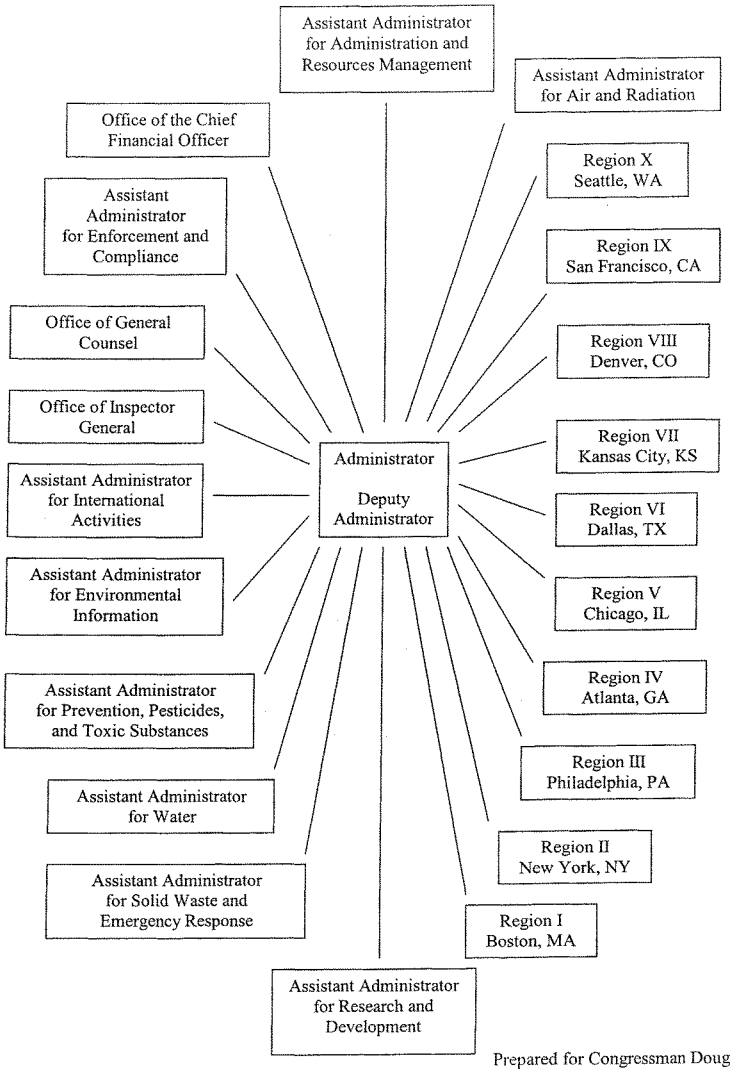
LAST SIX CABINET ELEVATIONS (Continued)

Department	Date	Law	Agency Transfers of Power
Homeland Security	11/25/2002	PL 107-296	**USDA** (agricultural import & entry inspection activities under the covered animal & plant health protection laws, & Plum Island Animal Disease Center) **DOC** (NOAA's Integrated Hazard Information System) **DOD** (National Bio-Weapons Defense Analysis Center) **DOE** (chemical & biological national security & supporting programs; nonproliferation & verification R&D program; nuclear smuggling program activities; proliferation detection program activities; nuclear assessment program; assessment, detection & cooperation program activities of the international materials protection & cooperation program; life sciences activities of the biological & environmental research program related to microbial pathogens; Environmental Measurements Laboratory; & Lawrence Livermore National Laboratory) **HHS** (Metropolitan Medical Response System, National Disaster Medical System, Office of Emergency Preparedness, Strategic National Stockpile, etc.) **DOJ** (Office of Domestic Preparedness, Domestic Emergency Support Teams; FBI's National Domestic Preparedness Office, Critical Infrastructure Assurance Office & National Infrastructure Protection Center; & INS' specified law enforcement & border management functions) **DOT** (Coast Guard homeland security missions & Transportation Security Administration) **Treasury** (Customs Service, various Secret Service functions, & Federal Law Enforcement Training Center) **FEMA** **GSA** (Federal Protective Service)

Prepared for Congressman Doug Ose

ENVIRONMENTAL PROTECTION AGENCY

Chart C



Prepared for Congressman Doug Ose

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108TH CONGRESS
1ST SESSION

H. R. 37

To elevate the Environmental Protection Agency to Cabinet-level status and redesignate such agency as the Department of Environmental Protection.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 7, 2003

Mr. BOEHLERT introduced the following bill; which was referred to the Committee on Government Reform

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A BILL

To elevate the Environmental Protection Agency to Cabinet-level status and redesignate such agency as the Department of Environmental Protection.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Department of Environmental Protection Act".

SEC. 2. REDESIGNATION OF ENVIRONMENTAL PROTECTION AGENCY AS DEPARTMENT OF ENVIRONMENTAL PROTECTION.

(a) REDESIGNATION.—The Environmental Protection Agency is redesignated as the Department of Envi-

ronmental Protection (hereinafter in this Act referred to as the "Department"), and shall be an executive department in the executive branch of the Government.

(b) SECRETARY OF ENVIRONMENTAL PROTECTION.—(1) There shall be at the head of the Department a Secretary of Environmental Protection (hereinafter in this Act referred to as the "Secretary") who shall be appointed by the President, by and with the advice and consent of the Senate, except as provided in paragraph (2).

(2) If so designated by the President, the individual who has been nominated and confirmed and is serving as the Administrator of the Environmental Protection Agency on the effective date of this Act shall become the Secretary of Environmental Protection, without reconfirmation by the Senate.

(c) TRANSFER OF FUNCTION, POWERS, AND DUTIES.—The functions, powers, and duties of each officer and employee of the Environmental Protection Agency are transferred to and vested in the corresponding officer or employee of the Department.

(d) DELEGATION OF AUTHORITY.—The Secretary may, consistent with other laws—

(1) delegate any functions, powers, or duties, including the promulgation of regulations, to such

officers and employees of the Department as the Secretary may designate; and

(2) authorize such successive redelegations of such functions, powers, or duties within the Department as the Secretary considers necessary or appropriate.

SEC. 3. REFERENCES.

Any reference in any other Federal law, Executive order, rule, regulation, reorganization plan, or delegation of authority, or in any document—

(1) to the Environmental Protection Agency is deemed to refer to the Department of Environmental Protection;

(2) to the Administrator of the Environmental Protection Agency is deemed to refer to the Secretary of Environmental Protection; and

(3) to a subordinate official of the Environmental Protection Agency is deemed to refer to the corresponding official of the Department of Environmental Protection.

SEC. 4. SAVINGS PROVISIONS.

(a) CONTINUING EFFECT OF LEGAL DOCUMENTS.—All orders, determinations, rules, regulations, permits, grants, contracts, certificates, licenses, privileges, agreements, registrations, and other administrative actions—

(1) which have been issued, made, granted or allowed to become effective by the President, the Administrator or other authorized official of the Environmental Protection Agency, or by a court of competent jurisdiction, which relate to functions of the Administrator or any other officer or agent of the Environmental Protection Agency actions; and

(2) which are in effect on the date of the enactment of this Act; shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, or other authorized official, by a court of competent jurisdiction, or by operation of law.

(b) PROCEEDINGS NOT AFFECTED.—(1) This Act shall not affect any proceeding, proposed rule, or application for any license, permit, certificate, registration, or financial assistance pending before the Environmental Protection Agency on the date of the enactment of this Act, and the effect of any such proceeding, proposed rule, or application shall continue. Orders shall be issued, and final determinations shall be made, in any such proceeding, proposed rule, or application, appeals shall be taken therefrom, and payments shall be made pursuant to such orders, as if this Act had not been enacted, and

orders issued with respect to any such proceeding, proposed rule, or application shall continue in effect until modified, terminated, superseded, or revoked by a duly authorized official, by a court of competent jurisdiction, or by operation of law.

(2) Nothing in this subsection prohibits the discontinuance or modification of any such proceeding, proposed rule, or application under the same terms and conditions and to the same extent that such proceeding, proposed rule, or application could have been discontinued or modified if this Act had not been enacted.

(c) SUITS NOT AFFECTED.—The provisions of this Act shall not affect suits commenced before the effective date of this Act, and in all such suits, proceedings shall be had, appeals taken, and judgments rendered in the same manner and with the same effect as if this Act had not been enacted.

(d) NONABATEMENT OF ACTIONS.—No suit, action, or other proceeding commenced before the effective date of this Act by or against the Environmental Protection Agency, or by or against any individual in the official capacity of such individual as an officer of the Environmental Protection Agency, shall abate by reason of the enactment of this Act.

(e) PROPERTY AND RESOURCES.—The contracts, liabilities, records, property, and other assets and interests of the Environmental Protection Agency shall, after the effective date of this Act, be considered to be the contracts, liabilities, records, property, and other assets and interests of the Department of Environmental Protection.

SEC. 5. CONFORMING AMENDMENTS.

After consultation with the appropriate committees of Congress, the Secretary shall prepare and submit to Congress proposed legislation containing necessary and appropriate technical and conforming amendments to the laws of the United States, to reflect the changes made by this Act. Such proposed legislation shall be submitted not later than one year after the effective date of this Act.

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108TH CONGRESS
1ST SESSION

H. R. 2138

To elevate the Environmental Protection Agency to cabinet-level status and redesignate such agency as the Department of Environmental Protection.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2003

Mr. OSE introduced the following bill; which was referred to the Committee on Government Reform

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A BILL

To elevate the Environmental Protection Agency to cabinet-level status and redesignate such agency as the Department of Environmental Protection.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Department of Environmental Protection Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The United States is one of the few nations that does not place environmental protection at a cabinet-level position. Environmental protection is as important as other cabinet functions, and is critical to the health and well-being of this nation's ecology and population.

(2) During the 107th Congress, a subcommittee of the Government Reform Committee of the House of Representatives held 3 hearings to explore the merits of elevating the Environmental Protection Agency to department-level status. These hearings addressed two bills that would reorganize the Agency as a department and that were introduced, respectively, by Congressman Sherwood Boehlert and former Congressman Steve Horn. Several "think tanks", industry groups, and Federal and State officials testified not only about current organizational problems at the Agency that hinder effective envi-

ronmental protection, but also about the merits of reorganizing the Agency as a department.

(3) Currently, each Environmental Protection Agency regional office, program office, and division reports directly to the Administrator and Deputy Administrator of the Agency. This stovepipe organization results in the Agency's inability to effectively address cross-media environmental protection. The Agency lacks adequate oversight and coordination of its offices to ensure that science, policy, and implementation are integrated throughout the Agency.

(4) Several Federal departments have their own statistical agencies to provide independent and reliable data for decisionmaking and analysis. These include the Department of Commerce's Bureau of the Census, the Department of Education's National Center for Education Statistics, the Department of Energy's Energy Information Administration, the Department of Health and Human Services' National Center for Health Statistics, and the Department of Labor's Bureau of Labor Statistics. The Environmental Protection Agency lacks statistical data on current environmental conditions necessary to measure whether the Agency's policies and regu-

lations efficiently and successfully protect the environment.

(5) Currently, the Environmental Protection Agency lacks scientific leadership and critical science for decisionmaking. Scientific activities take place in both the Office of Research and Development and the program offices without sufficient coordination and intraagency dissemination of information.

(6) Reorganization of the Environmental Protection Agency, in addition to its elevation to the Cabinet, could facilitate efficient and successful environmental protection in a budget-neutral manner.

SEC. 3. DEFINITIONS.

For purposes of this Act—

(1) the term "Secretary" means the Secretary of the Department;

(2) the term "Department" means the Department of Environmental Protection or any component thereof;

(3) the term "research" means any research, development, and demonstration; and

(4) the term "environmental media" includes air, land, water, and other media.

SEC. 4. REDESIGNATION OF ENVIRONMENTAL PROTECTION AGENCY AS DEPARTMENT OF ENVIRONMENTAL PROTECTION.

(a) REDESIGNATION.—The Environmental Protection Agency is redesignated as the Department of Environmental Protection (hereinafter in this Act referred to as the "Department"), and shall be an executive department in the executive branch of the Government.

(b) MISSION OF DEPARTMENT.—The mission of the Department is to—

(1) protect and improve the quality of the environment;

(2) protect the public from actual and potential unreasonable environmental risks, including risks from wastes, products, and other substances that may be found in the environment;

(3) identify, analyze, monitor, and report on existing and potential unreasonable risks to humans and the environment; and

(4) assist State, regional, and local government agencies in protecting humans and the environment from unreasonable risks.

(c) GOAL; COOPERATION.—In undertaking responsibilities under this and other laws, the Department—

(1) shall be guided by the goal of improving overall environmental quality as effectively and efficiently as possible; and

(2) shall cooperate with States, other government agencies, other nations, international agencies, and the general public.

SEC. 5. SECRETARY OF ENVIRONMENTAL PROTECTION.

(a) SECRETARY OF ENVIRONMENTAL PROTECTION.—

(1) IN GENERAL.—There shall be at the head of the Department a Secretary of Environmental Protection (hereinafter in this Act referred to as the "Secretary") who shall be appointed by the President, by and with the advice and consent of the Senate, except as provided in paragraph (2).

(2) CONTINUATION BY ADMINISTRATOR.—If so designated by the President, the individual who has been nominated and confirmed and is serving as the Administrator of the Environmental Protection Agency on the effective date of this Act shall become the Secretary of Environmental Protection, without reconfirmation by the Senate.

(b) TRANSFER OF FUNCTION, POWERS, AND DUTIES.—

(1) IN GENERAL.—The functions, powers, and duties of each officer and employee of the Environmental Protection Agency are transferred to and vested in the corresponding officer or employee of the Department.

(2) DESIGNATION OF OFFICER OR EMPLOYEE.—In any case in which the Secretary determines that the corresponding officer or employee of the Department is not apparent for purposes of paragraph (1), the Secretary may designate such officer or employee.

(c) DELEGATION OF AUTHORITY.—The Secretary may, consistent with this and other laws—

(1) delegate any functions, powers, or duties, including the promulgation of regulations, to such officers and employees of the Department as the Secretary may designate; and

(2) authorize such successive redelegations of such functions, powers, or duties within the Department as the Secretary considers necessary or appropriate.

SEC. 6. OTHER OFFICERS.

(a) SENATE-CONFIRMED OFFICERS.—There are the following officers of the Department, who shall be ap-

pointed by the President, by and with the advice and consent of the Senate:

(1) A Deputy Secretary of Environmental Protection, who shall be the Secretary's first assistant for purposes of subchapter III of chapter 33 of title 5, United States Code.

(2) 3 Under Secretaries of Environmental Protection, as follows:

(A) An Under Secretary for Science and Information.

(B) An Under Secretary for Policy, Planning, and Innovation.

(C) An Under Secretary for Implementation, Compliance, and Enforcement.

(3) A Chief Financial Officer as provided in chapter 9 of title 31, United States Code.

(4) An Inspector General, as provided in section 3(a) of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) OTHER OFFICERS.—To assist the Secretary in the performance of the Secretary's functions, there are the following officers, appointed by the President:

(1) Up to 5 Assistant Secretaries of Environmental Protection.

(2) A General Counsel, who shall be the chief legal officer of the Department.

(c) REGIONAL ADMINISTRATORS.—There shall be up to 10 Regional Administrators of the Department, who shall be appointed by the Secretary and who shall report to the Under Secretary for Implementation, Compliance, and Enforcement.

SEC. 7. FUNCTIONS OF OFFICERS.

(a) IN GENERAL.—Subject to the provisions of this Act, every officer of the Department shall perform the functions specified by law for the official's office or prescribed by the Secretary.

(b) DEPUTY SECRETARY.—The Deputy Secretary of Environmental Protection—

(1) shall perform such functions as the Secretary shall assign or delegate; and

(2) shall act as Secretary during the absence or disability of the Secretary or in the event of a vacancy in the office of Secretary.

(c) UNDER SECRETARY FOR SCIENCE AND INFORMATION.—The Under Secretary for Science and Information shall be responsible for management and oversight of the Bureau of Environmental Statistics, research and development, the Department's laboratories, scientific analysis, and data on the status, trends, and human health risks

associated with the environment, including the following functions:

(1) Identifying and defining the important scientific issues facing the Department, including those embedded in major policy or regulatory proposals to ensure that critical science is identified early and developed in time to inform decisions.

(2) Developing and overseeing an integrated Department wide strategy for acquiring, disseminating, and applying information.

(3) Ensuring that scientific and technical information is analyzed across environmental media.

(4) Conducting, sponsoring, and evaluating environmental science and technology research, the results of which shall be used to help initiate, formulate, and carry out the Department's agenda.

(5) Ensuring that the complex scientific outreach and communication needs of the Department are met, including—

(A) the use of credible science in support of the regulatory offices, regions, and Department wide policy deliberations; and

(B) communication with the broader domestic and international scientific community

for scientific knowledge that is relevant to a Department policy or regulatory issue.

(6) Coordinating and overseeing scientific quality assurance and peer review practices throughout the Department to ensure that critical science used in decisionmaking is of sufficient quality and that the quality of the science and the associated uncertainty is clearly described.

(7) Producing an annual report assessing environmental and human health risks, including comparison of such risks to other human health risks.

(8) Such other functions as the Secretary shall assign.

(d) UNDER SECRETARY FOR POLICY, PLANNING, AND INNOVATION.—The Under Secretary for Policy, Planning, and Innovation shall be responsible for the development of nationwide programs and policy to address environmental and human health risks based on statistical and other scientific information, including the following functions:

(1) Promulgation of nationwide regulations and nonbinding guidance.

(2) Oversight of the Assistant Secretaries of the Department.

(3) Such other functions as the Secretary shall assign.

(e) UNDER SECRETARY FOR IMPLEMENTATION, COMPLIANCE, AND ENFORCEMENT.—The Under Secretary for Implementation, Compliance, and Enforcement shall be responsible for oversight of regional offices of the Department to ensure consistent implementation of and compliance with Department programs, including the following:

(1) Coordinating Department programs with, and assisting, State and local governments in implementing environmental programs.

(2) Such other functions as the Secretary shall assign.

(f) ASSISTANT SECRETARIES.—The Secretary shall delegate among the Assistant Secretaries of Environmental Protection functions otherwise authorized by law.

(g) CHIEF FINANCIAL OFFICER.—The Chief Financial Officer of the Department shall, in addition to functions under chapter 9 of title 31, United States Code, and other laws, be responsible for the following:

(1) Ensuring that the budget, human resources, and regulatory costs imposed by the Department accurately reflect environmental and human health risks.

(2) Ensuring that the Department's annual performance plan under section 1115 of title 31, United States Code, includes performance indicators on the status of the environment for each departmental program.

(3) Ensuring that the Department's annual program performance report under section 1116 of title 31, United States Code—

(A) reviews the success of achieving the performance goals of the fiscal year covered by the report; and

(B) evaluates the performance plan under section 1115 of that title for the current fiscal year relative to the performance achieved toward the performance goals in the fiscal year covered by the report.

(4) Such other functions as the Secretary shall assign.

SEC. 8. BUREAU OF ENVIRONMENTAL STATISTICS.

(a) ESTABLISHMENT.—There shall be in the Department the Bureau of Environmental Statistics (in this section referred to as the "Bureau"). The purpose of the Bureau is to provide in accordance with this section such environmental quality and related public health and economic information, and such evaluation and analyses of

such information, as may be appropriate, to meet adequately and fully the needs of the Department in carrying out its functions under applicable law, and the Congress.

(b) DIRECTOR OF ENVIRONMENTAL STATISTICS.—

(1) IN GENERAL.—The Bureau shall be under the direction of the Director of Environmental Statistics (hereinafter in this section referred to as the "Director"), who shall be appointed by the President, by and with the advice and consent of the Senate. The Director shall report to the Under Secretary for Science and Information.

(2) APPOINTMENT, TERM, AND REMOVAL.—

(A) APPOINTMENT AND TERM.—The Director shall—

(i) be appointed by the President for a term of 4 years; and

(ii) be selected from individuals who are well qualified through experience or training in the collection and analysis of environmental statistics.

(B) SERVICE AFTER EXPIRATION OF TERM.—An individual may, at the request of the Secretary, serve as Director after the expiration of his or her term for not more than 3

months until his or her successor has taken office.

(C) REMOVAL.—An individual may be removed as Director by the Secretary only for malfeasance in office or neglect of duty.

(D) REAPPOINTMENT.—An individual serving as Director may be reappointed for additional terms.

(c) FUNCTIONS OF DIRECTOR.—

(1) IN GENERAL.—The functions of the Director shall include the following:

(A) Collecting, compiling, analyzing, and publishing a comprehensive set of environmental quality and related public health, economic, and statistical data for determining environmental quality and related measures of public health, over both the short- and long-term, including assessing—

(i) ambient conditions and trends; and

(ii) the distribution of environmental conditions and related public health conditions across all affected populations, including those populations identifiable on the basis of income, race, ethnicity, or national origin.

(B) Evaluating the adequacy of available statistical measures to determine the Department's success in fulfilling statutory requirements.

(C) Ensuring that data and measures referred to in this subsection are accurate, reliable, relevant, and in a form that permits systematic analysis.

(D) Collecting and analyzing such other data as may be required by the Director to—

(i) efficiently and effectively fulfill the Director's responsibilities, or

(ii) identify new environmental problems.

(E) Conducting specialized analyses and preparing special reports on particular subjects whenever required to do so by the President, by law, or by the Secretary, or when considered appropriate by the Director.

(F) Making readily accessible or, to the extent practicable, disseminating all publicly available data collected under subparagraph (A) or (B), in a timely manner and using dissemination methods that will maximize the utility of

such publicly available information to the public.

(G) Preparing and submitting to the Congress and the Secretary an annual report on environmental conditions and public health conditions, using, to the maximum extent practicable and consistent with the Director's duties under this Act, reliable statistical sampling techniques.

(H) Making available to the public, upon request, the annual report under subparagraph (G), and publishing a notice of such availability in the Federal Register.

(2) TECHNICAL CAPABILITIES TO PERFORM ANALYSES.—The Director shall establish and maintain the scientific, engineering, statistical, and other technical capability to perform analysis of environmental quality and related public health and economic data, to—

(A) verify the accuracy of items of environmental quality and related public health and economic data submitted to the Director; and

(B) ensure the coordination and comparability of such data.

(d) POWERS OF DIRECTOR.—

(1) IN GENERAL.—The Director is authorized on a nonexclusive basis to exercise and enforce any authority vested in the Secretary by law that relates to the collection, gathering, reporting, evaluating, analysis, or dissemination of environmental quality data and related measures of public health in order to carry out fully the functions of the Director.

(2) ACTIONS NOT SUBJECT TO APPROVAL.—The Director shall not be required to—

(A) obtain the approval of any other officer or employee of the Department in connection with the collection, compilation, evaluation, analysis, or dissemination of any information; or

(B) obtain, prior to publication, the approval of any other officer or employee of the United States with respect to the substance of any reports prepared in accordance with law.

(3) PROVIDING ASSISTANCE.—The Director may, upon request, provide technical assistance to offices of the Department and to other Federal agencies for the purpose of assuring the technical quality and the coordination of statistical activities of the Department. Such assistance may include reviewing data collection plans, survey designs, and

pretests, management of data, and quality of data. The Director shall, upon request, promptly provide any information or analysis in the possession of the Bureau to any office within the Department which such office determines relates to the functions of such office.

(4) COLLECTION OF DATA FROM OTHER AGENCIES, PERSONS, ETC.—Subject to other applicable provisions of law, the Director, in carrying out responsibilities under this Act, may collect data from such Federal agencies, State or local governments or instrumentalities, Indian tribes, businesses, and other individuals, persons, organizations, and institutions as the Director considers appropriate.

(5) USE OF DATA COLLECTED BY FEDERAL AGENCIES.—

(A) IN GENERAL.—The Director may—

(i) use data collected by any Federal agency, and

(ii) enter into interagency or intraagency agreements for the collection of data for the purposes of this section.

(B) PROVISION OF DATA TO DIRECTOR.—Subject to applicable law, all Federal agencies (including agencies in the Department) shall

provide to the Director, in a timely manner and to the extent possible in a usable electronic format, any data that the Director requires to carry out responsibilities under this Act.

(C) COOPERATIVE COLLECTION OF DATA.—The Director may—

(i) arrange with any agency, organization, or institution for the cooperative collection of data for the purposes of this section, and

(ii) assign employees of the Bureau to any such agency, organization, or institution to assist in such collection.

(6) OBTAINING EMPLOYEES AND SERVICES.—The Director—

(A) may select, appoint, and employ such officers and employees as may be necessary to carry out the functions of the Bureau, subject to—

(i) the provisions of title 5, United States Code, governing appointments in the competitive service, and

(ii) the provisions of chapter 51 and subchapter III of chapter 53 of such title

relating to classification and General Schedule pay rates; and

(B) may obtain services as authorized by section 3109 of title 5, United States Code, at a rate not to exceed the equivalent daily rate payable for level V of the Executive Schedule under section 5316 of such title.

(e) STAFF.—The Secretary shall ensure that the Bureau of Environmental Statistics has staff sufficient to enable the Director to efficiently carry out the duties of the Director.

(f) CONTINUING PERFORMANCE OF FUNCTIONS OF DIRECTOR.—An individual who, on the effective date of this Act, is performing any of the functions required by this section to be performed by the Director may continue to perform such functions until such functions are assigned to an individual appointed as the Director under this Act.

(g) AVAILABILITY OF DIRECTOR TO CONGRESS; SPECIAL REPORTS.—The Director—

(1) shall be available to the Congress to provide testimony on subjects under the authority of the Director as any committee of the Congress may request, including on environmental quality data and

related measures of public health and analyses thereof;

(2) shall, subject to otherwise applicable law, make available to any committee of the Congress having jurisdiction over any program of the Department, upon written request of the committee, any information reported or otherwise obtained, and any evaluation or analysis made, by the Director or any officer or employee of the Bureau under this section that relates to that program; and

(3) may provide, and charge for, statistical records, compilations, surveys, and reports to State and local officials, public and private organizations, and individuals.

(h) CONFIDENTIALITY OF INFORMATION.—

(1) IN GENERAL.—Information obtained by the Bureau under this section shall be cataloged and, upon request, shall be promptly made available to the public in a form and manner easily adaptable for public use, except that this subsection shall not require disclosure of matters exempted from disclosure pursuant to paragraph (2) of this subsection or section 552(b) of title 5, United States Code, the Homeland Security Act of 2003 (Public Law 107–296), or other applicable law.

(2) RESTRICTION ON DISCLOSURE.—The Director shall not disclose personally identifiable or corporately identifiable data collected by the Bureau.

(3) ACCESS TO INFORMATION IN POSSESSION OF OTHER FEDERAL AGENCY.—In furtherance and not in limitation of any other authority, the Director, on behalf of the Secretary, shall have access to environmental and health related economic and statistical information in the possession of the Department or any other Federal agency, except information—

(A) the disclosure of which to another Federal agency is expressly prohibited by law; or

(B) the disclosure of which the agency having possession determines would significantly impair the discharge of authorities and responsibilities that have been delegated to, or vested by law, in such agency.

(4) OBTAINING INFORMATION TO WHICH ACCESS IS DENIED.—In any case in which the Director is denied information that is necessary to achieve the purposes of this Act, the Director shall take appropriate action, pursuant to paragraph (3), to obtain such information.

(5) DISCLOSURE OF INFORMATION TO FEDERAL AGENCIES.—Notwithstanding paragraphs (1) and (3) and section 552(b)(4) of title 5, United States Code, the Director may disclose any information obtained under this section to—

(A) the General Accounting Office;

(B) the Inspector General of the Department; and

(C) any department or statistical agency of the Federal Government that requests the information to carry out its lawful functions.

(6) CONTINUING APPLICATION OF OTHER RESTRICTIONS.—Any information disclosed by the Director under paragraph (5) shall continue thereafter to be subject to any restriction, requirement, or condition regarding the use or disclosure of the information that applies to the Department.

(i) ESTABLISHMENT OF PUBLIC PARTICIPATION PROCESS.—The Director shall establish an ongoing balanced process for obtaining public advice, guidance, and recommendations on the implementation of the functions of the Director.

(j) PEER REVIEW OF BUREAU.—

(1) REVIEW REQUIREMENT.—The statistical procedures and methodology of the Bureau shall be

subject to peer review every 2 years. Such review shall be conducted by a Peer Review Team, which shall prepare and submit to the President and the Congress a report describing its investigation and findings.

(2) PEER REVIEW TEAM.—The Peer Review Team shall consist of at least 5 professionally qualified persons who are officers or employees of the United States, of whom at least—

(A) 1 shall be designated by the Director of the Bureau of the Census;

(B) 1 shall be designated by the Commissioner of Labor Statistics;

(C) 1 shall be designated by the Director of the National Center for Health Statistics;

(D) 1 shall be designated by the Administrator of the Energy Information Administration; and

(E) 1 shall be designated by the Comptroller General of the United States.

(3) CHAIRMAN.—The Secretary shall appoint the Chairman of the Peer Review Team.

(4) RESPONSIBILITIES OF DIRECTOR AND SECRETARY.—The Director and the Secretary—

(A) shall cooperate fully with the Peer Review Team; and

(B) notwithstanding any other provisions of law, shall make available to the Peer Review Team such relevant data, information, documents, and services as the Peer Review Team determines are necessary for successful completion of its peer review.

(5) CONFIDENTIALITY OF INFORMATION.—Information made available to the Peer Review Team under paragraph (4)(B) shall be subject to the confidentiality standards applicable to the information under subsection (h).

(6) CONFLICTS OF INTEREST.—Each member of the Peer Review Team who is a non-Federal employee shall not possess any interest that conflicts with the member's duty as a member of the Peer Review Team.

(k) SPECIFICATION IN BUDGET OF PROPOSED APPROPRIATIONS.—The President shall include in each budget submitted under section 1105 of title 31, United States Code an estimate of expenditures and appropriations necessary to carry out this section for the fiscal year covered by the budget.

SEC. 9. EXECUTIVE SCHEDULE COMPENSATION OF DEPARTMENT OFFICERS.

(a) EXECUTIVE LEVEL I.—Section 5312 of title 5, United States Code, is amended by inserting after the item relating to the Secretary of Homeland Security the following:

"Secretary of Environmental Protection.".

(b) EXECUTIVE LEVEL II.—Section 5313 of title 5, United States Code, is amended by adding at the end the following:

"Deputy Secretary of Environmental Protection.".

(c) EXECUTIVE LEVEL III.—Section 5314 of title 5, United States Code, is amended by adding at the end the following:

"Under Secretaries of Environmental Protection (3).".

(d) EXECUTIVE LEVEL IV.—Section 5315 of title 5, United States Code, is amended—

(1) by inserting after the item relating to Inspector General, Department of the Treasury, the following:

"Inspector General, Department of Environmental Protection."; and

(2) by inserting after the item relating to Chief Financial Officer, Department of Treasury, the following:

"Chief Financial Officer, Department of Environmental Protection.

"Assistant Secretaries of Environmental Protection (5).

"General Counsel, Department of Environmental Protection.".

(e) EXECUTIVE LEVEL V.—Section 5316 of title 5, United States Code, is amended by adding at the end the following:

"Regional Administrators, Department of Environmental Protection.

"Director of Environmental Statistics, Department of Environmental Protection.".

SEC. 10. REFERENCES.

Any reference in any other Federal law, Executive order, rule, regulation, reorganization plan, or delegation of authority, or in any document—

(1) to the Environmental Protection Agency is deemed to refer to the Department of Environmental Protection;

(2) to the Administrator of the Environmental Protection Agency is deemed to refer to the Secretary of Environmental Protection; and

(3) to a subordinate official of the Environmental Protection Agency is deemed to refer to the corresponding official of the Department of Environmental Protection.

SEC. 11. SAVINGS PROVISIONS.

(a) CONTINUING EFFECT OF EXISTING STATUTES.—Nothing in this Act shall be construed as altering, affecting, amending, modifying, or otherwise changing, directly or indirectly, any law that refers to and provides authorities or responsibilities for, or is administered by, the Environmental Protection Agency or the Administrator of the Environmental Protection Agency.

(b) CONTINUING EFFECT OF LEGAL DOCUMENTS.—All orders, determinations, rules, regulations, permits, grants, contracts, certificates, licenses, privileges, agreements, registrations, and other administrative actions—

(1) that have been issued, made, granted or allowed to become effective by the President, the Administrator or other authorized official of the Environmental Protection Agency, or by a court of competent jurisdiction, which relate to functions of the

Administrator or any other officer or agent of the Environmental Protection Agency actions; and

(2) that are in effect on the date of the enactment of this Act;

shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, or other authorized official, by a court of competent jurisdiction, or by operation of law.

(c) PROCEEDINGS NOT AFFECTED.—

(1) IN GENERAL.—This Act shall not affect any proceeding, proposed rule, or application for any license, permit, certificate, registration, or financial assistance pending before the Environmental Protection Agency on the date of the enactment of this Act, and the effect of any such proceeding, proposed rule, or application shall continue. Orders shall be issued, and final determinations shall be made, in any such proceeding, proposed rule, or application, appeals shall be taken therefrom, and payments shall be made pursuant to such orders, as if this Act had not been enacted, and orders issued with respect to any such proceeding, proposed rule, or application shall continue in effect until modified, terminated, superseded, or revoked by a duly authorized official,

by a court of competent jurisdiction, or by operation of law.

(2) DISCONTINUANCE OR MODIFICATION.—Nothing in this subsection prohibits the discontinuance or modification of any such proceeding, proposed rule, or application under the same terms and conditions and to the same extent that such proceeding, proposed rule, or application could have been discontinued or modified if this Act had not been enacted.

(d) SUITS NOT AFFECTED.—The provisions of this Act shall not affect suits commenced before the effective date of this Act, and in all such suits, proceedings shall be had, appeals taken, and judgments rendered in the same manner and with the same effect as if this Act had not been enacted.

(e) NONABATEMENT OF ACTIONS.—No suit, action, or other proceeding commenced before the effective date of this Act by or against the Environmental Protection Agency, or by or against any individual in the official capacity of such individual as an officer of the Environmental Protection Agency, shall abate by reason of the enactment of this Act.

(f) PROPERTY AND RESOURCES.—The contracts, liabilities, records, property, and other assets and interests

of the Environmental Protection Agency shall, after the effective date of this Act, be considered to be the contracts, liabilities, records, property, and other assets and interests of the Department of Environmental Protection.

SEC. 12. CONFORMING AMENDMENTS.

(a) PROPOSED LEGISLATION.—After consultation with the appropriate committees of the Congress, the Secretary shall prepare and submit to the Congress proposed legislation containing necessary and appropriate technical and conforming amendments to the laws of the United States, to reflect the changes made by this Act. Such proposed legislation shall be submitted not later than one year after the effective date of this Act.

(b) INSPECTOR GENERAL.—Section 11(2) of the Inspector General Act of 1978 (5 U.S.C. App.) is amended—

(1) by inserting "Environmental Protection," after "Energy,"; and

(2) by striking "the Environmental Protection Agency,".

(c) CHIEF FINANCIAL OFFICER.—Subsection (b)(1) of section 901 of title 31, United States Code, is amended—

(1) by striking subparagraph (O);

(2) by redesignating subparagraphs (F), (G), (H), (I), (J), (K), (L), (M), (N), and (P) as subparagraphs (G), (H), (I), (J), (K), (L), (M), (N), (O), and (P), respectively; and

(3) by inserting after subparagraph (E) the following:

"(F) The Department of Environmental Protection.".

(d) EXECUTIVE SCHEDULE COMPENSATION.—Title 5, United States Code, is amended—

(1) in section 5313 by striking the item relating to the Administrator of the Environmental Protection Agency;

(2) in section 5314 by striking the items relating to the Deputy Administrator of the Environmental Protection Agency; and

(3) in section 5315 by striking the items relating to—

(A) the Assistant Administrator for Toxic Substances, Environmental Protection Agency;

(B) the Assistant Administrator, Office of Solid Waste, Environmental Protection Agency;

(C) Assistant Administrators, Environmental Protection Agency;

(D) the Inspector General, Environmental Protection Agency;

(E) Chief Financial Officer, Environmental Protection Agency; and

(F) Chief Information Officer, Environmental Protection Agency.

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Mr. OSE. I would like to recognize our distinguished chairman for the purposes of an opening statement.

Mr. TOM DAVIS OF VIRGINIA. Well, thank you very much, Chairman Ose, for holding the hearing today on the EPA and whether it would function better if elevated to a department level. I think this hearing is going to provide an opportunity to explore in an open-minded and bipartisan way whether the time has come to make drastic changes in the organization and mission of the EPA.

Mr. Chairman, over the years you have done important work chairing this subcommittee, and your work in the 107th Congress on this issue created a strong legislative history and record of effective congressional oversight on these matters.

In the 30 years since it was created, EPA has supervised and implemented the cleanup of urban industrial waste sites, fought for the protection of our forests, streams, and rivers, and educated the Nation about the importance of cleaner air in our suburban communities. In that period of time, the Agency has grown from around 4,000 employees to 18,000 employees. The EPA has offices located literally all over the Nation. It is charged with enforcing many diverse and sometimes even contradictory interests as it seeks to improve and sustain the Nation's environment. It is possible the elevation would better equip the Agency to meet and face these challenges. If that were the case, then we ought to be open to all feasible options.

I look forward to the testimony from our experts today. I appreciate your subcommittee taking the time to consider this important legislation. I would just say, as chairman of the full committee, we take this effort seriously. Thank you.

Mr. OSE. Thank you, Mr. Chairman.

I would like to ask unanimous consent that the statement of Sherwood Boehlert be entered into the record. Hearing no objection, that will take place.

[The prepared statement of Hon. Sherwood Boehlert follows:]

Testimony of Honorable Sherwood Boehlert
Hearing on "Elevation of the Environmental Protection Agency to Departmental Level Status: H.R. 37 and H.R. 2138"
Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs
Government Reform Committee
2154 Rayburn House Office Building
June 6, 2003

Mr. Chairman, thank you for allowing me to submit testimony on H.R. 37, the Department of Environmental Protection Act.

This hearing is a continuation of a long-time discussion of the elevation of the Environmental Protection Agency to the Department of Environmental Protection. It is a discussion that dates back at least to 1988, when Rep. Jim Florio and I first introduced an EPA elevation bill. That 15 years has passed and an elevation bill has not been signed into law should make us mindful of the challenges before us.

Let me make just three brief points.

1. Congress should elevate EPA to the Cabinet-level status it deserves and needs.

The United States has very little company in having an environmental agency that does not enjoy ministerial rank. Indeed, the U.S. stands with Monaco, Libya, Panama, Peru, and a few other countries as a "holdout" in not granting their primary environmental agency Cabinet-level status. This can have real consequences.

It means that in both international discussions, and sometimes even in discussions within our own government, protocol can work against EPA. At a time when environmental issues are critically important and increasingly global, there's no reason to disadvantage our top environmental official, however slightly.

2. Don't be tempted by other environmental issues or controversies.

We simply will not rectify this situation with anything other than a "clean bill" that simply and straightforwardly grants EPA cabinet status. The record of the last 15 years has demonstrated that unequivocally. When elevation bills in 1993 and 1994 addressed wide-ranging and controversial issues they became magnets for further controversy and ultimately failed.

This is not to say, of course, that Cabinet-level status is the only improvement EPA could use. That's obviously not the case. But the particular, achievable and valuable improvement of Cabinet-level status won't happen if a bill is weighed down with other issues. Other issues should be addressed in separate vehicles.

I appreciate all the work you and your staff have put into H.R. 2138, and I especially appreciate the open manner in which you've done your work and your interest in consulting with the Science Committee. My concerns with H.R. 2138 are not a reflection on the value of your bill, although it does contain provisions that I believe need refining. But H.R. 2138 is not likely to be a successful vehicle for elevation. That's a major reason why the Administration has endorsed my bill.

3. The Committee should only move forward with those provisions of H.R. 64 that passed the House in the 107th Congress.

I will comment here on only one matter beyond elevation that you've included in H.R. 2138 because it relates directly to actions that have been taken by the Science Committee. In your bill, you have incorporated the introduced version of Dr. Ehlers' bill, H.R. 64 from the 107th Congress. The Science Committee significantly amended the bill before approving it in Committee. The bill then was passed by the House under suspension. The changes we made reflected valuable discussions we held with a wide range of parties.

Any effort to move H.R. 64 in this Congress – and we do not believe that should be part of an elevation bill – should use the version of H.R. 64 passed by the House in the last Congress.

Thank you again, Mr. Chairman. I look forward to continuing to work with you.

Mr. OSE. In this committee, we always swear our witnesses in. So, if you would all rise, please.

[Witnesses sworn.]

Mr. OSE. Let the record show that the witnesses answered in the affirmative.

We have received your statements. They are going to be entered into the record in total. We have read them. I actually read them. I am sure Chairman Davis did, too. To the extent that we can, we would like to move through the statements expeditiously. We are going to give each of you 5 minutes to summarize. You don't have to use all of the 5 minutes, but hit your high points, if you would.

I will go left to right here. We will start with Dr. Portney. Dr. Portney is the president for Resources for the Future.

We welcome you to our committee. You are recognized for 5 minutes.

STATEMENTS OF PAUL R. PORTNEY, PRESIDENT, RESOURCES FOR THE FUTURE; GEORGE M. GRAY, ACTING DIRECTOR, CENTER FOR RISK ANALYSIS, HARVARD UNIVERSITY; STEVEN F. HAYWARD, F.K. WEYERHAEUSER FELLOW, AMERICAN ENTERPRISE INSTITUTE FOR PUBLIC POLICY RESEARCH; WESLEY P. WARREN, SENIOR FELLOW FOR ENVIRONMENTAL ECONOMICS, NATURAL RESOURCES DEFENSE COUNCIL; AND RENA I. STEINZOR, ESQ., PROFESSOR, UNIVERSITY OF MARYLAND, AND BOARD MEMBER, CENTER FOR PROGRESSIVE REGULATION

Dr. PORTNEY. Thank you very much, Mr. Chairman and Congressman Davis. I am pleased to be here, and I appreciate the opportunity to testify.

The one thing I will say by way of introduction is that, while I am president of Resources for the Future, a think tank here in Washington that specializes in energy and environmental issues, I want to make clear that the comments today that you'll hear from me are my own and do not represent the views of RFF.

I will cut directly to the chase, taking you at your admonition, and say that I am strongly supportive of the elevation of EPA to Cabinet status and even more enthusiastic about the creation of a Bureau of Environmental Statistics within the Environmental Protection Agency. I have long believed that elevation of EPA to Cabinet status has been a good idea. It was a good idea when former President George Bush put it forward, it was a good idea when former President Bill Clinton put it forward, and it remains a good idea today.

Several brief observations about the consequence of making EPA a Cabinet department, if I can. My view is that having EPA become a Cabinet department is largely symbolic, but as I said in my prepared remarks, sometimes symbols matter. I believe that having an EPA administrator who would be a Secretary of Environmental Protection would facilitate international negotiations on environmental issues, and it would be a strong signal to the rest of the world that we take environmental protection as seriously as we take the provinces of the other Cabinet departments.

With respect to the reorganization that is proposed in H.R. 2138, I can see a number of advantages to those proposed changes,

though I am more agnostic on those changes than I am on the issue of elevation to Cabinet status itself. As somebody who has studied environmental regulation for 31 years—it pains me to cite that figure, I have to confess—I am now of the belief that if the Administrator of EPA, whoever he or she may be, wants to make use of good science and good economic analysis in regulation, then that analysis will be forthcoming. If the Administrator of EPA is not a strong client for strong science and economic analysis in regulation, then there won't be a market for it and that kind of information will not be forthcoming.

In the legislation, you talk about the organizational structure of EPA as being an obstacle to cross-media tradeoffs, to experimentation along the lines of things like Project XL, etc. I agree with you that the organization of EPA can be an impediment to these kinds of things, although I have to be honest and say that I think it is the statutory framework under which we regulate in the environment—with a clean air statute that makes no connection to solid waste or water pollution, and a water pollution statute that does the same—that is the bigger obstacle to cross-media regulation or experimentation.

Turning quickly to the Bureau of Environmental Statistics, I think it is badly needed, and I have felt that way for a long time. In a Nation where we spend, according to EPA's estimates, on the vicinity of $150 billion each year on environmental regulation, I think the Members of Congress, other parts of the administration and, most of all, the American public deserve an annual reporting on the progress that we are making in cleaning up the environment.

Currently, we have fragmented, periodic efforts to report to the public. One of my fellow co-panelists here today, Steve Hayward, has participated in such an effort for 8 or 9 years, for which he is to be congratulated.

The Heinz Center recently issued a State of the Nation's Ecosystems Report which I think is an excellent summary of some of the environmental progress that we are making.

The Council on Environmental Quality in its annual report, in the past at least, has contained voluminous information on ambient environmental protection. I am aware of that because for 2 painful years that I spent at CEQ I was responsible for pulling all of that information together.

Nevertheless, there is no comprehensive annual estimate that comes from the Federal Government, as I think this information should come, on environmental conditions and trends.

I think that the independence of the Director of the Bureau of Environmental Statistics is absolutely essential. I think that person should have the same kind of protection that the head of the Bureau of Labor Statistics has within the Labor Department and the head of the Bureau of Economic Analysis has within the Commerce Department.

And, finally, let me say that, in thinking about the kinds of information that the Bureau of Environmental Statistics would provide, I would urge that we envision that this be done somewhat cautiously, beginning with the presentation of information on trends in environmental quality, air quality, water quality, land contamina-

tion, etc.; broadening them to contain information and data on emissions, levels of waste generated, etc.; possibly then expanding to include information on compliance and enforcement. I mention this having read the article that I am sure you have seen in today's Washington Post about compliance and noncompliance with the Clean Water Act.

And then, finally, in a perfect world, the Bureau of Environmental Statistics could present evidence on health and economic indicators that are related to the environment. I mention those last not because those are not important—indeed, we need to know about asthma and other things—but, rather, because the link between environmental quality and a variety of health end points is the subject of considerable debate. I would rather see the BES present environmental quality data first and then gradually build itself up to presenting this other data.

Thank you so much for having me here today, and I will be happy to answer any questions that you have.

Mr. OSE. Thank you.

[The prepared statement of Mr. Portney follows:]

TESTIMONY

Paul R. Portney
President, Resources for the Future

before the
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy Natural Resources and Regulatory Affairs

June 6, 2003

Mr. Chairman and distinguished members, thank you very much for inviting me here to testify before you this morning on H.R. 37 and H.R. 2138, bills that pertain to the elevation of the Environmental Protection Agency to cabinet status. I am Paul R. Portney, President of Resources for the Future (RFF), a research organization that concerns itself with natural resources and the environment. Let me make clear from the outset that RFF takes no institutional positions on legislative or regulatory matters. The views I will express this morning are mine alone.

Like many of those who have testified before this subcommittee over the last two years, I have had a long interest—31 years, in fact-- in the substance of U.S. environmental policy and the way our government is organized to provide environmental protection. Also like many of those who have testified, I am enthusiastic about legislation that would elevate the U.S. Environmental Protection Agency to cabinet status. As you and many previous witnesses have pointed out, Mr. Chairman, the U.S. is one of a very small number of countries (nine at last count) in which the chief environmental official is *not* a cabinet member. While I do not expect it to be an easy task, it is past time to for our country to change this situation and make EPA a cabinet department.

Let me be clear in saying that such a change would not give the EPA any additional legal powers it now lacks, nor would it constrain the EPA in any meaningful way, either. Rather, the importance of such a move would be principally symbolic. But symbols matter. In international environmental negotiations, the Secretary of Environmental Protection would be dealing on even footing with the environment ministers (secretaries) from other nations. Having cabinet status would make these dealings easier for the Secretary, and it would be a signal to the rest of the world that we take the environment every bit as seriously as they do. Indeed, other than the great bureaucratic inertia that often stops organizations (whether public or private) from taking obvious steps, I cannot think of a single good reason why any one would oppose the creation of the Department of Environmental Protection.

Let me say a brief word about the organizational structure envisioned in H.R. 2138, before I turn my attention to the proposed Bureau of Environmental Statistics—which I regard as the most exciting part of the proposed legislation. Under the current wording in Section 7(g)(1) of H.R. 2138, the Chief Financial Officer of the Department of Environmental Protection would be given the responsibility of "ensuring that the budget, human resources and regulatory costs imposed by the Department accurately reflect environmental and human health risks." While it is critically important that someone at the Department perform that function, it strikes me as a policy responsibility that is better left to the Undersecretary for Policy, Planning and Innovation. I would fully expect that the Chief Financial Officer would be so absorbed with budget, contracting, grant management and other purely financial responsibilities that she/he would not be the best person to assure that the Department's budget and risk management priorities were

in proper alignment. I regard this as an easy thing to fix, but wish to bring it up because I think it is an important fix to make.

Turning to the proposed Bureau of Environmental Statistics (or BES), I could hardly be more enthusiastic, though this will not be surprising. While there have been many calls over the years for better environmental data collection and dissemination to elected officials and the public, I believe I was the first to call (in an article I wrote in 1988) for the creation of a BES. I felt then, as I do now, that the creation of such a bureau would have a number of favorable effects. It would creative an imperative that would almost immediately begin improving the quality of this nation's environmental data; it would better inform our elected officials in congress and in the administration (including those at the Department of Environmental Protection itself) as to environmental conditions and trends; it would elevate considerably the quality of policy debates about which environmental programs are working and which are not; it would improve our ability to compare the benefits and costs of both current and prospective environmental programs; and it would do much more.

If a BES is created within the EPA, preferably as part of the elevation of the EPA to cabinet status, but even if not, I believe the Bureau should have the same quasi-independent status as the Bureau of Labor Statistics enjoys within the Department of Labor or the Bureau of Economic Analysis has within the Commerce Department. That is, ideally the Director of the BES should be appointed by the president for a fixed term (H.R. 2138 envisions a four-year term, though I might prefer a slightly longer one), one that the Director should be able to complete even if the president who appoints him or her is no longer in office. Moreover, ideally the Director should be someone with a

reputation for independence and experience in matters related to environmental data collection and dissemination. It is essential that the Director *not* be seen as someone who might slant the presentation of environmental data for political purposes.

As the members of this subcommittee are aware, there are a number of difficult questions that would have to be answered once the proposed Bureau began its work. One has to do with the types of data it would be required to collect and make available to policymakers and the public in its annual reports. If I might, I'd like to raise a word of caution with respect to the language in Section 8 (c)(1)(A) and subsequent sections of the bill dealing with the information the BES will collect. There the Director is charged with "collecting, compiling, analyzing and publishing a comprehensive set of environmental quality and related public health, economic, and statistical data..."

I understand full well the reasons for suggesting that the Bureau go beyond the collection and dissemination of data on environmental quality. After all, we care about environmental quality at least in part because it bears on public health, and also because pursuing it sometimes entails unpleasant economic tradeoffs. Nevertheless, we should keep in mind the challenge the Bureau will face merely deciding upon a set of agreed-upon *environmental* measures to present. For instance, would "tons of solid waste produced annually" be considered a relevant measure? How about estimates of pollutant *emissions,* as opposed, say, to ambient concentrations of these same pollutants in either our air or our water? Should the Bureau present data on forested acreage in the U.S.? What about tons of fish caught, or the number of acres under grazing? Many other questions could be asked about possible measures just within the environmental ambit.

Because it will be a great challenge for the Bureau to reach agreement on environmental quality measures alone, I would prefer to see its attention focused there. If it must also wrestle with more traditional public health measures, or measures of economic performance, I fear that the Bureau's attention could be spread too thinly and also that its mandate will begin to infringe upon that of the BEA or the National Center for Health Statistics. For that reason, I would urge you to think carefully about the types of information that you would ask the Bureau to collect, compile, analyze and publish. We would not want to let the "best be the enemy of the good" in this case.

Mr. Chairman, thank you again for allowing me to appear before you today to discuss this important legislation. I would be happy to answer any questions that you or your colleagues have.

Mr. OSE. Our next witness is Dr. George Gray. He is with the Harvard Center for Risk Analysis at the Harvard School of Public Health.

Dr. Gray, you are recognized for 5 minutes. Thank you for coming.

Dr. GRAY. Thank you, Chairman Ose, Mr. Davis. It is a pleasure to be here.

A similar sort of introduction to Dr. Portney: These remarks are mine alone and shouldn't be attributed to the Harvard Center for Risk Analysis or the Harvard School of Public Health. They are also informed by my almost 15 years working as a scientist, a risk analyst, and a public health professional.

I am here to support the idea of elevating the Environmental Protection Agency to departmental status. I think that EPA's mission is important to the citizens of our country, and raising it to the highest level will recognize the priority that we give to human health and our natural resources. But, like many others, I do believe that this transition is an opportunity to evaluate the ways in which this new department acts to achieve these goals, and for this reason I support many of the provisions of H.R. 2138. And, I want to touch very quickly on two of those.

Touching on this notion of restructuring EPA, I think the development of a Bureau of Environmental Statistics has a variety of very positive attributes. First, I think it is very important that we have concrete evidence of the effective efforts to address environmental problems.

Another thing that I think is important that we may often overlook is that it is a communication device for the new department, and I want to touch on that especially. I think it will help to identify and prioritize emerging challenges.

And the last thing that I want to spend a little bit of time on is the fact that we do have to be, I think, a little bit humble about what we can actually learn from a Bureau of Environmental Statistics.

Turning to the communication aspects. There is a problem in this country in that an awful lot of people don't understand, don't appreciate the progress that we have made in the environment over the last 30 years. In a 2002 survey that was conducted by Wirthlin Worldwide for the Foundation for Clean Air Progress, they asked 1,000 American adults: Do you believe that the Nation's air has gotten better or worse in the last 10 years? And, over two thirds of them said the air has gotten worse. That is wrong, and that is a problem. Because how can we expect the public to support environmental measures, some of which are going to be inconvenient or possibly expensive for them—things that address tailpipe emissions could increase the price of cars, it could increase the price of fuel—if they don't think they are getting anything for these efforts?

I think that a well-respected and trusted national Bureau of Environmental Statistics can help build support for the Department of Environmental Protection and its efforts and can also provide this important information and context for citizens.

However, I do think we have to be humble about what we could learn with this Bureau. Many of EPA's rules and regulations focus on reductions in risk to human health, yet it is extremely unlikely

that any effort to gather statistical information on public health will identify changes that you can associate with a specific regulation. The risks that the EPA addresses in general are just too small. I don't think you could find an epidemiologist or a public health statistician who believes that we could detect any change in health status in a town, for example, that reduces arsenic in its drinking water to meet the new EPA standard. It is important to be aware of the information that this new Bureau can and cannot provide to help guide decisionmaking.

The EPA uses the tools of risk assessment and management to inform their important decisions. The way that this approach is intended to work, science is done on one side, we bring the best information we can to bear on problems, and then policies are then formulated. These policies include information that goes well beyond science. They include economics, they include engineering, they include social sciences, and a lot of other things that are important.

There is a perception today, I will tell you, in the scientific community that right now policy in EPA influences their science, and that influence undermines the credibility of both EPA's science and EPA's decisions. So I think that the proposal in H.R. 2138 to restructure the Department by function would go a long way to improving both the perception and the reality of the credibility of EPA's science and decisions.

In closing, I think elevating EPA to departmental status is a positive thing to do; and while we are doing that, I do welcome attention to improving the information that is available for confronting current and future environmental challenges with sound science and with environmental statistics. I think careful consideration of opportunities for restructuring is also warranted to build confidence in the science and the decisions that guide our efforts in environmental protection.

So I want to thank you and applaud you for your efforts looking forward to equip our country with the tools we need to ensure wise environmental protection in the future, and I would be happy to answer any questions.

Mr. OSE. Thank you, Dr. Gray.

[The prepared statement of Dr. Gray follows:]

Testimony of George M. Gray
Harvard Center for Risk Analysis
Harvard School of Public Health

U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
June 6, 2003

Chairman Ose, Representative Boehlert, members of the Committee, thank you for the opportunity to appear before you today. I am George M. Gray, Acting Director of the Harvard Center for Risk Analysis. My comments today are based upon my research and experience as a scientist, risk analyst, and public health professional. These comments are my own and should not be attributed to the Harvard Center for Risk Analysis or Harvard School of Public Health.

I am here to support he idea of elevating the Environmental Protection Agency (EPA) to Departmental status. EPA's mission "*to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends*" is important to the citizens of our country. Elevating EPA to the highest level of government will recognize the priority given to protection of human health and our natural resources.

Like others, I believe that this transition is also an opportunity to evaluate the ways in which the new Department acts to achieve its goals and measure success. For these reasons I support many of the provisions of Mr. Ose's bill, H.R. 2138. I would like to briefly address two important aspects of this bill, the creation of a Bureau of Environmental Statistics and reorganization of the structure of EPA as it becomes the Department of Environmental Protection.

I am enthusiastic about the development of a Bureau of Environmental Statistics for several reasons. First, it will provide concrete evidence of the effect of efforts to address environmental problems. Second, it will be a useful communication tool for the new Department. Finally, it will provide a means to identify and prioritize emerging environmental challenges. However, we must also be aware that the Bureau will not resolve all of the debates about public health or environmental questions.

Many EPA efforts seek to reduce levels of pollutants in air and water or on land. Without sound data, evaluating the changes that result from new rules it is very difficult to gauge their success. With a proper orientation, a new Bureau of Environmental Statistics will provide information to help the Department measure success that are directly related to the goals of the specific Departmental rules.

Sound environmental statistics will serve a valuable communication function for the new Department. Knowledge of progress in addressing environmental problems can help build support for the Department and help the public see the results from the sometimes difficult or costly requirements placed upon them.

Clearly, the public needs a greater knowledge of the environmental progress made over the last several decades. For example, in a 2002 survey conducted by Wirthlin Worldwide for the Foundation for Clean Air Progress, two thirds of the 1000 American adults asked if they ""believe that the nation's air has gotten better or worse in the last ten years " responded that air quality is worse[1]. This is in direct contradiction to the facts and should be of concern to the EPA. How can we expect the

[1] http://www.cleanairprogress.org/news/quorum_res_01_14_02.asp

public to support environmental measures that may be inconvenient or costly, like measures to decrease automobile emissions that may increase the cost of cars or fuel, if they don't believe we have made any progress with our efforts over last 10 years? A well-respected and trusted National Bureau of Environmental Statistics can help build support for the Department of Environmental Protection and its efforts and provide information and context for citizens.

Sound data on environmental conditions will also be a valuable tool in priority setting within the Department. It may also aid in looking over the horizon for new and emerging environmental challenges. Making these data widely available, as called for H.R. 2138, will allow others to monitor environmental progress, evaluate the costs and benefits of particular rules, and understand how well the Department is addressing its mission.

We must be humble about what we can learn with an NBES. Many of EPA's rules and regulations focus on reduction of risks to human health. Yet it is extremely unlikely that any effort to gather statistical information on public health will identify changes associated with specific regulations. The risks addressed are just too small. I don't think you could find an epidemiologist or a public health statistician who believes that we could detect any change in cancer rates in a town that reduces levels of arsenic in drinking water to meet the new EPA standard. It is important to be aware of the information the new Bureau can and cannot provide to guide the Department.

The EPA uses risk assessment and management tools to inform many of its important decisions. The Office of Research and Development, EPA's scientific research arm, is explicitly organized around the risk assessment/risk management paradigm. This approach is built upon bringing the best available scientific evidence to bear on a problem to understand its size, severity and management options. Policy decisions, informed by the science as well as economics, engineering, social sciences and other factors, then determine how a risk is to be managed. There is a perception that in many cases policy is influencing EPA's science and use of science to arrive at specific answers in ways that undermine the credibility of both the science and the decisions.

The proposal in H.R. 2138 to restructure the Department of Environment by function would go a long way to improving both the perception and the reality of the credibility of EPA science and decisions. When the science is done on one side of the house, and then injected into the policy process to be considered along with other important factors, it will help remove some of the pressures on scientists to "get the right answer" and will put the decision making responsibility not in the hands of scientists but with policy makers where it belongs.

This significant a change in the structure of the Agency/Department will require further tweaking. Attention to ensure that "science policy" doesn't influence the conduct and interpretation of scientific information will be important. A recognition that engineering and economic analysis are "science" and deserve the same insulation from policy as toxicology and epidemiology will be important. Nevertheless, in the long run, this restructuring may be one of the most important steps we take to meet environmental challenges yet to come.

In closing, as elevation of EPA to departmental status is considered I welcome attention to improving the information available to confront current and future environmental challenges with sound science and environmental statistics. Careful consideration of the opportunities for restructuring is also warranted to build confidence in the science and the decisions that guide our efforts at environmental protection. I applaud your efforts to look forward and equip our country with the tools necessary to ensure wise environmental protection in the future.

Mr. OSE. Our next witness is Dr. Steven Hayward, who is the resident scholar at the American Enterprise Institute for Public Policy Research.

I want to thank you for coming, Dr. Hayward. You are recognized for 5 minutes.

Dr. HAYWARD. Thank you, Mr. Chairman.

I guess I will depart from my written testimony a little bit and add to it, if I can, by noting a little bit of history.

President Nixon originally intended the EPA to be a Cabinet-level department of environment and natural resources. He intended it as a sweeping reorganization of the entire executive branch, and it didn't happen for reasons unrelated to the merits of the idea of having the environment as a Cabinet-level agency. So, instead, the EPA was created as an administrative organization at the same time we created a lot of things like the Consumer Product Safety Commission and OSHA; and I think it is increasingly clear today, for reasons that have already been alluded to, that the EPA is much more like the Department of Health and Human Services in terms of its public importance than it is like the Consumer Product Safety Commission.

I mean, one reason I think it is a good idea to elevate the EPA to Cabinet rank is that it will help in a broad sense to educate the public better about environmental issues in much the same way that the reorganization of the Department of Homeland Security focuses the public mind better on the issues that Department is intended to address—because it could have been kept the way it was, with Tom Ridge in the White House trying to coordinate different agencies—and the way the Council of Environmental Quality now tries to coordinate between all the government agencies that work on the environment. So the point is it is long overdue to put the EPA on a higher plane.

We are going to sound a bit like a broken record so far, because I think the heart of this bill to me is the proposed Bureau of Environmental Statistics. I spend most of my time trying to research environmental data and find out what's going on and what we know and more importantly perhaps what we do not know.

The EPA does an excellent job of monitoring air quality, and the data they produce and the annual report they produce is superb. They do a less good job, as we learned from the Post story today, on water quality. And, the problem of identifying good data and water quality is immense. But that is the kind of problem that the Bureau of Environmental Statistics can begin to get its hands around, rather than right now having those data be generated by individual regulatory programs that don't fit together in any kind of intelligible whole.

I first learned this idea from Paul. I have to give him full credit for it and return the kindness he gave to me.

If you go back to the very first report of the President's Council on Environmental Quality in 1972, they said this: The use of a limited number of environmental indices by aggregating and summarizing available data could illustrate major trends and highlight the existence of significant environmental conditions. It could also provide the Congress and the American people measures of the suc-

cess of Federal, State, local, and private environmental protection activities.

An analogy might be drawn with the economic area, where the Consumer Price Index, the Wholesale Price Index, and unemployment rates provide a useful indication of economic trends.

Well, here we are 31 years later, and we are still not doing all that; and I think the time has come. Thank you.

Mr. OSE. Thank you, Dr. Hayward.

[The prepared statement of Dr. Hayward follows:]

Testimony of Steven F. Hayward, Ph.D
Resident Scholar
American Enterprise Institute for Public Policy Research*
Regarding H.R. 2138

Friday, June 6, 2003
House Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources
and Regulatory Affairs

I am pleased to speak on behalf of the merits of H.R. 2138, the Department of Environmental Protection Act. The EPA was created contemporaneously with a slew of semi-autonomous independent administrative agencies usually devoted to narrow purposes, such as the Consumer Product Safety Commission and OSHA. By the very nature of environmental issues today, it is increasingly obvious that the EPA is more like the Department of Health and Human Services than the CSPC. The EPA should be more fully and prominently integrated into the highest levels of the executive branch, instead of continuing along in the political no-man's land of administrative agencies.

The most important feature of H.R. 2138 is Section 8, which would establish a Bureau of Environmental Statistics. This idea, long championed by Paul Portney of Resources for the Future (among others), is long overdue. There is a striking need for dispassionate environmental data and trend analysis to

* Steven Hayward is the author of the annual *Index of Leading Environmental Indicators* (AEI-Pacific Research Institute), and the author of AEI's *Environmental Policy Outlook*. The views expressed in this testimony are the author's, and do not necessarily represent the views of the American Enterprise Institute.

replace environmentalism-by-anecdote and policy-by-headline. Although the Environmental Protection Agency and other federal departments that share responsibility for environmental matters collect and publish reams of statistics about the environment, there has never been a consistent, systematic national effort to report on environmental trends—an astonishing lacuna in a nation where hundreds of billions of dollars are spent annually for environmental protection. Without such an effort, it is difficult or impossible to evaluate the performance of the EPA, the effectiveness of its individual policies, or to choose intelligent priorities among the various environmental problems it is charged with addressing. Imagine the Federal Reserve setting monetary policy, or Congress making tax policy, without the systematic measures of economic output, employment, inflation, and other factors produced by the Bureau of Labor Statistics, the Census Bureau, and other government data collection efforts. Yet that is exactly the kind of fog in which much environmental policy is made today.

The very first report of the President's Council on Environmental Quality in 1972 noted the usefulness of such an approach:

> The use of a limited number of environmental indices, by aggregating and summarizing available data, could illustrate major trends and highlight the existence of significant environmental conditions. It could also provide the Congress and the American people measures of success of Federal, State, local, and private environmental protection activities. An analogy might be drawn with the economic area, where the Consumer Price Index, Wholesale Price Index, and unemployment rates provide a useful indication of economic trends. . .

Despite the widely acknowledged need for such an effort, it has never been attempted in a serious way.

Section 11 of this bill makes clear that elevating the EPA to cabinet rank will not change any existing EPA policy. One might sensibly ask: why bother then? What is the advantage of elevating the EPA if such a change does not lead to reforming some of the problems and frustrations that critics on all parts of the political spectrum have identified? Doesn't this just amount to rearranging deck chairs? I argue that putting the EPA on commensurate footing with other cabinet agencies will make it more accountable to the President and other cabinet officers, will enhance its ability to increase public sophistication about environmental matters, and will improve the prospects for step-by-step reforms of its operations.

Mr. OSE. Our next witness is Wesley Warren. He is the senior fellow for environment economics at the Natural Resources Defense Council.

We are very grateful for you appearing, and you are recognized for 5 minutes.

Mr. WARREN. Thank you. I would like to express my appreciation both to the chairman of the subcommittee and the full committee for giving this such attention today.

The Natural Resources Defense Council does support legislation to elevate EPA to Cabinet status. We believe that this would put the Agency on par with other Departments and would also send an international signal about the importance of environmental issues generally.

However, we do not support this objective to such an extent that we would accept changes in the Agency's authorities or structure that would actually hamper its ability to get its job done. Therefore, we urge the committee, if it takes up this issue, to pass a clean bill, free of any other types of provisions.

Repeatedly, attempts to add other issues to this legislation have derailed these legislative proposals, and we think it would just end up, because of the controversy, being a one-way ticket to nowhere.

Accordingly, we have endorsed H.R. 37, which is legislation that would be a simple and direct elevation. But we do oppose H.R. 2138 which we believe, for reasons that I will discuss in greater detail, do not meet this description.

I believe when people look at the issue of elevating EPA to a Cabinet agency, there are two great temptations. One is to change the authorities of the Agency, and the other is to reorganize its structure. This is something that H.R. 2138 does in both cases. And, I believe in fact that it is very well intended, that it is looking at important issues, like how do we encourage cross-media work at the Agency, and how can we improve the quality and quantity of good environmental information, both of which are objectives that we also share support for.

However, we would not like to see those objectives pursued in a way where we might actually create more bureaucracy and as a result more litigation and gridlock. And so, again, whatever the merit of those issues might be at a separate time and place, we strongly urge their exclusion from this legislation.

If I can take a couple of moments to detail what our main concerns are—I won't go into all of them, which are in my testimony—I would say I believe the most troubling is the statutory mission statement that is included in the bill that would create a vague new standard hinging on the concept of unreasonable risk. We believe that unreasonable risk is only one standard that could be considered in terms of environmental protection, but it is by no means the one, that is used most generally in statutes; and that the mission of the Agency should be, plain and simple, to administer the statutes that Congress has already passed or may pass in the future.

Second of all, in respect to the reorganization, I would like to point out a couple of issues that we also consider troubling. But I believe that the main point on reorganization is this: That, by and large, the Agency already has the authority it needs to accomplish

the purposes of providing better information and doing cross-media work if it has the will and resources to do so.

I, too, read the article in the Post today. Part of the headline is: Agency Says It Must Do a Better Job of Monitoring. Yet the Bush administration budget for this year actually would cut compliance monitoring and civil enforcement activities at the Environmental Protection Agency by nearly 100 positions, at the same time that the State of California in this article says what it needs more than anything else to provide more and better monitoring statistics is money.

So we believe that merely bringing together information functions into a single place in the Agency and relabeling it doesn't necessarily mean that the Agency is going to be able to provide this job; and we would urge the committee to first look at ways in which they could make those current authorities and resources fit more closely the needs of the Agency.

Finally, I would like to say that, if the committee decides what it would like to do is to try to improve the operation of the Agency by changing authorities or structure, then in fact we would have many suggestions of actions that could be taken that would improve environmental protection in this country. I have listed some of those suggestions in my testimony. I recommend them for consideration of the committee.

But I would just conclude by saying that I believe that any of those proposals might also be controversial and that the end result might be derailing our common objective of elevating EPA to a Cabinet-level agency, which should be the purpose of the legislation.

Mr. OSE. Thank you, Mr. Warren.

[The prepared statement of Mr. Warren follows:]

Testimony of Wesley P. Warren
Senior Fellow for Environmental Economics
Natural Resources Defense Council

Before the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
Committee on Government Reform
U.S. House of Representatives

June 6, 2003

INTRODUCTION

Good morning, Mr. Chairman and members of the subcommittee. Thank you for inviting me to appear before you. My name is Wesley Warren. I am the Senior Fellow for Environmental Economics at the Natural Resources Defense Council. Prior to joining NRDC, I served as Associate Director for Natural Resources, Energy and Science at the Office of Management and Budget and the Chief of Staff at the Council on Environmental Quality in the White House.

NRDC is a non-profit organization of scientists, lawyers, and environmental specialists dedicated to protecting public health and the environment. NRDC was founded in 1970 and has more than half a million members nationwide. I am pleased to testify today regarding proposals to create a Department of Environmental Protection and to improve environmental quality.

CABINET ELEVATION: A "CLEAN" BILL IS CRUCIAL

I have a single plea for you today: pass as "clean" an Environmental Protection Agency (EPA) cabinet bill as possible. Last Congress, in a Senate hearing on cabinet elevation, the last three EPA Administrators cautioned against weighing cabinet legislation down with controversial amendments.[1] They did so with good reason. Elevating EPA to a cabinet position enjoys significant bipartisan support. After all, the United States is among a very small minority of nations that has not yet given its highest environmental official cabinet rank. It is therefore tempting to use that political momentum to advance other proposals to improve the way in which EPA does business. The undeniable truth, however, is that people do not agree about what needs fixing at EPA or how to fix the things that do not work well.

As you are aware, previous attempts to create a Department of Environmental Protection have failed. They did so in large part because the bills contained provisions that were controversial. Avoiding similar legislative language may enable you to succeed where others have not. Accordingly, NRDC supports H.R. 37, a narrowly tailored piece of legislation, which does no more and no less than transfers the functions of

[1] *See* John Heilprin, *EPA Meets Cabinet Agency Hurdle*, Associated Press (July 24, 2001).

EPA to a cabinet-level Department of Environmental Protection. As Congressman Boehlert has previously observed regarding his proposal, it is "baggage-free" and stands the best chance of passing in that form.[2]

I would like to briefly discuss a few issues that could be added to a cabinet bill, but in our view should not be. These issues include changing the organization of the agency or altering in statute its authorities or mission. Obviously, attempting to legislate these kinds of changes will be highly controversial. For that reason, former EPA Administrator Reilly stated at a Senate hearing last Congress that:

> At some later point it may make sense for the new Department in consultation with Congress to consider its organization and structure, whether its functions are grouped in the most sensible or effective fashion, and whether a single scientific template should be used to characterize threats and goals. But I would leave that until later. We needn't encumber this legislation with proposals that are sure to unleash protracted debate and maybe draw fire from friend and foe alike.[3]

A number of such potentially controversial proposals have been included in the EPA cabinet bill H.R. 2138, introduced by Representative Ose. For that reason, we cannot support this version of EPA cabinet legislation.

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[2] 147 Cong. Rec. E689 (daily ed. May 1, 2001)

[3] Testimony of William K. Reilly, Former Administrator of EPA, Before the Senate Committee on Governmental Affairs (July 24, 2001), available online at http://www.senate.gov/%7Egov_affairs/072401_reilly.htm (visited March 18, 2002).

First, the most serious flaw in H.R. 2138 is the creation of a vague, new statutory standard for the agency in the name of defining the Department's mission (sec. 4(b)). H.R. 37 more appropriately excludes any redefining of the agency's mission in its elevation. After all, the mission of the agency is to administer the statutes passed by Congress for which it is responsible. In those individual statutes, Congress sets out the mission of the agency in administering that part of the law depending upon the specific circumstances of the legislation. Because one size rarely fits all, Congress can and does vary the mission statute-by-statute.[4]

Most objectionable is the new statutory standard of protecting the public from "unreasonable environmental risks." The term "unreasonable risk" is at once too narrow and too vague to serve the functioning of the Department. Risk assessment is only one of many tools for considering and judging threats to the environment, yet this bill would give it paramount importance. The modifier "unreasonable" would narrow the purview of the

[4] For example, see the **Clean Air Act (§109(b)(1))**: "National **primary ambient air quality standards...** the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health"; **Clean Water Act §303(C)(2)(A)**: "Such **[water quality] standards** shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this Chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation"; **Safe Drinking Water Act (§300g-1(b)(4)(A))**: "Each **maximum contaminant level goal (MCLG)** established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."

agency even more to a subset of such risks. At the same time, there is no real consensus in the field of risk assessment as to what constitutes "unreasonable risk" and no definition in the bill, inevitably inviting confusion, expensive litigation, bureaucratic gridlock, and the delay or loss of sensible protections for the public

Second, there has been some significant thought about using the cabinet bill to reorganize the agency significantly. One example would be legislation to create a Deputy Administrator for Science at EPA. A bill to create a science deputy was passed by the House last Congress. NRDC opposed this legislation, and we strongly urge you to avoid linking the two issues as part of final EPA cabinet bill. We think that it is unlikely that the new position will substantially advance the cause of science and instead think it is possible that this person will act as another political player in a potentially over-politicized process.

H.R. 2138 also proposes several major structural changes to the organization of the agency that cause us concern. These changes seem to be well intended and are directed at important issues, such as encouraging cross-media work and providing better environmental information. However, it is not be necessary to make these structural changes to improve

the performance of the agency and making these changes could have the unintended consequence of making the situation worse.

The bill attempts to address the agency problem of media "stovepiping" by creating three new undersecretaries: (1) Science and Information; (2) Policy, Planning, and Innovation; and (3) Implementation, Compliance, and Enforcement. However, aggregating responsibilities currently held by several assistant administrators into a super function, like a policy undersecretary, does not ensure that the agency will work in a fully integrated fashion. Indeed, the bill's proposed structure could reinforce bureaucratically the separation of science and enforcement from the agency's core policy and planning work. Currently, the responsibility for integrating the agency's work across media resides where it should – at the top with the Administrator or the Deputy Administrator – and it should remain there with the Secretary and Deputy Secretary.

The bill also attempts to help the agency provide better information on the environment by creating a Bureau of Environmental Statistic, ostensibly modeled after statistical offices in other agencies. NRDC supports the purpose of this provision, which is to ensure that the Department's information needs are adequately met. However, again it does not seem necessary to legislate more bureaucracy as the means to the end. The

agency currently has enough authority to produce sufficient, high-quality information for its needs, if the agency is adequately funded for this purpose. At the same time, the proposed legislation could have undesirable consequences on the flow of quality information, and the details of the bill need to be double-checked for such adverse effects. For example, the confidentiality provision as written may in fact bar the distribution of valuable information that the public receives presently under current law. The peer review provision is especially troublesome since it would create a Peer Review Team that would subordinate the Department to the statistical offices of other agencies in a way they are not subordinated to the Department or one another. Furthermore, individuals representing private interests could sit on this Peer Review team without adequate safeguards to prevent conflicts of interests.

Beyond its structural flaws, H.R. 2138 simply does not address the major science failings at EPA, if that is its intent. In NRDC's experience, the greatest scientific shortcoming at the Agency is its influence by polluting industry. EPA commonly relies heavily, and sometimes exclusively, on studies created or funded by industry, often without access to the raw data underlying these studies. Armed only with the information industry gives it, EPA frequently underestimates the risk posed by a given environmental

problem. To make matters worse, EPA's already biased product may then be subjected to review by an external advisory committee dominated by industry representatives and researchers. This subversion of peer review frequently results in a less environmentally protective position.[5]

Third, at least two witnesses at your prior hearing on cabinet legislation suggested that elevation might be married with so-called "second generation" legislation;[6] but that legislation is a not a good idea on its own, much less as part of a cabinet bill. The "Second Generation of Environmental Improvement Act of 1999," introduced in the last Congress,[7] empowered EPA to enter into "innovative strategy agreements" with a regulated entity. While the legislation included some constructive efforts to improve reporting and monitoring for many environmental indicators, it also weakened protections by allowing EPA to waive environmental rules and even permit more pollution if the facility met one of several easily achieved performance goals.[8] Moreover, the legislation included a recipe for EPA

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[5] *See* Linda Greer and Rena Steinzor, *Bad Science*, The Environmental Forum (January/February 2002).
[6] Testimony of J. Clarence Davies, Senior Fellow, Resources for the Future, Before the House Committee on Government Reform, Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs (Sept. 21, 2001); Testimony of Janice Mazurek, Director, Center for Innovation and the Environment, Progressive Policy Institute, Before the House Committee on Government Reform, Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs (Sept. 21, 2001).
[7] H.R. 3448, 106th Cong., 1st Sess. (1999).
[8] *Id.* §§ 203(a)(1) (requiring that agreements "reasonably be expected to produce better environmental results"); (c) (defining "better environmental results" to include, among other things, improved monitoring).

paralysis by requiring the agency to review any application for regulatory relief within 90 days of its submission and to provide a written explanation for rejecting any one, no matter how antithetical to EPA's mission.[9]

Finally, just to be clear about how important we think a clean bill is, we have not called for adding provisions to the cabinet bill that we might otherwise support on their own. For instance, there were suggestions during previous attempts to elevate EPA that strong whistleblower protections should be incorporated into such legislation.[10] Likewise, there have been proposals to continue the Office of Environmental Justice. [11]

Although these both may be good ideas, we think they are ill advised in the context of a cabinet bill for the simple reason that there may be controversy about how to accomplish either laudable goal. Indeed, if legislative provisions were added to an EPA cabinet bill that could weaken environmental protection in this country, then our support for the concept of a Department of the Environment would turn into strong opposition to the bill. The result could well be a legislative free-for-all as all sides (including

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[9] *Id.* § 202(b).

[10] William Sanjour & Stephen M. Kohn, *Environmental Whitstleblowers: An Endangered Species* (Environmental Research Foundation, Feb. 1994) (describing efforts of the National Whistleblower Center to enhance whistleblower protections as part of cabinet legislation), available online at http://pwp.lincs.net/sanjour/Endangered.htm.

[11] *See* H.R. 2694, 107th Cong., 1st Sess., § 112 (2001); *see also* Boxer Testimony, *supra* note 2 ("I . . . would like to see the EPA's Office of Children's Health and the Office of Environmental Justice written into law. But when I wrote this [cabinet] bill in January, I resisted the attempt to use this bill as a vehicle.").

the environmental community) pursue particular proposals for the agency, in the end dooming progress on the issue.

OTHER IMPORTANT REFORMS HAVE BEEN IGNORED

I hope that these examples illustrate the difficulty of agreeing on specific legislative reforms aimed at restructuring EPA and highlight the necessity of passing a clean bill. However, if the Subcommittee elects to consider linking cabinet status with an agency overhaul, then we feel compelled to point out that reforming EPA would be incomplete without several important improvements that we support.

First, the legislation would need to include provisions to counteract the current influence over EPA science by polluting industry. To do so, EPA and the public should have adequate access to the data upon which industry-performed and industry-sponsored studies are based. In addition, Congress must enact meaningful reforms to improve the integrity of EPA's peer review process.[12] This should include a general ban on EPA peer review panelists who themselves (or whose funders or financial backers) have a financial stake in the outcome of the decision they are reviewing.

[12] *See generally* General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance (June 12, 2001), available online at http://www.gao.gov/new.items/d01536.pdf.

Second, cost-benefit analysis and risk assessments (including comparative risk analysis) should not be allowed to supersede the requirements of the underlying statute for environmental decision-making. To the extent that cost-benefit analysis is used by the agency to inform decision-making, the agency should more systematically reduce the biased tendency of cost-benefit analysis to overstate costs and undervalue benefits. For instance, EPA should be prohibited from treating the value of human lives differently depending upon their income, age, race, and gender or the time at which they die following exposure to a hazard. The value of all human lives – our children and grandparents, the elderly, the rich and the poor – are equally precious.[13] EPA should also develop an analytical protocol by which nonquantitative benefits can be taken into account more fully and not simply ignored by the cost-benefit test.

Third, Congress should establish requirements for adequately addressing children's special environmental exposures and vulnerabilities. In a report that provided the impetus for Congress to mandate important changes to the way EPA regulates pesticide residues in food, the National Research Council stated:

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[13] A number of common cost-benefit accounting tools, known as "discounting," can lower the estimated benefits of environmental protection by placing a lower dollar value on preventing premature death. Some of these death discounting tools include lowering the value of life placed on saving seniors, reducing the value of saving the life of the disabled, and choosing an inappropriately high discount rate for lives saved in the future. *See* Wesley Warren, OMB Comments on Draft Guidelines and Draft Report (May 5, 2003).

> A fundamental maxim of pediatric medicine is that children are not "little adults." Profound differences exist between children and adults. Infants and children are growing and developing. Their metabolic rates are more rapid than those of adults. There are differences in their ability to activate, detoxify, and excrete xenobiotic compounds.[14]

Legislation directing EPA to consider these special sensitivities and guard against harms to children in all environmental media should be a priority. Senator Boxer introduced a bill in the past to help accomplish this important goal, titled the "Children's Environmental Protection Act."[15]

Fourth, the legislation should ensure transparency in environmental decision-making by making public the agency's policy negotiations with other parts of the administration. Existing requirements provide a starting point for such disclosures, but are not sufficient. [16]

Fifth, Congress should end EPA's role in the practice of unethically testing toxic chemicals on humans. Many such tests are sponsored by chemical manufacturers to help weaken health standards, lack benefits for the subjects of the study, and are of insufficient statistical power to be of any scientific value. Thus, they violate a number of standards regulating the

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[14] Pesticides In the Diets of Infants and Children 3 (National Research Council, 1993).
[15] S. 1112, 106th Cong., 1st Sess. (1999).
[16] For instance, section 6(a)(3)(E) of Executive Order 12866 and section 307(d)(4)(B) of the Clean Air Act, 42 U.S.C. §7607(d)(4)(B), each demand that drafts of regulatory actions and the Office of Management and Budget's comments thereon be made public. Such a requirement omits interactions that occur prior to the generation of a draft, and is too narrowly focused on OMB.

propriety of human testing, not limited to the "Nuremberg Code," adopted in the wake of the Nuremberg trials of Nazi doctors after World War II.[17]

Sixth, the statute should require manufacturers of consumer and commercial goods to report to EPA any potential adverse health or environmental effects from their products, much in the same way that section 6(a)(2) of FIFRA regulates pesticide manufacturers. The federal government lacks the ability to independently test all of the tens of thousands of industrial chemicals on the market to ensure their safety. Thus, requiring manufacturers to disclose the adverse effects information about which they are aware at least provides EPA and the public with the opportunity to review available information about a given product's hazards.

CONCLUSION

NRDC supports elevation of EPA to a cabinet agency as a "clean bill" but only if it is free of extraneous provisions, including so-called second generation ideas that could actually result in weakened environmental protection. If the subcommittee considers such sweeping reforms in legislation, it should adopt instead proposals that actually strengthen environmental protection instead of weakening them.

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[17] *See Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10* (Oct. 1946–April 1949) (requiring, among other things, that experiments on humans "be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study"), available online at http://www.ushmm.org/research/doctors/Nuremberg_Code.htm; *see also Grimes v. Kennedy Krieger Inst., Inc.*, 366 Md. 29, 99 (2001) ("The breach of obligations imposed on researchers by the Nuremberg Code, might well support actions sounding in negligence in cases such as those at issue here.").

Mr. OSE. Our final witness is Rena Steinzor, who is a professor at the University of Maryland School of Law and a Board Member at the Center for Progressive Regulation.

Thank you for joining us this morning. You are recognized for 5 minutes.

Ms. STEINZOR. Thank you, Mr. Chairman, for the opportunity to appear before you today. My comments do represent the views of the Center for Progressive Regulation, also a think tank doing much of its work in Washington.

As the chairman explained at the outset, you have two very distinct pieces of legislation before you today. CPR would like to make five points about these legislative proposals and their potential impact on environmental protection.

Point one, elevation is far less therapy than this gravely patient really needs. There is a broad-based consensus among the Agency's major constituencies that it should be elevated to Cabinet status, and CPR agrees with that view. However, at this juncture, elevation has the flavor of fiddling while Rome burns. Opponents have laid siege to the Agency which just lost Governor Whitman. A range of deregulatory initiatives imposed by the White House have undercut its daily work more drastically than at any point in the last 15 years. A ceremony in the Rose Garden celebrating its Cabinet status would convey a profoundly misleading impression about its stability and effectiveness.

Beginning with broken promises at Kyoto, this administration has pursued a series of initiatives designed to roll back protections established by Presidents on a bipartisan basis over three decades. Among the most troubling are those that undermine the work of the President's father who led Congress to pass the 1990 Clean Air Act amendments, among the most comprehensive environmental initiatives ever to be enacted in this country.

Meanwhile, the political appointee in charge of the Office of Water has launched an expensive and time-consuming initiative to eliminate Federal controls on pollution for 50 to 60 percent of streams and 20 percent of wetlands. Unless and until the States pick up the slack left by EPA and the Army Corps of Engineers' abrupt departure from the field, these vast and irreplaceable natural resources could be polluted, drained, or filled in by industrial dischargers, real estate developers, and sewage treatment plants.

Point two, clean bill, or proverbial Christmas tree? Many of the EPA's critics, especially on the business side of the spectrum, have grown extremely frustrated by their inability to persuade Congress to undertake radical surgery on its core authorizing statutes. Efforts to impose similarly radical changes in the form of generic across-the-board regulatory reform have also failed. You will face a great deal of pressure to load the Cabinet bill up with yet another series of reform measures. This approach is likely to, and without a doubt should, doom passage. The only democratic and sufficiently transparent way to accomplish such reform is to undertake the difficult debates that are necessary to determine how much and how fast we will protect our air, our water, and our land, as well as the condition of the environmental legacy we will leave to our children.

Point three, this bill represents an unreasonable risk of undermining democracy. Perhaps as a reflection of the pressure to reform EPA through Cabinet elevation legislation rather than the normal legislative process, H.R. 2138 would define EPA's mission as protecting the public from unreasonable environmental risks. This standard is borrowed from the Toxic Substances Control Act, the least effective and least protective of all the statutes that EPA administers.

There are more details in my testimony about the impact of the Fifth Circuit's decision in Corrosion Proof Fittings versus EPA, which has basically crippled the Agency's effort to deal with asbestos which continues to plague the health of many Americans.

Point four, reorganizing into more bureaucracy and less enforcement. The reorganization plan fragments EPA's core regulatory missions and creates a new layer of bureaucracy that will further congeal proactive efforts to enforce the law. The draining task of implementing this plan will cost EPA at least 2 years of progress on other aspects of its mission as positions in policymaking jurisdiction are shuffled and turf wars are fought.

Point five, environmental statistics and the States. Interestingly, I did not read today's front page Washington Post story as supporting the idea that we don't have enough data to decide what to do. In fact, what that story said was that one-quarter of major dischargers of pollution into the Nation's surface waters are routinely violating the Clean Water Act. We have data; we just are not doing anything about it.

I appreciate the opportunity to testify.

Mr. OSE. Thank you, Ms. Steinzor.

[The prepared statement of Ms. Steinzor follows:]

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Testimony of

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before the

Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs

of the

Committee on Government Reform

U.S. House of Representatives

regarding

EPA Cabinet Elevation

Washington, D.C.
June 6, 2003

Mr. Chairman and members of the Committee, thank you for the opportunity to appear before you today to testify on behalf of the Center for Progressive Regulation (CPR) regarding the elevation of the Environmental Protection Agency (EPA) to Cabinet status.

CPR is an organization of academics specializing in the legal, economic, and scientific issues that surround federal regulation. CPR member scholars reject the idea that government's only function is to increase the economic efficiency of private markets. CPR's mission is to advance the public's understanding of the issues addressed by the

country's regulatory laws. CPR is committed to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment. It seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. You can learn more about our work at www.progressiveregulation.org.

You have before you two very different pieces of legislation. While both would elevate the Environmental Protection Agency (EPA) to Cabinet status, H.R. 2138, introduced by Chairman Ose, would undertake an ambitious reorganization of the new department and could be read to fundamentally alter the standard for when the federal government could act to protect public health and natural resources. In contrast, H.R. 37, introduced by Representative Boehlert, is what is typically referred to as a "clean" bill that would accomplish elevation without making any other changes in EPA's legal mandates and organization.

CPR would like to make five distinct points about these legislative proposals and their potential impact on environmental protection in the United States.

Point One: Elevation Is Far Less Therapy Than This Gravely Ill Patient Really Needs

There is a broad-based consensus among the Agency's major constituencies that it should be elevated to Cabinet status, and CPR agrees with that view. However, at this juncture, elevation has the flavor of fiddling while Rome burns. Opponents have laid siege to the Agency, which just lost Governor Whitman. A range of deregulatory initiatives imposed by the White House have undercut its daily work more drastically than at any point in the last 15 years. A ceremony in the Rose Garden celebrating its Cabinet status would convey a profoundly misleading impression about its stability and effectiveness.

Beginning with broken promises at Kyoto, this Administration has pursued a series of initiatives designed to roll back protections established by presidents, on a bi-partisan basis, over three decades. Among the most troubling are those that undermine the work of the President's father, who led Congress to pass the 1990 Clean Air Act Amendments, among the most comprehensive environmental initiatives ever to be enacted in this country.

Thus, we have witnessed the rejection of badly needed tightening of the fuel emission standards that apply to motor vehicles. The Administration has effectively abandoned efforts to compel Midwestern power plants to stop smothering Northeastern cities. EPA, under pressure from OMB, has engaged in systematic attempts to avoid the deadlines and explicit instructions the law applies to the control of hazardous air pollutants. And, under the misleading rubric "Clear Skies," the Administration has proposed the substitution of market-based trading for proven facility-specific pollution limits, with trading to occur under overall caps on total emissions that are significantly

less ambitious than what is necessary to avoid losing ground, much less make affirmative progress.

Last week, the *New York Times* carried a front-page story detailing EPA's failure to update the data base it uses to track implementation of the Clean Water Act's flagship program – National Pollutant Discharge Elimination System (NPDES) permitting for major point sources. The Agency's Inspector General warned ominously that without a modernized database, EPA "cannot effectively manage" the program. To add insult to injury, the funding gap crippling EPA's completion of this vital task is in the ballpark of $12 million.

Meanwhile, the political appointee in charge of the Office of Water has launched an expensive and time-consuming initiative to eliminate federal controls on pollution for 50 to 60 percent of streams and 20 percent of wetlands. Unless and until the states pick up the slack left by EPA and the Army Corps of Engineers' abrupt departure from the field, these vast and irreplaceable natural resources could be polluted, drained, or filled in by industrial dischargers, real estate developers, and sewage treatment plants. The cumulative impact of these changes will produce grave erosions in water quality, not just in the affected streams and wetlands, but also in the vast bodies of water into which they feed.

A final example of EPA's tragic condition is its failure to address a glaring threat to our national security: the prevention of terrorist attacks on chemical plants nationwide, many of which store acutely toxic chemicals in amounts that could kill millions if released. Despite abortive efforts to impose stricter government oversight on those facilities, as recently reported by the *Washington Post*, Administrator Whitman was foiled at every turn, and we remain dependent on a voluntary program initiated by a trade association that covers only about 30% of the industry.

Point Two: Clean Bill or Proverbial Christmas Tree?

Many of EPA's critics, especially on the business side of the spectrum, have grown extremely frustrated by their inability to persuade Congress to undertake radical surgery on its core authorizing statutes. Efforts to impose similarly radical changes in the form of generic, across-the-board regulatory reform legislation have also failed. You will face a great deal of pressure to load the Cabinet bill up with yet another series of reform measures. This approach is likely to – and without a doubt should – doom passage. The only democratic and sufficiently transparent way to accomplish such reform is to undertake the difficult debates that are necessary to determine how much and how fast we will protect our air, our water, and our land, as well as the condition of the environmental legacy we will leave to our children.

That said, CPR has its own ideas of what types of reforms are needed to make EPA operate more effectively. As just one example, EPA's use of science is dominated by scientists funded by companies with a direct financial stake in the outcome of the Agency's decision-making. In our view, efforts to reform EPA's statutory mandates must address these concerns. Congress should consider four separate reforms:

- EPA should not rely on scientific studies submitted by regulated industries until all of the underlying data, modeling methodology, and other techniques and protocols are publicly disclosed.
- All such studies should be subject to peer review by panels that eliminate any person with a financial conflict of interest in the outcome of its deliberations.
- Peer review panels should be carefully composed to ensure that members represent a full and balanced range of views, taking into consideration not only their members' expert opinions, but also their organizational affiliations.
- EPA should not use research conducted under contracts that place limits on the disclosure of results adverse to the interests of the study's corporate sponsors.

H.R. 2138 addresses the need for EPA to use "sound" science at some length without ever reaching such crucial reforms. For EPA science to be really sound, these reforms are necessary.

CPR also has ideas about which reforms are *not* necessary. For example, we believe that the imposition of strict cost-benefit analysis as a threshold to action is both illegal and misguided. The vast majority of environmental statutes, crafted after years of debate and covering thousands of carefully considered pages, require EPA to regulate in a cost-effective manner. But they do not allow misleadingly precise efforts to monetize costs and benefits to establish insurmountable barriers to EPA's determinations of what steps must be taken to protect human health and the environment. Not only is the Office of Management and Budget (OMB) imposing such illegal methodology, it is basing its own review of regulations on highly unreliable and technically unsound data, in clear violation of the Data Quality Act. If Congress were to undertake a careful and deliberate reevaluation of each of EPA's individual statutory mandates, we would urge legislation barring such practices.

Point Three: "Unreasonable Risk" of Undermining Democracy

Perhaps as a reflection of the pressure to reform EPA through Cabinet elevation legislation rather than the normal legislative process, H.R. 2138 would define EPA's mission as protecting the public from "unreasonable environmental risks." This standard is borrowed from the Toxic Substances Control Act, the least effective and least protective of all of the statutes that EPA administers. If this standard was read to trump the more protective provisions of such vital laws as the Clean Air and Clean Water Acts, EPA would be crippled, perhaps beyond repair. H.R. 2138 contains a "savings clause" announcing its intent not to "alter," "affect," "amend," or "modify" any other federal environmental law. If this last statement is truly the bill's goal, the unreasonable risk standard announced in its mission statement must be eliminated. If, on the other hand, the unreasonable risk standard is intended to govern the Agency's regulatory policies, H.R. 2138 represents among the most devastating proposals yet advanced to deregulate harmful industrial practices.

The most prominent interpretation of the "unreasonable risk" standard is the Fifth Circuit's decision in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The case struck down an EPA regulation banning most uses of asbestos under Section 6 of the Toxic Substances Control Act (TSCA). Among other things, the Court noted with approval that the unreasonable risk standard requires EPA to consider how much money should be spent on saving a human life by regulatory intervention. It also held that under TSCA's section 6, human life must be discounted if death as a result of asbestos exposure would not occur for many years. Thus, the question becomes not whether we should act to save lives, but rather whether the money we would need to invest today to come up with the amount life might be worth in 30 years justifies the expense to industry of preventing pollutants from harming people.

Not content to simply require monetization and discounting in the context of such deceptively rigorous cost-benefit analysis, the Court further held that it was entitled to ask whether EPA had considered every "less burdensome" regulatory alternative that could conceivably be imposed before deciding to ban asbestos products. Not only did it need to dream up and then quantify the costs and benefits of such alternatives, it needed to conclude that *none* of the weaker alternatives would provide *any* adequate level of protection. If the Court could envision any other regulation that would achieve an acceptable level of risk, it was justified in striking down the regulation. This approach is a very sharp departure from the usual standard of judicial review, which asks whether the regulation is consistent with the statutory mandate and supported by a reasonable basis as document by the rulemaking record.

It is worth noting in this regard that this harsh interpretation of the TSCA standard has paralyzed EPA's efforts to eliminate asbestos from the marketplace, with potentially devastating results for thousands of consumers. For example, the Agency just posted a new warning on its web site concerning vermiculite attic insulation, which is heavily contaminated with asbestos. The warning reads:

> What should I do if I have vermiculite attic insulation? DO NOT DISTURB IT. Any disturbance has the potential to release asbestos fibers into the air.

Thus, EPA recognizes what the court in *Corrosion Proof Fittings* did not: asbestos presents an "unreasonable risk" to human health throughout all the stages of its life cycle. The enshrinement of the "unreasonable risk" standard in the Cabinet elevation bill threatens to stymie EPA efforts under other statutory regimes just as it has stymied efforts under TSCA.

Point Four: Reorganizing into More Bureaucracy, Less Enforcement

The reorganization plan for the new Department set forth in H.R. 2138 fragments its core regulatory missions and creates a new layer of bureaucracy that will further congeal proactive efforts to enforce the law. The draining task of implementing this plan will cost EPA at least two years of progress on other aspects of its mission, as positions

and policymaking jurisdiction are shuffled and turf wars fought. The environment and public health cannot afford such delays, especially given EPA's central role in addressing the threats posed by terrorism in such arenas as chemical plant safety and federal facility decontamination.

The legislation would create three, presumably co-equal under-secretaries: one to police EPA's use of science and other information; a second to develop policy, including regulations; and a third to implement such policies and enforce the law, primarily by riding herd on the new Department's regional offices. The legislation would retain the five senior officials now known as Assistant Administrators, and the ten senior officials now known as Regional Administrators. But the five newly minted Assistant Secretaries would report first to the Under Secretary for Policy, Planning, and Innovation, next to the Deputy Secretary, and finally to the Secretary. The ten Regional Administrators would report to the Under Secretary for Policy, Planning, and Innovation, next to the Deputy Secretary, and finally to the Secretary.

It is difficult to see how this approach solves the supposed problem of EPA's "stovepipe" organization identified by some of the witnesses at the Subcommittee's previous hearings on Cabinet elevation. Further, because the Secretary retains authority to determine what each of the five Assistant Secretaries will do, the reorganization contemplated by H.R. 2138 does not necessarily accomplish the goal of forcing EPA to regulate by industry sector, across all media, as recommended by some of the Agency's more thoughtful critics.

CPR believes that proposals to promote cross-media regulation are well worth exploring, outside the context of a clean Cabinet elevation bill. The reorganization envisioned by H.R. 2138, however, is highly unlikely to achieve those goals, and instead will drain energy and resources desperately needed to implement EPA's core mission.

Point Five: Environmental Statistics and the States

CPR supports the concept of an independent Bureau of Environmental Statistics, but believes it should be pursued via a free-standing piece of legislation. Comparable entities throughout government, such as the Bureau of Labor Statistics, have made significant contributions to sound policymaking.

Unfortunately, however, H.R. 2138 fails to recognize that much of the data that would be gathered and analyzed by such an entity originates at the state level. Much of this data must be gathered by monitoring equipment that is expensive to install and operate. The legislation fails to address the severe resource constraints that afflict the states and, if recent history is any guide, without such funding, they are likely to strenuously resist any effort to improve the quality of the data they gather.

Performance-based regulation is a promising development that must be pursued actively by all participants in the ongoing debate over EPA's appropriate role. But such alternative systems must be based on sound data, as H.R. 2138 recognizes. Until and

unless Congress commits significant resources to this vital effort, performance-based systems will be exceedingly vulnerable to abuse.

Thank you for the opportunity to appear before you today. I would be pleased to answer any questions you may have.

Mr. OSE. All right. We are going to go to questions now. The way this works is that I have a number of questions that I need to get through here, and we will go left to right and right to left and left to right and right to left. If someone has something they want to offer, we have plenty of time. I am sure my colleagues up here will give me plenty of time to go to everybody. So we will just go forward. I do appreciate everybody's succinctness in summarizing their testimony.

In the last Congress this subcommittee heard testimony regarding problems with EPA's operations, its science, its effectiveness of its regulations, its impact on the regulated community, its regional offices, its program offices, its lack of cross-media research, etc. The sum and substance of that was that many believe that, after 30 years of seeking piecemeal improvements, EPA needs to be reformed.

Dr. Portney, we will start with you. Should Congress make reforms to EPA's organizational structure? And, is it appropriate to do it concurrent with the elevation to Cabinet-level status?

Dr. PORTNEY. Mr. Chairman, I think that there are respects in which EPA's operation can certainly be improved.

I guess I would answer your question this way: If the reorganization that this legislation proposes becomes the overwhelming impediment to elevating EPA to Cabinet status and to creating a Bureau of Environmental Statistics, then I would be inclined to say that I would be happy to move a cleaner bill that incorporates the Bureau of Environmental Statistics and not run the risk of compromising what you have proposed, elevation and the creation of a Bureau that I think is overwhelmingly in the best interest of the public.

Mr. OSE. So your de minimus standard is, at least, the Bureau of Environmental Statistics?

Dr. PORTNEY. To me, that is the most important part of the legislation that you have introduced. Yes, sir.

Mr. OSE. OK. Dr. Gray, the same question.

Dr. GRAY. I really see a change like this as an opportunity, and I think that this may be the time to take the opportunity to try to address many of the pathologies of decisionmaking in EPA that have been identified by this committee in the past. I don't think we should waste it.

And, it would be important—I share Dr. Portney's view that the Bureau of Environmental Statistics is extremely important to us, and I think that elevation is extremely important, but I think we should be very careful not to waste an opportunity, because it would be very difficult to do this under other circumstances. Don't waste the opportunity to address many of the problems that you've identified.

Mr. OSE. So you would prefer to make structual changes as opposed to de minimus changes providing for at least the Bureau of Environmental Statistics?

Dr. GRAY. I think that would be my preference, yes.

Mr. OSE. OK. Dr. Hayward.

Dr. HAYWARD. Well, I don't have much expertise in administrative organization. But as I look at your two organizational charts over there, the one in the poster, if that really reflects the way

EPA works, sort of reminds me about that politically incorrect joke about a certain kind of firing squad; and it can't strike me that is a good way to continue. It strikes me that the one that's up on the screen, which is the proposed reorganization, almost surely looks more like other departments are organized in the Cabinet. So, I mean, there is always going to be a lot of bureaucracy in government with that big an agency doing this many things. So it just seems to me it has to be much more sensible on the face of it to reorganize it the way your bill proposes.

Mr. OSE. Mr. Warren, another bite at the apple.

Mr. WARREN. Thank you. I appreciate that.

This is a very serious issue for the Agency, and I believe that your bill is actually a very thoughtful proposal in this field. But I think it is an issue that no one has actually solved this Rubik's Cube on yet.

People recognize stovepiping as a problem at the Agency, yet I think that merely creating three Under Secretaries doesn't solve that problem. You have fewer pipes, yet in some ways they are thicker. The Policy and Planning Under Secretary would oversee the other Assistant Secretaries, but Science and Enforcement and Compliance aren't really integrated into the policy and planning function. And so, in some ways it might reinforce the separation of those activities from being fully integrated.

Instead, I believe that, on that issue, Congress has already passed legislation that could serve this purpose, which is the Government Performance and Results Act: that, among other things, requires the Agency to produce a strategic plan, which they are in the process of revising; and that properly charges the head of the Agency with serving the integrating function, which I think is where the responsibility should reside.

Mr. OSE. Professor Steinzor.

Ms. STEINZOR. It is common wisdom among public management experts that any comprehensive reorganization means that agencies are deflected from their core work for a period of time. We are estimating 2 years. I think that is probably conservative. CPR questions whether this agency can afford that kind of deflection when you see the erosion in the past of its routine bread and butter activities in enforcing the Clean Water Act and also when you consider its crucial role in counterterrorism. EPA was the one that responded to anthrax, that estimated the health risk at the World Trade Center. EPA is the only agency with authority to ask the chemical plants to make themselves more secure and prevent accidents. That industrial sector is unregulated at this moment in terms of those issues, and we feel that those imperatives are sufficiently urgent that a clean bill is the way to go on this.

Mr. OSE. Thank you.

When President Nixon created EPA in 1970, he stated his reasons for doing so, but he did not provide a mission statement, and since that time EPA has developed its own mission statement. My question is, should a mission statement be included in a bill establishing a new department. Professor Steinzor, your input on that?

Ms. STEINZOR. I'm a little puzzled about the bill's intent, because I understand your wish to provide a mission statement, and yet the

bill has a savings clause that says it is not intended to affect any of the existing statutes.

If your mission statement says that the Agency's mission is unreasonable risk, which is a standard under the Toxic Substances Control Act, and yet you have a savings clause that says this legislation does not affect the Clean Water and Clean Air Act, we will end up in massive arguing, including in court, about which one is the right interpretation.

There is a broad constituency that would fight very hard against the idea that unreasonable risk should be the statutory standard across the board. So I am not sure how the legislation would ultimately be interpreted, but I can promise you full employment for all the law students in my class if it passes, unfortunately.

Mr. OSE. All right.

Mr. Warren.

Mr. WARREN. Well, I think there are two different issues. One is, does the Agency need a statutory mission statement; and second is whether the mission statement included in H.R. 2138 is the correct one. H.R. 37 does not have a statutory mission statement. We believe that is the way to go. We believe that is the way to go because, as I said in my oral comments, the mission of the Agency is to administer the statutes that Congress has passed and given EPA the responsibility to administer.

One of the statutes, again, is the Government Performance Results Act, which requires a strategic plan; and in that strategic plan the Agency has already included a mission statement. The mission is to protect human health and the environment. Therefore, we believe that the Agency already has come up with the necessary means to address the issue of what the mission should be.

In respect to the second question about whether you have correctly stated the mission, as I said in my oral comments, no, we don't believe that should be the stated mission.

Mr. OSE. Thank you.

Dr. Hayward.

Dr. HAYWARD. I don't have too much to say about this, except that it strikes me as entirely appropriate for Congress to state some congressional intent about what the mission of a Cabinet-level agency is going to be. It may not matter as much in this case, although, again, if you go back to the very beginning, lots of things about the environment and the mission of the EPA was left undefined. And although Nixon had some general intent, ultimately, he punted and said, I am going to leave it to the first administrator to decide what the scope is and how they are going to go about their mission. And, there was actually some talk of a time, because there was this big Presidential commission on population issues, that maybe the EPA will be a lead agency for confronting population issues, which has always been on the global scale a large environmental theme.

In the 30 years on, we sort of settled onto the EPA administering particular statutes for—you know, toxic substance has been mentioned, air quality, and so forth. And so, these kinds of larger issues of what should the mission, broadly speaking, of the Agency be have fallen away as a practical matter. But it seems to me en-

tirely appropriate for you to weigh in on what you think its general direction should be.

Mr. OSE. Dr. Gray.

Dr. GRAY. Well, as a scientist, I don't feel that I am particularly well-equipped to comment on the dance between the executive and the legislative branch. But what I can say very briefly is that I really like this mission statement as an aspiration for and a way to guide the thinking and the decisions of the Environmental Protection Agency.

And, I guess that's where I'd leave it. I don't know if it's the right thing to do, but if you do it, I like this one.

Mr. OSE. Dr. Portney.

Dr. PORTNEY. Three quick points in response. First of all, I know when you took testimony on comparable legislation in previous years you heard from one of my colleagues, Terry Davies, who is I think one of the wisest students of environmental protection in the country. He would just, frankly, kill me if I didn't use this opportunity to say that he has always been a champion of the notion that there ought to be an organic statute empowering the EPA. So I will say that, to the extent this mission statement question is a manifestation of congressional belief in having some kind of organic statute empowering EPA, I am supportive of that.

Second, I always support the idea of Congress pointing out to the Environmental Protection Agency, that while there are any number of risks it is absolutely essential that the Agency regulate, there ought to be some notion of de minimus risk; and pointing out to the Agency that they can't control every single thing that appears in every single media isn't harmful, even though I don't see something like that trumping the individual statutes under which EPA regulates.

And, finally, at the risk of sounding like a stuck record, I want to respond the way I did to your first question and say that if this question of having a mission statement or the language of unreasonable risk in the bill imperils elevating EPA to statutory or to Cabinet status or stands in the way of creating the Bureau of Environmental Statistics, I would throw it overboard.

Mr. OSE. You have come to a conclusion as to what your objective is, haven't you?

Dr. PORTNEY. Man on a mission.

Mr. OSE. Thank you. EPA, as you see the chart to my left, is currently structured in a manner that many refer to as a stovepipe approach. That is that many Assistant Administrators and various divisions of EPA each report independently to the Administrator without other oversight. During our hearings in the previous Congress, witnesses discussed how to improve the organization of EPA. We are going to start, Dr. Portney, with you. What are your views regarding H.R. 2138's reorganization of the Department into three Under Secretaries? Does this structure improve or not improve the Secretary's ability to manage the Department?

Dr. PORTNEY. I think that the structure that you propose would improve the Secretary's ability to manage the Department. There is no question in my mind about that.

The types of problems that you have cited, though—the inability to make these cross-media tradeoffs, etc.—I think are probably due

more to the fragmented statutory arrangement under which EPA regulates now than to the way the Agency is currently organized administratively. But I am supportive of the proposed reorganization and I hope in the future we will be able to take on the individual statutes to allow EPA to make these kinds of cross-media tradeoffs.

Mr. OSE. One of my concerns is that we only pick a fight we might be able to win.

Dr. Gray, any comment on that, on the questions I asked?

Dr. GRAY. Just one quick comment. Again, as I look at this primarily from a scientific point of view, we have to remember that science is a credibility that underlies all of EPA's decisions. My interest is in having those decisions be as credible as possible. I think this structure would help increase the credibility of EPA by making that clear distinction between policy and science. It would allow their science to get the recognition for its quality that it deserves, policy decisions to be made explicitly by policymakers, not hidden in the science.

Mr. OSE. Dr. Hayward.

Dr. HAYWARD. Nothing.

Mr. OSE. Mr. Warren.

Mr. WARREN. I would like to focus on one aspect of that, since I discussed some of the points generally before, which is, I think everyone's common concern is that the Agency have the best science possible and that the science be used in the most effective way possible. And, I believe my concern about the organization into the three Under Secretaries is: that, again, the Under Secretary responsible for science and information is set apart from the Under Secretary for policy and planning; that you in some ways might unintentionally reinforce the balkanization of those functions within the Agency; and that now you will have even more powerful players responsible for activities that are not fully integrated. And, that whatever we do I think we at least do not want to make worse the bureaucratic tendency not to make science a function that the entire agency is concerned about at all times.

Mr. OSE. Professor Steinzor.

Ms. STEINZOR. I won't repeat my points from before about reorganizing costing time and energy when we can't afford it. I will say, though, that I think that Terry Davies' proposals that Dr. Portney mentioned had to do with rewriting all the statutes to accomplish cross-media integrated regulation; and that would be a major, momentous task, as Terry Davies has acknowledged every time I have discussed it with him.

I think it would be a very interesting debate, but it is not something that can be done simply by shuffling bureaucratic seats. In fact, as I understand your bill, the Assistant Secretaries could still be air, water, solid waste. They would be determined by the administrator. So we would still have unintegrated media-specific regulation. But I could be wrong about that. That is how I read it.

Mr. OSE. That is one of the points of the hearing, is to try and get this input. So, thank you.

The next question I have is in regard to the IG's report of November 2002, which examined the use of science in 16 post-1994 rules. The Inspector General reported that program offices or their

contractors developed virtually all the technical support documents that made the scientific case for the 16 rules included in the study, with little input from the Office of Research and Development. Currently, program offices and not the Office of Research and Development do the scientific work in support of regulatory actions.

The most widely criticized aspect of EPA seems to be the quality of its science. Both sides of the political spectrum, or maybe all sides of the political spectrum, claim that EPA does not use what is referred to as sound science.

We are going to start with Professor Steinzor, and we will move to my left. Would you support the relocation of science from the program offices and the centralization of the science at the new department under a Secretary of Science and Information? And then, part of that question is, if you could define from your perspective what sound science is, that would be helpful.

Ms. STEINZOR. Well, I have actually written on that subject; and perhaps I could submit the article about science at the EPA for the record.

Mr. OSE. Hearing no objection, we will allow that.

Ms. STEINZOR. I actually would share Mr. Warren's concerns about putting it in a separate organization. But I would also say, in a nutshell, that the problem of science at EPA is not that it is junk but that it is overly influenced by regulated industries. And, I would refer you to a GAO report that came out in 2001 that showed that when it was doing crucial peer review EPA was not ensuring that panels were balanced for bias, wasn't even asking panelists if they had conflicts of interest, such as working for companies that sell the chemicals that were being reviewed. And, that those kinds of problems, as I said in my written testimony, are much more urgent. Before we can make science sound, we have to make it clean. I guess that is what I would suggest.

Mr. OSE. Mr. Warren? Do you want me to repeat the question?

Mr. WARREN. No, I think I remember it. But it raises many different issues at once. So I will do what I can to pick out what I think are the most important, which is that there should be fewer, more important, responsibilities and sound science at the Agency. Sound science is using the best available information according to generally accepted scientific protocols in a way that is transparent and can pass the test of an independent review. But I believe that often the claim of sound science is just used by critics of the Agency to dispute outcomes that they don't like when the underlying science may, in fact, be perfectly sound.

So I think that we want to try to avoid making this issue just a political football within this legislative debate.

Once again, I think I would say that I think it has been more a problem on the part of the Agency of having inadequate resources. You sort of get what you pay for. If you want more, better science, then you really have to sort of put money into it, and not use it, as an excuse not to take action until we know more, and then not really try to do what is necessary to find out more about the environment.

I think that one of the essential points here, and this will be my final point, has to do with conflicts of interest and managing peer review processes at the Agency. In respect to the legislation, I have

certain concerns about that for the Bureau of Environmental Statistics, that it creates a peer review process that in some ways, actually ironically while we are elevating the EPA on one hand to a Cabinet department, would subordinate the Agency to review by other Cabinet departments in ways in which they are not subject to review by the Department of Environmental Protection.

So I believe that there are other ways to address issues of ensuring quality science and that those should be our top priorities.

Mr. OSE. In terms of the centralization of the science at the new department as opposed to leaving them in a program or in the regional offices?

Mr. WARREN. If I can briefly address that issue, I would like to say again, this is a part of the Rubik's Cube that no one has quite figured out the solution to. Science is not one thing. The Agency needs to do several different kinds of scientific activities. One of those is to broadly look at the state of the environment and emerging environmental issues that people may have not thought about before, and a separate science office may properly do that. Several of those activities are to make sure that regulatory actions are directly supported by good science, and you may not want to separate that from the program office because you may actually worsen stovepiping.

Last but not least, I would say that there is a role for the Agency to support work outside of the department, that not all of the work should be done in house, that in many ways, supporting the work of independent researchers can be much more fruitful in the long run.

Mr. OSE. Dr. Hayward, same questions: Do you support the relocation of science from the program offices and the centralization of science at the new department under an Under Secretary, and what do you think constitutes sound science?

Dr. HAYWARD. I don't really have a firm opinion on the first question, the narrow administrative question. The broader question that drives all of this is what is sound science. I have a very hard time answering that question in a meaningful way. It is a motherhood-and-apple-pie concept. No one is for unsound science. The difficulty arises when you have perfectly scrupulous and unbiased scientists who disagree and/or who produce results with large ranges of uncertainty, and that characterizes a lot of our science and environmental matters. So at the end of the day, it is not so much the soundness of the science that is in question, although it can be sometimes, as it is how we judge the risk threshold we decide to apply with the information we have, given the uncertainties we have.

Dr. Gray knows a whole lot more about this than I do, so I am going to punt to him here in a minute. But ultimately, sound science gets subsumed in the political decisions about which particular risks we are going to go after and what threshold of risk we find reasonable or unreasonable, to bring up that term again. Just to conclude in one sentence, I don't think this is a problem that can or should be sorted out in legislation necessarily.

Mr. OSE. All right.

Dr. Gray.

Dr. GRAY. I think the first thing that I want to say is that it is important to recognize that EPA in fact does and uses good, sound science. They use peer-reviewed work, they publish work. They do and use good science. The question isn't the science, it is the interpretation of the science. This is exactly what Dr. Hayward was getting at. The interpretation is what is important. I think that is where peer review is necessary and it is one of the places that we don't look very often.

In terms of structure, again as a scientist, I don't have strong opinions about how we think about the way to organize things, but my concern is that as long as the science is embedded in the program offices, there is a perception, if not the reality, that the scientists are used, are interpreting that science to get the right answer, the answer that will advance the policy of that program office. For that reason, I think that making a clean distinction between the scientific work, the scientific interpretation, and the policies in the program offices is something that will increase the credibility of EPA science and their decision.

Mr. OSE. In terms of the person making the interpretation of the science, are you suggesting that we need to provide the maximum insulation, if you will, for that person's scientific credibility?

Dr. GRAY. Well, the way in which this sort of risk assessment and management process has been envisioned for many, many years is that it is very important to bring the best available scientific information to a problem, consider that information along with all of the other things that we want to take into consideration in coming to a decision. There is a perception, and you can see it, in fact, in, for example, EPA guidelines that influence the way in which the Agency and outside groups interpret data, how they are supposed to use scientific information to inform decisions, that there are policy choices, policy assumptions all through that have a very strong influence on what ends up coming out. They are not science; and in that way, they are contaminating the science with the policy decisions. The more we can make those two things separate to make distinct the scientific choice and the policy choice, I think the better, the more you would enhance the credibility of EPA's decisions.

Mr. OSE. Thank you. Dr. Portney, we know that you would trade everything for the establishment of the Bureau of Environmental Statistics. Would you still care to offer some comments on this question?

Dr. PORTNEY. Not everything. I would still keep my stepchildren. I want the record to reflect that.

Two things here. First of all, we all know what the definition of sound science is. It is that body of studies that supports what it is you want the Agency to do, and the body of science that supports what you want the Agency not to do gets deemed unsound science. I mean that is de facto; I think that is the way this debate has evolved.

Congressman Ose, I really think there is a tradeoff in centralizing science at the EPA. I certainly can see some advantages, because I think as you look across the program offices even within the EPA, not to mention the way science gets conducted between the EPA and other Federal agencies, you see certain inconsist-

encies with respect to high to low-dose extrapolation, etc. EPA has worked very hard to try to centralize this through the risk assessment guidelines that the Agency establishes, but I think you could probably improve on some of the inconsistencies through some kind of centralization of science.

The other side of that tradeoff, though, is the following: as the science gets pushed up to or out of the program offices, you run the risk of the science becoming irrelevant to or not directly connected to the regulatory problems that the program offices have to deal with.

Briefly, I can give you one analogy. The same issue has been debated within the Occupational Safety and Health Administration, and there was concern that by virtue of having the research done within OSHA, somehow the quality of the science wasn't very good and it was being driven by the answers that OSHA wanted the scientists to find. So a separate agency was created, the National Institute of Occupational Safety and Health. I presume that the quality of the science done at NIOSH is better than the quality of the science that was done within OSHA, but the complaint is that the regulators at OSHA feel that NIOSH funds basic research and doesn't produce scientific research that helps the OSHA regulators actually deal with the problems that you and other Members of Congress have directed them to deal with.

So you can improve science on the one hand, but sometimes it is at the risk of making the science relevant to the individual regulatory decisions that the Agency has to make.

Mr. OSE. Is it your point that before NIOSH was established, there were problems in separating the science from the policy?

Dr. PORTNEY. That is my understanding, and that the idea of creating NIOSH was to professionalize and elevate the quality of the science that was conducted.

Mr. OSE. And, even in its establishment and existence, there remain problems?

Dr. PORTNEY. What I have heard in the past from people at OSHA is that NIOSH has become a research agency whose mission has become somewhat divorced from the day-to-day problems that OSHA has to regulate, and that some of the science funding drifted in the direction of basic science, rather than more applied issues that were germane to the individual regulatory problems that the Agency had.

Mr. OSE. Dr. Gray, on page 2 of your written testimony you state that the change in the department's structure will require further tweaking to ensure that science policy does not influence the conduct and interpretation of scientific information. You touched on that a moment ago.

Do you have a specific solution in mind relative to the further tweaking that you reference in your statement?

Dr. GRAY. I think something that I would like to suggest, because this does exactly address the notion that I was speaking to a moment ago about the separation of policy and science. There are some very nice guidelines, draft guidelines for policy analysis, that address many of these issues separating the science from the policy, and those are in some draft guidance from the Office of Management and Budget that came out in February. I would rec-

ommend that you look closely at those as guidance for doing analysis which supports EPA regulations while keeping the policy attributes as distinct from those as possible.

Mr. OSE. Are you asking that they be made a part of the record?

Dr. GRAY. Yes, please.

Mr. OSE. Hearing no objection, we will do that.

[The information referred to follows:]

TABLE 11.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

Rule	Agency	Benefits	Costs	Other information
Water quality guidance for Great Lakes system.	EPA	Given the site-specific nature of water quality benefits and the unavailability of site-specific data across the Great Lakes Basin, only case study monetized benefits are estimated in the RIA. Average monetized benefits across the three case studies evaluated are $0.3 million per year to $6.2 million per year, with a midpoint of $2.9 million per year (in 1996 dollars); average annual costs across case studies are also $2.8 million per year (1996 dollars)..	$64.0–394.6 million ($1996, annualized).	"The benefit analysis is based on a case study approach, suing benefits transfer applied sources to three case studies . . . The case studies include: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in Northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio . . . EPA did attempt to calculate longer-term benefits to human health, wildlife, and aquatic life once the final Guidance provisions are fully implemented by nonpoint sources as well as point sources and the minimum protection levels are attained in the ambient water." (60 FR 15382). "The three case studies combine to account for nearly 14 percent of the total cost of the final Guidance, nearly 17 percent of the loadings reductions, and from four percent to 10 percent of the benefits proxies (i.e.,. basin-wide population, recreational angling, nonconsumptive recreation, and commercial fishery harvest." (60 FR 15382). "In addition to the cost estimates described above, EPA estimated the cost to comply with requirements consistent with the antidegradation provisions of the final Guidance. This potential future cost is expressed as a 'lost opportunity' cost for facilities impacted by the antigradation requirements. This cost could result in the addition of about $22 million each year." (60 FR 15381).
Interim Requirements for Deposit Control Gasoline Additives, Regulations of Fuels and Fuel Additives.	EPA	HC, CO and NO_X reduction during the 18-month interim period: 700,000 tons (59 FR 54678–); HC, CO and NO_X reduction after the interim period: 600,000 tons per year (59 FR 54678–) Fuel economy savings: 390 million gallons in 1995–2000 (59 FR 54678–).	$650 million (NPV, discount rate = 7%, 1995–2000 (59 FR 54678–)).	

Appendix C. OMB Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements

Preface

This Circular provides OMB's guidance to federal agencies on the development of regulatory analysis as required under Executive Order No. 12866 and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This draft Circular refines OMB's "best practices" document of 1996 *http://www.whitehouse.gov/omb/inforeg/riaguide.html*, which was issued as a guidance in 2000 *http://www.whitehouse.gov/omb/memoranda/m00-08.pdf*, and reaffirmed in 2001 *http://www.whitehouse.gov/omb/memoranda/m01-23.html*. It will replace both the 1996 "best practices" and the 2000 guidance. Before issuing the Circular, this draft will go through a process of peer review, public comment and interagency review.

Introduction

These guidelines are designed to help analysts in the regulatory agencies by encouraging good regulatory impact analysis—called either "regulatory analysis" or "analysis" for brevity—and standardizing the way benefits and costs of Federal regulatory actions are measured and reported.

Why Analysis of Proposed[16] Regulatory Actions Is Needed

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of their actions. It provides a formal way of organizing the evidence on the key effects—good and bad—of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective. By choosing actions that maximize net

[16] We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

benefits, agencies direct resources to their most efficient use.

A good regulatory analysis informs the public and other parts of the Government as well as the agency conducting the analysis of the effects of alternative actions. Regulatory analysis will sometimes show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Where all significant benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decisionmakers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society ignoring distributional effects. This is useful information for the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to assign monetary values to all of the important benefits and costs, and when it is not, the most efficient alternative will not necessarily be the one with the largest net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantifiable benefits or costs may be in tipping the analysis one way or the other, but you should not use non-quantifiables as "trump cards," especially in cases where the measured net benefits overwhelmingly favor a particular alternative. When there are other competing public policy objectives, as there often are, they must be balanced with efficiency objectives.

What Should Go Into a Regulatory Analysis?

A good regulatory analysis should include the following three basic elements:

(1) A statement of the need for the proposed action.

(2) An examination of alternative approaches.

(3) An evaluation of the benefits and costs of the proposed action and the main alternatives identified by the analysis.

To properly evaluate the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This is normally a "no action" baseline, what the world would be like if the proposed rule was not adopted.
- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct costs and benefits as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, sometimes called a "regulatory accounting statement," so that readers can evaluate them.

As you proceed through your regulatory analysis, you should seek out the opinions of those who will be directly affected by the regulation you are considering as well as the views of those individuals and organizations with special knowledge or insight into the regulatory issues. Consultation can be useful in making sure your analysis addresses all of the relevant issues and that you have access to all the pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

A good analysis is transparent. It should be possible for anyone reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the discount rates or the monetary value of a statistical life. It is usually helpful to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are influenced by plausible changes in the main assumptions.

You will find that you cannot conduct a good regulatory analysis according to a formula. The conduct of high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

I. Why Regulatory Action is Needed

Before proceeding with a regulatory action, you must demonstrate that the proposed action is necessary. Executive Order 12866 states that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." This means that you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting distributional fairness, privacy, or personal freedom. If you are trying to correct a significant market failure, the failure should be described both qualitatively and (where feasible) quantitatively, and you should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action.

If your regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use.

A. There Is a Market Failure or Other Social Purpose To Address

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality

An externality occurs when one party's actions impose uncompensated benefits or costs on another. Environmental problems are a classic case of externality—for example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. Common property resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent a second example. "Public goods," such as defense or basic scientific research, provide a positive externality, where provision of the good to some individuals cannot occur without providing the same benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry. They may exercise market power collectively or unilaterally. Government action can be a source of market power, for example, if regulatory actions exclude low-cost imports. Generally, regulations that increase market power should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer—local gas and electricity distribution services, for example—a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and production decisions.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. The market will often supply less than the appropriate level of information because it is infeasible to exclude people from reaping the benefits from the information others have provided even though they have not paid for the information. The providers will not willingly supply the socially optimal quantity of information, unless they are paid for it, and that may not be possible.

Because information, like other goods, is costly, your evaluation will need to do more than demonstrate the possible existence of less than optimal or asymmetric information. Even though the market may supply a less than an optimal amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers do have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, for example, if a buyer's search costs are low (as when the quality of a good can be determined by inspection at the point of sale), if a buyer has previously used the product, if the seller offers a warranty, or if adequate information is provided by third parties.

In the case of uncertain information about low-probability high-consequence events,

markets may underreact or overreact depending on the rules-of-thumb and other mental assumptions that people use to cope with difficult issues. Regulators should be aware of such mental quirks and not adopt policies based on a misunderstanding of the underlying reality.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In other cases, regulation may be used to reduce unfairness. Regulatory action may also be appropriate to protect privacy or to promote civil rights or permit more personal freedom.

B. Showing That Regulation at the Federal Level Is the Best Way To Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to regulation. Alternatives to regulation include the courts acting through the product liability system, antitrust enforcement, consumer-initiated litigation, or workers' compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

A diversity of regulation may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate, for example, to address interstate commerce issues, you should try to examine whether it would be more efficient to reduce State and local regulation. For example, the burdens on interstate commerce arising from different State and local regulations such as compliance costs for firms operating in several States, may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

C. The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede the efficiency with which markets function. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- Price controls in competitive markets;
- Production or sales quotas in competitive markets;
- Mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- Controls on entry into employment or production, except (a) where indispensable to protect health and safety (*e.g.*, FAA tests for commercial pilots) or (b) to manage the use of common property resources (*e.g.*, fisheries, airwaves, Federal lands, and offshore areas).

II. Alternative Approaches To Consider

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, it will be possible to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider:

A. Different Choices Defined by Statute

When a statute establishes a specific regulatory requirement and the agency plans to exercise its discretion to adopt a more stringent standard, you should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement.

B. Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. For example, costs of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs efficiently. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately, although delay would also typically lower the value of the benefits.

C. Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and compliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their costs and benefits, you should consider promising alternatives in identifying the most appropriate enforcement framework. For example, in some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring in achieving compliance.

D. Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

E. Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms basing any difference in the standards on perceptible differences in the costs of compliance or in the expected benefits. The balance of costs and benefits can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost; this has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create.

You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act.

F. Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation and it is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in costs and/or benefits, you should consider the possibility of setting different requirements for the different regions.

G. Performance Standards Rather Than Design Standards

Performance standards are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. This is only possible, of course, if there is more than one feasible way to meet the performance standard. In general, you should consider setting a performance standard if performance can be measured or reasonably imputed and where controlling performance provides a scope appropriate to the problem the regulation seeks to address. For example, compliance with air emission standards can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as "hot spots" from local pollution concentration).

H. Market-Oriented Approaches Rather Than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties.

I. Informational Measures Rather Than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be the preferred approach. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be made mandatory or left voluntary), mandatory disclosure requirements (*e.g.*, by advertising, labeling, or enclosures), and government provision of information (*e.g.*, by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information (particularly about the concealed characteristics of products) provides consumers a greater choice, than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and with a comprehensive view of their costs. Some effects of informational measures are easily overlooked. For example, the costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information, the effect of providing too much information that is ignored or information that is misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. For example, to correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

III. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the expected health and safety outcomes. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA.

A. Benefit-Cost Analysis

The distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure. This can be especially helpful in choosing the appropriate scope for your regulatory intervention. By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes societal net benefits.

The size of net benefits, the absolute difference between total benefits and total costs, is the key to determining whether one policy is more efficient than another. That will be achieved at the point where the cost of a marginal increment in regulatory stringency is just matched by the marginal benefit. The ratio of total benefits to total costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units, and if it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantifiable factors, where they exist, and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. Non-quantifiable benefits or costs may be important in tipping an analysis one way or the other, but you should not use non-quantifiables as "trump cards," especially in cases where the measured net benefits overwhelmingly favor a particular alternative.

B. Cost-Effectiveness Analysis (CEA)

Cost-effectiveness analysis provides a rigorous way to identify options that achieve the most effective use of the resources available without requiring you to monetize all of the relevant benefits or costs. Generally, cost-effectiveness analysis is most helpful for comparing a set of regulatory actions with the same primary outcome (*e.g.*, an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (*e.g.*, units of health improvement).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the one that maximizes net benefits, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the "effectiveness" measure does not weight appropriately the consequences of each of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (*e.g.*, different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical where there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

Accuracy of CEA depends on the consistency of analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to construct very carefully the two key components of any CEA: The cost and the "effectiveness" or performance measures for the alternative policy options.

With regard to measuring costs, you should be sure to include all the relevant costs to society—whether public or private. Rulemakings may also yield cost savings (*e.g.*, energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred in meeting the requirements (sometimes called "total" costs) minus any cost savings.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weigh the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation's different benefits, then you should do so, but in that case you will be doing BCA not CEA.

When you can estimate the monetary value of some but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. This net cost estimate for the rule may turn out to be negative—that is, the other benefits exceed the cost of the rule. If you are unable to estimate the value of

some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits that have not been incorporated in the net cost estimates.

You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

C. The Effectiveness Metric for Public Health and Safety Rulemakings

The validity of cost-effectiveness analysis depends on the application of appropriate "effectiveness" or performance measures that permit comparison of the regulatory options being considered. Agencies currently use a variety of methods for determining effectiveness, including number of lives saved, number of equivalent lives saved, and number of quality-adjusted life years saved. It is difficult for OMB to draw meaningful cost-effectiveness comparisons between rulemakings that employ different cost-effectiveness measurements. As a result, agencies should provide OMB with the underlying data, including mortality and morbidity data, the age distribution of the affected population, and the severity and duration of disease conditions or trauma, so that OMB can make apples-to-apples comparisons between rulemakings that employ different measures.

D. Evaluating Distributional Effects

Both benefit-cost analysis and cost-effectiveness analysis tend to focus on economic efficiency. Decision-makers may desire (or be required) to consider other values as well such as fairness. Your regulatory analysis should provide a separate description of distributional effects (*i.e.*, how both benefits and costs are distributed among sub-populations of particular concern) so that decisionmakers can properly consider them along with the effects on economic efficiency. E.O. 12866 authorizes this approach. The presentation of distributional effects is especially important when you have reason to believe that there will be significant disparities in how your regulatory actions may affect different groups of people. Effects that fall most heavily on those least able to bear the cost should be highlighted for policymakers' attention. Actions that benefit small groups at the expense of the larger public also deserve special scrutiny.

IV. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order No. 12866 and the "Regulatory Right-to-Know Act." The preliminary analysis described in Sections I, II and III will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

A. How To Develop a Baseline

1. General Issues

You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of a proper baseline may require consideration of a wide range of potential factors, including:

- Evolution of the market,
- Changes in external factors affecting expected benefits and costs,
- Changes in regulations promulgated by the agency or other government entities, and the degree of compliance by regulated entities with other regulations.

You may often find it reasonable to forecast that the world absent the regulation will resemble the present. If this is the case, however, your baseline should reflect the future effect of current programs and policies. For review of an existing regulation, a baseline assuming "no change" in the regulatory program generally provides an appropriate basis for evaluating reasonable regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in these sensitivity analyses.

EPA's 1998 final PCB disposal rule provides a good example. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA's 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in EPA's implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy—especially allowing the disposal of automobile "shredder fluff" in municipal landfills—reduced the cost of the program by more than $500 million per year.

In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.

2. Evaluation of Alternatives

You should decide on and describe the number and choice of alternatives available to you and discuss the reasons for your choice. Alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For example, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance.

You should carefully consider all appropriate alternatives for the key attributes or provisions of the rule. Section II above outlines examples of appropriate alternatives.

Where there is a "continuum" of alternatives for a standard (for example, the level of stringency), you should generally analyze at least three options:

- The option serving as a focus for the Agency or program office regulatory initiative;
- A more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and
- A less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose options that are reasonable alternatives deserving careful consideration. In some cases, the regulatory program will focus on an option that is near or at the limit of technical feasibility or that fully achieves the objectives of the regulation. In these cases, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs. It is not adequate to simply compare the Agency's preferred option to a "do nothing" or "status quo" option.

Whenever you can compare the benefits and costs of alternative options, you should present them in terms of both total and incremental benefits and costs. You must measure total benefits and costs against the same baseline. By contrast, you should present incremental benefits and costs as differences from the corresponding estimates associated with the next less-stringent alternative.[17] It is important to emphasize incremental effects are simply differences between successively more stringent alternatives.

In some cases, you may decide to analyze a wide array of options. For example, DOE's 1998 rule setting new energy efficiency standards for refrigerators and freezers analyzed a large number of options and produced a rich amount of information on their relative effects. This analysis—examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers—enabled DOE to select an option that produced $200 more in net benefits per refrigerator than the least attractive option.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

[17] For the least stringent alternative, you should estimate the incremental benefits and costs relative to the baseline. Thus, for this alternative, the incremental effects would be the same as the corresponding totals.

Analyzing all possible combinations of provisions in this way is impractical if their number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order No. 12866, you should identify these constraints and estimate their opportunity cost.

B. How To Develop Benefit and Cost Estimates

1. Some General Considerations

You should discuss the expected benefits and costs of the selected regulatory option and any reasonable alternatives for each rule. How is the proposed action expected to provide the anticipated benefits and costs? What are the monetized values of the potential real incremental benefits and costs to society? To present your results, you should:

- Include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs and express the estimates in this table in constant, undiscounted dollars (for more on discounting see part C below).
- List the benefits and costs you can quantify, but cannot monetize, including their timing.
- Describe benefits and costs you cannot quantify.
- Identify or cross-reference the data or studies on which you base the benefit and cost estimates.

Similarly, you should discuss the expected cost of the selected regulatory option and any reasonable alternatives.

When benefit and cost estimates are uncertain (for more on this see part D below):

- You should calculate benefits (including benefits of risk reductions) and costs that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and include the upper and lower bound estimates as complements to central tendency and other estimates.
- If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits under plausible assumptions and characterize the evidence underlying each alternative.

2. The Key Concepts Needed To Estimate Benefits and Costs

"Opportunity cost" is the appropriate concept for valuing both benefits and costs. The principle of "willingness-to-pay" (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's "willingness-to-accept" (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost. WTP and WTA are comparable measures when the change being evaluated is small and especially where there are reasonably close substitutes available. WTP is generally considered to be more readily measurable and to provide a more conservative measure of benefits. Adoption of WTP as the measure of value implies that individual preferences of the affected population should be a guiding factor in the regulatory decision and that the existing distribution of income is acceptable.

Market prices provide the richest data for estimating benefits based on willingness-to-pay if the goods and services affected by the regulation trade in well-functioning free markets. The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. The opportunity cost of banning a product—a drug, food additive, or hazardous chemical—is the forgone net benefit (*i.e.*, lost consumer and producer surplus [18]) of that product, taking into account the mitigating effects of potential substitutes. The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities. To the extent possible, you should monetize any such forgone benefits and add them to the other costs of that alternative. You should also try to monetize any costs averted as a result of an alternative and either add it to the benefits or subtract it from the costs of that alternative.

Estimating benefits and costs when market prices are hard to measure or markets do not exist is more difficult. In these cases, regulatory analysts need to develop appropriate proxies that simulate market exchange. Estimates of willingness-to-pay based on observable and replicable behavior generally are the most reliable. As one example, analysts sometimes use "hedonic price equations" based on multiple regression analysis of market behavior to simulate market prices for the commodity of interest.[19] Going through the analytical process of deriving benefit estimates by simulating markets may also suggest alternative regulatory strategies that create such markets.

Other approaches may be necessary when a commodity is not directly or indirectly traded in markets. Valuation estimates developed using these approaches are less certain than estimates derived from market transactions or based on behavior that is observable and replicable. While innovative estimation methods are sometimes necessary, they increase the need for quality control to ensure that estimates conform closely to what would be observed if markets did exist.

Ultimately, the method selected to develop a monetized estimate should focus on a value for the specific attribute or end-point of interest (for example, lost school-days). As a cautionary note, the transfer of a valuation estimate from an unrelated context (say, for example, the valuation of lost work-days from labor market studies) as a measure of the value of the attribute (lost school-days) may yield an incorrect benefits estimate.

You also need to guard against double-counting, since some attributes are embedded in other broader measures. For example, when a regulation improves the quality of the environment in a community, the value of real estate in the community generally rises to reflect the greater attractiveness of living in a better environment. Simply adding the increase in property values to the estimated value of improved public health would be double counting if the increase in property values reflects the improvement in public health. To avoid this problem you should separate the embedded effects on the value of property arising from improved public health. At the same time, of course, valuation estimates that fail to incorporate the consequence of land use changes will not capture the full effects of regulation.

3. How To Use Market Data Directly

Economists ordinarily consider market prices as the most accurate measure of the value of goods and services to society. In some instances, however, market prices may not reflect the true value of goods and services. If a regulation involves changes to goods or services where the market price is not a good measure of the value to society, you should use an estimate that reflects the true value to society (often called the "shadow price"). For example, suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant is the value of the increase in crop yield as a result of the controls. That value is typically measured by the price of the crop. If the price is held above the market price by a government program that affects supply, however, a value estimate based on this price would overstate the true benefits of controlling the pollutant. In this case, you should calculate the value to society of the increase in crop yields by estimating the

[18] Consumers' surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the area between the price and the demand curve for that unit. Producers' surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit.

[19] The hedonic technique allows analysts to develop an estimate of the price for specific attributes associated with a product. For example, houses are a product characterized by a variety of attributes including the number of rooms, total floor area, and type of heating and cooling. If there are enough data on transactions in the housing market, it is possible to develop an estimate of the implicit price for specific attributes, such as the implicit price of an additional bathroom or for central air conditioning. This technique can be extended, as well, to develop an estimate for the implicit price of public goods that are not directly traded in markets. For example, the analyst can develop implicit price estimates for public goods like air quality and access to public parks by adding measures for these attributes to the hedonic price equation for housing.

shadow price, which reflects the value to society of the marginal use of the crop. If the marginal use is for exports, you should use the world price. If the marginal use is to add to very large surplus stockpiles, you should use the value of the last units released from storage minus storage cost. If stockpiles are large and growing, the shadow price may be low or even negative.

4. Indirect Uses of Market Data

Some benefits or costs correspond to goods or services that are indirectly traded in the marketplace. Their value is reflected in the prices of related goods that are directly traded. Examples include reductions in health and safety risks, the use-values of environmental amenities (for example, recreational fishing or hiking and camping), and the value of improved scenic visibility. You should use willingness-to-pay measures as the basis for estimating the monetary value of such indirectly traded goods. When practical obstacles prevent the use of direct "revealed preference" methods based on actual market behavior to measure willingness-to-pay, you may consider the use of alternative "stated preference" methods based on survey techniques. As discussed below, you may use alternative methods where there are practical obstacles to the accurate application of direct willingness-to-pay methodologies.

A variety of methods have been developed for estimating indirectly traded goods or services. Examples include estimates of the value of environmental amenities derived from travel-cost studies, hedonic price models that measure differences or changes in the value of land, and statistical studies of occupational-risk premiums in wage rates. Under each of these methods, care is needed in designing protocols for reliably estimating the value of these attributes. For example, the use of occupational-risk premiums can be a source of bias because the risks, when recognized, may be voluntarily rather than involuntarily assumed,[20] and the sample of individuals upon which premium estimates are based may be skewed toward more risk-tolerant people.

Many goods that are affected by regulation—such as preserving environmental or cultural amenities—are not traded directly in markets. These "non-market" values arise both from use and non-use. Estimation of these values is difficult because of the absence of an organized market. However, overlooking or ignoring these values in your regulatory analysis may significantly understate the benefits of regulatory actions.

a. Use Values—the value an individual derives from directly using the resource now (or in the future). Use values are associated with activities such as swimming, hunting, and hiking where the individual comes into direct contact with the environment. These values also include commercial uses of natural resources, such as fishing, and consumptive uses, such as clean air and drinking water.

[20] Distinctions between "voluntary" and "involuntary" are arbitrary and should be treated with care. These terms are merely a proxy for differences in the cost of avoiding risks.

b. Nonuse Values—the value an individual places on an environmental resource even though the individual will not use the resources now or in the future. Non-use value includes bequest, existence and option values.

Use values are typically estimated through "revealed" preference models, which rely on observed behavior. It is important that you utilize revealed preference models that adhere to economic criteria that are consistent with utility maximizing behavior [example of RUM study]. Examining averting or defensive expenditures (as distinct from avoided cost of compliance with other regulatory requirements) is another way to estimate use values. This approach may reveal a minimum willingness to pay, particularly if there is reason to believe the market for averting behavior is not in equilibrium.

5. Contingent Valuation

Contingent valuation (CV) methods have become increasingly common for estimating indirectly traded benefits. However, the reliance of these methods on stated preferences regarding hypothetical scenarios and the complexities of the goods being valued by this technique raise issues about its accuracy in estimating willingness to pay compared to methods based on (indirect) revealed preferences. Accordingly, value estimates derived from contingent-valuation studies require greater analytical care than studies based on observable behavior. For example, the contingent valuation instrument must portray a realistic choice situation for respondents—where the hypothetical choice situation corresponds closely with the policy context to which the estimates will be applied. Below we provide a more complete list of important criteria that affect the reliability of results from contingent valuation surveys. The practice of contingent valuation is rapidly evolving, and agencies relying upon this tool for valuation should judge the reliability of their estimates using this technique in light of advances in the state of the art.

Some types of goods, such as preserving environmental or cultural amenities apart from their use and direct enjoyment by people, are not traded directly or indirectly in markets. The practical obstacles to accurate measurement are similar to (but generally more severe than) those arising with respect to indirectly traded goods and services, principally because there are no related market transactions to provide data for willingness-to-pay estimates.

For many of these goods, particularly goods providing a substantial "nonuse" component of value, contingent-valuation methods may provide the only analytical approaches currently available for estimating values. The absence of observable and replicable behavior with respect to the good or service, combined with the complex and often unfamiliar nature of the goods being valued, argues for great care in the design and execution of surveys, rigorous analysis of the results, and a full characterization of the uncertainties in the estimates to meet best practices in the use of this method. Current "best practices" for CV surveys include the following:

Sampling, etc.

- Probability sampling: this usually requires the guidance of a professional sampling statistician;
- Low non-response rate: high non-response rates would make the results unreliable;
- Personal interview: face-to-face and telephone interviews may elicit more reliable information.

Survey Instrument Design

- Accurate description: adequate information must be provided to respondents about the good or amenity they are being asked to value;
- Reminder of substitute commodities: respondents must be reminded of substitute commodities, and this reminder should be introduced forcefully and directly prior to the main valuation question;
- Reminder of alternative expenditure possibilities: respondents must be reminded that their willingness to pay would reduce their expenditures for other goods;
- Deflection of transaction value: the survey should be designed to deflect the general "warm glow" of giving or a particular dislike of the source of the problem being addressed.

Transparency and Replicability of Results

- Reporting: CV studies should make clear the definition of population sampled, sampling frame used, overall sample non-response rate, and item non-response rate on all important questions; the report should also include the exact wording and sequence of questionnaire and other communications to respondents;
- Data quality: special care should be taken to ensure compliance with OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies' ("data quality guidelines") *http://www.whitehouse.gov/omb/fedreg/reproducible.html;*
- Since there is no economic theory that can describe hypothetical behavior, it is important to assure the respondents that their decisions are consequential and may influence policy.

As with all other estimates of benefits and costs, your CV results should be consistent with economic theory. First, as price increases and the amount of the good is held constant, the number of respondents willing to pay a particular price should fall. This is akin to negative own-price elasticity for a marketed good. Second, respondents should be willing to pay more for a larger amount (or higher quality) of the good. This is often referred to as being sensitive to scope. If your only test of consistency with economic theory is a scope test, it should be an external (split sample) test rather than an internal (within sample) test.

6. Benefit Transfer Methods

In many cases, conducting an original study may not be possible due to the time and expense involved. The alternative to an original study is the use of benefit transfer methods. Benefit transfer is defined as the practice of transferring existing estimates of

non-market values from the context of study to a new context.

Although benefit transfer offers a quick, low cost approach for establishing values for goods and attributes of goods, you should consider it as a last resort option. Several studies have documented difficulties in applying benefit transfer methods. If a benefit transfer approach is necessary, you should adopt the approach of transferring the entire demand function (referred to as benefit function transfer) rather than adopting a single point estimate (referred to as benefit point transfer). The former approach has been shown to yield more precise estimates than the latter approach.

In conducting benefit transfer, the first step is to specify the value to be estimated at the policy site. The analyst should identify the relevant measure of the policy change at this initial stage. For instance, you can derive the relevant willingness-to-pay measure by specifying an indirect utility function. This identification allows an analyst to "zero in" on key aspects of the benefit transfer.

The next step is to identify appropriate studies to conduct benefit transfer. In selecting transfer studies for either point transfers or function transfers, you should base your choices on the following criteria:

a. The selected studies should be based on adequate data, sound empirical methods and defensible empirical techniques.

b. The selected studies should document parameter estimates of the valuation function.

c. The study context and policy context should have similar populations (*e.g.*, demographic characteristics, target population size).

d. The good, and the magnitude of change in that good, should be similar in the study and policy contexts.

e. The relevant characteristics of the study and the policy contexts should be similar. For example, are they similar in the following respects?

- The reversibility of the policy change
- The degree of embedding of other values
- The order in which the good is supplied
- The functional relationship between the consumer surplus and its determinants.

f. The distribution of property rights should be similar so that the analysis uses the same welfare measure. If the property rights in the study context support the use of willingness-to-accept (WTA) measures while the rights in the policy context support the use of willingness-to-pay (WTP) measures, benefit transfer is not appropriate.

g. The availability of substitutes across study and policy contexts should be similar.

Clearly, all of these criteria are difficult to meet. However, you should attempt to satisfy as many as possible when choosing studies from the existing economic literature. In addition to the above criteria, an analyst should keep in mind some of the difficulties in transferring benefit estimates or functions from one context to another:

- Is the policy change irreversible?
- Does the order in which the good is supplied affect valuation?
- Is the embedding problem significant?
- Is the assumed functional relationship between the consumer surplus measure and its determinants explicit and appropriate?

Finally, you should not use benefit transfer in estimating benefits if:

- Resources are unique or have unique attributes.
- If the study examines a resource that is unique or has unique attributes, you should not transfer benefit estimates or functions to value a different resource and vice versa. For example, if a study values visibility improvements at the Grand Canyons, these results should not be used to value visibility improvements in urban areas.
- There are significant problems with applying an ex ante valuation estimate to an ex post policy context. If a policy yields a significant change in the attributes of the good, you should not use the study estimates to value the change using a benefit transfer approach.
- You also should not use a value developed from a study involving, small marginal changes in a policy context involving large changes in the quantity of the good.

7. Methods for Treating Nonmonetized Benefits and Costs

Sound quantitative estimates of benefits and costs are preferable to qualitative descriptions of benefits and costs to help decision-makers understand the full effects of alternative actions. Although we prefer that agencies use acceptable monetized benefit and cost estimates, we recognize that monetizing some of the effects of regulations is difficult, and even quantifying some effects may not be feasible.

a. What To Do With Benefits and Costs That Are Difficult To Monetize?

You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize costs and benefits, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information. For example, if you can quantify, but cannot monetize, improvements in water quality and increases in fish populations resulting from water quality regulation, you can describe benefits in terms of stream miles of improved water quality for boaters and increases in game fish populations for anglers. You should describe the timing and likelihood of such effects and avoid double-counting of benefits when estimates of monetized and physical effects are mixed in the same analysis. You should also apply the discounting procedures described above to all quantified effects, whether or not you are able to monetize them.

b. What To Do With Benefits and Costs That Are Difficult To Quantify?

If you are not even able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantifiable effects. Such descriptions could include ecological gains, improvements in quality of life, and aesthetic beauty. For cases in which the presence of unquantifiable benefits or costs affects a policy choice, you should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs. Also, please include a summary table that lists all the unquantifiable benefits and costs, ordered by expected magnitude, if possible.

8. Monetizing Health and Safety Benefits and Costs

We expect you to provide a benefit and cost analysis of major health and safety rulemakings in addition to a CEA. The BCA provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some different strengths and drawbacks, it is important that you provide decision makers with both perspectives.

In monetizing health benefits, a willingness-to-pay measure is the conceptually appropriate measure as compared to other alternatives (*e.g.*, cost of illness or lifetime earnings), in part because it attempts to capture pain and suffering and other quality-of-life effects. Using the willingness-to-pay measure for health and safety allows you to directly compare your results to the other costs and benefits in your analysis, which will also typically be based on willingness to pay.

If well-conducted, revealed-preference studies of relevant health and safety risks are available, you should consider using them in developing your monetary estimates. If appropriate revealed-preference data are not available, you may consider whether valid and relevant data from stated-preference studies are available. You will need to use your professional judgement when you are faced with limited information on revealed preference and substantial information based on stated preference studies.

A key advantage of stated-preference and health-utility methods (compared to revealed preference) is that they can be tailored in their design to address ranges of probabilities, types of health risks and specific populations affected by your rule. In many rulemakings there will be no relevant information from revealed-preference studies. In this situation you should consider commissioning a stated-preference study or using values from published stated-preference studies. For the reasons discussed in the section above IVB5, you should be cautious about using values from stated-preference studies and describe in the analysis some of the inherent drawbacks of this approach.

a. Nonfatal Health and Safety Risks

With regard to nonfatal health and safety risks, there is enormous diversity in the nature and severity of impaired health states. A minor traumatic injury that can be treated effectively in the emergency room without hospitalization or long-term care is different from a traumatic injury resulting in paraplegia. Severity differences also are important in evaluation of chronic diseases. A severe bout of bronchitis, though perhaps less frequent, is far more painful and debilitating than the more frequent bouts of

mild bronchitis. The duration of an impaired health state, which can range from a day or two to several years or even a lifetime (*e.g.*, birth defects inducing mental retardation), need to be considered carefully. Information on both the severity and duration of an impaired health state are necessary before the task of monetization can be performed.

When monetizing nonfatal health effects, it is important to consider two components: (1) The private demand for prevention of the nonfatal health effect, to be represented by the preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production. Revealed-preference or stated-preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities of poor health. If you use literature values to monetize nonfatal health and safety risks, it is important to make sure that the values you have selected are appropriate for the severity and duration of health effects to be addressed by your rule.

If data are not available to support monetization, you might consider an alternative approach that makes use of health-utility studies. Although the economics literature on the monetary valuation of impaired health states is growing, there is a much larger clinical literature on how patients, providers and community residents value diverse health states. This literature typically measures health utilities based on the standard gamble, the time tradeoff or the rating scale methods. This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

b. Premature Mortality Risks

The adoption of a monetary value for projected reductions in premature mortality is the subject of continuing research and discussion within the economics and policy analysis communities. Although there is a substantial academic literature on this topic, the methods used and resulting estimates vary substantially. The two most widely used measures consider the number of statistical lives saved and the number of expected years of life saved and their associated monetary values. Both of these measures are applicable to settings where a rule changes small probabilities of death faced by the public.

The phrase "statistical life" is widely used in the technical literature but it can be misleading and easily misinterpreted. Unlike an identified life, whose name and background are known (*e.g.*, a trapped coal miner or patient dying of kidney failure), a statistical life refers to the sum of risks experienced by a population. For example, if 10,000 people each face a risk of 1 in 10,000 of immediate death, one statistical life is expected to be lost. Statistical lives that are lost are real people but, given the background rate of fatal events in the population, it is not feasible to determine which actual lives will be saved or lost by a specific rule.

The monetary value of saving a statistical life (VSL) is derived by assessing the public's willingness to pay to avert one statistical fatality. The bulk of the studies in the literature, which address wage premiums for hazardous jobs, are based on revealed preference. A small but growing number of stated-preference studies have also been used to derive VSLs. The estimates of VSL in the literature vary considerably but this is not surprising because VSL is not expected to be a universal constant. Economic theory predicts that VSLs may vary in different lifesaving contexts depending upon factors such as the magnitude of the probabilities and the health preferences of the target population.

You should not use a VSL estimate without considering whether it is appropriate for the size and type of risks addressed by your rule. Studies aimed at deriving VSL values for middle-aged populations are not necessarily applicable to rules that address lifesaving among children or the elderly. Moreover, VSL values based on fatal cancers or heart attacks are not necessarily relevant to a rule that prevents fatal causes of trauma, violence, or infectious disease. If you choose to apply a VSL derived in one setting to a different setting, you should disclose the salient differences in the lifesaving contexts and, where feasible, make appropriate quantitative adjustments to the VSL value.

Since everyone is expected to die sooner or later, it has been suggested that the VSL be replaced or augmented by the monetary value of a statistical life year (VSLY). The assumption is that the public is willing to pay more money for a rule that saves an average of 10 life years per person than a rule that saves one life year per person. A key assumption implicit in this approach is that public willingness to pay for risk reduction is strictly proportional to the number of life years at risk. This may not always be the case. For example, the elderly may have substantial willingness to pay for reductions in their mortality risk precisely because they have relatively few life years remaining. Where there is good reason to believe that these values are not strictly proportional, you should attempt to develop appropriate estimates. In all instances, whether or not you are able to develop ideal estimates, agencies should consider providing estimates of both VSL and VSLY, while recognizing the developing states of knowledge in this area.

In summary, you should use valid, relevant data and methods to assign monetary values to changes in the risk of premature death, illness or injury. Some of the key issues include:

- Whether the monetary valuations have been shown to be appropriately sensitive to the scope of the health change, considering probability, severity and longevity.
- Whether the specific data and methods used for monetization are relevant to the specific health change induced by a proposed regulation.

The valuation of fatal and nonfatal risk reduction is an evolving area in terms of research design, methods and results. You should utilize valuation methods that you consider appropriate for the regulatory circumstances. You should present estimates based on alternative approaches, and if you monetize mortality risk reduction, you should do so on a consistent basis to the extent feasible. You should clearly indicate your methodology and document your choice of a particular methodology. If you use different methodologies in different rules, you should clearly disclose the fact and explain your reasons.

C. What Discount Rate To Use

Benefits and their associated costs do not always take place in the same time period, and when they do not, it is usually incorrect simply to add up all of the expected benefits or costs without taking account of when they actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.

As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. In presenting the stream of benefits and costs, it is important to measure them in constant dollars. That way you avoid the misleading effects of inflation on your estimates. If the benefits or costs are initially measured in prices reflecting expected future inflation, you can convert them to constant dollars by dividing through by an appropriate inflation index, one that corresponds to the inflation rate underlying the initial estimates of benefits or costs.

Once these preliminaries are out of the way, you can begin to adjust your estimates for differences in timing. This is a separate calculation from the adjustment needed to remove the effects of future inflation. Whether or not inflation is expected, it is generally true that the sooner benefits occur the more valuable they are. Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, because you are giving up that expected return when you consume today. Looking at it another way, postponed benefits have a cost because people are impatient and generally prefer present to future consumption. Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because as total consumption increases, its marginal value tends to decline. These are all reasons for valuing future costs and benefits less than those occurring in the present.

A discount factor should be used to adjust the estimated costs and benefits for differences in timing . The further in the future the costs and benefits are expected to occur, the larger is this discount factor. The discount factor can be calculated given a discount rate. The formula is $1/(1+\text{the discount rate})^t$ where "t" measures the number of years in the future that the benefits or costs are expected to occur. Benefits or costs that have been adjusted in

this way are called discounted present values. Once the estimated benefits and costs have been discounted, they can be combined to determine the overall value of net benefits.

OMB's basic guidance on the discount rate is provided in OMB Circular A–94. This Circular states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. OMB revised Circular A–94 in 1992 after extensive internal review and following public comment. The average rate of return to capital remains near the 7 percent rate estimated in 1992. Circular A–94 also recommends using other discount rates to show the sensitivity of the estimates to the discount rate assumption.

The effects of regulation do not always fall exclusively on the allocation of capital. When regulation primarily affects private consumption (*e.g.*, through higher consumer prices for goods and services), a lower discount rate may be appropriate. The alternative most often used is called the "social rate of time preference." This simply means the rate at which "society" discounts future consumption flows to their present value. Economic distortions, including taxes on capital, create a divergence between this social rate and the private rate of return to capital. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. This rate has averaged around 3 percent since the mid-1950s.

For regulatory analysis, you should provide estimates of net benefits using both 7 percent and 3 percent. An example of this approach is EPA's analysis of its 1998 rule setting both effluent limits for wastewater discharges and air toxic emission limits for pulp and paper mills. In this analysis, EPA developed its present discounted value estimates using real discount rates of 3 and 7 percent applied to benefit and cost streams that extended forward for 30 years. (*See* EPA, Economic Analysis, October 1997, pages 10–3 and 10–4.) You should present a similar sensitivity analysis in your own work.

In some instances, if there is reason to expect that the regulation will cause resources to be reallocated away from private investment in the corporate sector, then the opportunity cost may be appreciably greater than the 3 to 7 percent discount rate. For example, Tresch suggests that rates in the range of 10 to 25 percent may be appropriate to reflect this opportunity cost, depending on the sector affected by the regulation. If you are uncertain about the nature of the opportunity cost, then you should present benefit and cost estimates using a higher discount rate as a sensitivity analysis as well as using 3 percent and 7 percent.

Circular A–94 points out that the analytically preferred method of handling timing differences between benefits and costs would be to adjust all the benefits and costs to reflect their value in equivalent units of consumption.[21] Due to distortions in the economy such calculations require you to value the costs and benefits using shadow prices, especially for capital goods. If all costs and benefits are measured in terms of consumption equivalents, it is appropriate to discount them using the social rate of discount. Any agency that wishes to tackle this challenging analytical task should check with OMB before proceeding.

When future benefits or costs are health-related, some have questioned whether discounting is appropriate. Although some of the rationales for discounting money may not seem to be applicable to health (*e.g.*, lives saved today cannot be invested in the bank to save more lives in the future, although the resources that would have been used to save those lives can often be saved with a higher pay-off in future lives saved). However, people do prefer health gains that occur immediately to identical health gains that occur only in the future, which would justify discounting the future gains. Also, if future health gains are not discounted while future costs are, then the following perverse result occurs: an attractive investment today in future health improvement can always be made more attractive by delaying the investment. For such reasons, there is a professional consensus that future health effects, including both benefits and costs, should be discounted at the same rate as generally used in both BCA and CEA.

A common challenge in health-related analyses is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status will be observed in the target population. In such situations, you must carefully consider the timing of health benefits before present-value calculations are performed. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. For rules addressing traumatic injury, this lag period may be short while for chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population. When a time period between exposure to a toxin and increased probability of disease is likely (*e.g.*, a so-called latency period), it is also likely that there will be a lag between exposure reduction and reduced probability of disease. This latter period has sometimes been referred to as a "cessation lag" and it may or may not be the same as the latency period. As a general matter, cessation lags will apply only to populations with at least some higher-level exposure (*i.e.*, before the rule takes effect). For populations with no such prior exposure, such as those born after the rule takes effect, only the latency period will be relevant.

Ideally, your exposure-risk model would allow calculation of reduced risk for each year following exposure cessation, perhaps incorporating total cumulative exposure and age at the time of exposure reduction into the calculation as well. The present value calculation of benefits could then reflect an appropriate discount factor for each year's risk reduction. Recent analyses of the cancer benefits of reducing public exposure to radon in drinking water have adopted this approach, supported by formal risk-assessment models that allow estimates of how the timing of lung cancer incidence and mortality are affected by different radon exposure levels. In many cases, you will not have the benefit of such detailed risk assessment modeling. You will need to use your professional judgement as to the average cessation lag for the chronic diseases affected by your rule. In situations where information exists on latency but not on cessation lags, it may be reasonable to use latency as a proxy for the cessation lag, unless there is reason to believe, based on data, modeling, or knowledge of the mechanism of action, that the two are different. When the average lag time between exposures and disease is unknown, a range of alternative yet plausible values for the time lag should be used in your analysis.

Special ethical considerations arise when comparing benefits and costs across generations. Although most people demonstrate in their own consumption behavior a preference for consumption now rather than in the future, it may not be appropriate for society to demonstrate a similar preference when deciding between the well-being of current and future generations. Future citizens who are affected by such choices cannot take part in making them, and today's society must act in their interest. One way to do this would be to follow the same discounting techniques described above, but to supplement the analysis with an explicit discussion of the intergenerational concerns and how they will be affected by the regulatory decision. Policymakers would be provided with additional information when the analysis covers many generations, but without changing the general approach to discounting.

Some have argued, however, that it is ethically impermissible to discount the utility of future generations. On this view, government should treat all generations equally. Even under this approach, it would still be correct to discount future costs and consumption benefits, although perhaps at a lower rate than for intragenerational analysis. There are two reasons for thinking that a nonzero discount rate is the appropriate assumption for intergenerational analysis, even when all generations are to be treated equally. First, future generations are likely to be wealthier than those currently living, so a marginal dollar of benefits or costs will be worth less to them than it would be to those alive today, at least on average. If that holds true, it is appropriate to discount future benefits and costs relative to currently consumed benefits and costs even if the welfare of future generations is not being discounted. Estimates of the discount rate

[21] A thorough discussion of this approach to discounting is provided in Robert C. Lind (ed.), Discounting for Time and Risk in Energy Policy, Baltimore: The Johns Hopkins University Press for Resources for the Future, 1982.

appropriate in this case made in the 1990s ranged from 1 to 3 percent per annum.[22]

A second reason for discounting the benefits and costs accruing to future generations at a lower rate is increased uncertainty about the appropriate value of the discount rate, the longer the horizon for the analysis. Aversion to uncertainty discourages any such long-term investments. Private market rates provide a reliable reference for determining how society values time within a generation, but for extremely long time periods no comparable private rates exist. Symmetric uncertainty would have the effect of lowering the discount factor applied to future costs and benefits. Again the reasonable range might be expanded to include rates as low as 1 percent per annum.

If you choose to use a lower discount rate for intergenerational analysis, you should still be sure to show the calculated net benefits using discount rates of 3 and 7 percent as well. Discounting is appropriate whether you are doing a BCA or a CEA. Even costs and benefits that are not expressed in monetary units should be discounted if they are separated in time. This also includes health benefits for reasons discussed above. For example, in its 1998 rule, "Control of Emissions from Nonroad Diesel Engines," EPA estimated cost-effectiveness by discounting both the monetary costs and the emission reduction benefits over the useful expected life of the engines at the 7 percent real rate recommended in OMB Circular A–94.

It may be possible in some cases to avoid discounting non-monetized benefits, if the expected flow of benefits begins as soon as the cost is incurred and if it is expected to be constant over time. In such cases, annualizing the cost stream is sufficient, and further discounting of benefits is unnecessary. As an example, such an analysis might produce an estimate of the annualized cost per ton of reducing emissions of a pollutant.

D. Treatment of Uncertainty

The precise consequences (benefits and/or costs) of regulatory options are not always known for certain, but the probability of their occurrence can often be predicted. The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis. Your analysis of uncertainty should consider both the quantifiable risk associated with the potential outcomes of alternative regulatory actions (for example, the expected change in the distribution of automobile accidents that might result from a change in automobile safety standards) and the incomplete knowledge or uncertainty about the relevant relationships (for example, the uncertain science of how some economic activities might affect future climate change).

The treatment of uncertainty must be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Any data and models that you use to analyze uncertainty should be fully identified. Inferences and assumptions used in your analysis should also be identified, and your analytical choices should be explicitly evaluated and adequately justified. Your presentation should explain how your analytical choices have affected your analysis.

Uncertainty arises from various and fundamentally different sources. These include the fundamental unpredictability of various natural and social phenomena, but they also include lack of data and the lack of knowledge about key relationships resulting from limitations in fundamental scientific knowledge (both social and natural). The different sources of uncertainty suggest different approaches for dealing with it. For example, when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data. We recognize that delaying a decision will also have costs, as will further efforts at data gathering and analysis. You will need to weigh the benefits of delay against these costs in making your decision. Formal tools for assessing the value of additional information are now well developed in the applied decision sciences and can be used to help resolve this type of complex regulatory question.

In some cases, the level of scientific uncertainty may be so large that you can only present discrete alternative scenarios without assessing the relative likelihood of each scenario quantitatively. For example, in assessing the potential outcomes of an environmental effect, there may be a limited number of scientific studies with strongly divergent results. In such cases, you might present results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most plausible.

Your analysis should include two fundamental components: A quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes. It is essential that both parts be conceptually consistent. In particular, the quantitative analysis should be conducted in a way that permits it to be applied within a more general analytical framework, such as BCA. Similarly, the general framework needs to be flexible enough to incorporate the quantitative analysis without oversimplifying the results. For example, you should address explicitly the implications for benefits and costs of any probability distributions developed in your analysis.

1. Quantitative Analysis of Uncertainty

Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, *e.g.*, the cost savings associated with increased energy efficiency. Your analysis should be credible, objective, realistic, and scientifically balanced. In your presentation, you should delineate its strengths along with any lingering uncertainties about its conclusions. You should describe the assumptions and the models you used and their impact on the overall analysis. You should also discuss the quality of the available data used.

As with other elements of regulatory analysis, you will need to balance thoroughness with the practical limits on your analytical capabilities. Your analysis does not have to be exhaustive, nor is it necessary to evaluate each alternative at every step. In the absence of adequate data, you will need to make assumptions. These should be clearly identified and consistent with the relevant science. Your analysis should provide sufficient information for decision-makers to grasp the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs to changes in key assumptions. For major rules involving threshold costs of $1 billion, you should present a formal quantitative analysis of the relevant uncertainties.

In your analysis, you should try to provide some estimate of the probability distribution of risks with and without the regulation, and you must do this for rules that exceed the $1 billion threshold. In characterizing the probability distributions quantitatively, you should provide some estimate of the central tendency (*e.g.*, mean and median) along with any other information you think will be useful such as ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Your estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Your analysis should not reflect any unstated or unsupported preferences, even for such worthy objectives as protecting public health or the environment. Unstated assumptions can affect the analysis in unsuspected ways, making it difficult for decision-makers to evaluate the true magnitude of the uncertainties involved.

Acceptable Analytical Approaches: Whenever possible, you should use appropriate statistical techniques to determine a probability distribution of the relevant outcomes, and for rules that exceed the $1 billion threshold a formal quantitative analysis is required.

You may consider the following analytical approaches. They entail increasing levels of complexity:

- Disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs. These disclosures should address the uncertainties in the data as well as in the analytical results. However, major rules above the $1 billion threshold require a formal treatment.
- Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches. Sensitivity analysis is especially valuable when the information is

[22] Approaches to discounting across generations are discussed in a recent symposium volume published by Resources for the Future. Paul R. Portney and John P. Weyant (eds.), Discounting and Intergenerational Equity, Washington, DC: Resources for the Future, 1999.

lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find "switch points"—critical parameter values at which estimated net benefits change sign or the low cost alternative switches. Sensitivity analysis usually proceeds by changing one variable or assumption at a time, but it can also be done by varying a combination of variables simultaneously to learn more about the robustness of your results to widespread changes. Again, however, major rules above the $1 billion threshold require a formal treatment.

• Apply a formal probabilistic analysis of the relevant uncertainties—possibly using simulation models and/or expert judgment as revealed, for example, through Delphi methods. Such a formal analytical approach is appropriate for complex rules where there are large multiple uncertainties whose analysis raises technical challenges, or where the effects cascade, and it is required for rules that exceed the $1 billion threshold. For example, in the analysis of regulations addressing air pollution, there is uncertainty about the effects of the rule on future emissions, uncertainty about how the change in emissions will affect air quality, uncertainty about how changes in air quality will affect health, and finally uncertainty about the economic and social value of the change in health outcomes. You should make a special effort to portray the probabilistic results—in graphs and/or tables—clearly and meaningfully.

• New methods may become available in the future. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

2. Assigning Economic Values to Uncertain Outcomes

Uncertainty affects the values that you assign to the costs and benefits of regulatory actions. Because the outcome of regulatory action is not certain, but is instead best represented by a probability distribution of potential outcomes, the value assigned to the expected outcome from this probability distribution may be different from that for an expected outcome of the same magnitude that is certain to occur. In the financial world, for example, riskier instruments must generally earn a higher rate of return, and investors receive a higher expected reward for bearing uncertainty. This principle can carry over to the analysis of regulations depending on who bears the uncertainties from regulatory decisions.

When reporting benefit and cost estimates, where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the "best estimates" of both benefits and costs with those of competing alternatives. These "best estimates" are usually the average or the expected value of benefits and costs. Emphasis on these expected values is appropriate as long as society is "risk neutral" with respect to the regulatory alternatives. This, however, may not always be the case. For a risk-averse individual, the certainty equivalent of an uncertain net benefit stream is less than its expected cash value, because the uncertainty itself is valued negatively.

E. Other Key Considerations

1. Other Cost Considerations

You should include these effects in your analysis and provide estimates of their monetary values wherever possible.

• Private-sector compliance costs;

• Government administrative costs;

• Losses in consumers' or producers' surpluses;

• Discomfort or inconvenience; and

• Loss of time.

Estimates of costs should be based on credible changes in technology over time. For example, a slowing in the rate of innovation or of adoption of new technology because of delays in the regulatory approval process or the setting of more stringent standards for new facilities than existing ones may entail significant costs. On the other hand, a shift to regulatory performance standards and incentive-based policies may lead to cost-saving innovations that should be taken into account. The weight you give to a study of past rates of cost savings resulting from innovation (including "learning curve" effects) should depend on both their timeliness and their direct relevance to the processes affected by the regulatory alternative under consideration. In some cases agencies are limited under statute to considering only technologies that have been demonstrated to be feasible. In these situations, it may also be useful to estimate costs and cost savings assuming a wider range of technical possibilities.

Occasionally, one or more components of the analysis address cost savings to one of the parties directly affected by the rule. For example, a requirement that manufacturers reduce emissions from engines they produce may lead to technologies that improve fuel economy. These fuel savings will normally accrue to the purchasers of the engines. There is no apparent market failure with regard to the market value of fuel saved because one would expect that consumers would be willing to pay for increased fuel economy that exceeded the cost of providing it. When these cost savings are substantial, and particularly when you estimate them to be greater than the cost associated with achieving them, it is incumbent on you to demonstrate convincingly why the market has not already captured these gains. As a general matter, any costs that are averted as a result of an alternative should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

2. The Difference Between Costs (or Benefits) and Transfer Payments

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. Cost and benefit estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. For example, a regulation that restricts the supply of a good, causing its price to rise, produces a transfer of income from buyers to sellers. The reduction in the total value of the supply of the good is a real cost to society, but the transfer of income from buyers to sellers resulting from the higher price is not. You should not include transfers in the estimates of the benefits and costs of a regulation.[23] Instead, address them in a separate discussion of the regulation's distributional effects.

Examples of transfer payments include the following:

• Scarcity rents and monopoly profits.

• Insurance payments.

• Indirect taxes and subsidies.

• Distribution expenses.

3. Alternative Assumptions

If benefit or cost estimates depend heavily on certain assumptions, you should make those assumptions explicit and carry out sensitivity analyses using plausible alternative assumptions. If the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate. Because different estimation methods may have hidden assumptions, you should analyze estimation methods carefully to make any hidden assumptions explicit.

V. Specialized Analytical Requirements

In preparing analytical support for your rulemaking, you should be aware that there are a variety of analytic requirements imposed by law and Executive order. In addition to the regulatory impact analysis requirements of E.O. 12866, you should also consider whether your rule will need specialized analysis of any of the following issues.

A. Impact on Small Businesses and Other Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. chapter 6), agencies must prepare a proposed and final "regulatory flexibility analysis" (RFA) if the rulemaking could "have a significant impact on a substantial number of small entities." Your agency should have guidelines on how to prepare an RFA and you are encouraged to consult with the Chief Counsel for Advocacy of the Small Business Administration on expectations concerning what is an adequate RFA. Executive Order 13272 (67 FR 53461, August 16, 2002) requires you to notify the Chief Counsel for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities. E.O. 13272 also directs agencies to give every appropriate consideration to any comments provided by the Advocacy Office.

B. Analysis of Unfunded Mandates

Under the Unfunded Mandates Act (2 U.S.C. 1532), you must prepare a written statement about costs and benefits prior to issuing a proposed or final rule (for which

[23] However, transfers from the United States to other nations should be included as costs, and transfers from other nations to the United States as benefits.

your agency published a proposed rule) that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation). Your analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.

C. Information Collection, Paperwork and Recordkeeping Burdens

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), you will need to consider whether your rulemaking (or other actions) will create any additional information collection, paperwork or recordkeeping burdens. These burdens are permissible only if you can justify the practical utility of the information for the implementation of your rule. OMB approval will be required of any new requirements for a collection of information imposed on 10 or more persons and a valid OMB control number must be obtained for any covered paperwork. Your agency's CIO should be able to assist you in complying with the Paperwork Reduction Act.

D. Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality. The Statistical and Science Policy Branch of OMB's Office of Information and Regulatory Affairs can provide you assistance.

E. Environmental Impact Statements

The National Environmental Policy Act (42 U.S.C. 4321–4347) and related statutes and executive orders require agencies to consider the environmental impacts of agency decisions, including rulemakings. An environmental impact statement must be prepared for "major federal actions significantly affecting the quality of the human environment." You must complete NEPA documentation before issuing a final rule. The White House Council on Environmental Quality has issued regulations (40 CFR 1500–1508) and associated guidance for implementation of NEPA, available through CEQ's Web site (see NEPANet).

F. Impacts on Children

Under Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," each agency must, with respect to its rules, "to the extent permitted by law and appropriate, and consistent with the agency's mission," each agency must "address disproportionate risks to children that result from environmental health risks or safety risks." For any substantive rulemaking action that "is likely to result in" an economically significant rule that concerns "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," the agency must provide OMB/OIRA "an evaluation of the environmental health or safety effects of the planned regulation on children," as well as "an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency."

G. Energy Impacts

Under Executive Order 13211 (66 FR 28355, May 22, 2001), agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law. This Statement is to include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" for the action and reasonable alternatives and their effects. You need to publish the Statement or a summary in the related NPRM and final rule. For further "Guidance on Implementing E.O. 13211," see OMB Memorandum 01–27 (July 13, 2001), available on OMB's Web site.

VI. Accounting Statement

You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency. You should use the guidance outlined above to report these estimates. We have included a suggested format for your consideration.

Categories of Benefits and Costs

To the extent feasible, you should quantify all potential incremental benefits and costs. You should report benefit and cost estimates within the following three categories:

- Monetized
- Quantified, but not monetized; and
- Qualitative, but not quantified.

These categories are mutually exclusive and exhaustive. Throughout the process of listing preliminary estimates of costs and benefits, agencies should avoid double-counting. This problem may arise if more than one way exists to express the same change in social welfare.

Quantifying and Monetizing Benefits and Costs

Yes, you should develop quantitative estimate and covert them to dollar amounts if possible. In many cases, quantified estimates are readily convertible, with a little effort, into dollar equivalents.

Treatment of Benefits and Costs Over Time

You should monetize and quantify effects as real, undiscounted streams of estimates for each year over the entire period for which you have estimated them. You should also annualize these same effects using real discount rates of 3 and 7 percent. The stream of annualized estimates should begin in the year the final rule is published even if the rule does not take effect immediately. Please report all monetized effects in 2000 dollars. You may convert dollars expressed in different years to 2000 dollars using the GDP deflator.

Treatment of Risk and Uncertainty

You should provide central tendency or primary estimates as well as distributions about the estimates, where such information exists. When you provide only upper and lower bounds (in addition to best estimates), you should, if possible, use the 95 and 5 percent confidence bounds. Although we encourage you to develop estimates that capture the distribution of plausible outcomes for a particular alternative, detailed reporting of such distributions is not required.

The principles of full disclosure and transparency apply to the treatment of uncertainty. Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. You may add footnotes to the table as needed to provide documentation and references, or to express important warnings.

In our discussion in Section I above, we identified some of the issues associated with developing estimates of the value of reductions in premature mortality risk. Based on this discussion, you should present alternative primary estimates where you use alternative estimates for valuing reductions in premature mortality risk.

Precision of Estimates

Reported estimates should reflect, to the extent feasible, the precision in the analysis. For example, an estimate of $220 million implies rounding to the nearest $10 million and thus a precision of ±$5 million; similarly, an estimate of $222 million implies rounding to the nearest $1 million and thus, a precision of ±$0.5 million.

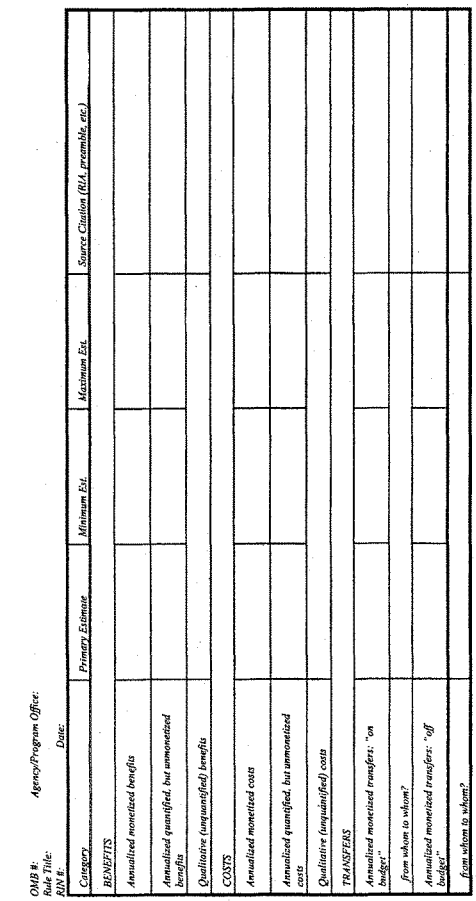
Separate Reporting of Transfers

You should report transfers separately and avoid the misclassification of transfer payments as costs or benefits. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare. To the extent that regulatory outputs reflects transfers rather than welfare gains to society, you should identify them as transfers rather than costs or benefits. You should also distinguish transfers caused by Federal budget actions—such as those stemming from a rule affecting Social Security payments—from those that involve transfers between non-governmental parties—such as monopoly rents a rule may confer on a private party. You should use as many categories as necessary to describe the major redistributive effects of a regulatory action. If transfers have significant effects in addition to distributional effects, you should evaluate them also.

Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth

You need to identity the portions of benefits, cost, and transfers received by State, local, and tribal governments. To the extent feasible, you also should identify the effects of the rule or program on small businesses, wages, and economic growth. Note that rules with annual costs that are less than one

billion dollars are likely to have minimal effect on economic growth.



OMB #: Agency/Program Office:
Rule Title:
RIN #: Date:

Category	Primary Estimate	Minimum Est.	Maximum Est.	Source Citation (RIA, preamble, etc.)
BENEFITS				
Annualized monetized benefits				
Annualized quantified, but unmonetized benefits				
Qualitative (unquantified) benefits				
COSTS				
Annualized monetized costs				
Annualized quantified, but unmonetized costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: "on budget"				
From whom to whom?				
Annualized monetized transfers: "off budget"				
From whom to whom?				

BILLING CODE 3110-01-C

Mr. OSE. Professor Steinzor, on page 4 of your written testimony, you have four suggestions for reforming science at EPA, including removing peer review panelists with ties to regulatory outcomes, prohibiting research contracts limiting adverse results and requiring full disclosure of all data, science, and techniques submitted by industry and, fourth, requiring more balanced peer review.

Do you have legislative language implementing these four suggestions?

Ms. STEINZOR. I don't have legislative language. CPR believes these issues are very important to pursue, but again, would do it outside the context of the Cabinet-elevation bill.

Mr. OSE. Could we send you a followup question in writing to get some feedback on that?

Ms. STEINZOR. Certainly. I would be delighted by that opportunity.

Mr. OSE. All right. I appreciate that.

Now, relative to these four suggestions by Professor Steinzor, do any of the other members of this panel have suggestions, observations? I don't know if you have seen her testimony or not.

Dr. Gray, have you had a chance to look at it?

Dr. GRAY. I haven't. All I would suggest is that peer review is important. We want to encourage peer review and we want it to be credible, and I think that anything that increases the level of disclosure in that peer review is very important. I think we have to make sure that we keep peer review focused on expertise, but within that world, I think more disclosure of potential conflicts of interest and other sorts of things is very important.

Mr. OSE. Let's examine that for a minute. With respect to my business career, I had everybody telling me that I should have done something differently and they could have done it better. Let's examine for a moment what the purpose of peer review is and how you get it.

The EPA's Inspector General in November 2002 noted that critical science supporting their rules was often not peer reviewed by an independent body, and that caused some uncertainty relative to the quality of the science supporting a rule.

Now, tell me how the peer review thing works.

Dr. Portney, how does peer review work in this process, from your perspective? What is your experience with it?

Dr. PORTNEY. Well, I have had both favorable and unfavorable experiences with peer review in the sense that I have done research which has been turned down when I have sent it to a peer-reviewed and refereed journal, but I think that process is very, very important.

The way it works is, you conduct a body of research, whether it is toxicological or legal or economic or whatever. You try to do this to the highest standards, collect the data according to the best protocols, analyze it in as sophisticated a way as possible, you write up the research and you send it to the best journals in one's respected profession.

The editor of the journal then typically selects one or two or three reviewers, generally reviewers whose identity is not known to the person who has written up the research, and they decide whether or not that research merits publication. They send ref-

erees' reports to the editor of the journal, and ultimately the journal editor makes a decision as to whether or not it is publishable.

And,I think that this process, while certainly having all kinds of problems, as any process does involving human beings, I think it is absolutely essential, and to the greatest extent possible, the EPA or any other regulatory agency ought to try to rely upon as great an extent possible research which has been through this review and vetting process and has passed.

Ms. STEINZOR. Mr. Chairman.

Mr. OSE. You are actually exactly where I was going to, Professor, so I appreciate your raising your hand.

I do want to ask a question, because this same EPA Inspector General report noted that 276 of 496 critical documents supporting the rules that were put forward were either not peer reviewed or their peer review status was indeterminable that is we were unable to determine whether or not it was done.

Now, I want to come back to you because it is your original point we are talking about, one of those four, if you will. How do we deal with this peer review requirement under the parameters you have described?

Ms. STEINZOR. There are two different kinds of peer review I think that are at issue, and one is what Dr. Portney was just talking about, peer review by professional journals. EPA has its own process for peer review which is done by the Science Advisory Board, and it was the operations of that board that were criticized by the GAO for compiling peer review panels that the members never asked to disclose what their affiliations were.

So one answer is to clean up the SAB and have it do peer review in a more balanced, less biased, with full disclosure, more transparent way.

The problem with relying on peer-reviewed journals is that many of the questions that EPA is dealing with have to do with the effects of exposure to certain kinds of chemicals. And, unlike the pharmaceutical industry, there is not as lively a publication market for those kinds of studies, and they are often done by the companies who manufactured the chemical, which is the party that is most interested in what the results of the study would be. I have no question about that. The problem is that if the study itself has not been peer reviewed by publication and an independent journal and, instead, arrives at EPA to be peer reviewed, it needs to go to the Science Advisory Board, and it also needs to be accompanied by all the underlying data or no one can tell what is going on. And, that is the recommendation that I am making.

Now, Dr. Gray said we need to focus on expertise, and I agree with him. We certainly can have incompetent scientists doing peer review. The problem is that if you say expertise in a specific chemical, the only people that have very well-developed expertise in a very specific chemical are the people that make it, and you can't have people peer reviewing themselves.

Mr. OSE. How do we deal with that?

Ms. STEINZOR. I think it is very important to balance these panels for bias and to look long and hard for people who are independent in the academic community. They do exist. And to balance, I

mean not to have people on who have a direct financial stake in the outcome of whatever the regulatory decision is.

A company that makes chemical——

Mr. OSE. I think you just said that the people who know the most about a chemical are probably those who put forward the request for a peer review of their product. In other words, the people who manufacture——

Ms. STEINZOR. They do the studies.

Mr. OSE. They do the studies, and they are probably the most knowledgeable about the product in terms of its scientific impact?

Ms. STEINZOR. Well, that's right, but should we have somebody who has done a study for a company that stands to benefit financially look over his own study and decide if its adequate?

Mr. OSE. I am trying to figure out if we are looking for quality peer reviewers, if you will, if the best are with industry, how do we get an appropriate peer review panel? This argument is circular.

Ms. STEINZOR. Well, there are independent academic scientists. I actually think it is fairly well established that if you have a financial stake in the outcome of a decision, you are not allowed to be a peer reviewer. The problem with EPA's SAB was that there was no disclosure, so you couldn't tell if somebody had a financial stake. But what I am suggesting is, if you have people like that serving, you also need people who are expert in the area of the effects that are being investigated, who are not affiliated with industry; otherwise, you end up having a perception that the fox is guarding the chicken coop.

Mr. OSE. So the current rules or statutes preclude someone with a direct financial interest from participating in the peer review, even though there is no means of investigating whether that is the case or enforcing it?

Ms. STEINZOR. Well, there are means of investigating and there are means of enforcing it. It can be waived on occasion by the Agency. It has been. But the problem was that EPA's practice was never to ask.

Mr. OSE. I see.

Ms. STEINZOR. So there are tools, but the Agency wasn't implementing them.

Mr. OSE. The other panelists—I would like your input on this issue; it is kind of like the chicken or the egg, speaking of the fox and the henhouse—Dr. Portney, Dr. Gray, Mr. Warren?

Dr. PORTNEY. Sure. If I could briefly, I understand what Rena Steinzor is saying, and I think I agree with her. As a former member of EPA's Executive Committee of the Science Advisory Board, I do think in the past the Science Advisory Board has had people on peer review panels who have not made clear, or the SAB has not asked them to make clear, what their ties may be, whether or not they are a scientist employed by a pharmaceutical company or a chemical company or a research scientist, most of whose research has been supported by a company. I mean, I can't see any reason why you wouldn't require people to make clear the sources of their support.

But I think you are absolutely right. As Professor Steinzor points out, in some cases, the people who know the most about and are

the best, the most technically versed in research about a particular substance, are often the people who derive their livelihoods from studying that; and I wouldn't want to see them excluded from a peer review panel. I think they ought to have the right to participate, so long as they disclose their backgrounds, where the research support comes from, etc. I also agree with Rena that there are people out there who have no ties, financial or otherwise, to the production process, etc., in question who can be found to sit on these panels and every effort should be made to include them.

Mr. OSE. Mr. Warren.

Mr. WARREN. Well, NRDC does support the type of reforms that Ms. Steinzor has been describing. There are two important objectives. One is you want balanced expertise, and two you also want transparency and as little conflict of interest as possible.

So in many ways this goes to the heart of the issue of what the Agency really needs to be focusing on to ensure sound science. It requires an extra effort for the Agency to beat the bushes, as it were, to get people who don't have a direct interest or a conflict of interest where the review is concerned. But we need much better disclosure to ensure the transparency where participants in the panel may have conflicts of interest.

Mr. OSE. Dr. Hayward, any input? Dr. Gray.

Dr. GRAY. I would just say very briefly that this can be done. I serve on a variety of national advisory committees at the National Institute of Environmental Health Sciences for the Food and Drug Administration, where this is done routinely. Disclosure is done, things are vetted, and people know where people are coming from; and it can be done and it is done.

Mr. OSE. Let me examine that for a minute. In terms of the disclosure that you undergo as a participant in these bodies, give us some sense of what it is you put on the table.

Dr. GRAY. Well, for example, serving on the National Advisory Environmental Health Sciences Council, which advises the National Institute of Environmental Health Sciences, I disclose everything from my sources of income, my wife's sources of income, investments that we have, sources of funding for my research, in complete detail. So I think almost anything that one could imagine could give a clue as to someone having a potential conflict of interest is examined by, in this case, the Department of Health and Human Services to determine whether—and there are times, potentially, where one could be asked not to comment on specific issues because it is inappropriate.

Mr. OSE. Has that ever happened?

Dr. GRAY. Not to me. And, I am sure that it has happened on this council. An event doesn't come to mind, but I am sure that it has happened.

Mr. OSE. OK. If you put information on the table of that nature and someone challenges it, is it a requirement for disclosure, or is it a disqualifier for participation?

I want to be clear on this. In other words, if you just disclose it, does that meet the requirement, or does it actually serve as a disqualifier for participation?

Dr. GRAY. No. There is a specific individual within the department that then reviews this information, and for a particular meet-

ing that is coming up and a particular topic that is going to be discussed, that person makes a judgment about whether it is appropriate for me, for example, to speak on this or not because of a conflict of interest.

Mr. OSE. OK.

Dr. GRAY. So a judgment is made. It is not just disclosure, but a judgment is also made.

Mr. OSE. All right. Let's go on to the next question here.

EPA does not have a mechanism, an adequate mechanism, for systematically collecting and analyzing current environmental and human health data. H.R. 2138 provides for a Bureau of Environmental Statistics modeled after the Bureau of Labor Statistics and the Energy Information Agency. H.R. 2138 provides that the Bureau shall collect environmental quality and related public health and economic information, including data on ambient conditions and trends and distribution of environmental conditions and related public health conditions across populations.

Dr. Portney, I believe you proposed this concept in 1988, and I am frankly hopeful that with this bill it will finally become a reality. I am going to allow you another opportunity to say that you support the Bureau of Environmental Statistics within the new department, so the first question is, do you support that; and the second question is, does the EPA currently collect valid statistical data on the quality of the environment, including health outcomes such as morbidity and mortality data?

Dr. PORTNEY. Well, I am relatively indifferent on the creation of a bureau! I have made it abundantly clear that I support that. With respect to the provision of data on health outcomes, I will just echo something I said earlier and I will do it briefly.

The farther a Bureau of Environmental Statistics has to get from providing data on ambient environmental quality or emissions from sources, the more difficult its job becomes. Let me give you an example.

Some people have suggested that there is a link between ambient air pollution and the apparently increasing incidence of asthma. I think asthma is a very serious public health problem. It is hard for me to understand how it can be linked to deterioration in air quality, though, because as Steve Hayward and other people have pointed out, air quality has improved in every metropolitan area around the United States consistently over a 30-year period with respect to every air pollutant. So if asthma is getting worse at the same time air pollution is getting better, either it is linked to an air pollutant for which we don't currently collect data, or something else—lice, fungus, etc.—is causing the increase in asthma.

The point I am trying to make is that if the Bureau of Environmental Statistics had to present evidence, collect and disseminate evidence on the incidence of asthma, that would create the presumption that somehow that is an environmentally mediated disease, and in fact, I think there is reasonable doubt about whether or not that is the case. In other words, it is not like smoking and lung cancer or some other disease where there is a one-to-one link.

So as long as we are talking about ambient air quality, water quality, land contamination, drinking water quality, etc., then I think it is a no-brainer for the Bureau of Environmental Statistics.

It gets more challenging the farther away we move into the health and economic area.

Mr. OSE. Are you suggesting that the Bureau would serve to facilitate the cross-media analysis of environmental concerns?

Dr. PORTNEY. Well, to some extent, I guess. I think that its mission ought to be to report to you, the Members of Congress, people in the administration and in the general public the kind of progress we are making on environmental quality; thus, a Bureau of Environmental Statistics. We have a National Center for Health Statistics that presents evidence on trends in respiratory disease, cardiovascular illness, etc. I don't want to see the BES verge too far from the principal reason for creating it, for fear, to some extent, that we would undermine support for it.

Mr. OSE. OK.

Professor Steinzor.

Ms. STEINZOR. Mr. Chairman, I want to respond to this point that air quality is getting better and, therefore, asthma must be due to other causes by saying that, first of all, we live in an area that is severe nonattainment for ozone, and there is not any question that the Baltimore and Washington metropolitan areas are not going to make attainment by 2005.

So while there may have been a broad trend toward improvement, it is very clear that many metropolitan areas in the country—Houston, Los Angeles, Atlanta, etc.—are not going to make attainment of levels necessary to protect health by 2005; and when the new fine particulate matter standards come into effect, they will fall even further behind.

So a broad trend does not make a safe, health-based level, and our cities are in very serious trouble, and are going to be back in front of you very shortly, begging for yet another extension. I think this would be the fifth one for the area that we live in.

So perhaps I am a little sensitive on this as the mother of an asthmatic child, but I think we need to be careful; and this is an illustration of how the Bureau of Environmental Statistics, to get to your original point, needs to be constructed and implemented and handled very, very carefully.

Mr. OSE. All right.

Mr. Warren, any input?

Mr. WARREN. Well, I believe that the objective is definitely desirable. I think we all want more, better environmental information. Representing an environmental organization, I believe that will support in the long term our claims that environmental protections on the books have been worthwhile and that more environmental help is necessary.

I believe that the Agency already has the authorities to fulfill the sort of charge that you described, that it is, by and large, a resource issue, that you can only do so much, that you can only do what you have the resources for, and that merely moving these functions around into one place in the Agency and calling it a "bureau," I don't think by itself, will ensure that the information is better.

Mr. OSE. Dr. Hayward.

Dr. HAYWARD. Well, I can't help but weigh in a little bit here on the question that is engaged at the ends of the table on pollution and asthma.

You represent part of Solano County, I think?

Mr. OSE. I come from a severe nonattainment area also.

Dr. HAYWARD. Which is what, Sacramento?

Mr. OSE. Yes.

Dr. HAYWARD. Yes. I lived there for 6 years. I looked at California counties very closely between the air quality status and their asthma rates, and I found an interesting thing.

Right now, the highest asthma rate in California is Fresno County, and it also has right now the highest exceedences of the new ozone standards, actually even more than the South Coast's, which is a remarkable record of improvement. The next two highest rates of asthma in California are Marin County and Solano County, both of which have had zero exceedences of the ozone, the new ozone standard for the last 3 years, and then it jumps around as you go on down. San Bernardino and Riverside Counties, which are the next worst places, are sort of in the middle on their asthma rates.

I mean, any statistician would tell you that an air pollution/asthma correlation will not pass the statistical significance test. Now, we can argue about this for a long time, and I think we will. But this illustrates the difficulty that Paul, I think, is trying to bring up between correlating environmental conditions and health standards. This falls into that large area we referred to earlier of great uncertainties and the science of this, the sound science of all of this.

I just wanted to add one other little clarification. You know, the way we regulate air in cities, we have dozens of monitors in the large areas. If a single monitor is out of compliance, the whole metropolitan area is deemed to be out of compliance with the Clean Air Act. That makes perfect sense from a regulatory point of view because downwind areas may be getting their pollution from the upwind areas. In other words, in San Diego, it turns out there has only been one monitor out of compliance with the ozone standard in the last 3 years, out in the eastern part of the county, where less than 1 percent of the population lives. I don't know what the monitors look like for Washington and Baltimore, but in San Diego, 99 percent of the population is not exposed to ozone that exceeds the standard.

So it is a mistake in my mind to say, therefore, the entire population of San Diego is at risk of asthma because that area is found out of compliance with the Clean Air Act.

Mr. OSE. Your point is the quality of the information or the quality of the monitoring could stand improvement?

Dr. HAYWARD. Well, no, the quality of how we interpret and understand how localized problems are.

Mr. OSE. Would a Bureau of Environmental Statistics help or hinder improving the quality?

Dr. HAYWARD. I think it would help. I don't think it solves any of our difficulties of the links, as Paul has tried to say, I don't think this solves any of our difficulties with the link between pollution and health effects that we currently argue about.

Mr. OSE. That is a different question.

Dr. HAYWARD. Right.

Mr. OSE. Dr. Gray.

Dr. GRAY. To answer the first part of your question, EPA does gather some very good and very useful data in some areas, and that is very important for us. One of the problems that I tried to illustrate in my testimony is that in many ways, people don't know about those data, and it may well be that is why most Americans think the air today is less clean than it was 10 years ago when all of the data that have been collected suggest the opposite is true.

I think that having an independent group, that perhaps is seen as not having some of the same conflicts of interest as EPA might have in these statistics, might increase their acceptance and increase people's willingness to understand their knowledge about the state of the environment.

I do want to comment on this issue that has come up about health effects and whether those are appropriate for a Bureau of Environmental Statistics. A very large fraction of EPA's regulations are expressly based on the notion that they are going to decrease risk to human health: Particulate standards will reduce mortality and morbidity; the ozone standard will reduce rates of disease. If we don't monitor those diseases, how will we know if the progress is being made? Just simple changes in the indicator chemicals doesn't take us to the point that, in fact, justifies that entire rule.

I think it is important that a Bureau of Environmental Statistics does include not just measuring parts per million of something here and there, but tries to get at these notions of health effects so we can understand whether these rules are having the effects that they intended.

That said, it is a very difficult thing to do. And in fact, I said in my testimony, for example, meeting the arsenic standard is something that probably would never be detected in a town. The fact that those risks are so small is also useful information for people to know that we are looking at risks that we are not going to be able to find in our public health statistics. That is information that should be in the national debate about the kinds of programs that we are undertaking.

Mr. OSE. Is the Bureau of Environmental Statistics an appropriate place to collect that information?

Dr. GRAY. I think it is a very good idea because of its independence and, I think, because of its peer review function, the idea that people are checking on the techniques, the tools, and the models that are being used.

Mr. OSE. OK.

Mr. Warren, I was perplexed by something on page 7 of your testimony. You were talking about your concerns about the Bureau's confidentiality provisions on any statistics they gather, and I think the direct quote is "Such confidentiality provisions may, in fact, bar the distribution of valuable information that the public receives presently under current law."

Could you explain that? I don't know if you have it with you or not, but have you identified in the proposed legislation itself, the specific language that you believe is the source of that debarment, or disbarment?

Mr. WARREN. I can give you an example of it. We are in the process of reviewing the details of it. I have to say that issues like this, and the scrutiny that would require to go through all of the provisions of the legislation is again one of the reasons we would prefer at this point to just have a simple elevation. Issues like this should be dealt with at another time and place.

But in this particular case, one of our concerns was provisions of the Clean Air Act that required the disclosure of certain kinds of emission data. So we are currently looking at whether the general confidentiality statement could be construed as conflicting with that provision of the Clean Air Act. We understand you have a savings clause in the back, so there would have to be some interpretation of how that savings clause would be reconciled with those provisions. But as you know, any subsequent legislation always takes precedence over prior legislation, all other things being considered, and I think it follows into one of those areas of concerns that has been expressed before about unintended consequences and perhaps litigation quagmires.

Mr. OSE. Well, as we are sitting here, I am just reviewing the confidentiality provisions, and I understand the issue as it relates to the Homeland Security Act of 2003 in terms of information put forward pursuant to that particular legislation, but there are caveats here prohibiting the director, in some cases, from disclosing any personally identifiable or corporately identifiable data collected by the Bureau, but also giving the director the opportunity to take action to collect such data from any department or any other Federal agency. I am trying to find the specific language in here that your concern stems from.

Mr. WARREN. Well, of course, collecting the information from other agencies is really not the question. The question here is under what circumstances, what kinds of information might be disseminated to the public, and whether the general statement of confidentiality in this legislation would be seen as being in conflict with that provision of the Clean Air Act that distributes information to the public on emissions data.

And, I would like to make it clear that in our testimony, we raised this as a concern as opposed to an objection and sort of said, I think your language should be double-checked, which we are in the process of doing. So I want to be fair. I want to say that perhaps we will do further research and say that this is not a concern. But on the other hand, I think it does raise a suite of issues in terms of additional scrutiny that these types of provisions need to be given where they may conflict with a range of statutes.

Mr. OSE. Why don't we send you a question in writing asking you to specify the language in the bill, the proposed legislation that generates your concern on this confidentiality issue?

Mr. WARREN. We would be glad to respond to that.

Mr. OSE. We are going to go to the next question.

H.R. 2138 provides that the Bureau's director shall not be required to obtain internal departmental approval on the collection, analysis, dissemination, or publication of its data. What we are trying to do is insulate the director from the vagaries of political trends. What we want is the data as it is scientifically delivered.

Now, we will start in middle here today. Dr. Hayward, do you support an independent director of the Bureau of Environmental Statistics? If so, why? If not, why not? And, does the language in H.R. 2138 provide adequate protections to the integrity of the proposed Bureau's efforts?

Dr. HAYWARD. Well, I am not a lawyer or an expert on statutory construction, so I don't have an opinion on the second half of that question.

But as to the first half, the reason I like the idea is that, as I look around at data sources in government, it strikes me that the Bureau of Labor Statistics which, by the way, took some time—when it was forged, I think in the 1930's—to establish its credibility, to filling out some of the methodological problems on data gathering and interpretation; and even, still, today there is debate about some of their findings. But the Bureau of Labor Statistics and I think an equally or maybe better model is the Energy Information Administration, whose data I think is universally respected across the political spectrum. It has been independent from political pressures to a very large degree, so I think those are good models to emulate.

Mr. OSE. Mr. Warren, any input on this? We will add the caveat, if we set up the Bureau of Environmental Statistics.

Mr. WARREN. Well, that is an important caveat, because otherwise I would be compelled to say that I don't think in terms of the criticisms of EPA in the past that their head science officials, in fact, have had their credibility or integrity challenged in terms of how they operate.

So while I believe that we all believe that science should operate according to sound principles and not be subject to undue influence of some sort, I don't actually think that has been even the basis of the criticisms of the Agency science.

So I have to counterbalance the stated desire to ensure the independence of the head of the Bureau of Environmental Statistics with the concern of the isolation of that office from being policy relevant. We would certainly want to make sure that to the extent sound environmental information is collected and generated, that it was properly integrated into the rest of the organization, and there would be tension between their independence and that integration.

Mr. OSE. Dr. Gray, any input on this?

Dr. GRAY. I just think that independence increases credibility and the credibility of these data are going to be important to their use in evaluating our environmental progress.

Mr. OSE. All right.

Professor Steinzor.

Ms. STEINZOR. I would only urge you to consider that the States are responsible for generating a lot of this data, and have, in the past, resisted vigorously EPA's efforts to get them to cough more of it up, largely because they feel very stretched in terms of resources.

And, to give just another example, I don't know if you, when you are here, live in Maryland, but we have a State agency that went from $232 million budget in fiscal year 2001 to $164 million in fiscal year 2004, a 30 percent cut. And, I would be very surprised if that wasn't happening all over the country.

So they will scream, and that will be a problem without Federal help.

Mr. OSE. OK.

Let me go to Dr. Portney first.

Dr. PORTNEY. Go ahead.

Dr. HAYWARD. Something that just occurred to me: The EPA probably in the next couple of weeks is going to come out with a report on the state of the environment that they have been putting together for probably a year and a half now. They probably haven't done one since 1989. I haven't seen any advanced peeks, I am going to see one next week, but what I hear from those involved is that it has suffered from the usual interagency squabbling because they are trying to do things that are covered under the Department of Interior, the Department of Agriculture and the Forest Service purview and so forth.

So the likelihood is that it is going to reflect some of the usual clashes and compromises and concessions for an interagency process to try and do this and, therefore, it will be of limited value, I think. That, to me, is an argument in the obverse for doing it the way you propose to do it.

Mr. OSE. Dr. Portney.

Dr. PORTNEY. I am strongly supportive of the language that you have written into the bill that would protect the independence of the director, and let me give you an example.

Coming down here to testify today, I was in a cab, the driver of which had on one of these talk radio shows that said that in new information released yesterday by the Bureau of Labor Statistics, the unemployment rate has risen to 6.1 percent. Then they had a call-in, and the people who called in argued about why it had gone up to 6.1 percent. Is it administration policies? Is it overall economic deterioration around the world? No one said that the unemployment rate is not really 6.1 percent, that the Bush administration is lying.

Everybody understands that given the way that we measure unemployment, that 6.1 percent is an honest measure, given the procedures that we have established for that.

I think it is really important that an independent Bureau of Environmental Statistics be able to say that air quality in Baltimore has deteriorated or improved with respect to this pollutant, and have the nature of the policy debate center around whether or not it makes sense to spend money to further improve air quality or prevent deterioration when, in fact, I think we spend too much time arguing about whether or not air quality really is as we have stated it or we have discussed today: Well, is it because the monitors are located where they are, or is it because there are only two monitors in this metropolitan area?

I really think elevating EPA to Cabinet status, as you have proposed, and incorporating in that a Bureau of Environmental Statistics will force us to confront these issues and get the public focused on the kinds of questions that we ought to be focused on.

Mr. OSE. There is a related question here.

Dr. Hayward, you just talked about a report coming out on the status or the condition of the environment, the last having been issued in 1989. There is a requirement in the legislation that the

Bureau's director submit an annual report to Congress and the Secretary, as well as the public. Would this be useful? Does it help the process? Does it introduce accountability, both to the Department or the Bureau? Is it too much? Is it too little?

Dr. HAYWARD. Oh, boy. A whole basket of questions there. I mean, I think it is helpful in that it would help move forward public understanding of environmental issues beyond, as I put it, environmentalism by anecdote and policy by headline. That is a general thought.

Mr. OSE. Mr. Warren.

Mr. WARREN. I don't disagree with that really.

Mr. OSE. OK.

Dr. Gray.

Dr. GRAY. I don't have a comment, other than it would be helpful, and I think that annual helps us track things a lot better than every 12 years or 13 years.

Mr. OSE. Professor Steinzor.

Ms. STEINZOR. I agree with that and think that environmental indicators are a very important tool. But if they are to achieve the status that Dr. Portney just described, which I also agree with everything he said, they need to be done very honestly and be comprehensive.

Mr. OSE. Dr. Portney.

Dr. PORTNEY. I agree with what I said earlier.

Ms. STEINZOR. He agrees with himself.

Mr. OSE. All right.

During the subcommittee's prior hearings, witnesses testified that EPA's program offices occasionally operate as fiefdoms that impede innovation and efficient regulations, that do make national policy and that do conduct science without coordination of scientific data. The program offices also reflect the piecemeal organization of environmental statutes.

H.R. 2138 locates program offices under the supervision of the Under Secretary for Policy, Planning and Innovation. The bill's goal is to have a central regulatory and policy office that works with the program offices under the direction of an Under Secretary.

Professor Steinzor, do you support the centralization of policy under the Under Secretary for Policy, Planning and Innovation as proposed under H.R. 2138, and would that centralization facilitate some cross-media rulemaking?

Ms. STEINZOR. I don't support it, because it would separate the people who write the regulations from those who implement and enforce them. And while I think that cross-media integration would be a useful goal, it is not clear to me that separating things out by function would make any difference in that area.

Mr. OSE. OK. Mr. Warren.

Mr. WARREN. I think my concern in this case is that this particular Under Secretary really acts as the super-Under Secretary by consolidating all of the policy and planning functions under that secretary. My perception is that Under Secretary would have much more authority within the Agency as a whole than the other two; and that, in effect, what you have done is, whereas now, you have several Assistant Secretaries reporting to the deputy administrator and then the administrator, you have replaced the deputy adminis-

trator with this Under Sectretary, and then left out science and enforcement; and that those two Under Sectretaries now operate all outside of the other policy review and planning process that is being channeled up to the secretary.

And I would just have to ask the question, why aren't science and information and monitoring and enforcement somehow being given a status where they are much more integral to the policy and planning process?

Mr. OSE. Dr. Hayward.

Dr. Gray, any input on this? I will repeat the question if you want me to.

Dr. GRAY. That is OK. I do think that this sort of a structure helps ensure the credibility of the scientific decisions that are made.

I do think that it is important not to repeat the mistakes of the past and have these be stovepipes. As Steve said, we don't want just three bigger, thicker stovepipes. I think we want to make sure that they are surrounded by perhaps a screen rather than steel, so that there is communication back and forth between enforcement and science and the policy offices.

Mr. OSE. Dr. Portney.

Dr. PORTNEY. I do think that the administrative arrangement that you have proposed would facilitate a little bit more awareness that solving an air pollution problem can sometimes create a water pollution or a solid waste problem.

So I understand the administrative advantages of the decisions that you have made in the proposed legislation. Ultimately though, I think, Chairman Ose, the real problem comes as a result of the fact that the Clean Air Act tells EPA's Office of Air and Radiation to solve air pollution problems and doesn't tell it what to do if in the process of solving an air pollution problem you create a solid waste problem that is even greater.

So I think this gets——

Mr. OSE. Or a water problem.

Dr. PORTNEY. Exactly. Exactly right.

So you get us part of the way there. To get all the way there, I think Congress may have to look at all of the statutes together and decide how can we give the Agency the power to avoid creating a bigger problem in the process of solving a smaller one.

Mr. OSE. I think the poster child for my concern here in terms of this cross-media issue is the efforts we made in California, for instance, to have cleaner air emissions for MTBE and the consequence to water pollution from leaking tanks where the MTBE just drops right to the water table. I am trying to figure out how it is we prevent a similar situation from arising with some other well-meaning scientific advancement.

What this really boils down to is, and Mr. Warren led me to this thought in the first place—what is to prevent the Under Secretary for Policy, Planning and Innovation maintaining the focus on air, water, land, in the context of their everyday deliberations anyway?

Professor Steinzor, any input on that?

Ms. STEINZOR. Well, I think you are right, there is nothing that would prevent it, and it may just be that there is no way to accom-

plish this other than going through the statutes and deciding how to integrate all of them.

Mr. OSE. Because those statutes——

Ms. STEINZOR. The Clean Air Act, the Clean Water Act.

Mr. OSE. We are not even trying to do anything with them. What did he call it, a savings clause?

Ms. STEINZOR. Savings clause. I guess what I am saying is, I think that is the unavoidable problem, that if you don't change them, there is an irresistible temptation to set up offices that have to accomplish rulemakings under deadlines because the Agency has been very slow.

May I address MTBE?

Mr. OSE. Certainly. If you have any thoughts as to what we can do about that, I would welcome them.

Ms. STEINZOR. Well, the President of CPR is writing a book on MTBE, so he would welcome, if you asked a question about it, to provide you with information. I think he would say, if he was sitting here—and this is Thomas McGarity, who is a professor of law at the University of Texas—that in fact, California EPA did not say do MTBE; it was the industry that chose that additive, and that the problem was that the tanks were leaking, and that is a failure in compliance with earlier regulation.

I mean, it is not that we would at all disagree that it is a terrible problem, but it was not the regulator's choice to pick MTBE. That was done by the industry because it was a cheaper substance, and the leaking tanks is what got it into the water. I am painfully familiar from my days in private practice with the underground storage tank regulation. They are quite extensive and those things were supposed to have been pulled and replaced 15 years ago.

Mr. OSE. Anybody else?

Dr. Gray.

Dr. GRAY. I just wanted to ask if perhaps this notion of the Under Sectretary looking broadly across the media in the different environmental areas is, in fact, contained in the goal of the department as laid out in the legislation, which simply says that the department should be guided by the goal of improving overall environmental quality. There is an exhortation, there is an aspiration here to make this overall, to look broadly—and perhaps something a little more concrete would help there as a place to start—to make that something that can be used to measure or to check how that particular office is working.

Mr. OSE. OK.

Mr. WARREN. If I could just add, I think it is a very serious issue, in fact, how you encourage that cross-media work and that integration. And, I think that the solution, for better or worse, is that it needs to be done from the top down; that really it has to be the responsibility of the secretary and the deputy secretary to take on those actions, which are necessary to make sure that it is done across the Agency, not only air, water and land, but science and enforcement and monitoring all together; and that they have the ability to do that, in fact, I believe through again such tools as the Government Performance Results Act, which forces them to do a strategic plan.

And, if you look at the current strategic plan in terms of how it has done its goals, the goals are not simply done by traditional media, and within each goal, you will see different media working together. I am not endorsing their current strategic plan; what I am pointing to is the fact that does present a means for them, and that simply another layer of bureaucracy, as opposed to having the deputy secretary and secretary being charged with that directly, I don't think necessarily ensures the result.

Mr. OSE. OK. In developing this legislation, we received a lot of input. Some of the groups have put forward the thought that the regulations promulgated by EPA should be subjected to a cost-benefit analysis.

My question would be, should such a requirement be included as part of an EPA elevation bill, should EPA be required to prioritize not only its proposed activities, but also the regulations it wishes to promulgate? I think that is part and parcel of the question, in particular that Professor Steinzor and Mr. Warren hinted at, as to whether or not this provision should be included in this elevation bill. So we will deal with that accordingly.

Mr. Warren, we are going to go to you first. Should EPA be required to do a cost-benefit analysis of all of its regulations? Should such a requirement be included in the EPA elevation bill? Should EPA be required to prioritize its activities and the regulations it might wish to promulgate, and should those activities be included in the elevation bill?

Mr. WARREN. When you say "those activities," do you mean the first three activities or the prioritization exercise alone?

Mr. OSE. Separate the two. There are actually two things. There is a cost-benefit analysis and then prioritization. Should the cost-benefit analysis be included in the elevation bill? Should the prioritization requirement be included in the elevation bill?

Mr. WARREN. OK. Well, our answer would be no and no. In respect to cost-benefit analysis, the Agency is already required under an Executive order to do a cost-benefit analysis for major rules. Therefore, it doesn't seem necessary to have an additional requirement in that respect. Cost-benefit can, if done right, provide useful information to policymakers. But it should not become the overriding statutory decisionmaking criteria. Those should remain as they are in the statutes where they exist now.

In respect to the prioritizing exercise, I believe that it is desirable for the Agency to have a good process by which it sets priorities and by which Congress then can review them and pass judgment on them. But I think that you would just be opening a tremendous Pandora's box to ever get people to agree on what the right priority-setting process or priorities would be. And, I think that it would really have the effect of dooming the legislation.

Mr. OSE. Professor Steinzor.

Ms. STEINZOR. Our answer would be no and no as well. First of all, I would like to offer, we have done comprehensive analyses in several different forms of the type of cost-benefit analysis that is being done now by the agencies under pressure from the Office of Management and Budget. And, I would be delighted to provide that. I think that much of that methodology and underlying infor-

mation illustrates that the kind of cost-benefit analysis we are doing now is unsound cost-benefit analysis.

Furthermore, there are statutes such as the Clean Air Act, as affirmed in a Supreme Court decision that was unanimous and authored by Justice Scalia relatively recently, that upheld the specific decision in the Clean Air Act not to allow costs to be considered in the formulating of health-based standards as an initial matter. And so, to enact something like that as part of Cabinet elevation, once again, would have the effect of repealing that statutory provision, and is only appropriate if you were engaged in a debate about whether it was desirable in that context.

Mr. OSE. OK. Dr. Hayward.

Dr. HAYWARD. I think I will pass on this one, too.

Mr. OSE. Dr. Gray.

Dr. GRAY. I think in an ideal world the answer to your questions would be yes and yes. It would be very good to know what sorts of benefits we were getting for the resources that we are putting into complying with specific rules and regulations. That would be ideal. And, lots of folks have told us that is a useful part of the decisionmaking process. Priority setting would be great.

Given the fact that the Executive order already requires benefit-cost analysis of major rules, and the fact that it is my understanding that this sort of provision has really held up previous elevation bills, it seems to me that would be something that would potentially lose a lot of the advantages that are there. I do think that a Bureau of Environmental Statistics will help us with priority setting. It is something that, inadvertent or in an indirect way, will be very valuable for priority setting. Benefit-cost analysis is being done in the Agency. I think more of it will be done. Making it an explicit requirement of this bill I am afraid will just stop the bill.

Mr. OSE. Dr. Portney.

Dr. PORTNEY. I am in the same place that George Gray is. I think that it is inconceivable to me that you wouldn't want a regulatory agency to ask the question, What is the good that this regulation will do and how does that compare to the costs that it will impose on the economy? So I think that agencies should have to do benefit-cost analysis.

But I also agree with Wes and several of the other panelists who pointed out that they are required to do so under a Presidential Executive order and under the Unfunded Mandates law of several years ago. I don't see any reason to risk all the advantages that I think this bill offers in terms of Cabinet department, Bureau of Environmental Statistics by putting that in there. And, I feel the same way on prioritization. Yes, it should. I don't think this bill ought to become the vehicle to require the EPA to do that.

Mr. OSE. All right.

My last question here has to do with the public's access to data at EPA. What changes, if any, should the Department make in its implementation of the Data Quality Act? And, should an EPA elevation bill contain a provision to ensure data quality and the public's access to that data? And, if so, what language do you recommend? I am going to start with Dr. Portney on this.

Dr. PORTNEY. I am going to have to pass on this one. I know that this Data Quality Act has become a very controversial issue. What

I don't know is whether or not this government, or any government, would use it to frustrate the ability of a regulatory agency to issue regulations, or whether it is a constructive step in the direction of making sure that the public can see the data base upon which regulations are based. So I'm afraid I don't have a very good response to you there.

Mr. OSE. Professor Steinzor.

Ms. STEINZOR. Well, Mr. Chairman, CPR has been in the forefront of questioning how we should properly interpret the Data Quality Act. No one can be against quality data. But it seems to us that the act has been stretched way out of shape by the Center for Regulatory Effectiveness, whose founder claims to have authored the act.

Yesterday we became aware that a letter had been circulated here that accused us of violating the Data Quality Act when we expressed an opinion about how it was being used by the Center for Regulatory Effectiveness, which leaves me with the impression that the Data Quality Act is bigger than the first amendment in Mr. Tozzi's mind. And, I find that kind of troubling. I think we should be able to have a robust debate, as we did with all the panelists who were sitting here. It has been a very stimulating discussion. And, having fears that we have violated the Data Quality Act as interpreted by Mr. Tozzi, and therefore our views should be discounted.

So I would urge you to be very, very cautious about feeding this idea that anyone who disagrees with you is violating the Data Quality Act. I would just urge you to focus on your other very worthwhile goals.

Mr. OSE. Dr. Hayward.

Dr. HAYWARD. I am pretty much where Paul is. I haven't spent a lot of time yet figuring out how the Data Quality Act was going to unfold. I was going to wait for some more time to pass and things to settle out a bit. In general, I find that EPA, at least on their Web site, breaks down a lot of their data, like their air quality data especially, superbly. It is voluminous and extremely useful.

You do occasionally get into these debates about the confidentiality of raw data that goes into some of their epidemiological research. This has come up in the context of the new ozone and particulate standards. And, I am not sure what the answer is there, because that opens up a can of worms on all kinds of legitimate concerns about privacy of the people being surveyed and so forth. And, I don't know what the solution to that is. But I think it is the kind of thing that a Bureau of Environmental Statistics would have to wrestle with very seriously and figure out some kind of way to make both sides happy.

Mr. OSE. Mr. Warren.

Mr. WARREN. Well, I believe that you can support quality data and yet not support the Data Quality Act. I believe that piece of legislation still has the potential in fact to be a source of great mischief. And by that, I mean that self-interested opponents of environmental protection may see the act as an opportunity to just constantly challenge any piece of information that the Agency has at its disposal to prevent it from being used in a decision or to prevent

it from being disseminated to the public. And, I think that would be a perversion of the intention to ensure quality data.

Having said that, as you know, this was adopted as an appropriations rider. The administration has carried the interpretation far beyond the literal reading of it. Our organization objected to it both in terms of the content also the process. This is the type of proposal that should have gone through the authorizing committees. We should have had a free and open public debate. Congress should have had a chance to consider all of the implications before enacting it. And now we are struggling to live with the consequences.

I have to say that I think your legislation has been much more careful about avoiding the interjection of those kinds of pernicious concepts into place that might actually undermine the objective of quality data.

Mr. OSE. Dr. Gray.

Dr. GRAY. Nothing.

Mr. OSE. All right. Well, I have no further questions.

I do want to offer a couple comments. I think everybody's interested in improving the quality of our environment. That is pretty basic. It is not even partisan. One thing I do want to examine in future hearings is one of you, I think Professor Steinzor or Mr. Warren, I think one of your testimonies talked about the difference in how an adult human is affected by environmental influences, as opposed to a child.

Mr. WARREN. Yes.

Mr. OSE. And, I think I want to examine that a little bit more, because I am curious about what role, if any, this legislation might have in facilitating a far more comprehensive look at that.

I do want to thank you all for coming today. This has been highly educational for me. This is not an easy issue, because we have all sorts of different influences pulling on us in different directions. We are going to try and work our way through it. Our objective remains to get an Agency that can prevent situations such as like MTBE, regardless of the source, from leaky tanks or otherwise, from recurring time after time after time. We want a cleaner environment for ourselves, our children, and our grandchildren. It is an appropriate time for us to look at this.

I appreciate you all taking the time to come down and testify and help us in our efforts. This hearing is adjourned.

[Whereupon, at 12:12 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

COVER STORY

Bad Science

EPA's industry critics urge Congress and the new administrator to upgrade the science used in regulatory decisionmaking. They are right that science at the agency needs improvement — largely because these same self-interested critics overwhelmingly dominate research agendas and peer review

LINDA GREER and RENA STEINZOR

"The right to search for truth implies also a duty: one must not conceal any part of what one has recognized to be true." —ALBERT EINSTEIN

In Washington circles, "sound science" has become the remedy of choice for most of what ails the regulatory system. Whether it's arsenic in drinking water or particulates in the air, proponents of this seemingly simple solution argue that if the Environmental Protection Agency would only get more scientists on board and listen carefully to their sage advice, we could eliminate or at least reduce those excessive health and safety regulations that squander public funds, freeing scarce resources to address far more urgent problems.

EPA indeed practices a great deal of "bad science," but not in the sense asserted by its industry critics. What really upsets regulated industry is not the agency's supposed failure to consider "good science." Instead, the business community is driven to distraction by the fact that EPA must make most decisions on the basis of incomplete or uncertain science. However, as we explain below, Congress and EPA administrators have long recognized that the agency must act in the face of uncertainty to achieve its mission. While it is important to debate the issue of how to operate in the face of scientific uncertainty, it is unhealthy to allow that debate to obscure far more profound and troubling problems with scientific practice at EPA.

Although agency scientists do many tasks, one of their most important responsibilities is to select the salient developments among various research methodologies and findings. It is critical that they perform this function with objectivity. If their analyses are infected with bias, their scientific practice, by definition, is unsound. Unfortunately, bias and secrecy increasingly compromise not only the work of EPA's in-house scientists, but also the ultimate failsafe intended to guarantee the soundness of agency science: peer review by the ostensibly independent and objective Science Advisory Board.

EPA science is dominated by self-interested industry research and peer reviewed by self-interested industry experts. The impact of these influences on the agency's rules is magnified by a lack of transparency about what pieces of research were used as the basis for important policy conclusions and why others were rejected. These problems are compounded by the fact that "science" at the agency is increasingly thrust into the role of final arbiter of all decisionmaking. Science cannot serve this purpose because the evidence on most issues considered by EPA is not definitive.

Two case studies support our diagnosis and suggest prescriptions for a cure. The first involves the inexplicable decision by EPA's Office of Research and Development (the primary location of in-house research and analysis) to revisit the toxicity profile of vinyl chloride and downgrade its estimate of the chemical's carcinogenic effects. The second involves a misguided opinion issued by the Science Advisory Board challenging an EPA staff conclusion that dioxin is significantly more toxic than first supposed. In both cases, experts working for chemical manufacturers dominated the process, managing to manipulate the pace, content, and final outcome of those deliberations.

At this point, readers may well wonder why, if the state of EPA science is as bad as we say it is, we don't agree with the critics who call for "sound science" — or "more science" or "better science, " etc. Many reputable people, including several generations of EPA administrators, have recommended the expansion and elevation of science within

the agency, arguing that it is the crucial, missing element of wise decisionmaking. In fact, this spring Congress may consider a bill by Representative Vernon Ehlers (R-Michigan) that would establish a deputy administrator for science, to centralize administration and evaluation of the agency's research. (See "A View from the Hill," page 30.) But, as we indicate at the top of this article, the call for sound science collapses two separate issues into one.

The first of these issues is the appropriate role of science in EPA decisionmaking: should scientific evidence serve as the sole determinant — or gate-keeper — of agency decisions whether to regulate? The second issue concerns the fundamentals of what *we* would call "sound" science: when EPA evaluates available technical information, what core principles must govern its deliberations to ensure scientifically valid results? An explication of where we stand on the first issue will make it clearer why we are so concerned about the second.

EPA mismanages the scientific function to the point that it can no longer be relied upon to be either objective or fair

The unavoidable reality is that, despite widespread demands that EPA employ more science, the scientific information available to the agency rarely gives definitive answers to the difficult questions that confront it. Toxicology, epidemiology, conservation biology, ecology — these and related fields have yet to produce research results that map a straightforward path to uncontroversial policy solutions. In many, if not most, cases EPA faces the conundrum of implementing environmental statutes that command it to protect public health and the environment from risks that are unknowable, understudied, or poorly understood from a scientific perspective.

Congress appreciated this problem when it passed the statutes that define EPA's mission. Look at the language of the basic laws that protect the air we breathe and the water we drink. The Clean Air Act commands the agency to protect public health with an "adequate margin of safety." The Safe Drinking Water Act requires the EPA administrator to regulate contaminants that "may have an adverse effect on the health of persons" where "there is a substantial likelihood" that the contaminant will be "of public concern" and present "a meaningful opportunity for health risk reduction." The Clean Water Act's central purpose is to "restore and maintain the chemical, physical, and biological integrity of the nation's waters," a phrase that has no defined meaning in science and requires human judgment.

As recently as last year, in *American Trucking Associations v. Whitman*, a unanimous decision authored by no less a regulatory skeptic than Justice Antonin Scalia, the Supreme Court reaffirmed Congress's Clean Air Act mandate that EPA protect public health with an adequate margin of safety and without regard to costs. Recognizing that this and similar mandates mean acting in the face of scientific uncertainty, Governor Christine Todd Whitman told the National Academy of Sciences in a speech delivered in 2000: "The absence of certainty is not an excuse to do nothing. . . . Environmental policy should always be based on the soundest information available at the time." The Earth Summit's action plan, Agenda 21, used similar language, admonishing all signatories (including the United States): "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Under all these formulations, the crucial challenge is to ensure that the available science is factually correct and appropriately interpreted, and is then weighed with other factors in making final decisions.

Consider EPA's efforts to reduce cancers caused by exposure to toxic chemicals. Despite decades of research, cancer remains a mysterious disease. Because we do not understand how it is triggered in the body, no scientist can tell how many people will suffer cancer following exposure to a given level of a suspected carcinogen. Given these and other gaps in our understanding of the toxi-

Linda Greer, Ph.D., an environmental toxicologist, is a Senior Scientist at the Natural Resources Defense Council in Washington, D.C. She serves as a member of the EPA Science Advisory Board and the National Academy of Sciences Board on Life Sciences. Rena Steinzor is a Professor of Law at the University of Maryland School of Law who is spending a sabbatical year at NRDC.

Both Sides Are Right: EPA Needs To Improve Science Function

The public discourse over how Environmental Protection Agency decisionmakers use science when determining controversial regulatory action or inaction always seems to fall into two camps. One view comes from the regulated community, who claim a controversial decision ignores the underlying science, which, in their view, shows the decision does more harm than good. Another view comes from environmental and public advocacy communities, who claim that the agency ignores the underlying science while letting the regulated community unduly influence the process. While these constituencies may forever diverge on the merits and effectiveness of a controversial decision, one theme is common to both camps — that science does not adequately imbue the regulatory decisionmaking process at the EPA.


Rep. Vernon Ehlers

The next stop for this debate is usually the halls of Congress and the judiciary, where these decisions are thoroughly scrutinized. Time and again I have heard my colleagues say, "What I really want is the use of sound science at the EPA." Time and again I have seen court decisions overturn a regulation because it did not have a proper scientific foundation. That science is not infused throughout EPA's regulatory process becomes a credible argument to wage both just and unjust legislative and legal battles over EPA action or inaction. Members of Congress and the judiciary do not have confidence that the agency uses science appropriately in its decisions. Science should not be used as a cudgel to win a battle, or as an afterthought to the regulatory process; rather it should serve as a decision's foundation.

Congressional and judicial doubt about EPA's process is borne out of both right and wrong motivations. However, it is not unfounded. Several independent reviews commissioned by Congress and EPA have concluded that there are significant problems with how science is used within the agency's decisionmaking structure. It is worth noting that these studies, for the most part, did not quarrel over the quality of the scientific research at EPA, but how it is used as proposed regulations move through the agency's bureaucracy.

In 2000, the National Academy of Sciences concluded a series of four reports collectively titled *Strengthening Science at the U.S. Environmental Protection Agency.* The NAS reviewed how science was conducted at EPA and incorporated into the regulatory decisionmaking process. The report concluded that while the use of sound science is one of the agency's avowed major goals, both intramural and extramural science should be more fully integrated into its management and decisionmaking structure.

The NAS concluded with this important statement: "The importance of science in EPA decisionmaking process should be no less than that afforded to legal considerations. Just as the advice of the agency's general counsel is relied upon by the administrator to determine whether a proposed action is legal, an appropriately qualified and adequately empowered scientific official is needed to attest to the administrator and the nation that the proposed action is scientific."

In a 1998 science policy report, approved by the House Science Committee and the full House, titled *Unlocking our Future: Toward a New National Science Policy Study,* I had reached similar conclusions about the use of science in decisionmaking — that science should not be used as a mere adjunct to the regulatory system; rather, it should be used at the beginning, middle, and end of an agency's decisionmaking process — and about its proper place in an agency's bureaucracy.

I introduced H.R. 64, The Strengthening Science at the Environmental Protection Agency Act, to capture the two primary recommendations of the NAS report and meet the goal I laid out in the science policy report. First, the legislation would establish a new Deputy Administrator for Science and Technology to serve as an advocate for and reviewer of science at the most senior levels of the agency. Second, the legislation would convert the position of the Assistant Administrator of the Office of Research and Development to a set term and give that position the title of the agency's Chief Scientist.

The Deputy Administrator position will bring a much needed change to the culture of the EPA and ensure that science has a higher profile in the agency's decisionmaking process. This person would not only be accountable to the administrator for improving and overseeing science at the agency, but would also be accountable to Congress. This relationship would bolster Congress's confidence in the appropriate role of science at EPA, and therefore in regulatory decisions.

The Deputy Administrator is also needed to coordinate research between the regulatory and scientific arms of the agency. A common problem with trying to ensure that science is involved throughout the regulatory process is that the head of the scientific arm of the agency, the Assistant Administrator for ORD, shares the same rank as the heads of the regulatory offices. The authors of the NAS report argued that since the new Deputy would rank higher than the existing AAs, this person could foster research relationships between ORD and the regulatory offices.

Furthermore, the Deputy Administrator could develop and oversee an agency-wide inventory of scientific activities. Various efforts to do this inventory have all died after fits and starts because there is no central science policy authority to administer this work. The Deputy Administrator would have the appropriate authority to ensure that the best possible peer-review and research-plan-

ning practices are used for all of the agency's scientific endeavors.

While the first recommendation of the legislation and the academy report is intended to increase the political clout that science has at the agency, the second recommendation, to establish a set term for the AA of ORD, seeks to decrease political pressures on this office. The report notes, "Although the political aspect of the Assistant Administrator's job often receives considerable attention, the most important aspects of the job are not political." Since the Deputy Administrator could bear many of the political pressures inside the agency, the AA for ORD could refocus on his or her role as the agency's Chief Scientist and running a world-class scientific organization.

The tenure of an AA for ORD averages two to three years and is typically a lower priority appointment in new administrations. Under the current political appointment model, this position changes at least as often as the administration changes. The NAS noted that frequently changing goals, priorities, practices, structure, or funding are particularly disruptive to research organizations because of the long-term nature of research activities. Research endeavors cannot be easily stopped and then started again without significantly hurting productivity. A longer tenure for the AA would help insulate the office during changes in the administration, thereby providing more continuity for research conducted at the agency.

The NAS report captured the challenge that EPA's science mission faces in the future and the need to strengthen science at the agency by saying, "In the three decades since the U.S. Environmental Protection Agency was created, great progress has been achieved in cleaning the nation's worst and most obvious environmental pollution problems. Belching smokestacks and raw-sewage discharges are now scarce, and air pollution alerts and beach closings are more rare. EPA deserves a significant share of the credit for the accomplishments, but some of the most difficult and challenging tasks remain. Many past illusions about simple and easy solutions to environmental problems have been replaced by greater realization that environmental protection is a complicated and challenging mission." It is time that Congress and EPA rise up to meet this challenge by passing and implementing the provisions of H.R. 64.

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cology of common chemicals, EPA must act in advance of definitive scientific evidence in order to fulfill its statutory mandate to protect human health. If scientific evidence is called upon to resolve policy disputes where definitive answers are unavailable, science will lose the unique value it has to policymakers, converting the interpretations of scientific findings into an exercise in advocacy rather than an ongoing quest for truth.

Since such a broad and authoritative range of policymakers, over the course of several decades, have recognized that scientific uncertainty is inevitable, why is it so difficult to resolve the equally inevitable question of how much uncertainty is too much? Recent developments suggest that regulated industries use routine scientific data gaps opportunistically, by insisting that until EPA has "better science," it should not act. The infamous case of how much arsenic should be allowed in drinking water illustrates this phenomenon perfectly. In 1996, a unanimous Congress told EPA to change the 50-year-old standard that scientists conceded was not adequate to protect public health. The agency's in-house scientists worked diligently over a period of several years, supplemented with expert panels convened by the National Academy of Sciences. EPA conducted an exhaustive rulemaking that gave affected constituencies ample time to submit information. Cumulatively, the research demonstrated that EPA should lower the standard dramatically to avoid unacceptable adverse health effects, although the scientists could not reach a consensus on the appropriate numerical level. As is usually the case, there was no science that indicated precisely when exposure levels stop being "safe."

Operating competently in the face of remaining uncertainties, EPA Administrator Carol Browner was close to making a new standard final late in the Clinton administration when congressional appropriators invoked the specter of incomplete — and therefore "bad" — science in order to delay promulgation of the rule into the new administration. Browner nonetheless published the standard as final right before George W. Bush took office as president. Then, as the appropriators and their allies, mining interests and drinking water system operators in the West, had hoped, Whitman moved to delay the rule's effective date, declaring that she wanted to review the adequacy of the underlying science. Subsequently confronted

with consistent support from NAS experts for an even tougher standard, Whitman ultimately was forced to reverse her decision and allow the promulgated standard to go into effect. The arsenic episode is a powerful example of how, even when the National Academy of Sciences concludes that there is sufficient basis to lower allowed exposures to a toxic chemical, enough is never enough for those whose true intent is to hold back government intervention to protect public health.

Scientists are comfortable with data gaps and uncertainties. They view them not as "problems" but as future research agendas. It is policymakers who are plagued by these realities because they must make decisions in the face of uncertainty or stop trying to protect public health until some indefinite, far-off day. As the arsenic example reveals, the call for "more science" heard in the halls of Congress and from regulated industries often serves as nothing more than a ruse for indefinite delay on a rule, sometimes for decades. Given the political muscle of those who have mounted this campaign, scientists watching these developments from the sidelines would do well to take note: the fruitless quests for more and more definitive evidence from environmental policymakers unwilling to suffer political consequences for restricting pollution will inevitably make scientists the whipping boys for the consequences of regulatory gridlock. Unless we recognize that "science" cannot determine all that EPA is required by law to do, the agency will never have the breathing room it needs to craft wise policy.

As important as the issue of what role science can and should play at EPA is the issue of the fundamental principles that should govern the agency's on-going scientific deliberations. In this long-overlooked area, we have found problems that would shock most traditional, academic scientists. The remainder of this article is devoted to demonstrating our case that too much of the science used by EPA is intrinsically unsound, straying far from the principles that have long served as the ground rules of the discipline. Too often, EPA deems scientific evidence supporting more rigorous standards to be marginal and more readily accepts research suggesting that standards can be loosened. We begin with a review of the principles that define *truly* sound science and then apply those standards to the recent vinyl chloride and dioxin reassessments.

Congress and EPA administrators have long recognized that, as required by its core statutes, the agency must act in the face of uncertainty to achieve its mission

Science enjoys a unique reputation as an objective and dispassionate human endeavor. Because we consider it to be inherently unbiased, science is accorded a privileged role in deliberations about the organization of human affairs. Unlike many other human endeavors, scientists preserve the integrity of the scientific process exclusively through self-regulation. Although there are isolated examples of outside, lay investigations challenging the credibility of scientific research, the repetition of experiments by fellow scientists and objective peer review are the routine methods for uncovering mistakes and assessing when progress in understanding a topic has been made.

For centuries, scientists have engaged in their search for the truth by circulating the results of original research among their colleagues, first for informal discussion and then for formal, outside peer review. Colleagues first repeat work accomplished by others and then extend the experiments into additional areas. By exposing all of the underlying elements of one's work to inspection by dispassionate peers, and revealing details sufficient to replicate results, researchers build on others' successes and avoid others' failures.

The transparency of results and the impartiality of conclusions derived from those results are the indispensable foundation of science. Peer review and replication are the only reliable methods to ensure that experiments are conducted in a scientifically appropriate manner and that the results and conclusions presented by the researchers are supportable by the data generated. The peer-

review process is often challenging and difficult. But without it, results and conclusions cannot be accepted as valid.

The public trust in science depends on its unique reputation for objectivity. Scientists are expected to have opinions, but are also expected to resist bias. They are expected to reach careful conclusions and limit their conclusions to those supported by data. Or, to put this central principle more crassly, a scientist's quest for the truth and expression of opinion at the end of the quest should not be for sale or subject to control by self-interested sponsors, supervisors, the government, or any other entity with control over the scientist's career. Once financial considerations and legal constraints interfere with a quest for scientific truth, the public trust is broken, and science loses its power and authority.

If scientific evidence is called upon to resolve policy disputes where definitive answers are unavailable, science will lose the unique value it has to policymakers

Unfortunately, funding for the replication of experimental results and peer review of scientific research is most abundant in the context of topics that have captured public attention or, to put it another way, where the results of the research are of widespread economic or social importance. Claims that a scientific team had created cold fusion were immediately dissected because of the potentially monumental implications of such a discovery on the world's need for safer and cheaper energy. Similarly, discovery of a wonder drug to treat such widespread ailments as diabetes or stroke would inspire careful and extensive inspection — by the discoverer's competitors, potential allies, the larger medical community, and the government.

In a modern world overwhelmed by information and disinformation, extensive peer review or replication of certain other types of scientific findings is difficult to instigate, especially in the private sector. So, for example, efforts by a chemical manufacturer to prove that a given substance is not as toxic as EPA had originally assumed are unlikely to be scrutinized, much less validated, by other private sector scientists. Competitors have a low interest in refuting such results because they typically manufacture the same chemical and like the way the results came out. Only producers of an arguably safer alternative have an economic incentive to second-guess, and they would likely place a higher priority on testing their own compounds.

For better or worse, these economic incentives mean that the government must play an active, rigorous role in reviewing and challenging scientific research developed by self-interested private parties. The National Academy of Sciences, the National Institutes of Health, and the Centers for Disease Control, to name just a few, have erected infrastructures of in-house scientists and external peer-review panels to undertake these functions. Unfortunately, these outside institutions have limited resources and too rarely are able to double check EPA's work.

Science at EPA supports decisionmaking through two main activities. In-house scientists assigned to the Office of Research and Development analyze the outside studies that are relevant to the issues at stake. They maintain the Integrated Risk Information System, or IRIS, an internationally influential compendium of "toxicological profiles" that describe the characteristics of specific chemicals and set quantitative levels for safe exposures to them. Our case studies involve reassessments of long-standing toxicological profiles. The second activity is peer review, performed by panels of outside experts convened by the EPA Science Advisory Board and several other, smaller boards, such as the Science Advisory Panel, which focuses on pesticides. The SAB receives inquiries from agency staff working on regulatory issues and responds with advice based on its assessments of relevant scientific research. Our dioxin case study concerns an SAB peer review.

Many of EPA's in-house scientists and SAB experts serve the agency and the public with distinction, laboring diligently to produce informative and dispassionate science to guide policymaking. Too often, however,

both enterprises flout the fundamental precepts of scientific research: first, the disclosure of methods, data, and calculations sufficient for appropriate experts to review the work or evaluate whether the conclusions reached were adequately supported by the study's findings and, second, conducting peer-review that is free of conflicts of interest.

Even a cursory look at the science EPA has practiced over the past decade shows that it has strayed far from the mandates of transparency and impartiality. Much of the science that EPA uses as a basis for decisions with far-reaching implications for public health is not peer-reviewed, and it is often based on confidential information or analysis. As a result, it would not be considered credible by disinterested researchers.

At the root of this crisis in credibility is the dominance of industry funding as the source of support for environmental health research. The vast majority of research on the toxicological properties of common chemicals occurs outside of the government (or sometimes in other agencies). EPA's toxicological profiles are based on this outside work. Corporate sponsorship does not, in and of itself, render such research invalid. But it does unquestionably put industry in the driver's seat for both the pace and focus of data development to support EPA rulemaking. More insidiously, it also puts industry in charge of deciding what information it would like to disclose and what analyses it would like to do, presenting ample opportunities for industry-funded researchers to keep underlying data and discrepancies confidential and to make strategic decisions as to whether to submit research studies for EPA's consideration.

Vinyl chloride is notorious for causing liver cancer among workers handling it. Studies have also linked vinyl chloride to a number of other cancers, including brain cancer

For several decades, the scientific community has achieved a rare consensus that three substances — lead, asbestos, and vinyl chloride — are not just extraordinarily toxic but produce well-characterized consequences of exposure, known colloquially as "fingerprint diseases." Vinyl chloride, a volatile industrial chemical used since the 1930s to make plastics, is notorious for causing a rare and serious tumor, angiosarcoma of the liver, primarily among workers manufacturing and handling the compound. Studies have also linked vinyl chloride to a number of other cancers, including brain cancer.

In 1975, following a series of animal and epidemiological studies demonstrating the chemical's hazards, the Occupational Safety and Health Administration used the evidence on liver cancer as the basis for tough regulations limiting workplace exposure. These regulations resulted in sharp reductions in the prevalence of the chemical in the workplace and, as a result, the environment.

So it was a surprise when, in May 2000, EPA completed a 20-fold downgrading of the toxicological profile for vinyl chloride. EPA's decision to review vinyl chloride's toxicity was especially startling because the OSHA regulations, among other factors, have had their desired effect. At the same time that worker exposures have plummeted in the last decade and public exposure to the chemical has been minimal, industry has been able to continue using it, producing such goods as upholstery and waterpipes from its polymerized form. Given the demonstrated benefits of the regulations to both workers and industry, and the greatly lowered risk to the public, vinyl chloride should be off the list of chemicals requiring toxicological review, leaving the agency free to pursue more prevalent, less understood chemicals.

The decision to revisit the well-trodden ground of vinyl chloride toxicity appears especially irrational because EPA has faced extensive criticism for failing to assess the toxicity of many other chemicals produced and used in large amounts annually. EPA has *no* toxicity information on 43 percent of the nearly 3,000 organic chemicals produced or imported in amounts above one million pounds annually, and a full set of basic toxicity information is available for only 7 percent. Toxicological studies of these chemicals should be its overriding priority.

Further, little new technical information on vinyl chloride's toxicity has become available since the agency's last review of the chemical, in 1994. Instead, EPA staff based the reassessment on animal studies completed in 1991 and earlier. Only one unpublished epidemiological study update was new, and it reached conclusions similar to previous analyses.

Although no changes in existing regulations were made when EPA made its decision, the revised characterization of the hazards posed by vinyl chloride exposure will prove very valuable to manufacturers of the chemical now engaged in toxic tort litigation with workers who contracted brain cancer following exposure on the job, as well as companies still facing liability at Superfund sites contaminated by the chemical. (Vinyl chloride has been found at one-third of the sites on the National Priorities List.) The decision will have these effects because EPA's toxicological profiles play the crucial role of informing regulatory and judicial decisions — not just domestically but internationally. Regretfully, given the potential implications of this change, the details of EPA's reevaluation of the science reveal biased technical judgment that resulted in poor selection of evidence practices and disproportionate reliance on information generated by self-interested parties.

OSHA regulation of vinyl chloride has worked. So it was a surprise when, in May 2000, EPA completed a 20-fold downgrading of the chemical's toxicological profile

EPA made two fundamentally flawed decisions in justifying the downgrade. First, the agency decided to confine its reassessment to statistically significant liver tumors, ignoring the various other cancers that frequently appear in both animal and epidemiological reports. Second, although the reassessment continued to rely on animal data, EPA decided to abandon certain default "safety factors" it has historically used when applying animal data to humans. Instead, the agency relied on a newly developed, "pharmacokinetic" model designed to predict an internal concentration of vinyl chloride in the human body.

Epidemiological studies of vinyl chloride workers have generally reported the occurrence of many cancers besides liver angiosarcomas, including cancer in the lung, lymphatic and blood tissue, and the brain, with the last of particular concern. Richard Monson first found an excess of brain cancers in his study of Swedish workers in 1974, as did Irving Tabershaw and William Gaffey in 1974 and Richard Waxweiler in 1976. In 1981, W. Clark Cooper enlarged the Tabershaw and Gaffey study and found statistically significant increases in brain and central nervous system malignancies. In a 1991 update of the Cooper study, Otto Wong confirmed statistically significant brain cancers. The evidence concerning brain cancers is sufficiently convincing that in 1989 the Vinyl Institute, an industry-funded advocacy group, acknowledged brain tumors as a valid concern in a letter to the California Air Resources Board: "For brain cancer, three out of five studies demonstrate statistically significant findings, although the results were somewhat variable. Positive findings occurred in studies with the greatest statistical power."

Written correspondence included in the EPA docket on vinyl chloride reveals that the Chemical Manufacturers Association, the trade association that recently was renamed the American Chemistry Council, became quite upset with Wong for publishing his positive results on brain tumors without first submitting the study to its scientists for review. Wong did the work under a research contract with CMA that apparently included a "prior review" clause giving it the right to comment before publication.

In what was likely a response to the trouble that the Wong update caused industrial users of vinyl chloride, CMA commissioned yet another study of the same worker cohort, updating some data post-Wong but also re-analyzing some of Wong's data in a way that raised questions about his conclusions. This study was never published in a peer-reviewed journal, but it was submitted to EPA

and became a primary basis for its 2000 reassessment.

In justifying its decision to focus exclusively on liver cancer in recalculating the vinyl chloride potency factor, EPA cites this unpublished work, as well as two peer-reviewed research review articles. The unpublished CMA study was not, by itself, a sufficient basis for EPA to eliminate brain cancers from its list of concerns. To the contrary, this study also reported statistically significant incidences of brain cancers.

As for the two articles reviewing available research (as opposed to reporting the results of original research), the first was written by Sir Richard Doll in 1988, two years before the publication of the Wong study. Without the benefit of the Wong or subsequent epidemiological updates of vinyl chloride workers, Doll had raised questions about the strength of the data supporting brain tumors, but had concluded with the relatively mild statement: "There is too little evidence either to confirm or refute the suggestion that vinyl chloride might cause melanoma or cancers of the thyroid, brain, and lymphatic and hematopoietic systems." This equivocal conclusion from an outdated paper hardly provided a reliable basis for ignoring the numerous studies in EPA's decisionmaking docket that found statistically significant incidences of brain tumors. Indeed, Doll has cautioned against using epidemiological results to dismiss chemical hazards in this and other publications.

In justifying its downgrade of vinyl chloride, EPA cites an unpublished review and two reviews of technical literature, one outdated, the other irrelevant

The other cited research review article was authored by Jan Storm and Karl Rozman in 1997, but it does not address the issue of brain or other tumors caused by vinyl chloride exposure. Rather, the paper compares various risk assessment extrapolation models used and proposed by EPA. Given the weakness of Doll's conclusion, and the inappropriateness of the Storm and Rozman citation, EPA is left without evidence to support its decision to limit its reassessment of vinyl chloride's carcinogenicity only to tumors of the liver.

EPA's second technical misstep was the decision to abandon the conventional approach used to apply animal data to likely human health effects. When scientists conduct animal studies, they expose the animals to increasing doses of a chemical, and then perform an autopsy on the animal to see how many tumors were generated at each dose. Because chemicals may take a different course within the bodies of rats, mice, and other creatures than they do in the human body, and may be metabolized at different rates, animal studies using traditional dose measurements can either overstate or understate the consequences of comparable human exposures. Up until recently, the best way to eliminate such uncertainties would be — hypothetically, that is — to intentionally expose people to different amounts of a chemical and then track the "fate and transport" of the chemicals within their bodies by drawing samples, taking biopsies of organs, etc. Such studies should be unthinkable for obvious reasons.

Pharmacokinetic models are an emerging, as yet experimental, alternative method designed to bridge this gap. Such models estimate internal concentrations within the human body by using a computer program to predict how fast the chemical is absorbed in the bloodstream, whether it reaches the brain, etc. The models then derive an "effective" dose for a given organ over the time that the human body metabolizes the chemical. If doses of vinyl chloride at X levels caused Y incidences of tumors in rats, but pharmacokinetic models show that humans metabolize the chemical more effectively than rats, and therefore experience lower internal concentrations, the model provides support for downgrading estimates of the chemical's carcinogenic effects on people.

The catch here is that pharmacokinetic models are at the cutting edge of the already highly uncertain science of environmental modeling as a whole. It is certainly true that reputable scientists are working to refine

such models in order to better predict effects of exposure. It is also likely that, once they are developed, such models should allow us to better understand the correlation between internal concentrations of toxic compounds and adverse health effects. But at this point in the evolution of scientific understanding, these models cannot be validated with respect to exposures at environmentally realistic concentrations. This uncertainty means that pharmacokinetic modeling unquestionably does not put EPA in a position to remove default safety factors.

Mindful of these concerns, when EPA staff considered the application of pharmacokinetic models in a proposed reassessment of the toxicological profile of trichloroethylene, they made a concerted effort to compare several versions of the models, as well as to quantify the level of uncertainties in each model's estimates of liver, lung, and kidney tumors in response to the modeled doses. This analysis quantified uncertainties so huge (as high as 20,000-fold) that EPA staff insisted on continuing to apply default safety factors, thereby sharply curtailing their reliance on any of the models. This carefully qualified application of an emerging scientific methodology stands in stark contrast to the wholesale reliance on pharmacokinetic modeling results in the context of the vinyl chloride reassessment. Such extraordinarily high rates of uncertainty raises obvious concerns about modeling accuracy, as well as concerns about "model shopping" by researchers trying to find a model that gives a desired outcome rather than one that predicts outcomes accurately.

The agency removed default safety factors in applying animal data by relying on an unproven computer program designed to model how a chemical behaves in the human body

The general problems of pharmacokinetic models are severely compounded in the case of vinyl chloride by EPA's decision to confine its consideration of modeling to a single version developed by Harvey J. Clewell. The Clewell model was not validated for exposures that occur routinely in the environment. It thus could not and was not validated for its intended purpose — to accurately predict effects in humans. The inadequate verification of the Clewell model makes it a very poor policy choice as a basis for the reevaluation of vinyl chloride toxicity. Furthermore, the Clewell model was confined to liver tumors, ignoring all the other tumors of concern. Using such a limited model to justify dropping safety factors for cancers other than liver cancer added insult to injury.

The fatal blow to the technical credibility of EPA's vinyl chloride decision is that industry scientists drafted the final decision-making document. The revised toxicological profile, known formally as the 2001 Vinyl Chloride Toxicological Review, is known in the world of science as a "technical review paper," consisting of a literature collection, analysis, and interpretation. Vinyl chloride is but the first of four chemicals where industry is drafting the review. (The others are styrene, ethylene oxide, and toxaphene.)

In the scientific community, it is widely understood that technical reviews, like similar efforts in other disciplines, are heavily influenced by an author's subjective judgment regarding such issues as which studies to include, which studies to declare flawed or irrelevant, and which methodologies to favor. The danger of tainting a technical review with the unrestrained bias of its author provoked the prestigious *New England Journal of Medicine* to prohibit "editorialists and authors of review articles" from having "*any* financial connection with a company that benefits" from the subject of the article. The *Journal's* decision was announced in a lengthy editorial published in 1996 expressing mortification about its earlier publication of such a paper authored by two industry experts with obvious, but undisclosed, conflicts of interest.

In theory, EPA's Science Advisory Board is where the buck stops on bad scientific practice within the agency, serving as a safety net to protect against the types of abuses that run rampant when the generation of scientific evidence and the

selection of salient research are both determined by industry. In reality, the SAB suffers from many of the same weaknesses that were manifest at the staff level in the vinyl chloride reassessment. Too often, the SAB operates in a context where self-interested research dominates the agenda of the outside experts recruited for peer review. The seriousness of these problems is exacerbated when studies important to EPA, such as those specifically delineating the potency of a certain carcinogen, have not been published in a peer-reviewed journal and therefore were never subject to an objective evaluation by a disinterested party.

Last June, a General Accounting Office report evaluating the SAB review process found that "to be effective, peer-review panels must be . . . free of any significant conflict of interest and uncompromised by bias." In the report, "EPA's Science Advisory Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance," GAO auditors examined the procedures employed by SAB staff to ensure panel effectiveness. GAO found that, despite the requirements of the Federal Advisory Committee Act, agency staff often failed to obtain conflict of interest disclosures from candidates and that EPA did not have either the information or processes in place that would preclude the appointment of panelists with direct conflicts of interest. The result of these omissions is the appointment of too many panels disproportionately influenced by industry experts motivated to clear chemicals of prior findings of toxicity. Many SAB panels escape this fate, but enough suffer from these ethical lapses to undermine the credibility of the entire EPA peer-review process.

After a decade of research pursuing claims that dioxin is not as toxic as initially thought, agency staff concluded that the chemical is in fact more toxic than original estimates

One example of these problems is EPA's star-crossed effort to strengthen public health standards for arsenic in drinking water, mentioned earlier. An SAB review panel took on no less an entity than the NAS arsenic panel. NAS experts typically spend two or more years reviewing available science on an issue, and this particular panel had clearly mastered the data before it recommended tightening the standard. In contrast, SAB panels too often make recommendations within a period of a few months and with many fewer world-renowned experts. Only after an additional NAS panel took the SAB panelists to task for flaws in its analysis did the SAB panel back off its contention that EPA's in-house scientists had erred. Although this episode had a happy ending, the SAB arsenic toxicity panel was part of the problem, not the solution, of this contentious public health debate.

But perhaps the best case study of the weaknesses that increasingly overwhelm the SAB is its participation in the reassessment of dioxin, which is released by incineration of chlorinated materials and also by paper bleaching. Starting in 1990, EPA staff spent a decade pursuing claims that dioxin was not as toxic as initially thought, producing a final report consisting of several thousand pages that concluded the opposite: that dioxin is even more toxic than the agency's original estimates. But an SAB panel appointed to peer review a draft of the study concluded in 2001 that in-house scientists had exaggerated the risks posed by exposure to the chemical. These assertions not only challenged the competence of the EPA staff who wrote the report, they erected a barrier to its release. During the public outcry that followed, it emerged that a large number of panel members had worked for — or received funding from — industries with a clear financial stake in the outcome of the deliberations.

For example, John Graham, a political scientist appointed to the panel, served as director of the Harvard Center of Risk Analysis, which receives extensive funding from companies facing liability for dioxin contamination of the environment. (Graham now serves as head of the White House's Office of Information and Regulatory Affairs, which evaluates the

costs and benefits of rules before they are published as final. The Natural Resources Defense Council opposed his nomination.) Appointment of a second panelist, Dennis Paustenbach, was questioned for similar reasons. Research by the Center for Health and Environmental Justice found that fully a third of the panel members received organizational support from 91 dioxin-producing companies. As a result, members of Congress accused EPA of setting up a panel dominated by industry bias. Witnesses at the public hearing on the results of the SAB peer review repeated these charges, questioning the credibility and the integrity of the panel.

Yet the clear appearance — and likely existence — of impropriety is only a threshold conclusion that should prompt further investigation. Regardless of the panelists' links to self-interested industries, the crucial point is the soundness of the SAB's assertion that EPA staff did not consider alternative scientific theories about dioxin's toxicity and, as a result, overstated the degree of scientific certainty regarding the overall toxicity of the compound. Stung by these attacks, William Farland, the acting deputy assistant administration in charge of the reassessment, took the unusual step of entering the fray. In defending the agency's work, Farland provided the SAB's Executive Committee, which must ratify all SAB panel reports, with nine pages of blistering comments on the panel's draft. He said that the review contained "numerous errors or distortions of fact" and that its major conclusions "defied logic." He added that the panel's report was internally inconsistent with the discussion of the science held in open session at prior review meetings; was inconsistent with advice provided by SAB panels on earlier versions of the reassessment; and was inconsistent with EPA's general risk assessment procedures.

The SAB attacked the staff report. It said that dioxin does not initiate cancer but promotes existing cancers. And it said that low doses of dioxin might actually be beneficial

Farland was particularly critical of the SAB's review of the dioxin risk assessment methodology, asserting that the panel had a poor understanding of both EPA guidance on risk assessment and the research available on dioxin. For example, the panel had questioned whether a "linear dose response curve" for cancer was warranted because there is some evidence that dioxin is a promoter of the disease, rather than an initiator. A linear dose response curve is a line that runs all the way down to a dose of zero. It is used when evidence is inconclusive as to whether there is a threshold dose below which exposure does not cause cancer. In the interest of safety, where data are inconclusive, a linear curve assumes that any dose — no matter how small — will lead to an adverse health effect.

The SAB panel argued that exposure to dioxin exacerbates the growth of cancerous cells that have already begun to grow in the body as a result of another cause, but does not itself initiate the cancer. In other words, there is a threshold, the panel said, below which dioxin exposure is unimportant because some other factor is causing the disease. The panel further complained that use of a nonlinear model would have resulted in a significant downgrade of the chemical's overall toxicological profile because it would have shown that small doses of the chemical are not harmful. "Belief is one thing," Farland responded, "data is another." EPA policy commands the use of a linear model when use of alternative models cannot be justified from the available data, as was the case here. There were neither data nor policy justifications to diverge from a linear default model for dioxin's cancer effects.

Similarly, Farland was incredulous that the SAB panel gave credence to the possibility that very low doses of dioxin were actually beneficial, resulting in decreases in cancer rates. The panel had urged EPA to give this counter-intuitive possibility additional scrutiny. However, EPA's extensive data showed that dioxin could cause adverse health effects at the relatively low levels that already occur in the general population. Farland pointed out that animal data are unequivocal on this point and that human data, though limited, are also compelling.

Ultimately, the controversy triggered by the panel's report on dioxin compelled the SAB Executive Committee to substantially rewrite the summary and conclusions of the report, producing a credible outcome — but illustrating the perils of lax ethical rules in lower-profile proceedings. Recognizing that this incident and the GAO report threatened the credibility of the SAB itself, the Executive Committee agreed to set up a subcommittee that will recommend reform of SAB policies and procedures on bias and conflict of interest.

As it crafts these policy and procedural guidelines for release later this year, the SAB will undoubtedly consider the approach taken by 12 medical journals that have faced equally serious challenges to their reputations as sources of credible life science in the context of pharmacology, a discipline that is the genesis of environmental toxicology. The crisis in the medical community started simmering in 1988 when the Boots Company, a British pharmaceutical manufacturer, hired Betty Dong, a researcher at the University of California in San Francisco, to do a research study designed to demonstrate the superiority of the company's bestselling thyroid medication, Synthroid, in comparison to generic versions. With Synthroid sales in the $600 million range in the United States alone, Boots had a large stake in demonstrating that generic versions are not "bioequivalent," and therefore should not be substituted for its name brand. To Boots's horror, the study found that the generics were in fact bioequivalent. The company then spent four years working to discredit the research, raising a litany of technical objections to its protocols and their implementation. Despite this campaign, extensive investigation upheld the soundness of the study.

In 1994, in the midst of this maneuvering, Dong submitted an article based on the study to the *New England Journal of Medicine*. The article, accepted for publication following peer review by five outside experts, explained that the finding of bioequivalence meant U.S. health care costs could be cut by $356 million annually if patients substituted generic medications. The company immediately threatened to sue Dong, citing a provision in her research contract that required her to obtain the company's written consent before publishing. The University of California began to waver in its support, and Dong pulled the piece, triggering an intense investigation by the publication.

The *Journal* finally published the article in 1997, along with an article reporting that in a survey of 2,100 life science researchers, nearly 20 percent reported having delayed the publication of research results for more than six months. Of the 410 researchers willing to report such delays, 28 percent said the reason was "to slow dissemination of undesired results." A subsequent Carnegie Mellon University canvass of contracts at university-sponsored research centers found that 35 percent of signed agreements allowed sponsors the right to delete information from publication; 53 percent allowed publication to be delayed; and 30 percent allowed both. To medical journal editors, these troubling findings were the unavoidable byproduct of sharp increases in industry funding and increased blending of business interests and science at both the individual researcher and university levels.

The agency must reserve for its staff the sensitive task of writing toxicological profiles and should never again delegate such work to self-interested industry scientists

What are the implications of this all-pervasive industry funding of university research? In a recent article published in *Risk Policy Report*, David Clarke, a longtime observer of the controversies involved in toxic regulation who now participates in the sound science debate on behalf of the American Chemistry Council, argued that the simple fact that a study is funded by industry does not mean that it is wrong, or even biased. Regardless of whether you accept this counter-intuitive argument that money does

not buy influence, it is certainly true that industry-sponsored research will remain the primary source of information on toxics for the foreseeable future and that effective reform must be premised on that fact.

Empirical studies have documented the correlation between funding and results. For instance, one analysis found that 98 percent of industry-funded research reported positively on the efficacy of specific drugs, versus 79 percent of independent research. Because we cannot eliminate our dependence on such research, but suspect that funding may affect the outcome, all the other checks and balances — from disclosure of funding sources to peer review — become all the more important.

EPA should establish a peer review process that eliminates panelists with actual or potential conflicts of interest and balances competing scientific views

Last September, in reaction to stories and statistics like these, the editors of the world's leading medical journals announced that they would no longer "review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication." The editors promised to release detailed guidelines on this prohibition, and on their intention to require authors to disclose conflicts of interest related to a study, in early 2002. "I am not against pharmaceutical companies," Catherine DeAngelis, editor of the *Journal of the American Medical Association*, told the *Washington Post*. "What I object to is the use of my journal as an advertisement mechanism rather than a vehicle for the distribution of sound medical science."

The journals' new policy is expected to have a profound effect on the way medical research is funded and conducted. The journals are crucial to the dissemination of pharmaceutical research among the practicing physicians who serve as purchasing agents for all prescription drug sales. Television and print advertising are poor seconds to the influence they wield. Although these same reforms are necessary in the arena of environmental research, they may prove much harder to accomplish, especially given the fundamentally different economic incentives at work in investigations of the toxicological properties of common chemicals. In too many cases, chemical manufacturers have powerful incentives *not* to know whether their products are toxic; ignorance may help them sidestep liability and increased regulation. Unlike medicine, where publicizing efficacy is the quid pro quo for selling drugs, documenting the possible consequences of chemical exposure can only have a negative impact on sales. In fact, the only kind of scientific inquiry with potentially substantial financial benefits is research that exonerates chemicals — such as the two examples featured in our case studies.

As Wong's experience with the American Chemistry Council shows, the corporate funders of investigations into chemical toxicity, like the pharmaceutical companies, impose restrictive arrangements on their grantees. Given the dearth of government funding for such basic research, and the fact that it is unlikely to bring prestige to any truly independent research institution, these restrictions are likely to persist in the absence of strong action by EPA and other regulatory agencies.

Six categories of reform are needed to restore the credibility of science at EPA. First, the agency must focus on encouraging research that will close the gap in our understanding of the toxicity of common chemicals, rather than spending scarce resources on efforts to exonerate chemicals with a proven track record. Second, EPA must refuse to consider, in any context, the results of research that does not satisfy the central tenets of sound science: full disclosure of underlying data and no sponsor interference with the design of the study or release of results. As with the medical journals, EPA should disclose the sponsor of the research for all the key articles it relies upon for its decisionmak-

ing. Third, EPA must establish a peer review process that eliminates panelists with actual or potential conflicts of interest. Given the problems reported by the medical journals, it cannot rely exclusively on peer review by others, even peer-reviewed articles that have been published. Fourth, since many scientists are biased in the sense that they have strong opinions, peer-review panels must be balanced with regards to scientific view. To achieve the crucial objective of preventing the domination of peer review by one or another self-interested constituency, EPA must conduct expanded recruitment of experts who have no conflicts and represent a full range of scientific view. Fifth, EPA must reserve for its staff the sensitive task of writing toxicological profiles and should never again delegate such work to self-interested industry scientists. Last, increased government funding for basic research would go a long way toward making the first five reforms possible.

To implement the first reform, EPA scientists should make it their overriding priority to compile a research agenda based on such factors as the prevalence of a chemical in commerce and in the environment; the seriousness of its suspected adverse health or environmental effects; and the state of our ignorance of the chemical's toxicological properties. Once a list of priorities is developed, and the expense of further research can be estimated more accurately, the agency will be in the position to convince the executive branch and affected industries that further research is urgent.

Suspending decisions until scientists tell us exactly what will happen makes no more sense than forcing people to self-insure or refusing to engage in long-term military planning

Ending any consideration of studies that breach core principles of research ethics is the easiest reform to implement, and is most akin to the joint policy statement announced by the world's leading medical journals. Indeed, it is hard to imagine anyone arguing the converse of this proposition: namely, that EPA staff should rely on research findings to revise regulatory requirements even when they have never seen the underlying data that supports those conclusions. This principle is particularly important in the context of studies funded by entities with a financial stake in the regulatory decisions that the studies ostensibly inform, although it should by rights apply across the board to any piece of scientific evidence offered for EPA's consideration. It is worth noting that the government gives agencies specific powers in this regard for studies that they fund. Office of Management and Budget Circular A-110 specifies that an agency is entitled to unrestricted access to grantees' records related to the award, including research data. To accomplish this reform, EPA should require that authors of studies submitted for its consideration sign comprehensive statements regarding their funding sources and the limits imposed by their research contracts. EPA should publicize the sources of funding for each major study it relies upon for its decisions.

As for the troubled peer-review process, EPA should not recruit candidates with actual or potential conflicts of interest to serve on SAB advisory committees (including subcommittees) or any other panel of scientific experts convened to provide EPA with advice. Conflicts of interest should encompass any financial interest that would impair the individual's objectivity, including such characteristics as stock ownership or employment by an organization with a direct financial interest in the outcome of the review, such as the award of research grants. If the prohibition on nominees with conflicts of interest makes it impossible to convene a panel consisting of members with sufficient expertise to give EPA the advice it is seeking, the administrator should waive such conflicts in written, individualized determinations subject to public review. EPA may include candidates with actual or potential bias regarding the issues to be addressed by the panel, provided that the panel's overall membership is balanced. In this context, bias should encompass any predisposition resulting from professional affiliation, previous work, social relationship, or conflict of interest that could influence the

candidate's views of the information or policy alternatives at stake in the panel's deliberations.

At the moment, candidates for EPA peer-review panels and other scientific advisory functions are selected from an existing list kept by the SAB staff. The agency clearly needs to develop a larger pool of scientific experts qualified to serve on SAB committees and panels. Within legal constraints, the administrator should explore ways to compensate scientific experts at the prevailing market rate for their services, both to expand the pool of candidates and to eliminate the advantage of industry-funded scientists who are able to earn a living doing such work.

The precautionary principle lies at the heart of the controversy over the role of science in the regulatory state. The principle means taking action to prevent harm to human health or the environment, even if the relationship between the cause and the effect is not fully established scientifically. As applied, it can mean taking preventive measures to reduce pollution; shifting the burden of proving the safety of polluting activities to those who wish to engage in them; or searching for safer alternatives to releasing the pollutant into the environment. Or, as Governor Whitman put it so well: "The absence of certainty is not an excuse to do nothing."

Some commentators have argued that application of the precautionary principle is essentially a policy choice, implicitly suggesting that scientists leave the room when such decisions are made. At the opposite end of the spectrum, conservative commentators argue that when science becomes uncertain, the only alternative is to work harder to make it better, forestalling regulatory action until a reasonable level of certainty can be achieved.

While both arguments are extreme, the second is transcendent at the moment and is likely to prove far more harmful to the credibility of science over the long run. By cloaking a decision not to act as a purely scientific judgment, scientists are saddled with the burden of being wrong, of failing to take protective action in the face of what emerges as a real threat. When the sources of financial support for additional research are obviously self-interested, the public will be left with the clear impression that science was sold to the highest bidder.

Only by acknowledging that it is the exceptional case where we will have definitive data can we hope to restore science to its rightful place in environmental decisionmaking

We cope with uncertainty in all aspects of modern human endeavor. The whole concept of insurance is based on the proposition that we can try to predict the future on the basis of facts about the past, but in the end are willing to pay a fee to ameliorate the consequences if we end up among the injured. If we were certain what the future would bring, insurance would be unnecessary because we could either save funds to address the risk, or make plans to avoid the risk.

Similarly, as the United States becomes the world's dominant peacekeeper, we are constantly faced with the imperative of predicting the worst case scenarios that could occur in such situations and doing everything possible to ensure both the success and the safety of our military forces. No public official would consciously decide to absorb more casualties in order to lower the costs of equipping our troops to cope with such scenarios, although those precautionary measures often are triggered by no more than an educated guess by experts.

Like insurance underwriting or defense, environmental regulation needs to encompass the best information available at the time a decision must be made. Suspending decisions until scientists tell us exactly what will happen makes no more sense than forcing people to self-insure or refusing to engage in long-term military planning. Only by acknowledging that it is the exceptional case where we will have definitive data can we hope to restore science to its rightful place in environmental decisionmaking. •

June 10, 2003

BY FACSIMILE
Ms. Rena I. Steinzor
Professor, University of Maryland &
Board Member, Center for Progressive Regulation
500 West Baltimore Street
Baltimore, MD 21221

Dear Ms. Steinzor:

This letter follows up on the June 6, 2003 hearing of the Government Reform Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Elevation of the Environmental Protection Agency to Department Level Status: H.R. 37 and H.R. 2138." First, I would like to thank you for your thoughtful written and oral testimony on the merits of the two bills. Second, as discussed during the hearing, please answer the following question for the hearing record:

> At the top of page four of your written testimony, you provided four suggestions for reforming science at EPA. What legislative language would you propose to make these changes?

Please send your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building by June 24, 2003. If you have any questions about this request, please call Subcommittee Professional Staff Member Danielle Hallcom at 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural
Resources and Regulatory Affairs

cc The Honorable Tom Davis
The Honorable John Tierney

BY ELECTRONIC MAIL

June 20, 2003

The Honorable Doug Ose,
Chairman
The Honorable John Tierney,
Ranking Minority Member
United States House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy,
Natural Resources and Regulatory Affairs
Rayburn House Office Building
Washington, D.C. 20515-6143

Re: Follow up Question concerning Testimony on "Elevation of the Environmental Protection Agency to Cabinet Status," June 6, 2003

Dear Chairman Ose and Ranking Member Tierney:

Thank you for the opportunity to testify before the Subcommittee on behalf of the Center for Progressive Regulation (CPR). We appreciate your interest in our views.

I have received a letter dated June 10, 2003 from Chairman Ose asking me to propose legislative language to implement changes in the process for considering science that were mentioned on page 4 of my written testimony. As much as CPR would like to accommodate the Chairman's request, we are not yet ready as an organization to translate those reforms into legislative language.

The reforms were presented in the testimony as illustrative of reforms we have advocated, along with other changes, to improve the effectiveness of environmental and other health and safety regulation. We recently convened a group of CPR member scholars and scientists engaged in the Project on Scientific Knowledge and Public Policy to discuss these and other issues involving EPA's use of science. Until we have had an opportunity to pursue those discussions, we will not be in a position to present comprehensive recommendations in this area.

Again, thank you for your consideration of my views. If you have any further questions or comments, please do not hesitate to contact me.

Sincerely,

Rena I. Steinzor
Professor of Law,
University of Maryland School of Law
Board Member, Center for Progressive Regulation

June 10, 2003

BY FACSIMILE
Mr. Wesley Warren
Senior Fellow for Environmental Economics
Natural Resources Defense Council
1200 New York Avenue, N.W. - Suite 400
Washington, DC 20005

Dear Mr. Warren:

This letter follows up on the June 6, 2003 hearing of the Government Reform Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Elevation of the Environmental Protection Agency to Department Level Status: H.R. 37 and H.R. 2138." First, I would like to thank you for your thoughtful written and oral testimony on the merits of the two bills. Second, as discussed during the hearing, please answer the following question for the hearing record:

> On page seven of your written testimony, you state that the confidentiality provision as written in H.R. 2138 may "bar the distribution of valuable information that the public receives presently under current law." Please identify the language in question and explain how it could bar distribution of information to the public. Please provide proposed legislative language to adequately protect the confidentiality of sensitive information and ensure public access to information.

Please send your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building by June 24, 2003. If you have any questions about this request, please call Subcommittee Professional Staff Member Danielle Hallcom at 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

cc The Honorable Tom Davis
The Honorable John Tierney

NATURAL RESOURCES DEFENSE COUNCIL

BY HAND
The Honorable Doug Ose
Chairman
Subcommittee on Energy Policy,
Natural Resources and Regulatory Affairs
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Mr. Chairman:

On June 10, 2003 you requested additional views from the Natural Resources Defense Council on H.R. 37 and H.R. 2138, bills to elevate the Environmental Protection Agency to department level. The attached insert, prepared by NRDC in June of 2003, provides our answer to the question in your letter.

Thank you for the opportunity to provide this information to you. We greatly appreciate your consideration of our views on this important issue.

Sincerely,

Wesley Warren
Senior Fellow for
Environmental Economics

Enclosure

cc The Honorable John Tierney

www.nrdc.org 1200 New York Avenue, NW, Suite 400
Washington, DC 20005
TEL 202 289-6868 FAX 202 289-1060

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[insert]

NRDC raised as a concern in its testimony the possibility that section 8(h)(2) of the draft bill, which prohibits the Director from disclosing "personally identifiable or corporately identifiable data collected by the Bureau," could be construed to cover data and other information guaranteed to the public under environmental and public health statutes. Upon further analysis of the savings provisions in section 11(a), it is our conclusion that such data and information would not be affected if guaranteed in statutes administered by EPA. However, it would be helpful to the legislative history of this bill to receive confirmation of this conclusion from the Committee. Furthermore, due to the breadth of the language, it would be useful for the Committee to consider whether section 8(h) could inadvertently affect information shared with the Department of Environmental Protection but collected under statutes administered by other federal agencies.

The original concern in the NRDC testimony was prompted by the possibility that the language of section 8(h) was open to a unintended reading that would override public information guarantees in other statutes. In my oral testimony, I mentioned as an example the Clean Air Act's guarantee of the public availability of "emissions data," 42 U.S.C. 7414(c), which is basic pollution data crucial to public understanding of air pollution, its sources and magnitude, and its regulation. The Clean Air Act's acid rain trading program, for example could not function properly without the public availability of this type of emissions data. In our view, the language of section 8(h)(2) is broad enough to prohibit disclosure of "emissions data" otherwise available under the Clean Air Act, if submission of such data is first made to the Director. It may also be likely that other public availability and public disclosure provisions of federal environmental statutes, or other statutes for that matter, could be impacted by this broad language.

Nevertheless, as noted above, we now conclude that the savings provisions of section 11(a) are broad enough to prevent the override of otherwise available public information guarantees in statutes administered by EPA.

ELEVATION OF THE EPA TO DEPARTMENT LEVEL STATUS: FEDERAL AND STATE VIEWS

TUESDAY, SEPTEMBER 9, 2003

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2 p.m., in room 2154, Rayburn House Office Building, Hon. Doug Ose (chairman of the subcommittee) presiding.

Present: Representatives Ose, Shays, Cannon, Tierney, Kucinich, and Waxman [ex officio].

Staff present: Dan Skopec, staff director; Barbara Kahlow, deputy staff director; Danielle Hallcom, professional staff member; Melanie Tory, junior professional staff member; Anthony Grossi, legislative clerk; Yier Shi, press secretary; Phil Barnett, minority chief counsel; Alexandra Teitz and Krista Boyd, minority counsels; and Jean Gosa, minority assistant clerk.

Mr. OSE. Good afternoon and welcome, everybody, to today's hearing on the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs.

Today the subcommittee will hold its fifth hearing on the topic of elevating the Environmental Protection Agency to Cabinet-level status. President Nixon created EPA in 1970 and since that time, Congress has passed several landmark environmental laws such as the Clean Water Act, Clean Air Act, Safe Drinking Water Act. Each time, EPA's jurisdiction has increased significantly but its structure remains the same as originally envisioned. As Congress considers elevating EPA to the Cabinet, we should also consider whether an organizational structure created in 1970 is best suited for a new department charged with one of the government's most important roles, protecting the health of our Nation's citizens and environment.

During the last Congress, this subcommittee held three hearings addressing EPA elevation bills introduced by former Congressman Steve Horn and Congressman Sherwood Boehlert. Experts and public officials testified to the merits of elevation and current organizational problems at EPA that hinder effective environmental protection. On June 6, 2003, this subcommittee heard testimony from think tank and academic experts regarding the merits of the two EPA elevation bills before the current Congress. The first bill, H.R. 37, was introduced by our colleague, Congressman Sherwood Boehlert, and is identical to 2438, as introduced in the 107th Con-

gress. H.R. 37 elevates EPA to department-level status but makes no reforms in its structure.

I believe that EPA's structure as it currently exists lacks adequate oversight and coordination within offices to ensure that science, policy and implementation are integrated throughout EPA. I also believe that science at EPA must be improved. Based on the expert testimony from our previous hearings in the last Congress, I introduced H.R. 2138 on May 15. Currently, each EPA regional office, program office and division reports directly to the EPA's Administrator and Deputy Administrator. And the chart on the left over here is the diagram that reflects that.

My bill would make important organizational and institutional changes to EPA in order to eliminate the stovepipe structure reflected in that chart. It reorganizes EPA into three Under Secretaries: first, Policy, Planning and Innovation; the second, Science and Information; and the third, Compliance, Implementation and Enforcement. The Under Secretary for Policy Planning and Innovation would have authority over all program offices, regulations and policy development. The Under Secretary for Implementation, Compliance, and Enforcement would supervise the regional offices, assist States in coordinating with program offices, and head EPA's enforcement effort and that is reflected on that second chart on the right.

My bill responds to the overwhelming feedback about the lack of sound science at EPA by creating an Under Secretary for Science and Information. This section mirrors legislative language from H.R. 64, the Strengthening Science at the EPA Act, introduced by Congressman Vernon Ehlers, which passed the House in the 107th Congress. Witnesses at June's hearing supported this provision, stating that EPA's science should be consolidated into one centralized division. At a minimum, this organization will advance environmental protection by conducting peer-reviewed scientific studies of the highest caliber and provide a level of separation between regulators and scientists.

Finally, at June's hearing, witnesses testified that EPA needs an independent statistical agency to report on meaningful environmental and human health performance indicators. My bill creates an independent Bureau of Environmental Statistics modeled after the successful Energy Information Administration to collect, analyze, and report on environmental and human health conditions. Under the leadership of former administrator Whitman, EPA published a draft State of the Environment Report in an effort to move toward outcome measurements. While EPA's report is a step in the right direction, only a statutorily required, peer reviewed, and independent Bureau of Environmental Statistics will move EPA toward the goal of implementing meaningful outcome measurements.

It is important to note my intention that EPA elevation will not alter any of the Agency's jurisdiction nor will it address any substantive or nonsubstantive environmental laws that guide EPA's action. This is a structural discussion only. Instead, my bill will elevate the Agency to a Department and provide the Department of Environmental Protection with the structure and tools to most effectively address the environmental challenges of the 21st century. I am, of course, open to improvements to this bill to meet this

goal, and I hope that Congress does not pass up this opportunity to make important reforms.

I look forward to the testimony of our distinguished witnesses here today. They include Marianne Horinko, who is the Acting Administrator of the EPA; Mr. James Connaughton, chairman of the Council on Environmental Quality. Our second panel has State Representative Warren Chisum from the Texas House of Representatives; Mr. Howard Roitman, director of environmental programs from Colorado; Dr. Ron Hammerschmidt, director, Division of Environment, Kansas Department of Health and Environment; E. Donald Elliott, former EPA General Counsel and partner at the law firm of Wilkie, Farr & Gallagher; Dr. Alan Moghissi is president of the Institute for Regulatory Science; and Mr. Gary Guzy, former EPA General Counsel and partner at the law firm of Foley Hoag, LLP.

[The prepared statement of Hon. Doug Ose follows:]

Chairman Doug Ose
Opening Statement
Elevation of the EPA to Departmental Level Status: Federal and State Views
September 9, 2003

Today, the Subcommittee will hold its 5th hearing on the topic of elevating the Environmental Protection Agency (EPA) to a cabinet level department. President Nixon created EPA in 1970. Since that time, several landmark environmental laws, such as the Clean Water Act, the Clean Air Act, and Safe Drinking Water Act have been enacted. Each time, EPA's jurisdiction increased significantly but its structure remained the same. As Congress considers elevating EPA to the cabinet, we should also consider whether an organizational structure created in 1970 is best suited for a Department charged with one of government's most important roles: protecting the health of our nation's citizens and environment.

During the last Congress, this Subcommittee held three hearings addressing EPA elevation bills introduced by Congressman Sherwood Boehlert and former Congressman Steve Horn. Experts and public officials testified to the merits of elevation, and current organizational problems at EPA that hinder effective environmental protection. On June 6, 2003 this Subcommittee heard testimony from think tank and academic experts regarding the merits of the two EPA elevation bills before the current Congress. The first bill, H.R. 37, was introduced by Congressman Sherwood Boehlert and is identical to H.R. 2438, as introduced in the 107th Congress. H.R. 37 elevates EPA to department level status but makes no reforms.

I believe that EPA's structure, as it currently exists, lacks adequate oversight and coordination of its offices to ensure that science, policy and implementation are integrated throughout EPA. I also believe that science at EPA must be improved. Based on the expert testimony from our previous hearings in the last Congress, I introduced H.R. 2138 on May 15th. Currently, each EPA Regional office, program office and division reports directly to EPA's Administrator and Deputy Administrator (see the first chart on display). My bill would make important organizational and institutional changes to EPA in order to eliminate the stovepipe structure. It reorganizes EPA into three Under Secretaries: (1) Policy, Planning, and Innovation; (2) Science and Information; and, (3) Compliance, Implementation, and Enforcement. The Under Secretary for Policy, Planning, and Innovation would have authority over all program offices, regulations and policy development. The Under Secretary for Implementation, Compliance, and Enforcement would supervise the Regional offices, assist States in coordinating with program offices, and head EPA's enforcement effort (see the second chart on display).

My bill responds to the overwhelming feedback about the lack of sound science at EPA by creating an Under Secretary for Science and Information. This section mirrors legislative language from H.R. 64, "Strengthening Science at the EPA Act," introduced by Congressman Vernon Ehlers, which passed the House in the 107th Congress. Witnesses at June's hearing supported this provision, stating that EPA's science should be consolidated into one centralized division. At a minimum, this organization will advance environmental

protection by conducting peer-reviewed scientific studies of the highest caliber and provide a level of separation between regulators and scientists.

Finally, at June's hearing, witnesses testified that EPA needs an independent statistical agency to report on meaningful environmental and human health performance indicators. My bill creates an independent Bureau of Environmental Statistics, modeled after the successful Energy Information Administration (EIA), to collect, analyze, and report on environmental and human health conditions (see the third chart on display). Under the leadership of former Administrator Whitman, EPA published a draft State of the Environment Report in an effort to move towards outcome measurements. While EPA's report is a step in the right direction, only a statutorily-required, peer reviewed, and independent Bureau of Environmental Statistics will move EPA towards the goal of implementing meaningful outcome measurements.

It is important to note my intention that EPA elevation will not alter the agency's jurisdiction or the substantive environmental laws that guide EPA's action. Instead, my bill will elevate the agency to a department, and provide the Department of Environmental Protection with the structure and tools to most effectively address the environmental challenges of the 21st Century. However, I am open to improvements to this bill that meet this goal. Congress must not pass up this opportunity to make important reforms.

I look forward to the testimony of our distinguished witnesses here today. They include: Marianne L. Horinko, Acting Administrator, EPA; James L. Connaughton, Chairman, Council on Environmental Quality; State Representative Warren Chisum, Texas House of Representatives; Howard Roitman, Director of Environmental Programs, Colorado Department of Public Health and Environment; Dr. Ron Hammerschmidt, Director, Division of Environment, Kansas Department of Health and Environment; E. Donald Elliott, former EPA General Counsel and partner at the law firm of Willkie, Farr & Gallagher; Dr. A. Alan Moghissi, President, Institute for Regulatory Science; and Gary S. Guzy, former EPA General Counsel and partner at the law firm of Foley Hoag LLP.

September 2, 2003

MEMORANDUM FOR MEMBERS OF THE GOVERNMENT REFORM SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS

FROM: Doug Ose

SUBJECT: Briefing Memorandum for September 9, 2003 Hearing, "Elevation of the EPA to Department Level Status: Federal and State Views"

On Tuesday, September 9, 2003 at 2:00 p.m., in Room 2154 Rayburn House Office Building, the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs will hold a second legislative hearing on two bills seeking to elevate the Environmental Protection Agency (EPA) to department level status. The hearing is entitled "Elevation of the EPA to Departmental Level Status: Federal and State Views."

In the last Congress, the Subcommittee explored EPA elevation at three hearings held on September 9, 2001, March 21, 2002, and July 16, 2002. At the time, two EPA elevation bills were referred to the Subcommittee: H.R. 2438 introduced by Congressman Sherwood Boehlert, and H.R. 2694 introduced by former Congressman Stephen Horn. Witnesses testified to both the merits of elevating EPA to department level status and the various problems at EPA that hinder effective environmental protection. During the 107th Congress, the Subcommittee did not markup either EPA elevation bill.

In the current Congress, two EPA elevation bills have been referred to the Government Reform Committee: H.R. 37 and H.R. 2138. H.R. 37, introduced by Congressman Sherwood Boehlert, is identical to H.R. 2438, as introduced in the 107th Congress, and simply elevates EPA to department level status. H.R. 2138, introduced by Congressman Doug Ose, provides for elevation while instituting structural changes to EPA's organization and a Bureau of Environmental Statistics[1].

[1] Several departments have independent statistical agencies, including the Commerce Department's Bureau of the Census, the Education Department's National Center for Education Statistics, the Energy Department's Energy Information Administration, Health and Human Services's National Center for Health Statistics, and the Labor Department's Bureau of Labor Statistics.

On June 6, 2003, the Subcommittee held a legislative hearing on both bills. Several experts from think tanks and academia testified to the merits of both bills. Witnesses testified to the need to improve the quality of science at EPA and the need for an independent statistical agency, such as the Bureau of Environmental Statistics, to report on meaningful environmental and human health performance indicators. Moreover, witnesses reported that, to improve EPA's ability to meet the next generation of environmental challenges and implement cross-media analyses, the Agency's stovepipe structure should be reorganized.

Specifically, H.R. 2138 would reorganize EPA into three Under Secretaries: (1) Policy, Planning, and Innovation; (2) Science and Information; and, (3) Compliance, Implementation, and Enforcement (see Chart A). The Under Secretary for Policy, Planning, and Innovation would have authority over all program offices, regulations and policy development. The Under Secretary for Implementation, Compliance, and Enforcement would supervise the Regional offices and facilitate coordination with program offices. The Under Secretary for Science and Information would coordinate centralized scientific activities and ensure dissemination throughout the Department. Finally, the bill creates a Bureau of Environmental Statistics to collect, analyze and report on environmental and human health conditions, also supervised by the Under Secretary for Science and Information.

Many Federal departments utilize statistical agencies to provide independent and reliable data for decisionmaking and program evaluation. However, EPA does not systematically gather and analyze statistical data on environmental conditions to determine the success of EPA activities. Instead, EPA primarily uses output measurements (such as the number of permits and enforcement actions) instead of outcome measurements (such as cleaner water, fewer illnesses, and less days off from school or work) to determine whether EPA is reaching its goals. Under the leadership of former Administrator Whitman, in June 2003, EPA published a draft State of the Environment Report in an effort to move towards outcome measurements. However, the EPA science's lack of credibility, extensive use of policy advocacy, and revisions made by the Administration prior to issuance, caused many people to criticize EPA's report and discount its value. While EPA's report is a step in the right direction, only a statutorily-required, peer reviewed, and independent Bureau of Environmental Statistics will move EPA towards the goal of implementing meaningful outcome measurements.

Both H.R. 37 and H.R. 2138 redesignate EPA as the Department of Environmental Protection. Congress previously reorganized existing departments when creating new departments, such as the recently-enacted Homeland Security Act of 2003 (Pub. Law 107-296), Department of Education in 1979 (Pub. Law 96-98), and Department of Energy in 1977 (Pub. Law 95-91) (see Chart B). A question to be addressed at the hearing is whether Congress should include management and organizational changes in conjunction with the elevation of an existing Agency.

Under the current regime, EPA made great progress in the cleanup of the large industrial and municipal wastes that served as the impetus for EPA's establishment by President Nixon over 30 years ago. However, this nation faces a new generation of environmental challenges that stem not from major point source pollution, but from non-point

sources, such as agricultural and urban runoff, dry cleaners and mobile sources. The Subcommittee learned from both the June 6, 2003 and the last Congress' hearings that, in the face of these new challenges, the current fragmented structure and culture of EPA may hinder the Agency's ability to efficiently and effectively protect the environment and human health in the future.

Originally, the first EPA Administrator created a relatively small Agency with 4,084 employees, three Assistant Administrators, ten Regional offices, and five environmental commissioners. In the subsequent 30 years, EPA has grown to over 18,000 employees. Despite this expansion, EPA is organized into ten Regional offices, nine Assistant Administrators (program offices), and numerous other offices, each of which still reports directly to the Administrator and Deputy Administrator (see Chart C). In addition, since EPA's inception, Congress has passed at least 11 major environmental statutes based on environmental media or pollution source, each expanding EPA's jurisdiction. Hearing witnesses testified that this "stovepipe" structure hinders the dissemination of scientific data, innovative programs, and cross-media analysis. Witnesses reported that the lack of coordination and information sharing between program offices is particularly detrimental to successful policymaking.

Moreover, as a practical matter, scientific research is conducted in the program offices and the Office of Research and Development. During the Subcommittee's hearings, several witnesses testified that EPA's scientific decentralization requires regulators to search for data in multiple locations, facilitates incompatibility of databases, results in inefficient research planning, prevents adequate peer review, and fosters an uncooperative "fiefdom" culture within the program offices that stymies thorough scientific review. During the June 6, 2003 hearing, witnesses testified that, while science and policy are linked, too often regulators undermine scientific integrity by influencing the scientific studies and its interpretation.

Importantly, States play a vital role in the implementation of our environmental protection laws. Most States develop their own policies, regulations, and enforcement mechanisms based on the delegated authority of Federal environmental statutes. With these increased responsibilities, however, States face obstacles in coordinating with EPA program offices. Moreover, EPA Regional offices typically interpret Federal environmental laws inconsistently, causing uncertainty among States and the regulated community. Finally, States, faced with difficulties working with Regional and program offices, generally have no mechanism for resolving issues at a higher level.

EPA is charged with one of the most important tasks in government: protecting this Nation's environment and human health. Every President since President George H.W. Bush has asked the Administrator of EPA to sit on the Cabinet without formal designation as an executive department. In most industrialized nations, the leading environmental official is a formal member of the Cabinet or its equivalent.

The invited witnesses for the hearing are: Marianne L. Horinko, Acting Administrator, EPA; James L. Connaughton, Chairman, Council on Environmental Quality; State Representative Warren Chisum, Texas House of Representatives; Howard Roitman, Director of

Environmental Programs, Colorado Department of Public Health and Environment; Ron Hammerschmidt, Director, Division of Environment, Kansas Department of Health and Environment; Dr. A. Alan Moghissi, President, Institute for Regulatory Science; and Donald Elliott, former EPA General Counsel and currently a Partner in Willkie, Farr & Gallagher LLP.

Attachments

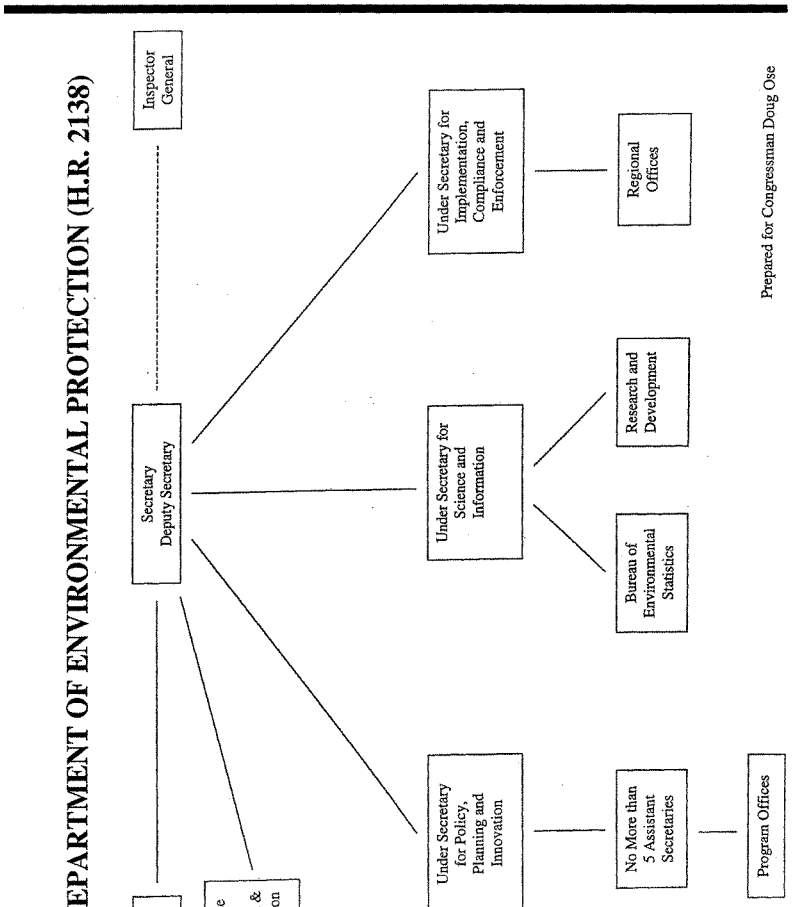


Chart A
DEPARTMENT OF ENVIRONMENTAL PROTECTION (H.R. 2138)
Secretary
Deputy Secretary
Inspector General
General Counsel
CFO / Office of Budget Management & Administration
Under Secretary for Policy, Planning and Innovation
Under Secretary for Science and Information
Under Secretary for Implementation, Compliance and Enforcement
No More than 5 Assistant Secretaries
Bureau of Environmental Statistics
Research and Development
Regional Offices
Program Offices
Prepared for Congressman Doug Ose

LAST SIX CABINET ELEVATIONS

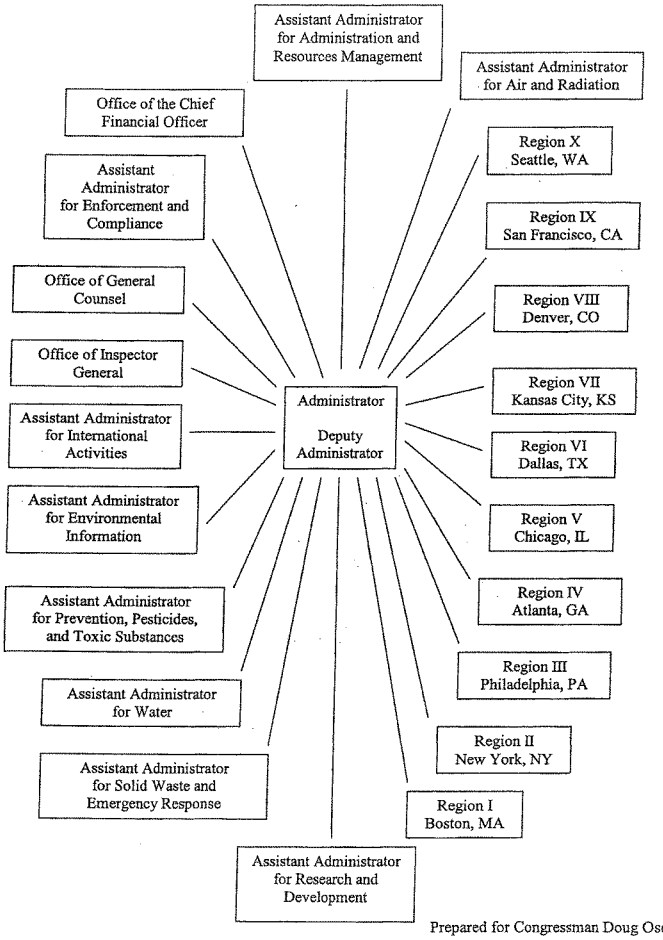
Department	Date	Law	Agency Transfers of Power
HUD	9/9/1965	PL 89-174	All of the functions, powers, & duties of the Community Facilities Administration, Federal Housing Administration, Federal National Mortgage Association (Fannie Mae), Housing & Home Finance Agency, Public Housing Administration, & Urban Renewal Administration
Transportation	10/15/1966	PL 89-670	**DOC** (Bureau of Public Roads, Nat'l Traffic Safety Agency/Nat'l Highway Safety Agency, Office of High Speed Ground Transportation, & Great Lakes Pilotage Administration), **DOI** (Alaska Railroad), **Treasury** (Bureau of Customs' vessel documentation functions & Coast Guard), Civil Aeronautics Board, Federal Aviation Agency, Interstate Commerce Commission, & St. Lawrence Seaway Development Corporation
Energy	8/4/1977	PL 95-91	All functions of **DOC** (Office of Energy Programs), **DOD** Navy (various), **HUD** (various), **DOI** (functions relating to electric power & 4 power marketing agencies - Bonneville, Southwestern, Southeastern, Alaska - & certain functions of Bureau of Mines), the Energy Research & Development Administration, Federal Energy Administration, & the Federal Power Commission
Education	10/17/1979	PL 96-88	Transfers from **DOD** (administration and operation of overseas dependents schools); **HEW** (Advisory Council on Education Statistics, Education Division, Federal Education Data Acquisition Council, Institute of Museum Services, Office for Civil Rights, & offices implementing the Rehabilitation Act of 1973); **HUD** (all functions relating to college housing loans); **DOJ** (all functions of the Attorney General & the Law Enforcement Assistance Administration with regard to the student loan & grant programs known as the law enforcement education & the law enforcement intern program); **DOL** (functions relating to programs for the education of migrant & seasonal farm workers); National Science Foundation (science education)
Veterans Affairs	10/25/1988	PL 100-527	Veterans' Administration (establishment & redesignation as a Department)

LAST SIX CABINET ELEVATIONS (Continued)

Department	Date	Law	Agency Transfers of Power
Homeland Security	11/25/2002	PL 107-296	**USDA** (agricultural import & entry inspection activities under the covered animal & plant health protection laws, & Plum Island Animal Disease Center) **DOC** (NOAA's Integrated Hazard Information System) **DOD** (National Bio-Weapons Defense Analysis Center) **DOE** (chemical & biological national security & supporting programs; nonproliferation & verification R&D program; nuclear smuggling program activities; proliferation detection program activities; nuclear assessment program; assessment, detection & cooperation program activities of the international materials protection & cooperation program; life sciences activities of the biological & environmental research program related to microbial pathogens; Environmental Measurements Laboratory; & Lawrence Livermore National Laboratory) **HHS** (Metropolitan Medical Response System, National Disaster Medical System, Office of Emergency Preparedness, Strategic National Stockpile, etc.) **DOJ** (Office of Domestic Preparedness, Domestic Emergency Support Teams; FBI's National Domestic Preparedness Office, Critical Infrastructure Assurance Office & National Infrastructure Protection Center; & INS' specified law enforcement & border management functions) **DOT** (Coast Guard homeland security missions & Transportation Security Administration) **Treasury** (Customs Service, various Secret Service functions, & Federal Law Enforcement Training Center) **FEMA** **GSA** (Federal Protective Service)

Prepared for Congressman Doug Ose

ENVIRONMENTAL PROTECTION AGENCY



Prepared for Congressman Doug Ose

Mr. OSE. I would like now to recognize my good friend and colleague, Mr. Tierney, for the purpose of an opening statement.

Mr. TIERNEY. Thank you, Mr. Chairman, and just to share with the two witnesses here, the big words on that is "small opening." I am glad we didn't have to sit through the big opening.

Thank you, Mr. Chairman, for conducting this hearing on an issue of great importance, I think, elevating the EPA to Cabinet-level status. I strongly support making it a permanent member of the President's Cabinet, but I couch that—as I say, we should do it in a manner that does not diminish the integrity of the Agency or its purpose. EPA's purpose is to protect the environment we live in, protect our land, our water, and our air. If Congress acts to change the status of the Agency, it should be acting to elevate the importance of environmental protection as a key policy of the U.S. Government.

Making EPA a Cabinet-level department is an important goal that should not be jeopardized through controversial provisions. We should not use an EPA elevation bill as a vehicle to weaken our enforcement laws while—environmental laws or their enforcement. I am concerned, however, that the chairman's bill contains some provisions that may warrant further discussion, certainly that some may see as controversial, and I mentioned that to the chairman before.

In considering any change to the EPA, it is important to look at the work that EPA is doing under the current administration. Several reports have surfaced this summer regarding EPA's lack of enforcement of our clean air and water laws. And just in the last few weeks EPA has taken a number of very troubling actions. For example, EPA finalized a rule that weakens the Clean Air Act by allowing thousands of old power plants to make upgrades to their power plants without installing pollution controls. These power plants and factories will be allowed to continue polluting the air without being held responsible for the damage they are causing to our health and to our environment. It was reported last week that EPA is relaxing restrictions on selling land contaminated with PCBs, the toxin that is known to have serious health consequences in children. Additionally, the EPA Inspector General recently issued a report stating that EPA was pressured by the White House to be less than candid about New York's air quality after the attacks on the World Trade Center. That caused understandable concerns to those brave first responders and emergency workers who risked their health to participate in weeks of grueling rescue and recovery efforts at Ground Zero.

It is not enough to talk about protecting our health and our environment. The actions of EPA and Congress must reflect a true commitment to the environment. Elevating the EPA should not be a vehicle for measures that would serve to weaken the laws that protect our health and environment nor that would redirect time and resources away from EPA's core missions.

I'm also a little bit concerned that the administration appears to have reversed its position on the EPA elevation bill and I look forward to hearing the administration witnesses explain this shift in position. Elevation of EPA should not be a divisive issue, but rather an issue that sends a clear and strong message that the protec-

tion of our national and global environment and our health is of the utmost importance. I look forward to hearing from you and our witnesses today.

Thank you, Mr. Chairman, for this hearing.

Mr. OSE. I thank the gentleman.

[The prepared statement of Hon. John F. Tierney follows:]

STATEMENT
REPRESENTATIVE JOHN F. TIERNEY
HOUSE GOVERNMENT REFORM COMMITTEE
SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND
REGULATORY AFFAIRS
HEARING ON EPA ELEVATION
SEPTEMBER 9, 2003

Mr. Chairman, thank you for holding this hearing on the issue of elevating EPA to cabinet-level status. As I have said before, I strongly support making EPA a permanent member of the President's cabinet. However, I support elevating EPA in a manner that does not diminish the integrity of the agency or its purpose. EPA's purpose is to protect the environment we live in--our land, our water and our air. If Congress acts to change the status of the agency, Congress should be acting to elevate the importance of environmental protection as a key policy of the United States government.

Making EPA a cabinet-level Department is an important goal that should not be jeopardized through controversial provisions. We should not use an EPA elevation bill as a vehicle to weaken our environmental laws or their enforcement. I am concerned, however, that the Chairman's bill contains some controversial provisions that warrant further discussion.

In considering any change to EPA, it is important to look at the work EPA is doing under the current Administration. Several reports have surfaced this summer regarding EPA's lack of enforcement of our clean air and water laws. And just in the last few weeks EPA has taken a number of very troubling actions. For example, EPA finalized a rule that significantly weakens the Clean Air Act by allowing thousands of old power plants to make upgrades to their plants without installing pollution controls. These power plants and factories will be allowed to continue polluting the air without being held responsible for the damage they are causing to our health and our environment.

It was reported last week that EPA is relaxing restrictions on selling land contaminated with PCB's, the toxin that is known to have serious health consequences in children. Additionally, the EPA Inspector General recently issued a report stating that EPA was pressured by the White House to be less than candid about New York's air quality after the attacks on the World Trade Center, causing understandable concern to those brave first responders and emergency workers who risked their health to participate in weeks of grueling rescue and recovery efforts at ground zero.

It is not enough to talk about protecting our health and environment. The actions of EPA and Congress must reflect a true commitment to the environment. Elevating EPA should not be a vehicle for measures that would serve to weaken the laws that protect our health and environment or that would redirect time and resources away from EPA's core missions. I am also concerned that the Administration appears to have reversed its position on an EPA elevation bill. I look forward to hearing the Administration witnesses explain this shift in position.

Elevation of EPA should not be a divisive issue but rather an issue that sends a strong and clear message that the protection of our national and global environment and our health is of the utmost importance. I look forward to hearing from all of our witnesses today on this issue. Thank you, Mr. Chairman.

Mr. OSE. As many of you know that have appeared before this committee, we routinely swear in our witnesses. I want to make sure I welcome them. We have two panels today. Our first panel, we are joined by representatives of the administration. We have Chairman James Connaughton from the Council on Environmental Quality. And we have the Acting Administrator for the Environmental Protection Agency, Ms. Marianne Horinko. And I welcome you both. And in line with our tradition here, if you would please rise.

[Witnesses sworn.]

Mr. OSE. Let the record show that the witnesses answered in the affirmative. And with that, we are pleased to welcome back to our forum Mr. James Connaughton, chairman of the Council on Environmental Quality. Mr. Connaughton, you are recognized for 5 minutes.

STATEMENTS OF JAMES L. CONNAUGHTON, CHAIRMAN, COUNCIL ON ENVIRONMENTAL QUALITY; AND MARIANNE L. HORINKO, ACTING ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

Mr. CONNAUGHTON. Thank you, Mr. Chairman, Mr. Tierney, and other members of the subcommittee. I am pleased to be here again before the subcommittee to discuss the Bush administration's support for elevating the U.S. Environmental Protection Agency to a Cabinet department. I am very pleased to share this panel with my good friend and colleague, Acting EPA Administrator Marianne Horinko.

In its short history, the U.S. Environmental Protection Agency has a long record of accomplishments. It is because of these accomplishments environmental quality in the United States has vastly improved.

Improved air quality is one of our Nation's greatest environmental successes. Air pollutants have been reduced by almost one-third since 1970, even as the Nation's gross domestic product has increased 160 percent, energy consumption increased 45 percent, and population increased 38 percent.

The Nation's water is cleaner. Today 192 million people are served by modern sewage treatment facilities. In the last decade alone, we provided safe drinking water to another 54 million Americans.

And the Nation's land is better protected. We are more able to provide benefit and refuge to our communities and support thriving ecosystems.

In 2002 and again this year, Representative Sherwood Boehlert of New York offered legislation to elevate EPA to a Cabinet department. I would like to take a minute to acknowledge and again thank Representative Boehlert for his continued leadership and ongoing support for elevating EPA to a Cabinet department. At the same time, I want to thank you, Representative Ose, Mr. Chairman, for your leadership and your desire to advance this important priority of the Bush administration and to do so in a way that meets the fundamental goal, the structural elements necessary to raise an agency up to a Cabinet department.

When I testified before this committee on the subject last summer, I emphasized that the Bush administration would work closely with the committee to advance EPA Cabinet legislation in order to make official what is already a reality in the Bush administration. Let me again highlight why EPA should be elevated to a Cabinet department and why we should do it now.

EPA carries out the work of a Cabinet department. EPA started out by overseeing four major environmental statutes. Today EPA implements 15 major statutes and numerous others, as well as a full complement of grant programs, voluntary initiatives, technical assistance and educational programs, as well as citizen outreach throughout the Nation.

EPA also advances the mission of a Cabinet department. As we move forward in tackling our environmental goals for the 21st century, EPA is reaching out to develop new approaches that promote stewardship that spur innovation, that instill sound science in its decisions, that advance federalism through greater involvement of State and local government and, as important, ensure compliance.

EPA plays a vital role in homeland security. EPA has the lead role in environmental monitoring, decontamination, and long-term site cleanup. Their expertise in offsite monitoring, contamination surveys, working with health officials working to establish safe cleanup levels, conducting protective cleanup actions and communicating technical information to its citizens is essential for Federal response to an act of terrorism that involves the release of biological, chemical, or radioactive material. EPA works with Federal partners in every phase, from the initial crisis to the final cleanup.

EPA also produces initiatives of national significance that one expects of a Cabinet department. EPA designed and is advancing the President's Clear Skies Initiative that will cut the Nation's power plant emissions of sulfur dioxide, nitrogen oxide, and mercury by 70 percent. This initiative, along with EPA's new comprehensive regulations and programs to cut emissions from diesel engines, will enable hundreds of counties across the country to meet the newest and most stringent national air quality standards for ozone particulate matter that the Bush administration is implementing.

EPA's influence and accomplishments now extend beyond our borders. Many nations turn to EPA for technical expertise and guidance in safeguarding the health of their own citizens and the sustainable use and enjoyment of their natural resources. For these reasons, the Bush administration strongly supports elevating EPA to a Cabinet department. And we support efforts to accomplish this objective in a straightforward manner that focuses on the organizational structure of a new Cabinet department.

Acting Administrator Horinko will outline some comments and recommendations for changes to certain elements of the legislation, but I wish to emphasize that overall, we believe it is important to build an organization better equipped to meet the increasingly complex environmental challenges facing the Nation and the world and an organization that will ultimately better protect the public health and environment. We look forward to continuing dialog with the committee on how best to accomplish this mutual objective.

Thank you for the opportunity to testify today and I look forward to answering any questions you may have.

Mr. OSE. The Chair thanks the chairman who did it in 4 minutes and 58 seconds. Very good.

[The prepared statement of Mr. Connaughton follows:]

STATEMENT OF
JAMES L. CONNAUGHTON, CHAIRMAN
WHITE HOUSE COUNCIL ON ENVIRONMENTAL QUALITY

BEFORE THE
SUBCOMMITTEE ON ENERGY POLICY,
NATURAL RESOURCES AND REGULATORY AFFAIRS
OF THE
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
ON
ELEVATION OF THE ENVIRONMENTAL PROTECTION AGENCY
TO CABINET STATUS
SEPTEMBER 9, 2003

Mr. Chairman and Members of the subcommittee, thank you for the opportunity to appear before the subcommittee again today to discuss the Bush Administration's support for elevating the U.S. Environmental Protection Agency (EPA) to a cabinet department. I am pleased to share this panel with my colleague, Acting EPA Administrator Marianne Horinko.

In 1970, President Richard Nixon created a small independent agency to take on the responsibility to "effectively ensure the protection, development, and enhancement of the total environment."

Over thirty years later, the United States Environmental Protection Agency has a long record of accomplishment in advancing that mandate. Because of these accomplishments, environmental quality in the United States has vastly improved.

Improved air quality is one of our nation's greatest environmental successes. Air pollutants have been reduced by almost one-third since 1970, even as the nation's gross domestic product increased 160 percent, energy consumption increased 45 percent, and population increased 38 percent. Airborne lead, the most dangerous air pollutant, has been cut 97 percent. And in the last decade alone, nitrogen oxide emissions are down 60 percent in the 12 eastern states most negatively impacted before.

The nation's water is cleaner. Today, 192 million people are served by modern sewage treatment facilities. Our Clean Water Act ensures that seven hundred *billion* pounds of pollutants are not discharged into our waters each year. In the last decade alone, we have provided safe drinking water to another 54 million Americans.

The nation's land is better protected, and we are more able to provide benefit and refuge to our communities and support thriving ecosystems. Land protection activities that focus on prevention, control, conservation, natural resource management, and cleanup are an ongoing priority.

The general health of the American public is good and improving. People are living longer than ever before. In the last century, life expectancy at birth increased from 51 to 79.4 years for women and from 48 to 73.9 years for men. Infant mortality has dropped to the lowest level ever recorded. The death rates for the nation's main health threats—heart disease, cancer, and stroke—are decreasing.

These gains provide great optimism for success in tackling the increasingly complex environmental challenges that remain. We are getting better all the time at finding more effective – and far more innovative – ways to address such challenges. The Bush Administration is confident that further dramatic environmental progress can be achieved more affordably and at a quicker pace.

In EPA's short history, its work has helped transform the way America views the environment – planting in the American consciousness a clear sense of environmental stewardship. EPA has helped underscore the universal agreement that our natural resources are valuable, not just for economic prosperity, but for a sustained quality of life.

In 2002, and again this year, Representative Sherwood Boehlert of New York authored legislation to elevate EPA to a cabinet department. I would like to acknowledge and thank Representative Boehlert for his continued leadership and ongoing support for elevating EPA to a cabinet department. When I testified before this Committee on this subject in July 2002, I emphasized that the Bush Administration would work closely with the Committee to advance EPA cabinet legislation and make official what is already a reality in the Bush Administration. Let me again highlight why EPA should be elevated to a cabinet department.

EPA carries out the work of a cabinet department. EPA started out by overseeing four major environmental statutes. Today, EPA implements 15 major statutes and numerous others, as well as a full complement of grant programs, voluntary initiatives, technical assistance and educational programs, and citizen outreach throughout the nation.

EPA advances the mission of a cabinet department. As we move forward in tackling our environmental goals for the 21st century, EPA is reaching out to develop new approaches that promote stewardship, spur innovation, instill sound science in its decisions, advance federalism through greater involvement of state and local government, and ensure compliance.

EPA plays a vital role in homeland security. EPA has the lead role in environmental monitoring, decontamination and long-term site cleanup. Their expertise in off-site monitoring, contamination surveys, working with health officials to establish safe clean-up levels, conducting protective clean-up actions, and communicating technical information to citizens is essential for a Federal response to an act of terrorism that involves a release of biological, chemical, or radioactive material. EPA works with Federal partners in every phase from the initial crisis to final cleanup.

EPA produces initiatives of national significance that one expects of a cabinet department. EPA designed and is advancing the President's Clear Skies Initiative to cut the nation's power plant emissions of sulfur dioxide, nitrogen oxide and mercury by 70 percent. This initiative, along with EPA's new comprehensive regulations and programs to cut emissions from diesel engines, will enable hundreds of counties to meet our newest and most stringent national air quality standards. In doing so, our states will have greater flexibility to maintain and grow jobs, even as their air quality improves dramatically. EPA's stewardship led to enactment of Brownfields legislation that President Bush signed into law to help cleanup thousands of abandoned, contaminated sites and spur renewed investment, development and jobs in often struggling communities.

EPA's influence and accomplishments now extend beyond our borders. Many nations turn to EPA for technical expertise and guidance in safeguarding the health of their citizens and the sustainable use and enjoyment of their natural resources. Our laws, regulations, and standards have been adopted by nations across the globe. Our scientific and technical expertise is respected world wide. Air pollution, global climate change, chemical use and transport, resource management, and a range of other issues are increasingly complex and global in scope.

For these reasons, the Bush Administration strongly supports elevating EPA to a cabinet department. We support efforts to accomplish this objective in a straightforward manner, and to improve the organizational structure of a new cabinet department. Acting Administrator Horinko will outline some comments and recommendations for changes to certain elements of the legislation. Overall, we believe it is important to build an organization better equipped to meet the increasingly complex environmental challenges facing the nation and the world, and an organization that will ultimately better protect public health and the environment. We look forward to continuing dialogue on how best to accomplish our mutual objectives.

In the Summer of 1970, in his supporting testimony for the creation of EPA, Russell Train, the first Chairman of the Council on Environmental Quality and future EPA Administrator, gave the Agency unqualified support, predicting that its "vision of clean air and water...will provide us with the unity and the leadership necessary to protect the environment." Thirty-three years later, as the tenth Chairperson of the Council on Environmental Quality, I predict that the *Department* of Environmental Protection, with its vision of clean air and water, better protected land, and improved public health will continue to provide us with the unity and leadership necessary to protect the environment into the 21st century and beyond.

Mr. OSE. The Chair is pleased to recognize the Acting Administrator for the Environmental Protection Agency who has joined us I believe for the first time today. Ms. Horinko, you are welcome here.

Ms. HORINKO. Mr. Chairman, thank you. Good afternoon. I am very pleased to appear before the subcommittee as Acting Administrator on so important an issue to the Agency, the elevation of EPA to a Cabinet department. And I am also pleased to have the opportunity to appear here today with Jim. I plan to give a brief oral statement and submit my longer testimony for the record.

Since its creation by President Richard Nixon more than 30 years ago, EPA has worked diligently to fulfill its mission to protect human health and safeguard the natural environment. To that end, EPA has changed and adapted to address the challenges associated with new environmental laws as they were passed by Congress. EPA's role is defined as well by increased public awareness and the expectation that our health and environment will be protected. That strategy has led to the need for an emphasis on the use of sound science as well as dependence on the public trust.

Today EPA faces more challenges than ever before to protect human health and the environment, and as a means to help the Agency face these challenges, the time has come to establish EPA as a permanent member of the President's Cabinet. Elevating EPA to Cabinet status is not a new idea. There are more than a dozen bills introduced in Congress to elevate EPA to Cabinet status since 1988. Former President Bush was the first President to support Cabinet status for EPA, a decision then followed by President Clinton and current President George W. Bush.

I want to thank Chairman Ose and other Members of Congress, including Chairman Sherwood Boehlert, for introducing legislation to elevate EPA to Cabinet status and for their continued support of the Agency.

I would like to touch briefly on some of the issues addressed by H.R. 2138, the Department of Environmental Protection Act. The principal goal of the bill to elevate EPA to Cabinet status and promote greater performance and efficiency at the Agency is certainly a goal that we share. I am concerned, however, that the consensus developing for elevation of EPA could be fractured by contentious debate over the details of a statutory EPA restructuring plan.

The bill's goal to improve the use and application of science at EPA is a sound one with the creation of an Under Secretary of Science and the consolidation of science activities under one office, changes that merit further discussion. We do believe, however, that the information management function should be separated from the science organizational structure, as mandated by the Clinger-Cohen Act. The creation of a Bureau of Environmental Statistics [BES] could promote the importance of accurate, thorough, environmental monitoring and reporting and could provide the Agency with better data. However, an EPA BES should be consistent with the structure and authority of other Federal statistical bureaus.

Also, as to the relationship between EPA and its regions, I agree that it is important to have close coordination and communication throughout the Agency. While the regional offices need to implement national goals and policies, they also need sufficient flexibil-

ity to implement their goals to reflect particular regional and local conditions. I would urge Congress to allow the executive branch sufficient flexibility to allow the new Department to manage the enforcement and regional office functions as effectively and efficiently as possible.

Finally, we support Cabinet elevation legislation that is free of provisions that would make significant policy changes to the Agency and its programs. We look forward to working with you and other Members of Congress as legislative deliberations over the elevation of EPA to Cabinet status continue in the 108th Congress.

That concludes my oral statement, Mr. Chairman, and I would be pleased to answer any questions that you or the committee members may have.

Mr. OSE. I thank the gentlelady and appreciate her brevity.

[The prepared statement of Ms. Horinko follows:]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

TESTIMONY OF

MARIANNE LAMONT HORINKO, ACTING ADMINISTRATOR

U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE

SUBCOMMITTEE ON ENERGY POLICY, NATURAL

RESOURCES AND REGULATORY AFFAIRS

OF THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 9, 2003

TESTIMONY OF
MARIANNE LAMONT HORINKO, ACTING ADMINISTRATOR
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS
OF THE
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 9, 2003

Mr. Chairman and Members of the Subcommittee, I want to thank you for the opportunity to be here this afternoon to discuss legislation to elevate the Environmental Protection Agency to the level of Department. I am pleased to share this panel with my colleague, James L. Connaughton, Chairman of the White House Council on Environmental Quality.

It was over 30 years ago that President Nixon affirmed America's commitment to the environment by creating the Environmental Protection Agency. Since that time, the EPA has effectively fulfilled its mission -- protecting human health and safeguarding the natural environment, and its organization has changed and adapted with each major new environmental law passed by Congress. The time has come to establish EPA as a permanent member of the Cabinet, modernizing its structure in a straightforward way to ensure it can respond effectively to future environmental challenges.

Establishing EPA as a Cabinet level Department is not a new idea. The first bill to elevate the EPA was introduced in the Senate in 1988. Since then, a dozen similar proposals have been introduced. Similarly, former President Bush became the first President to support elevating EPA to Cabinet level by including then Administrator Reilly in Cabinet meetings and according him Cabinet level status. President Clinton and President George W. Bush continued

this practice, and have supported legislation to elevate the Agency to the level of Department. And we are here today because our current leaders in Congress, Chairman Ose and Chairman Boehlert, also recognize the increasing significance of permanently elevating the Environmental Protection Agency to a Cabinet Department. I thank Chairman Ose and Chairman Boehlert for introducing their respective legislation and for their continued support of the EPA.

These actions emphasize the importance that past administrations and our current administration have placed on the role of government in environmental protection. This responsibility is as critical to our nation's public health and economic vitality as the responsibilities under the jurisdiction of other Federal level departments. Elevating EPA to Cabinet status will ensure that this type of cooperation and integral working relationship will continue into the future.

Of course, the environment is not just a domestic issue. Environmental issues continue to play a central role in international relations as well. The U.S. EPA is looked upon as an international leader and a tremendously important resource in environmental stewardship. As we work with other nations, with the concurrence of the Secretary of State, it is important to bring the head of the primary Federal domestic environmental organization in the U.S. on par with the majority of the G8 countries and more than 60 others by establishing a Secretary of the Environment.

Today, I would like to specifically address the major provisions of H.R. 2138, the Department of Environmental Protection Act.

Several studies and reports issued by organizations such as the National Academy of Public Administration and the General Accounting Office have recommended a restructuring of EPA so that it might better achieve its mission. In addition, the Human Capital component of the President Bush's Management Agenda includes a provision to ensure that the Agency is

restructured as appropriate to provide optimal service at lowest cost and respond to changing business needs.

H.R. 2138 addresses a key structural challenge to the optimal operation of EPA – the establishment of "stovepipes" where existing programs reflect the individual environmental statutes passed by Congress over the past 30 years. Each regional EPA office, and all the Assistant Administrators - in all, over 20 senior organizational leaders - currently report directly to the Administrator and Deputy Administrator of the Agency.

While this structure served us well in our statutory duties under environmental laws in the early years, today's complex environmental challenges require greater integration and a more comprehensive approach to protecting the air, water, and land. For example, sectors such as agriculture may face separate regulations under the Clean Air Act, Clean Water Act and Federal Insecticide, Fungicide, and Rodenticide Act, but EPA's current structure does not easily facilitate integration of these requirements.

EPA's structure should facilitate close coordination of policy throughout the organization – from formulation to regulatory development to compliance assistance to enforcement. For instance, when EPA is writing a new rule, all stages of implementation are covered, so that the rule reflects the general direction of EPA leadership, the best available science, and incorporates the perspectives of program experts and those responsible for enforcement.

H.R. 2138 creates Under Secretaries to consolidate certain functions and reduce the number of direct reports to the Secretary. Although the legislation as currently written may be too prescriptive with regard to writing detailed structural requirements into law, this general structure could help EPA overcome organizational challenges consistent with the Agency's overall direction as embodied in its Draft Strategic Plan for fiscal years 2004 and beyond.

The consolidation of science activities under one office would support the principle of elevating the stature of science in Departmental decision-making. Establishing an Under Secretary for Science, who would also be the Secretary's Science Advisor, would help achieve this goal. However, the information management function should be separated from the science organization. The legislation should establish a Chief Information Officer who would report directly to the Secretary, and follow the Clinger-Cohen Act of 1996 which created the position of Chief Information Officer with primary duties for information resources management as a direct report to the Department head.

We also support the creation of a Bureau of Environmental Statistics (BES), to recognize the importance of independent and expert monitoring and reporting of environmental conditions, which would provide better indicators and better data. EPA's BES should be consistent with the structure and authority of other Federal statistical bureaus. The Bureau Director should report directly to the Secretary to promote independence and credibility.

H.R. 2138 includes a statutory requirement that each of the ten Regional Administrators report to a newly-created Under Secretary for Implementation, Compliance and Enforcement. It is important for EPA's Regional offices to have close coordination and communication with the leadership of the Agency. While the regional offices need to implement goals and policies that are set nationally, they also need sufficient flexibility to implement these goals to reflect local conditions. I would urge the Congress to allow the Executive Branch to have sufficient flexibility in establishing a management structure that will enable the Department to manage the enforcement and regional office functions as effectively and efficiently as possible.

We support Cabinet elevation legislation that is free of provisions that would make significant policy changes to the Agency and its programs. We believe that your bill, with some modification, can provide the basis for better integrating existing policy with the Agency's

components, and provide us the opportunity to better organize in order to provide better environmental protection.

I would like to discuss in greater detail two important areas highlighted in the bill: strengthening science, and the creation of a Bureau of Environmental Statistics.

Strengthening Science

Reorganizing the Agency would provide an opportunity to further elevate science in Department decision-making. EPA has already been undertaking many activities to strengthen science in the Agency. Since the National Research Council (NRC) published its report in June 2000, the Agency has made significant progress to achieve relevant, peer-reviewed, sound science.

This summer, we published an accomplishment report, "The State of Sound Science at the EPA" which addresses the recommendations in the NRC Report, and highlights the progress that the Agency has made in strengthening EPA science in five areas: scientific leadership and talent; research continuity and balance; research partnerships and outreach; research accountability; and scientific peer review.

In particular, EPA has taken several steps to support and strengthen the peer review policy since its issuance in 1993, and will continue to improve the application of peer review across the Agency. Consolidating science activities under one Under Secretary will better enable us to apply the policy rigorously, ensuring that EPA's scientific and technical information is strong and consistently informs the Agency's policies and regulatory decisions. I believe that the proposed structure would help us to achieve this goal, and I look forward to further discussion with you and your colleagues in the House. I particularly want to acknowledge Representative Ehlers for his leadership on this subject.

Strengthening science at EPA is an ongoing effort of continuous improvement, always with an eye toward improving the scientific bases for the environmental policy decisions that impact our nation. We all share the goal of a cleaner and healthier environment, and strong science is increasingly critical to informing the actions EPA takes to achieve this goal on behalf of the American public.

Bureau of Environmental Statistics

EPA supports creation of a Bureau of Environmental Statistics (BES) to collect, compile, process, and analyze information for statistical purposes only. A strong, independent, and respected Bureau will produce the measures that will allow EPA and other Federal agencies with environment-related missions to move closer to the goal of quantitatively measuring environmental program outcomes to better evaluate the effectiveness of EPA's programs.

For the BES to be most effective, we believe it is important to have language in enabling legislation that assures protection of confidential information and prohibits release of such information in any form identifiable by individual or corporate entities. In addition, legislation should promote the efficient use of resources in collecting and sharing that information with other federal statistical agencies. The Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) addresses the need for efficiency in both collecting information and sharing statistical information across federal agencies, as well as clearly defining protections for confidentiality of information. I recommend that the legislation include language from the CIPSEA to provide needed protections.

We believe that the Director of the Bureau should report to the Secretary to ensure that statistical information is communicated directly to the Secretary, independent from any assessment of potential regulatory or enforcement program interests. A direct reporting relationship would enhance the independence and credibility of the Bureau's Director, and would

be consistent with the reporting arrangement for several other Federal statistical agencies.

We support a strong Bureau with a significant level of independence commensurate with its purpose of collecting and publishing objective statistical information on the environment. The Bureau's statistical activities, including the data it collects, should be kept clearly separate from any regulatory or enforcement purposes elsewhere in the Department.

The creation of a BES is a significant and vital undertaking both for EPA and other Federal agencies. A strong, independent, and respected Bureau that is a full member of the community of Federal statistical agencies will advance our ability to achieve our shared goal of protecting human health and the environment. Development of statistical measures will be invaluable to continued progress on our Environmental Indicators Initiative to fill identified gaps and create information needed to allow the remainder of the Agency to measure progress against environmental results.

Conclusion

The time has come to establish EPA as a permanent member of the Cabinet. Doing so would be consistent with more than 30 years of environmental work and accomplishments and with the status of our international partners. H.R. 2138 accomplishes this goal of elevating EPA to Cabinet status and also limits its focus to modernizing the organizational structure. We look forward to continuing to work with the Subcommittee and other Members of Congress to address the organizational and personnel issues in this important legislation, and to ensure coordination and consideration of activities across the Federal government.

Again, thank you for this opportunity to testify. I would be happy to answer any questions you may have.

Mr. OSE. I want to make sure I understand something before we start. It is my understanding that President George Herbert Walker Bush, President Clinton, and President George W. Bush all consider from a practical standpoint or operating standpoint that EPA is part of their Cabinet already; is that accurate?

Ms. HORINKO. That is indeed accurate.

Mr. OSE. So you are attending the Cabinet meetings as Acting Administrator anyway.

Ms. HORINKO. And in fact have the privilege of sitting at the table with the other Cabinet members.

Mr. OSE. At the table. In reality you are there now.

Ms. HORINKO. [Nods affirmatively.]

Mr. OSE. The second question I have—and I appreciate both of your responses—I have been very careful in drafting this legislation to keep any change from a policy standpoint out. This is strictly a management structure kind of thing. Have I succeeded in that, Mr. Connaughton?

Mr. CONNAUGHTON. You have succeeded on focusing on structural elements. We have comments and questions related to those elements.

Mr. OSE. But on the policy side.

Mr. CONNAUGHTON. We were pleased to see in your bill this year, Mr. Chairman, a strong effort to stay focused on the structure elements, which, as I indicated in my oral comments, when you elevate from an agency to a department, you do bring in the opportunity to make sure that you got some of the key pieces structurally in place so it can function as a department on par with the other agencies. And I would note that most other agencies do have a policy apparatus. The Department of Transportation is one example I would give, Department of the Interior is another, and your legislation has reflected that. And different agencies, depending on their mission, do put a strong prominence on the science function. So those are the elements that we think have particularly well captured equivalency with other Cabinet departments.

Mr. OSE. But you don't see anything in terms of any amendments to the Clean Water Act, Clean Air Act, within the legislation as drafted? Ms. Horinko, do you agree with that?

Ms. HORINKO. I agree.

Mr. OSE. I want to make sure we get that on the record. Section 7 of my bill outlines the duties of the Department's Presidentially appointed and Senate-confirmed officers. One of the more criticized functions of EPA is the quality of its science. Both sides of the political spectrum claim, and I have heard all the claims, that EPA does not use the best science in support of its regulations. There is a section of my bill, section 7(c), that establishes an Under Secretary for Science and Information for the purpose of co-locating scientific activities at EPA and to remove the regulatory science efforts from the program offices.

Now, Mr. Connaughton, in your testimony you state that the administration supports efforts to improve the organizational structure of a new Cabinet department. Is it the administration's position that Congress should institute organizational reforms concurrent with Cabinet elevation?

Mr. CONNAUGHTON. Structural reforms are necessary to elevate something to a Cabinet. So the answer to that is yes.

Mr. OSE. Because that is the template that is used in every other Cabinet department?

Mr. CONNAUGHTON. Correct.

Mr. OSE. Now in making those organizational changes to, in effect, evolve an agency to a department, would the administration generally support centralizing and professionalizing the science under EPA under a strong leader such as an Under Secretary for Science and Information?

Mr. CONNAUGHTON. Yes, we would.

Mr. OSE. Ms. Horinko, I do want to thank you for suggesting in your written testimony that the Department include a CIO. I missed that, so I appreciate your suggestion. Other than that modification, do you support an Under Secretary for Science within the new Department?

Ms. HORINKO. Yes, I do.

Mr. OSE. Do you think that centralizing the science at EPA can foster cross-media scientific analysis?

Ms. HORINKO. Yes. I think it will improve our coordination.

Mr. OSE. Section 7(c) of my bill removes scientific activities from the program offices in order to minimize the disparate decisions as it relates to scientific studies and conclusions. Do you agree that scientific studies and conclusions should be independent from policy?

Ms. HORINKO. Yes, I do.

Mr. OSE. I want to dwell a little bit on the Bureau of Environmental Statistics because I happen to think this is probably one of the more important factors of the bill. Section 8 of my bill establishes such a bureau, which is similar to the highly respected Bureau of Labor Statistics, the BLS, in the Labor Department, and the Energy Information Administration, EIA in the Energy Department. And I will say that having just weathered and continuing to, if you will, enjoy California energy markets, I have a great familiarity with the EIA.

Mr. Connaughton, many other Federal agencies and departments have valuable independent statistical agencies. Does the administration generally support the concept of the Bureau of Environmental Statistics within a Department of Environmental Protection?

Mr. CONNAUGHTON. We do generally. We have some specific comments that relate to that in terms of how that is executed to bring it in line with some of the other statistical agencies. And then I would want to underscore the fact that numerous other departments, in addition to the several that have statistical agencies, also have statistical functions within them that we rely on across the government for environmental information. So there are elements of your bill that ensure a close coordination among those different fact-gathering bodies that is of particular interest to talk through further.

My office and the White House relies on the statistical work of all of those agencies as we collectively use that information in our understanding of policy decisions. So the short answer is yes, and

then we have some specific issues that we are happy to work with you on.

My time has expired. Mr. Tierney.

Mr. TIERNEY. Thank you. I am happy to proceed if you are flowing and want to go on that.

The chairman's bill, as I look at it, would significantly reorganize the proposed department with the purported aim of increasing communication across the EPA. And obviously, it would seem to me it would take time and resources currently needed for the EPA's core mission on that. Do you see any problems with the organizational changes proposed in the chairman's bill? And will the addition of three new Under Sectretaries either solve those problems of information sharing or the stovepiping that has existed and how?

Ms. HORINKO. I think that on the whole, that having the new Under Sectretaries will improve coordination and help us to have more program integration. We have some minor suggestions in terms of making the bill a little bit less prescriptive, giving us a little more flexibility to manage inside those three boxes of the Under Secretaries. But on the whole, I think the creation of these Under Secretaries will improve cross-program coordination, break down the stovepipes and give us a little more program integration, all things that we do need at EPA.

Mr. TIERNEY. I would be interested in you sharing with the rest of the committee what your recommendations are, because as I see the bill now, I have some of those questions myself. I think the intention is there, but I would like to see how that works out. Do you think in its reorganization, if you don't provide additional resources at the same time, is it not going to make it harder for the EPA to issue or implement enforced environmental protections?

Ms. HORINKO. Simply reorganizing the Agency into a department I don't believe would be a huge resource issue. We may want to talk to you about creation of the new Bureau of Environmental Statistics and it is simply too early to say whether that will require some additional resources. We will need to proceed very slowly in a step-wise fashion. You don't build something like that overnight. Perhaps benchmark what other agencies have done as they have created their statistical bureaus and also work very closely with our appropriators to make sure that we do this in a measured way.

Mr. CONNAUGHTON. I would also note that the bill actually, thankfully from our perspective, does not designate the Assistant Secretaryships and the other components. It is our expectation that all of that stays in place at EPA. We have the Office of Water, Office of Air. As we move forward, the legislation provides flexibility in the future, but I think the resource issue is important. We think that the structural changes proposed are modest, even as we are able to keep intact the essential programs and the essential operating entities that you have referred to.

Mr. TIERNEY. I recall that when Governor Whitman was testifying here, she indicated that a budget increase would actually help the EPA address the problem of viewing things across the various media such as air pollution and water quality. So I am not real clear how this bill would address this problem and I'm not clear why it can't be addressed outside of a reorganization on that issue.

Mr. CONNAUGHTON. That is where the policy function becomes so important. Typically the policy offices in Cabinet departments are not that large. They do require some infusion of resources, but they are not that large. But by having a high-level political appointee overseeing the work of the different departments, it allows for that cross-media functionality to occur and it allows for somebody who is not the Administrator, who has to function, you know, across the entire scope and operation of the Agency, allows someone one or two steps down to be able to fulfill that function on a day-to-day basis. Not only does it bring efficiency but it helps us identify the opportunities for, you know, the air program, for example, to provide real deliverables when it comes to protection of water.

Mr. TIERNEY. Outside of this legislation, why can't we address the issue of working across various media, what we would do if we didn't have this legislation to improve that situation?

Ms. HORINKO. There are things we are doing now to try and improve cross-media coordination. And there are a large number of administrative things. We have cross-program task forces. We have the Innovations Action Council. We try to put together teams to break down the barriers, to break down the stovepipes. Those are cultural things that we can do and are doing at EPA. But perhaps it is time to start exploring some structural things as well. And the opportunity that is provided by Cabinet elevation provides an opportunity to have a full and fair public exchange such as this on what type of changes should be considered at the Agency.

Mr. CONNAUGHTON. The change proposed is very modest and yet would be meaningful.

Mr. TIERNEY. I will stop here.

Mr. OSE. I believe the gentleman from Ohio was in first. Gentleman from Ohio for 5 minutes.

Mr. KUCINICH. I thank the Chair. To Ms. Horinko, I have long supported a Cabinet-level status for the EPA and I hope that Congress can work to pass a clean bill to accomplish this goal. I am very concerned that the EPA is failing, however, in its current responsibilities. Congress expects agencies to follow the law that it passes, not change it. Yet with the signing of the recent new source review rule, EPA gutted a critical portion of the Clean Air Act in a definition of modification to stationary sources. The new rule provides an enormous exception for replacement activities costing less than 20 percent of the process unit placement. This new trigger, 20 percent is very high, seemingly arbitrary, and contrary to the current modification definition in the statute which states any physical change. So what I would like you to tell us is where in the statute is a 20 percent exemption to this broad definition.

Ms. HORINKO. Congressman, I am pleased to take on the NSR issue because it has been so miscast in public reports, in some public reports as a rule that would gut the Clean Air Act, and it does nothing of the sort. In fact, that rule doesn't affect any of the substantive safeguards of the Clean Air Act. And those safeguards have been incredibly successful and will continue to be incredibly successful in ratcheting down emissions of criteria pollutants. The acid rain program created by the 1990 amendments to the Clean Air Act, the No_x SIP Call that we are currently implementing, the ozone and PM regulations that Chairman Connaughton alluded to,

those regulations will continue to inexorably ratchet down emissions on regulated facilities of all types. In fact lost in the noise of the NSR rule was the fact that we signed some 14 other maximum achievable control technology rules, further imposing emissions controls on these facilities.

Mr. KUCINICH. I think it is interesting the EPA has never been challenged for routine maintenance exemption and that is because the exemption was read narrowly by the EPA and the courts affirmed a narrow exemption. For example, on August 7, the Justice Department won a landmark victory against the Ohio Edison Co. And as a result of this single decision, thousands of tons of emissions will be reduced, which improves the health and environment of the people I represent in Ohio. However, under the NSR rule signed by you, all but one of the illegal actions committed by Ohio Edison would be permitted.

Now, when the court decided this landmark case, it said if a rule exempted the pollution increasing projects proven in the case, which this new rule does, the rule would "vitiate the very language," and they were talking about the Clean Air Act itself. The court confirms that a broad exemption would gut the statute. So I just wanted to point that out in response to what you said.

And on a related issue I find it even more problematic that a comprehensive analysis was lacking in the NSR rules. And I wonder how many plants were analyzed in Ohio to determine if they would pollute more, and by how much.

Ms. HORINKO. Congressman, I would recommend your reading our regulatory impact analysis that we prepared in the final NSR rule. I read it myself. It is a lucid explanation of the justification for the rule, the impacts. It is a thorough analysis of the rule.

Mr. KUCINICH. Were zero plants analyzed or did you run a sophisticated modeling program?

Ms. HORINKO. I will followup with you as to the number of specific plants that were analyzed, where, and in what State and what location. But I'm confident, based on the best available information we've got, that any impact of this rule from an environmental standpoint will be very modest and it will be countervailed by the inexorable ratcheting down of emissions required by the substantive safeguards of the Clean Air Act. It will increase reliability and predictability and efficiency for operators so that they can plan around our Nation's energy supply. On balance, I think this is the right thing to do.

Mr. KUCINICH. I'm just going to suggest to you that if you didn't analyze any plants—let's assume that for the minute that Congress does expect agencies to act on sound science—and not only did the new source review changes originate with the industries regulated by the new source review, but a recent GAO report concluded that industry anecdotes which the EPA relied upon when creating the December rule that—you know, the EPA assumed what the industry said, that production would not increase, and the GAO found that this was not an accurate assumption because future levels of production could increase and emissions could increase and health risks could increase.

I want to suggest to you that Congress expects agencies to act on the basis of science. But once again in this August rule, the EPA

is relying on industry anecdotes for the second NSR rule. And I would like a specific answer, if you could communicate that to us in writing, to me or this committee, so I can tell my constituents in Ohio what's going to happen to air quality as a result of this rule.

I thank the Chair. Would the gentlelady—she indicated a willingness to communicate this information.

Ms. HORINKO. Yes, I do.

Mr. OSE. I understood her to say that she would communicate with you post-hearing in writing; is that accurate?

Ms. HORINKO. Yes, it is.

Mr. OSE. Gentleman from Utah.

Mr. CANNON. Thank you, Mr. Chairman. And I thank you for holding this hearing. You know that I am deeply concerned about this issue. I apologize to you and the panel for being late today and also the fact that I'm going to have to leave, and I hope I can get back for the next panel.

Ms. Horinko I want you to—in the last two flights I have had out to Utah, I have been sitting next to my Governor, Mike Leavitt, who is prepping like crazy to relieve you of the spotlight. I'm not sure whether you like that or not, but he is working on it.

Ms. HORINKO. Please do cheer him on, Congressman.

Mr. CANNON. This is a hard thing. I don't want to sound like that I am not a great supporter of my Governor, but by cheering him on, that would suggest that I support the departure. I think he will do a good job on the interior but I don't wish this job on any human being. So I told him that very directly. So he has support and a lot of help going in.

But I'm deeply concerned about how we deal with science, especially at EPA. We had some awful problems historically, and I have read a little position paper on where you all are. I get the sense that you support the idea of an Under Secretary for Science. Could you address that, Mr. Connaughton? I am not sure if I am clear on your position.

Mr. CONNAUGHTON. We do support that position and we actually look forward, as we analyze the legislation and look forward to that specific issue, the opportunity to bring under one Under Secretary the variety of science programs that exist in EPA at different locations. And so to bring some order to the overall scientific enterprise at the Agency would be helpful. To have someone at the level of Under Secretary co-equal with other Under Secretaries also then will enhance the opportunity of the science function of the EPA to intersect with the policy operation of EPA and the administrative side of EPA in a much more coherent way, all without changing the underlying statutory mission, the underlying directives from Congress as to the various programs, but again create that opportunity for a much, much better coordination function with the right level of political appointee that we can attract into that kind of a position.

Mr. CANNON. Thank you. Ms. Horinko.

Ms. HORINKO. I completely agree with what Jim said, and I want to note that while we certainly support any legislative efforts to strengthen science, including establishment of an Under Sectretary, I do want to acknowledge, however, that science can't

be completely walled off from the program offices. We want to make sure there is good coordination and integration so that the best available science that is elucidated by this part of the Agency is then reflected in proper regulation, implementation, and decisions in the field.

So we look forward to working this out with the subcommittee in our future discussions because the devil really is in the details here, but I think the concept is a good one.

Mr. CANNON. If we did not do legislation to elevate EPA to Cabinet level, would it make sense still to reorganize it and create the new Under Secretary for Science and the related aspects of this legislation?

Ms. HORINKO. We could certainly think about it. It would be hard as a practical matter. As an administrative agency we technically don't have an Under Sectretary.

Mr. CANNON. It would have to be a different title.

Ms. HORINKO. It would have to be some new title or structure or function, and I would have to sit down and talk to you about how we could do that. And I am not sure how we could do that other than as we currently have, which is an Assistant Administrator who reports directly to the Administrator, who Governor Whitman elevated by naming our Assistant Administrator for Research and Development as her Chief Science Advisor last year. We have taken some good administrative steps as well as some substantive steps to strengthen peer review, risk assessment, modeling policy and grants policy. I think we are doing many things administratively. But Cabinet elevation would give us more opportunity to think about restructuring.

Mr. CANNON. Do you need legislation to add or change the titles or duties of an Assistant Administrator?

Mr. CONNAUGHTON. The current statutory authority provides flexibility as to what the Assistant Administrators are called in their overall function, although those are pretty well established after time. What it does not allow for is some of the hierarchical structures that a Cabinet department would otherwise command in terms of how those offices relate to each other. And that is where the good work that EPA has done with advancing their science program with creating the post of a science advisor has helped. The science advisor is still an Assistant Secretary or the Assistant Administrator level.

Mr. CANNON. Just before my time expires, let me point out that we have established a Science Caucus in Congress. We intend to work with you or oversee or relate closely with what you do there. In addition there, I sit on the Judiciary Committee where I am the chairman of the Commercial and Administrative Law Subcommittee, a very important component of our jurisdiction. And my focus is going to be on how we use science, and I expect to work with you on these issues in the future.

Mr. OSE. Thank the gentleman.

Mr. Connaughton, my earlier questions, you were generally supportive of the concept of a Bureau of Environmental Statistics. You had some input. Is your input embedded in your testimony?

Mr. CONNAUGHTON. It is embedded in Ms. Horinko's testimony.

Mr. OSE. So we will be able to pick that up.

Ms. Horinko, as proposed in section 8 of my bill, do you support the creation of a Bureau of Environmental Statistics?

Ms. HORINKO. We do indeed support the creation of such a bureau with some clarifications—modifications to enhance the ability to share information among sister agencies, to help make that bureau essentially function the way bureaus such as the EIA and BLS function, to enhance confidentiality of information that is collected, and better define its mission consistent with these other agencies, and also just simply to streamline operations and reduce duplication. So some minor modifications, but we do indeed support the concept as outlined in your bill.

Mr. OSE. So the privacy or the respect for the privacy of the information is an issue that you are trying to address with your testimony citing CIPSEA.

Ms. HORINKO. Yes.

Mr. OSE. In talking about protecting individually and corporately identifiable data within CIPSEA, which provisions are you specifically referring to as being appropriate to embed in my legislation?

Ms. HORINKO. There are several specific things in CIPSEA that would enhance your legislation. First, we all think the definitions of statistical agencies and statistical activities would really help to clarify the mission of the Bureau of Environmental Statistics and bring it on a level par with the other statistical agencies in the Federal Government.

Mr. OSE. Do these other statistical agencies in the Federal Government, do they have such definitions in their authorizing language?

Ms. HORINKO. I believe that they do.

Mr. OSE. There is a template we can go to.

Ms. HORINKO. Absolutely. And that is what we are attempting to do is move to that template.

Mr. OSE. Why is this additional confidentiality template language important?

Ms. HORINKO. It's important for two reasons. First of all, without the CIPSEA protections, we can't share information from other Federal agencies because they are prohibited from doing so unless we are also covered by CIPSEA. So this would really have to improve coordination, cooperation, prevent duplication of effort.

The second thing is we are very concerned about protecting information that is submitted by survey recipients, businesses, individuals, information that should be kept private. The new BES should be able to aggregate data, roll it up and tell us what it means to the country. But we want to protect donor information and CIPSEA allows us to protect donor information.

Mr. OSE. And apparently there is a reciprocity requirement in terms of other agencies or departments giving you information. If you don't have that same reciprocity, they are prohibited from giving it you. Is that statute or regulation?

Ms. HORINKO. I believe it is the CIPSEA law itself.

Mr. OSE. You simply can't do it. You can, but you wouldn't look good in stripes.

Ms. HORINKO. That's right.

Mr. OSE. When EPA published its draft State of the Environment report this past June, sections of the report were revised

after the administration reviewed its content. Now the highly respected EIA, the Energy Information Administration, does not require the EIA's administrator to even seek approval from the Department of Energy or the White House in creating or publishing EIA's reports. And that is one of its great values to Congress.

I suppose this question is for both of you, Mr. Connaughton and Ms. Horinko, do you support the same political independence for the BES?

Mr. CONNAUGHTON. We do support the political independence of BES and they need to put that in context because it is the statistical function of the agency that is important. If the bureau's mission is so broadly defined as to get into policy analysis and other similar types of analytical exercises that crosses the line back into the policy and program domain, that is subject to statutory oversight and other kinds of internal policymaking oversight and that would create an issue.

We don't encounter that with the Bureau of Labor Statistics nor do we encounter it with the Energy Information Administration, because they have narrowly defined statistical development missions.

Mr. OSE. As crafted, with the caveat having to do with CIPSEA, would the BES as envisioned in this legislation enjoy that same sort of defined rule?

Ms. HORINKO. Yes, I think so, Mr. Chairman. Because adopting those definitions of statistical agencies and statistical activities defines an appropriate role for the BES on the same par as the BLS and EIA. So having that appropriate role well defined, as it is in CIPSEA, then provides the assurances that function, the statistical function, should enjoy that independence.

Mr. OSE. Gentleman from Massachusetts.

Mr. TIERNEY. Thank you. You touched on an area that has me very, very concerned. Arguably this is one of the most secretive administrations that we've ever experienced and their track record is just horrendous: the fact the GAO had to sue just to try to get information about their energy policy and how it was comprised and then was strong-armed into dismissing the suit; the fact the Congress's request for information has been largely ignored; the public and the public's request has been ignored.

Getting into this area concerns me to no end that this is going to be a method from keeping information from the public that we are entitled to. In your testimony you address the need to keep certain information collected by the Bureau of Environmental Statistics confidential. Currently the EPA carries out entire programs such as the toxic release inventory that rely on providing public information in lieu of establishing control requirements. The Clean Air Act specifically prohibits the EPA and provides that it cannot withhold from the public any information that constitutes emissions data regardless of whether the entity considers that information to be confidential business information.

So I am asking you, having looked at this language in the bill, does the administration believe that language would in fact limit the release of any information that the EPA otherwise has the authority to collect?

Ms. HORINKO. I don't believe this bill in any way limits the release of any information that we would otherwise collect. Our current policy now is to release information unless it is protected by FOIA or by specific confidentiality provisions such as confidential business information. This bill does not affect that in any way.

Mr. TIERNEY. My concern is that if EPA should decide to consolidate certain information collected in the bureau, whether or not this language seems to prohibit it from releasing that information, even if it's data that was on plant emission of air pollution.

Ms. HORINKO. We certainly don't read the bill that way.

Mr. TIERNEY. Would you take a look at section 8(h)(2) in the bill? Later write me a little note, in the context of what I just said to you; and when you read that, whether or not you might have the same concerns or the public might have the same concerns where you try to consolidate information from other sources by putting it in that context, you might then be able to avoid responsibility under other acts of actually disclosing information particularly with respect to air emissions.

Ms. HORINKO. We will take a careful look at that. That is certainly not our intent.

Mr. TIERNEY. Would the administration support an addition of explicit language protecting the release of all the data that EPA would otherwise have the authority to collect and release?

Ms. HORINKO. We would certainly support something along the lines of this bill that does not affect any of the other information protections that are afforded to EPA or obligations.

Mr. TIERNEY. Will you work with us for language on that?

Ms. HORINKO. I think our intent is the same.

Mr. TIERNEY. Mr. Connaughton, when you testified before the subcommittee last Congress, you indicated that any mission statement of the EPA should be flexible enough to allow for the evolution of the Department's work and focus. The inclusion of a mission statement to protect the public from what this bill says is unreasonable environmental risk seems to me very narrow and seems to overemphasize setting priorities on risk assessment rather than on a broader view of the Nation's environmental health.

Let me give you some examples of that. I mean right now, the purpose of the Clean Air Act is to protect and enhance the quality of the Nation's air resources. The mission of the Clean Water Act says the national goal that the discharge of pollutants into the navigable waters would be eliminated by 1985. But I want to note that neither of them seems to qualify the degree to which the Agency is to move on that, and this idea of unreasonable risk seems to me to be vague, ambiguous, and focuses it more on trying to determine what the cost/benefit is. And I want to know if you share that ambiguity, because I don't want this to become an idea of caused basis stuff as opposed to going out and aggressively taking affirmative action to clean up our environment, which those other acts seem to indicate that the EPA should do. Your general comments on that and how you feel about this law and whether or not it does limit that.

Mr. CONNAUGHTON. First and foremost, EPA went through a mission exercise this past couple of years and simplified their mission statement to the straightforward one of the mission being to

protect the human health and environment. Reasonable risk is inherent in any risk management activity whether it is at EPA or the FDA or even in the land management side of things at the Department of Interior. Anybody engaged in the risk assessment/risk management exercise, there is the question of reasonableness which has to do with scientific knowledge and information, has to do with cost and benefits, has to do with technological feasibility.

So in terms of the use of the word "unreasonable" risk or to assure that risks are reasonable, that doesn't run counter to how professionals in this area deal with those issues. So I don't see anything insidious in the expression.

But to the extent that the committees will work out language surrounding a very high-level mission statement, we are happy to work with you on that. But I don't see anything insidious in the expression per se.

Mr. TIERNEY. May not be the expression. I have faith in my colleague here, but the administration in their environmental record I don't, and how they might use as something we see as something that is not that serious and move it in the other direction. That I have a great feel, given their track record, and I probably would be a lot happier if that language was just eliminated and we stick with the very simple goal that you said the Department has gone through and worked on, rather than to give them license to move down that path, because unfortunately with this group, words are for and often used as an escape hatch.

Mr. CONNAUGHTON. I would strongly disagree with you given the track record. This EPA under the Bush administration has done and will do more to protect our air, bring air pollution down, do more to protect water and bring water pollution down and to pursue some very innovative programs, including the brownfields program which is of such great benefit to States like Massachusetts, to really clean up the land. So I would flat out disagree with you on that point.

Mr. TIERNEY. But I have to part with the question and say when are they going to start? And what they have done so far in terms of their policy pronouncements are exactly opposite of what you are saying. And that's why I think they are generally perceived and understood to be probably the worst administration on the environmental protection we have seen.

Mr. OSE. Gentleman from Utah.

Mr. CANNON. Nothing.

Mr. OSE. Gentleman from California.

Mr. WAXMAN. Thank you, Mr. Chairman. The Bush administration is asking Congress to elevate EPA to a Cabinet-level department, yet the administration's main environmental initiative has been a comprehensive campaign to weaken EPA and environmental protection. This administration has undermined EPA's authority and its credibility.

For example, just a few weeks ago, you signed a rule gutting the new source review requirements. This rule allows increased emissions from power plants, one of the largest sources of air pollution in the United States today. You claimed, however, that this rule, "will not affect emissions." That was reported by the Washington Post. Do you stand by that statement?

Ms. HORINKO. I do stand by that statement, Congressman. This rule is not a rule that is about the environment. This rule is about planning and process. The environmental safeguards of the Clean Air Act, the Acid Rain Program, all of our maximum standards, those safeguards remain in place and ratchet down from these facilities.

Mr. WAXMAN. I don't think your argument is credible. The new source review requirements only apply if a source increases emissions, yet polluters need this exemption. That's because they are increasing their emissions.

Second, the acid rain provisions only cap one pollutant, sulfur dioxide, and they only apply to power plants. They don't limit other pollutants from power plants such as nitrogen oxides and mercury, and they don't limit pollution from the other 16,000 facilities covered by your rule.

Third, we would get dramatic emissions reductions if EPA enforced the new source review provisions rather than gutting them. Just last April EPA trumpeted a $1.2 billion NSR settlement as the, "largest Clean Air Act settlement with a utility in the history of EPA," eliminating over 200,000 tons of air pollution per year. Yet the legal rationale for the NSR rule imperils the ongoing NSR enforcement cases, and you have said you are unlikely to bring any new enforcement actions based on the old rule. If the new rule caused EPA to lose even one ongoing enforcement case, it would affect emissions. But if the rule stands, it may largely derail the 5-year NSR enforcement effort. This would dramatically increase emissions compared to what we could have otherwise achieved.

Ms. Horinko, wouldn't it be more straightforward for the administration to admit that this rule allows increased emissions compared to enforcing existing law? Why not have an honest debate about whether we should weaken environmental protections to save industry money?

Ms. HORINKO. Congressman, a few things in response to that.

First of all, years worth of litigation resulted from the initiation of the New Source Review enforcement program, and after 8 some years of litigation, the first decision that we got in the Ohio Edison case in August hasn't even reached the damages phase. So we've yet to see any environmental improvement after years of litigation in that case. And even that case where prior legal theory was upheld, the judge said case-by-case enforcement policy is not the way to establish the law of the land. There should be some type of regulation that's uniform.

Second, we did conduct a regulatory impact analysis that's contained in the final rule. I recommend it for your reading. It is a very lucid and very compelling rationale for this rule, and we will be pleased to sit down with you to discuss any of the specifics. We will continue to monitor the implementation of this rule to make sure that it is done in a way that is environmentally neutral or even improves environmental protection.

Mr. WAXMAN. Well, I hear what you're saying, but I don't think it's very persuasive, and I don't think you seem to have persuaded many others.

I have here, Mr. Chairman, about 60 editorials from around the country all decrying this new rule, and I'll read just a few of the

headlines. Miami Herald says, "EPA in retreat. U.S. going soft on the Clean Air Act." Pittsburg Post Gazette says, "Dirty air, dirty politics." Tennesseean says, "The skies are murkier with 'clean air' rule." Omaha World Herald says, "Ignoring the evidence: Another black eye for Bush's record on the environment." Denver Post says, "Politics of pollution." The Buffalo News says, "Air pollution: The day the President sold the skies."

I've been discussing the NSR rule, but it's only the most recent and most egregious example of this administration's ongoing attack on environmental protection. This record calls into question the administration's purpose in supporting this EPA elevation bill.

Thank you, Mr. Chairman.

Mr. OSE. I thank the gentleman.

Mr. Connaughton, the Under Secretary for Policy Planning and Innovation Section, which is Section 7(d), outlines the duties for that person; and during this subcommittee's prior hearings witnesses testified that EPA's program offices frequently do not coordinate their efforts. They conduct their own regulatory science and in some cases impede environmental innovation. In other cases, program offices have occasionally obstructed the efforts of other offices within the Agency. In general, Mr. Connaughton, does the administration agree with the concept of a centralized policy division such as the Under Secretary for Policy, Planning and Innovation?

Mr. CONNAUGHTON. The short answer is yes. The more detailed answer that fills that out is we have had very good experience. The two examples I gave, the Department of Interior, Department of Transportation—with an Under Secretary level type function for policy that enables that horizontal coordination that's so important as we get into the next century of multimedia and more complex solutions that are needed. So a lot of the think tank work and other work that's contributed to where we are today toward the recommendation for such a function I think is underscored by the success of the policy operations of these other departments.

Taking that horizontal view, it doesn't diminish the programmatic power and authority of the individual Assistant Administrators or just the secretaries if elevation occurs. It won't diminish that but will enable somebody who's responsible for looking for opportunities in one program office and how they can link together with opportunities in another program office, and that's where the next generation of solutions resides.

Mr. OSE. And that would be the case regardless of who's in the White House or otherwise?

Mr. CONNAUGHTON. That's correct.

Mr. OSE. Now, Ms. Horinko, does the EPA support an Under Secretary for Policy, Planning and Innovation as proposed in this section of the bill?

Ms. HORINKO. Yes, we do, and I couldn't have put it more eloquently than Mr. Connaughton.

Mr. OSE. Thank you both for your testimony on that. We have heard concerns from many groups regarding the lack of coordination between the office of enforcement and the program offices. Recently some States—and we do have some folks who will testify in the second panel—have expressed frustration over the issue of blending at publicly owned wastewater treatment plans.

Without getting into the details and merits of the issue, regardless of which side you're on, the bottom line seems to be that the EPA's enforcement office has been enforcing one set of standards while EPA's Office of Water has been issuing another. The result is that States and owners of wastewater treatment plants are receiving inconsistent treatment from different EPA offices.

One of the objectives of this legislation is to coordinate the policy. Does this legislation assure us or is this legislation a step in the right direction toward making the reality in the field that enforcement and policy offices work more closely together?

Ms. HORINKO. This legislation is certainly a step in the right direction. I'm not sure that any Cabinet department or agency could assure that all 20,000 employees are all on the same page at any one time, but I think it will help with that important coordination function so that the enforcement in the program offices is more closely aligned.

Mr. OSE. I have to come back to this blending issue which is very important in California. It's a huge opportunity for some of my attorney friends in California.

Are you saying that we can at least take a positive step toward addressing, if you will, what might be conflicting input that a local agency receives by coordinating this policy issue? That's my objective, and I want to see if you read it the same way.

Ms. HORINKO. I do read it the same way.

Let me add, though, on blending that we are moving now even administratively to try and solve this very important issue. We've heard from municipal operators of POTWs. We've heard from States. We've heard from regulatory agencies at the local level, environmental advocacy groups. A number of folks have requested clarification on this issue. So we are actually planning to publish for comment a draft policy on this issue that will ensure that——

Mr. OSE. The policy thing is not what I'm after. I'm after the consistent application of whatever the policy is. I'm trying to keep this discussion to structure.

Ms. HORINKO. Well, as a practical matter, this structure will help facilitate that kind of coordination between the program and the enforcement offices.

Mr. OSE. All right. Thank you.

The gentleman from Utah.

Mr. CANNON. Let me just followup on this discussion a little bit. What I understand you're saying is that, under Section 7(e) of the bill, the Under Secretary for Implementation, Compliance and Enforcement, that position will have a tendency to make consistent the rulings in the various States, the various regions so that both the States and the people being regulated have the ability to be more—they will be able to predict better what they need to do to comply.

Ms. HORINKO. Yes. We do have some slight modifications to make to give us a little more flexibility in terms of how we manage our programs, but in general, integrating the program office operations with the enforcement office will, I think, improve our ability to have consistent application and interpretation of the laws.

Mr. CONNAUGHTON. And I would note the most important feature is actually the prevention of those kinds of inconsistencies. Because

you end up with, again, a few people at the horizontal view who will be better able to anticipate some of these inconsistencies that invariably will happen, whether it's region to region or between the enforcement office and the program office as they are evolving their programs. So it is that group at the top that will—again, I think will have a better preventive function to head some of those uncertainties off.

Mr. CANNON. Thank you very much.

Mr. Chairman, before I yield back, I note that the gentleman from California has departed. Unfortunately, I had wanted to know if the New York Times had opined on this issue of the roll of EPA under this administration, not to suggest that the media has any bias at all or that the media has any consistency or integrity on this issue.

With that, I yield back the balance of my time.

Mr. OSE. The Chair thanks the gentleman.

Mr. Connaughton and Ms. Horinko, we want to thank you for appearing before the subcommittee today and testifying on this particular legislation. We appreciate you taking the time. We may have some questions so we may submit them to you. We'd ask for a timely response.

Ms. HORINKO. Will do.

Mr. OSE. The record stays open for 10 days for submittal questions and the like. We thank you both. Have a great day.

Ms. HORINKO. Thank you very much.

Mr. OSE. If we could get the second panel to gather at the witness table, we'll take a very short recess here while they do that.

[Recess.]

Mr. OSE. OK. We're going to reconvene here. I want to thank the witnesses for gathering at the table quickly and expeditiously. I'm told three of you have planes to catch here. OK, four. What time is your plane?

Mr. CHISUM. 5:45.

Mr. ROITMAN. 6 o'clock.

Mr. HAMMERSCHMIDT. 6:30.

Mr. GUZY. 6:30 also.

Mr. OSE. Oh, Lord.

Mr. Elliott, Dr. Guzy, I appreciate you offering to stay. We're going to ask you for a little bit of your indulgence here.

We're going to go across left to right to Dr. Hammerschmidt, and then we're going to jump to Mr. Guzy, and we'll come back to Mr. Elliott and Dr. Moghissi.

Now, I want to welcome to our witness table our second panel. The first is State Representative Warren Chisum with the Texas House of Representatives. Welcome. We have Howard Roitman, director of environmental programs for the Colorado Department of Public Health and Environment. Welcome. We have Dr. Ron Hammerschmidt, who is the director, Division of Environment for the Kansas Department of Health and Environment. Welcome, Doctor. We have E. Donald Elliott, former EPA General Counsel and current partner at Willkie, Farr & Gallagher LLP. Welcome. We have with us Dr. A. Alan Moghissi, who is president of the Institute for Regulatory Science. Doctor, welcome. And we also are joined by

Gary Guzy, who is the former EPA General Counsel and current partner at Foley Hoag LLP. Welcome.

Now, as is our practice, if you'd all rise, we'll swear you in.

[Witnesses sworn.]

Mr. OSE. Let the record show the witnesses answered in the affirmative.

Our first witness on the second panel is the Honorable Warren Chisum with the Texas House of Representatives.

Sir, we have your testimony, as we have everybody else's. We have read it. Our practice here is to recognize you each for 5 minutes to summarize. We look forward to your testimony.

STATEMENTS OF STATE REPRESENTATIVE WARREN CHISUM, TEXAS HOUSE OF REPRESENTATIVES; HOWARD ROITMAN, DIRECTOR OF ENVIRONMENTAL PROGRAMS, COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT; DR. RON HAMMERSCHMIDT, DIRECTOR, DIVISION OF ENVIRONMENT, KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT; E. DONALD ELLIOTT, FORMER EPA GENERAL COUNSEL AND CURRENT PARTNER, WILLKIE, FARR & GALLAGHER LLP; DR. A. ALAN MOGHISSI, PRESIDENT, INSTITUTE FOR REGULATORY SCIENCE; AND GARY S. GUZY, FORMER EPA GENERAL COUNSEL AND CURRENT PARTNER, FOLEY HOAG LLP

Mr. CHISUM. Thank you, Mr. Chairman. Having served 16 years listening to the testimony, I assure you I'll be brief and be within your 5 minutes.

In my legislative career, I served as chairman of the ALEC committee, the NCSL vice chairman of their environmental committee as well as the energy council. I am currently the chair of the Southern Legislative Conference Energy Committee and Environmental Committee. Likewise, being in Texas, we work along the border on various environmental issues across borderlines in an effort to bring us into compliance with the Clean Air Act.

To be very upfront about it, I think making EPA a Cabinet-level position probably has a lot of credibility. I think it would put us on an equal footing with some other countries and give more credit to the fact that surely we make the environment a very high priority here in the United States.

On the issue that I particularly liked about the bill, on using peer-reviewed science in order to make policy and compiling that with statistical data I think that is a great way to make regulation. We try to do that in the State of Texas, but actually most environmental policies in the States nowadays are complying with Federal law, not actually trying to create State laws that do anything other than comply. We appreciate what EPA does in pursuing our bad actors. When we find bad actors, we can be sure that the Department of Justice applies the enforcement, and many, many times that helps us in the State of Texas as we pursue our goal to have a cleaner and better environment.

We also, being an agricultural production State, think that it's imperative that we give special emphasis on making sure that we are able to produce our food and fiber from our farmers. We think that they can be good stewards of the land, and with the knowledge

that they can receive from science, they can do a good job. Likewise, we think it's essential that we not give up our food production, as we have oil production, to the foreign countries.

Finally, Mr. Chairman, I would like to relate to you an incident where we were trying to come up with a State implementation plan [SIP] in order to comply with the Clean Air Act, and everything we tried we came up, we were still short, and so we borrowed from California what was known as the Carl Morio program, where the State of Texas taxed its citizens $800 million in order to create an innovative program whereby we could go out and retrofit on-road and off-road diesel engines, thereby bringing our regulation into compliance with the State of Texas. This would not have worked had the regional director not had the ability to have flexibility in order to allow our SIP program to be approved, provided that we spend this kind of money on new, innovative programs. So some flexibility at the regional level is essential.

I think that the States can work with EPA regional offices and can come up with better ideas to protect the environment, and I would encourage you to make sure in your program that you make sure that States have the ability to work with the regional offices and not have all policy made here in Washington, DC.

With that, Mr. Chairman, I'll yield the rest of my time.

Mr. OSE. I thank the gentleman. His word is good.

[The prepared statement of Mr. Chisum follows:]

Testimony before the House Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
by Texas State Representative Warren Chisum

Tuesday, September 9, 2003

Mr. Chairman and members of the Committee,

Thank you for inviting me to testify before you today on the issue of elevating the Environmental Protection Agency to Cabinet-level status. I understand that we are addressing our remarks today specifically to: H.R. 37 by Congressman Boehlert and H.R. 2138 by Chairman Ose.

Allow me to begin by sharing some of my background. I have been a Texas State Representative since 1989 and served as Chair of the House Committee on Environmental Regulation from 1993 to 2003. I am a former Chair of the American Legislative Exchange Council's Task Force on Energy, Environment, Natural Resources and Agriculture and currently chair the Task Force Subcommittee on Air Quality. I chair the Committee on Energy and the Environment of the Southern Legislative Conference and am the Vice Chair of the National Conference of State Legislators Environment and Natural Resources Committee. I also serve on the Executive Committee of the Energy Council and am the Immediate Past Chair of the Energy Council's Center for Legislative Energy and Environmental Research.

Needless to say, I have a lot of experience dealing with environmental issues not only within the state of Texas, but on a national basis as well. I have also had some experience dealing with environmental issues along the border as we have worked with Mexico to address common problems. My commitment to the environment includes promoting and supporting environmental education through service with the Texas Environmental Education Partnership.

I applaud your intent to elevate the Environmental Protection Agency to Cabinet-level status. The importance of our environmental work, and the fact that the EPA administrator has been participating in cabinet meetings for years under the direction of three Presidents speaks to the need that this be made a Cabinet-level position.

Having the EPA as a Cabinet-level position will enhance our ability to interact with other countries to address environmental concerns on an international basis. We are one of the few countries that has not placed our environmental agency at that level; doing so would place our administrator at the same level as those from most other countries. This is an opportunity to work more closely and effectively with not just other countries outside our borders but also with states and communities within our borders

With this change the American public in general, as well as business and industry specifically, will see the EPA in a whole new light. Currently too many see EPA as the regulatory ruler existing only to play "gotcha." It's time that we created a Department of Environmental Protection that would work with the public and with industry on preventive measures and

creative solutions. We need to encourage the ingenuity that has so often contributed to a better America and say, "Yes!" to creative alternative strategies as long as the bottom line is a cleaner and better protected environment.

Creative alternate strategies and technology will allow us to protect the environment, while at the same time maintaining a strong economy. It is, after all, a strong economy that can best afford a cleaner environment.

I am heartened by the mandate to use science and statistical trends throughout the Department's operations and policy. Policy and compliance can no longer stand aside from science and appropriate statistical data.. They must be intertwined. Mandating peer review for these will give heightened credibility to policy and compliance decisions that are made. In turn, this will increase the confidence level of Americans in their government's ability to appropriately address environmental issues through sound decisions that are based on solid facts.

The Department should continue their efforts to protect the American people from violators who would harm our environment. However, at the same time we need to be able to have electricity, clean and abundant water, and safe clean burning fuel to heat our homes and power our automobiles. We also have to work carefully to address pollution resulting from agricultural operations, while at the same time recognizing that our food production must continue to come from American farmers, lest we become as dependent on foreign nations for food as we are for oil.

Before I close, I would like to encourage you to be cautious about over doing the reorganization of the Department. While it is possible that inconsistencies in the application of environmental regulation can occur between the Regions, the centralization of all policy making in Washington may reduce the amount of innovation between the Regional offices and the State environmental agencies.

One example is the creation of the Texas Environmental Reduction Plan ("TERP") in Texas. In order to address air pollution from diesel vehicles in Texas, the Texas Legislature passed an incentive-based plan instead of traditional regulation. The Regional Administrator of Region VI championed the plan within EPA and was able to secure approval by the EPA for the substitution of the incentive plan within Texas' State Implementation Plan (SIP).

If the Regional Administrator, who is a political appointee, had not been granted the freedom to approve such a plan in consultation with headquarters EPA, but instead was required to wait for all policy matters to be decided in Washington, it is unlikely that the EPA could have timely supported the State of Texas in this innovative program.

In short, what you gain in consistency between regions of EPA may be offset by the creation of an even larger headquarters EPA in Washington that is less concerned about local and state issues. In many cases only the state environmental agencies know what will and what will not work within their jurisdiction. For this reason, the regional offices need to work closely with

state regulators.

With that one caution, I support this legislation and would be happy to answer any questions.

Thank you.

Mr. OSE. Our next witness is Howard Roitman.

Sir, you're recognized for 5 minutes. Thank you for joining us.

Mr. ROITMAN. Good afternoon, Mr. Chairman and distinguished members. Thank you for the opportunity to testify on H.R. 37 and H.R. 2138 on EPA elevation to Cabinet status.

We conceptually support H.R. 2138 because it makes tangible steps toward bringing our environmental laws into the 21st century through the reorganization of EPA to strengthen science and to provide more consistent policy direction and implementation across the Agency.

Current laws were designed to resolve discrete problems with air, land and water. This single media approach has been effective in achieving environmental improvements but has resulted in a fragmented patchwork of regulatory requirements that makes it more difficult to address cross-media environmental challenges.

So today we are at a crossroad. You have the opportunity to provide direction for environmental programs to move in the future. If we open one door, we continue a single media command and control approach that often discourages innovation and efficiency. This path will continue to require technology-based controls without considering their cross-media impacts.

To illustrate our point, if the air program requires a company to install a control device such as a wet gas scrubber, it typically considers the percentage of air emissions reduction. We don't consider the hazardous waste generated that must be managed, the system that must be built to treat the wastewater, the increased energy consumption which increases air emissions, the increased water usage or any other increase in natural resources consumed. Instead, the program simply considers the scrubber can control 99 percent of the sulfur dioxide emissions out of a stack.

In the alternative, the company could use a catalyst additive that once spent or used is purchased by a cement manufacturer which uses it as product in place of mining additional limestone, thus avoiding an environmental impact. The catalyst does not generate wastewater, nor does it use as much energy or water. The catalyst will control 95 percent of the stack emissions.

We call this approach the environmental balance sheet in making environmental decisions where we consider the full environmental costs and benefits of all the options. This approach is discouraged and at times not allowed under the current system due to significant institutional policy and regulatory barriers.

The current path drives companies' environmental staff to be paper pushers instead of environmental problem solvers. Companies spend an inordinate amount of time and resources providing information.

In our experience, the environmental professional in this country is one of the most underutilized resources in our companies. This person can be a profit center for the company, driving ideas for greater efficiencies, reduced costs and better environmental benefit if given the tools and flexibility to do so.

So what is the alternative? It would require agencies to make environmental decisions considering the environmental balance sheet. This approach allows companies to select the most efficient approach such as preventing pollution, engineering the use of toxics

out of products and designing products that have no waste stream. To pursue this direction requires better information to use when making decisions. This is why the creation of a Bureau of Environmental Statistics is important.

Agencies will be required to continually assess, using data and science, the greatest environmental issues that need to be addressed and whether the current programs are successful. This will not only encourage but make essential to success innovative approaches. It will also ensure that we have identified the real problem, the causes behind it and allow us to evaluate the alternatives.

This path has several benefits. First, it will require EPA to consider the full impact of its decisions. It will encourage innovative programs and ideas to be embraced by the Agency. It will garner even more significant environmental benefits; and, finally, it will encourage companies to search for the most efficient approach to reducing environmental impacts.

Colorado is currently implementing this approach, but it isn't easy. One of the barriers that we have to ensure against is different approaches and interpretations taken by different offices of EPA. In the past, we have found differences among the program offices, between regions and headquarters, and among regions. What we are looking for is a Federal system that requires cross-media approaches and encourages and integrates innovations across the board. The goals of the system would be to collect better data and use it to make environmental decisions.

Thank you for your time and attention. I would appreciate the opportunity to supplement this testimony. I'll be pleased to take any questions you may have.

Mr. OSE. I thank the gentleman.

[The prepared statement of Mr. Roitman follows:]

TESTIMONY OF HOWARD ROITMAN

September 9, 2003

Good afternoon Mr. Chairman and distinguished members, we would like to thank you for the opportunity to testify this afternoon on HR 37 and HR 2138, pertaining to the elevation of the U. S. Environmental Protection Agency to cabinet status. My name is Howard Roitman, and I am the Director of the Office of Environmental Programs, at the Colorado Department of Public Health and Environment.

The Colorado Department of Public Health and Environment conceptually supports HR 2138 because it not only elevates EPA to cabinet level, but it also makes tangible first steps toward bringing our laws into the 21st century. HR 2138 does this through the reorganization of EPA to: strengthen science, provide more consistent oversight for the regional offices, and provide leadership for the program offices and centralized policy making.

There is no question that the current regulatory system has garnered significant environmental improvements over the past 30 years. However, these laws were designed to resolve discrete problems that existed at the time. Congress did this through passing laws that dealt exclusively with air, land or water. This single media approach has been effective in achieving environmental improvements, but has also resulted in a fragmented, patchwork of regulatory programs and requirements. This patchwork makes it more difficult to achieve the cross-media environmental challenges of the future. New and innovative approaches and ideas will be necessary.

So, today with HR 2138 before you, we are at a cross road – you have the opportunity to direct the federal and state environmental programs as to which direction we will move in the future.

If we open one door, we will continue down our current path – a single media, command and control approach, which often discourages innovation and efficiency. This path will continue to require more prescriptive, technology-based controls without considering the cross media impacts of our decisions. And we will continue to struggle with how to address transfers of pollutants between media.

To illustrate our point, the current federal programs, being media specific, are not required and often are not allowed to consider the cross media impacts of the decisions we are making. If the air program has a regulation that requires a company to install a control device, such as a wet gas scrubber, the program is typically only allowed to consider the percentage of air emissions reductions that are gained from the proposed control. This means in deciding what controls to require, we do not consider the resulting hazardous waste generated by the scrubber that must be transported, stored, treated and disposed; we do not consider the treatment system that must be built to treat the wastewater generated by the control; we do not consider the increased in energy consumption – which increases air emissions; we do not consider the increased water usage – a precious natural resource; nor do we consider any other increase in natural resources consumed as a result of this decision. Instead, the program simply considers – the scrubber can control 99% of the sulfur dioxide emissions out of the stack. In the alternative, the company in our example could use a catalyst additive that once spent or used, is purchased by a cement manufacturer which uses it as product in place of mining additional limestone – thus, avoiding an environmental impact; the catalyst does not generate wastewater that then must be treated, nor does it use as much energy or water as the scrubber. The catalyst will control 95% of the stack emissions. We call this the "environmental balance sheet" approach to making environmental decisions – consider both sides of the balance sheet the costs and benefits of an option. This approach is discouraged and at times not allowed under the current system. The air quality program staff is told their job is to ensure air quality is benefited to the greatest extent possible. As a result, there are significant institutional, policy and regulatory barriers built into the current system preventing EPA staff from using the environmental balance sheet approach.

If we stay on our current path, we will continue to drive companies' environmental staff to be "paper pushers" instead of environmental problem solvers. The current system requires an enormous amount of record keeping, reporting, and monitoring for each media program. This results in companies spending an inordinate amount of time and resources providing us information and very little time trying to solve environmental problems. The environmental professional in this country is one of the most underutilized resources in our companies. If utilized as a problem solver, this person can be a profit center for the company – driving ideas for greater efficiencies and reduced costs. A multi-media system that better coordinates and streamlines these administrative requirements can achieve this end.

This path will also drive companies that are environmental leaders to continue to push against the prescriptive nature of the federal programs. These companies are moving beyond our current regulatory requirements and towards eliminating all wastes, using renewable energy resources, and prevention pollution before it happens. Certain prescriptive programs discourage and impede these opportunities. We also fail to full the "resource conservation" goals of environmental statutes like RCRA.

So, what is the alternative path? This path, which can be achieved through the concepts in HR 2138, would require agencies to make environmental decisions considering the environmental balance sheet or cross media approach. This approach asks the question – which solution to the environmental problem at hand results in the greatest environmental benefit with the least environmental cost? This allows companies to select the most efficient approach, such as preventing pollution before it is created, engineering the use of toxics out of products, and designing products that have no waste stream.

This alternative path will require the federal and state programs to gather better information and utilize that information when making decisions. This is why the creation of a Bureau of Environmental Statistics and the other Science and Technology elements of HR 2138 are important. Agencies will be required to continually assess, using data and science, what are the greatest environmental issues that need to be addressed and whether the current programs are successful in fixing these problems. This will not only encourage, but make essential to success, innovative approaches. It will also ensure that we have identified the real problem, the causes behind it, and allow us to evaluate the alternatives most effectively.

This path has several benefits. First, it will require EPA to consider the full impact of its decisions on the environment. Second, it will encourage innovative programs and ideas to be embraced by the agency. Third, it will garner even more significant environmental benefits. Finally, it will encourage companies to search for the most efficient approach to reducing environmental impacts, which usually results in making the company more competitive on a global scale.

Colorado is currently implementing the alternative path – but continues to run into roadblocks. Some of these are encountered by different approaches and interpretations taken by different offices of EPA. Sometimes there are differences among program offices, like OSWER and OECA; sometimes differences

between Regions and Headquarters; other times among Regions. What we are looking for is a federal system that requires cross media approaches and encourages and integrates innovations. The goals of this system would be: 1) to better collect and utilize data, 2) to achieve greater environmental benefits, 3) with less process, 4) while placing a greater degree of responsibility on the company to select the method of achieving compliance. We know this is possible, because we are moving down that path today. The way down this path could be made much faster and easier with better program implementation coordination and accountability.

So, we are at that cross road – one direction is the status quo with a diminishing rate of return on our investments; the other direction, proposed by HR 2138, provides us the opportunity to embrace innovations and efficiencies, consider the environmental balance sheet in decisions, and better collect, analyze and utilize the information we gather.

Thank you for your time and attention. I am pleased to take any questions at this time.

Mr. OSE. Our next witness is Dr. Ronald Hammerschmidt. He is the director of the Division of Environment for the Kansas Department of Health and Environment.

Sir, welcome. You're recognized for 5 minutes.

Mr. HAMMERSCHMIDT. Thank you, Mr. Chairman. I am glad to be here today to speak on the two proposals under consideration.

My professional experience is that of both laboratory chemist and environmental professional, and I have spent time in both the laboratory and office in policymaking in my 23 years with the Department.

We like many other agencies have a love-hate relationship with EPA. We work together. We depend on EPA to provide us with a significant source of funding, and we always receive direction on our programs, either in the form of guidance, regulation or sometimes under the guise of partnership. Many of our programs are joint programs such as that to protect the safe drinking water in the State. There are even times when State programs may have even actually progressed beyond those of EPA; and as is the case in Kansas, we've been in the regulatory business for confined animal feeding operations for a long time and feel that EPA is finally catching up to us.

We have many frustrations in dealing with EPA. They include slow decisionmaking, a lack of understanding of State programs and their challenges, rigid approaches to problem solving and inconsistent guidance between regions.

For me personally, one of the bigger frustrations is the amount of time it takes for EPA to deal with Kansas's multiple water quality regulations. The net result of this has been numerous lawsuits have been filed against us and Region VII which don't make us any better in protecting water quality but do take a significant amount of time.

There are decisionmaking processes within EPA that we can cite that we have experienced with multiple interpretations of the same guidance among various regions. Something that we may enforce in Region VII may not necessarily be even accepted in Region VIII or enforced in Region VIII.

In addition, regional managers must routinely confer with EPA headquarters, and they may or may not receive a response or authority to move ahead on an issue.

States have a need for scientific support for our decisionmaking processes. We are often asked by our State legislators and policymakers, what's the scientific and technical basis for what you're trying to do? We need both science, data and information. Unfortunately, there are cases when this is lacking.

The creation of an independent structure charged with science and information is an excellent proposal. We need quality science in all aspects of environmental protection. Although I avoid the use of the word "good" science, we do need rigorous peer-reviewed science, and we also need to convert a great deal of that statistical data into information that our citizens can understand and that we can use. I see the creation of a Bureau of Environmental Statistics as a very, very positive step.

In addition, the administrators, managers and staff of EPA—and I'm speaking specifically to those in policy, planning and innova-

tion—should also be charged to be knowledgeable with understanding the programs they're writing regulations for. If one is writing a regulation for public water supplies, one should have information both on a scientific and technical basis but also direct experience in what it takes to run those particular programs. It would be helpful if that EPA person in headquarters writing the regulations had actually ever been to a drinking water plant and seen how it worked.

An important function of this level of the Department, and that of the implementation, compliance and enforcement structure, is to bring consistency and equivalency to decisions in the Agency. These decisions are extremely important to States. They're also important to those that we regulate. We, like the batter in the major leagues, are looking for consistency in how to predict what the rules are. It would be nice to know what the strike zone is which sometimes moves on both us and the regulated community.

In addition, the last point I'd like to make before I close is, as a State program director, I'm very interested in maintaining the ability to go to the top. I think it's important for us to be able to influence decisionmaking within the Department, and I actually see this as an important role for the Under Secretary for Implementation, Compliance and Enforcement, should be to be and act as a State's advocate within the structure at U.S. EPA or the Department of Environmental Protection.

In conclusion, I want to say that we are supportive of elevation to Cabinet status, but we think many of the ideas that you've put in H.R. 2138 are a very positive approach to bring better science and more consistent decisionmaking to EPA.

With that, I thank you.

Mr. OSE. I thank you, Dr. Hammerschmidt.

[The prepared statement of Mr. Hammerschmidt follows:]

Testimony to Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
Committee on Government Reform

Elevating the Environmental Protection Agency to Cabinet Status
(HR 37 and HR 2138)

September 9, 2003

Ronald F. Hammerschmidt, Ph.D.
Director, Division of Environment
Kansas Department of Health and Environment

Introduction:

Good afternoon Chairman Ose and members of the Subcommittee. My name is Ron Hammerschmidt, Director of the Division of Environment, Kansas Department of Health and Environment. Thank you for the opportunity to speak on the two proposals currently under consideration to elevate the United States Environmental Protection Agency to cabinet status, HR 37 and HR 2138. My professional experience is that of a professional chemist and environmental professional. I have spent time in both a laboratory setting and in management of environmental programs during my 23 years of service in the department. In addition, it was my great pleasure to serve as the President of the Environmental Council of States (ECOS) from August 2001 through October 2002. I am currently the Past President of that organization. While I am not representing ECOS today, I have conferred with a number of my colleagues on this issue.

Background:

The Kansas Department of Health and Environment, like many other state agencies, has a love-hate relationship with the Environmental Protection Agency. We are faced with the implementation of both state programs and those mandated or directed by US EPA. Often the programs we conduct are supported financially through grants from US EPA. We always receive direction on these programs either in the form of regulation, "guidance," or partnership. Many of these programs are joint programs such as the protection of public water supplies under the Safe Drinking Water Act or similar state statutes regarding water quality under the Clean Water Act. There are times when a state program has progressed beyond the federal program. A case in point, is the Kansas regulatory program for animal feeding operations that has developed since the 1970's in a manner the federal program is now only beginning to approach.

There are many frustrations felt by states in dealing with US EPA. These frustrations include slow decision making, lack of understanding of state programs and their challenges, rigid approaches to problem solving, and inconsistent guidance between EPA regions. For example, one of the bigger frustrations for me personally is the length of time between the submissions of Kansas' water quality regulations and the regional office

response. While the current regional administrator has made a commitment to respond in a short time period, the prior track record on making these decisions is poor. The results of these delays have been a number of lawsuits filed by interest groups against the region. Similarly, requirements placed upon Kansas in implementing the National Pollution Discharge Elimination System (NPDES) by Region VII staff are not entirely consistent with those of Region VI to our south or Region VIII to the west. I note the regions that currently perform or recently performed the permitting activities associated with NPDES some times take a state-type approach to problem solving.

The decision-making process within EPA has also been a frustrating experience with multiple interpretations of the same rule or guidance among the various regions. An approach or regulatory language accepted in Region I, may not be acceptable in Region VII. In addition, regional managers must routinely confer with EPA headquarters from whom they may or may not receive authority to move ahead on any issue.

Finally, states have a need for scientific support for our decision-making processes. During my 15+ years of direct involvement in environmental regulatory programs, I have often been asked "What is the scientific and technical basis for this decision or approach?" In some cases, there is current information, research, and knowledge to support our decisions. Unfortunately, there are other instances in which the fundamental information is dated and in need of updating or nonexistent. Most states lack the resources to develop this science on our own. Rather we rely on federal and university sources for this science and technology.

Science and Information:

The proposed elevation of EPA to cabinet status has a number of positive outcomes, which include placing more emphasis on the importance of environmental and public health protection, giving environmental protection equal status with other federal activities, and an enhanced international prestige for EPA and the administrator. The two bills before you are designed to accomplish many of these positive goals. There are a number of provisions of HR 2318 which should be noted. The creation of an independent structure charged with Science and Information is an excellent proposal. As per my previous comments, there is a great need for quality science in all aspects of environmental protection -- from planning through implementation.

I have avoided the use of the term "good science" which takes on connotations of "manipulated interpretation of select facts" in some discussions. Of equal importance to the development of science is the communication of the science. My agency -- like many other government agencies -- has a great deal of data, but we lack information. My staff and many others struggle with transforming data into information. The creation of a Bureau of Environmental Statistics within a cabinet department is a positive step. This organization within the department should be able to begin the development of both

media specific and big picture information. For example, the recently published *Draft Report on the Environment* was a good start. However, there are numerous identified data gaps that must be addressed. The proposed Bureau of Environmental Statistics would be the logical organizational unit to plan and prepare this information. In addition, positive collaboration between this bureau and other entities such as the Centers for Disease Control, Agency for Toxic Substance and Disease Control, and the National Academy of Science can be easily envisioned .

As you move forward to increase and improve science and information in environmental protection, we must also learn from the past. Peer review boards including external members are very important. The new bureau should rely heavily upon external scientists and policy makers for input, interpretation, and guidance. The current Science Advisory Board of EPA and National Academy of Sciences have greatly aided EPA in the current science efforts. These success stories should be carried forward into a new structure.

While routine training and staff development can be handled in a standard manner, the Bureau of Science and Information should receive direction to monitor, analyze, and address any shortcomings among EPA staff in the area of science. The current workforce includes many staff with technical and scientific backgrounds. As changes occur within the agency or cabinet level department, the Bureau of Science and Information should have a leadership role in assisting new and existing staff in moving along a steep learning curve.

Policy, Planning and Innovation:

The second major component of the department described in HR 2318 is that for Policy, Planning and Innovation. This part of the department would be charged with the development of policy and regulation. As a state regulator, I have found that one area which causes all of us problems is the development of balanced regulation which provides adequate protection of the environment and public health while maintaining a connection to the practical realities of modern life. The administrators, managers and staff developing regulations and policies must have knowledge and experience in the area for which the regulations are designed. For example, the manager of the regulatory program for public water supplies should have an understanding of both conceptual and practical aspects of the operation of a public water supply system. This comment should not be construed as supporting only industry people for these EPA positions, but rather a need for knowledgeable individuals capable of understanding the regulated entity.

In addition, the staff in this organization should also be aware of the challenges of implementation. This is particularly important since the implementation is being assigned to the third organizational structure. Just as it is important staff be knowledgeable about the regulated community, it is equally important they understand the implementation ramifications of their decisions.

Implementation, Compliance and Enforcement:

The third organizational unit under HR 2318 is the Implementation, Compliance and Enforcement structure. This part of the proposed Department of Environmental Protection is of particular interest to state programs. The Undersecretary of this area would be charged with "Coordinating Department programs, with, and assisting, State and local governments in implementing environmental programs." The duties of this undersecretary would obviously include state programs as well as the regional offices.

An important function of this part of the department is to bring a level of consistency and equivalency to decisions directly affecting the states. Decisions and processes related to the approval of state regulations for delegated programs, or the conduct of delegated programs are examples of areas which can benefit from oversight. While I am not advocating a one-size-fits-all approach in all instances, there is a benefit associated with more inter-regional consistency. States like the regulated community need predictability.

As a state program director, I am very interested in maintaining a close working relationship with the upper management of the department. It is important to maintain the ability of state programs to influence decision-making within the department including the Secretary's office. It is important the new Department of Environment maintain an effective and comprehensive process for states and regional administrators to communicate directly with the other areas of the department including the Science and Information, and Policy, Planning and Innovation as well as the Secretary's office. An important role of the Undersecretary for Implementation, Compliance and Enforcement should be to facilitate communications between states, regions and other parts of the Department of Environmental Protection as well as be an advocate for states' issues and interests.

An additional positive aspect of the proposed structure should be the streamlining of the various levels of communication between the regional office staff and the current media-specific "stovepipes" staff from headquarters. A frustration on the part of states is the multiple levels of the agency involved in decision making. Let me use an example: the State of Kansas adopts a set of regulations required under a federal statute. The statute requires approval by the regional administrator before implementation. The regional office must "consult" with media-specific headquarters staff before proceeding. At worst, the approval of these state regulations can become entrapped in discussions and/or internal disagreements on multiple levels. The end result can be inordinate delays in the implementation by the state program.

Conclusion:

The proposal -- found in both HR 37 and HR 2138 -- to elevate the current Environmental Protection Agency to cabinet status is a positive step that clearly indicates the importance of protection of the public health and environment at the national level. The emphasis on science in HR 2138 is also a key component, which should lead to improvement in the communication and decision-making processes as well as consistency in the implementation of environmental protection programs across the country. In considering the design and organization of a Department of Environmental Protection, there should be an effort to streamline the decision-making process to eliminate unnecessary delays and overlapping reviews. In addition, states have enjoyed a level of access to the EPA Administrator in recent years, which has been very productive and effective for both EPA and the states. The structure of the cabinet-level department should maintain and facilitate this productive and desirable relationship.

Thank you for your attention and the invitation to speak with you today. I would be happy to answer any questions you have this afternoon or in the future.

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Mr. OSE. Now, as we discussed, we're going to go all the way over to Mr. Guzy who joins us. He is here. He has previously served two decades in practicing environmental law. He had the privilege of serving as the EPA General Counsel during the prior administration. He has practiced in the private sector, and he's represented EPA during his tenure at the Department of Justice.

Sir, you're welcome. You have 5 minutes.

Mr. GUZY. Thank you, Mr. Chairman, Mr. Tierney and members of the committee for today's invitation. I commend the chairman for his continued leadership in addressing this very important issue.

Former Administrator Reilly described EPA as "uniquely the environmental overseer, watchdog and point of reference regarding the status, needs and problems of ecology and environmental health in America," surely a Cabinet-level role.

I urge the committee to seize the current opportunity once and for all to elevate the Agency, but this will only happen if the implementing legislation is straightforward and unencumbered by limitations on EPA's authority.

H.R. 37, introduced by Congressman Boehlert, meets this test. H.R. 2138, in my view, unfortunately does not.

The history of efforts to elevate EPA could not be clearer. Time and again these efforts have stalled because an unencumbered approach became laden by controversial concerns. Please let's not make the same mistake again.

EPA's charter must remain fluid and nimble to respond to a future that is impossible to predict. When I first came to EPA in 1994, its Web sites received approximately 100,000 hits per year, and today they receive over 125 million hits per month. What a change in just a few years.

H.R. 2138's mission statement, limited to some vague notion of unreasonable risk, is unfortunately value laden, potentially too rigid, at odds in spirit with individual statutes and certainly will be controversial.

Would the new Department even be able to pursue under this standard some of the very areas of focus now recommended by NAPA, the National Academy of Public Administration, such as addressing climate change and nonpoint source pollution, their top priorities? If Congress wants to change the standards for protecting our air, our water or our land, it should have that debate in the context of the individual legislation and not under the guise of changing the Agency's name.

On science, I urge you to be cautious when you hear sound science as a justification for change. In the late 1990's, during my tenure at the Agency, the poster child for bad science repeatedly cited by Congress and industry was EPA's association of elevated fine particles and premature deaths. These criticisms at the time ignored the extensive peer review that had occurred both outside and inside the Agency, and since then these criticisms have been discredited by an independent review body, by ample newly developed peer-reviewed science and even through the crucible of litigation all the way to the Supreme Court, where EPA received a unanimous victory.

Too often claims of flaws in EPA science have been used by advocates to bolster mere policy disagreements, and some scientific uncertainty is inevitable as a fact of regulatory life.

Other proposed changes to EPA's structure, while well intentioned, may suffer from unintended consequences. Does placing regulatory development under the Under Secretary for Policy while having all regional permitting activity supervised by the Under Secretary for Implementation mean that EPA will lose touch with the real-world consequences of its regulatory actions? Does the Chief Financial Officer have the competence to address regulatory costs? Can the Bureau of Environmental Statistics' mission of transparency be squared with an approach that withholds from the public any corporately identifiable data?

My point is not that H.R. 2138 does or does not have it right. It is that these issues are complex and deserve careful analysis.

H.R. 2138 raises important issues about how EPA's operations can be improved. I agree with the need to take additional steps to integrate science into agency resource and regulatory decisionmaking, with strengthened independent statistical data and with the need to enhance EPA's ability to move toward creative multimedia approaches, but I recommend you join truly straightforward Cabinet elevation with the creation of a high-level commission to report back here on proposed changes to enhance the new Department's effectiveness.

Now, we'd be remiss if we didn't root this discussion in the context in which it's currently occurring. I am very concerned, as I believe the American people increasingly are, that Cabinet elevation will be seen as nothing more than window dressing if we continue down the road the administration has been taking on the environment.

The administration claims to want to empower States to carry out environmental protection, yet it undercuts them when their interests do not neatly align with its own. Within the last few weeks EPA compelled States to adopt its controversial new source review changes. The Solicitor General filed a brief in the Supreme Court opposing important tools that California uses to protect citizens from its unique air quality problems.

The administration claims to support sound science, yet EPA removed a comprehensive discussion of global climate change from its efforts to assess the state of the environment. It continues to ignore the findings made by the National Academy of Sciences at the administration's own request that climate change impacts are human-induced and real. It has issued gag orders on perchlorate. It has not allowed EPA staff to conduct studies of mercury emissions. It has revoked the requirements for science-based plans to accomplish watershed planning through total maximum daily loads.

These are just a few examples of an approach that seemingly at every turn belittles environmental and public health protections. Achieving the historic step of elevating EPA to Cabinet status, however worthy, cannot and will not obscure this troubling record; and I urge you to address these real problems as well.

Thank you most kindly for the opportunity to testify. I'd appreciate having my full statement placed into the record, and I'd be pleased to answer any of the committee's questions.

Mr. OSE. Thank you, Mr. Guzy.

[The prepared statement of Mr. Guzy follows:]

TESTIMONY OF GARY S. GUZY

**BEFORE THE U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON ENERGY POLICY,
NATURAL RESOURCES AND REGULATORY AFFAIRS**

SEPTEMBER 9, 2003

Mr. Chairman and Members of the Committee, thank you for inviting me to appear today. I am very pleased to provide my views on the elevation of the U.S. Environmental Protection Agency (EPA) to cabinet level status. I commend Chairman Ose for his continued leadership in addressing this important issue.

I come before you with two decades of environmental law experience, having had the privilege of serving as EPA's General Counsel during the prior Administration, having practiced in the private sector, and having represented EPA during my tenure at the Department of Justice.

I believe that it is important to provide our nation with all of the necessary tools to protect fully public health and the environment, and this includes having a Cabinet level Department of Environmental Protection. I therefore urge the Committee to seize the current opportunity to once and for all accomplish this change, but caution that it may only be achievable if the implementing legislation is straightforward and unencumbered by limitations on EPA's authority. I therefore urge you to support H.R. 37, introduced by Congressman Sherwood Boehlert, complemented by a high level process designed to improve EPA's operations.

Ratifying the EPA's Accomplishments and Equipping It for Future Challenges

Our nation has much to be grateful for when it comes to the environment and the work of EPA. Through its consistent efforts over the last 30 years -- in partnership with states, tribes, businesses, and the advocacy community -- many aspects of our environment have gotten cleaner and the health of Americans has improved, even while our economy has grown. We have seen major air pollutants decrease by some 30% since 1970, at the same time as vehicle miles traveled have increased by 145% and U.S. energy consumption has increased by 40%. *EPA's Draft Report on the Environment 2003.* We have seen significant portions of our Nation's landscape and waterways returned to health, public enjoyment, and resultant economic prosperity. Much of this progress has been the result of EPA's efforts to carry out the farsighted set of major environmental laws created by Congress, in a spirit of bi-partisanship, in the 1970's.

These improvements are not a reason, however, to let down our guard. We still face major environmental and public health challenges in the areas where EPA has not been as active or where the problems remain persistent. These include continuing smog in populous regions that leads to premature deaths, restrictions on outdoor activities, and respiratory ailments. They include contamination of waterways so that fish are inedible and beaches are closed for

swimming. They include seemingly inexplicable clusters of childhood cancers and increasing evidence of endocrine disruption in adults. They include mounting evidence of large scale global warming.

The National Academy of Public Administration has identified three priority areas on which EPA should focus its future efforts, each of which poses complex challenges beyond addressing end-of-pipeline industrial pollution from large sources. These are: reducing nutrients in watersheds resulting from non-point source pollution; controlling the many sources of ground-level ozone and smog; and clarifying the choices the Nation must make to bring about a reduction in carbon dioxide and other greenhouse gases. National Academy of Public Administration (NAPA), *Environment.gov: Transforming Environmental Protection for the 21st Century* (2000); Statement of Dr. Janet L. Norwood before the Subcommittee (Sept. 21, 2001).

An agency grappling with these complex issues has a vast effect upon the everyday lives of Americans in communities across our Nation. In the scope and importance of its work, in its budget and economic impact, and in the international consequences of its actions, it should be apparent that EPA is engaged in cabinet-level work. That status should be recognized for symbolic reasons, but also to ensure that our country is optimally equipped to confront these critical and difficult issues. As William Reilly, who served as EPA Administrator during the first Bush Administration, put it, "A more contemporary understanding that EPA is uniquely the environmental overseer, watchdog, and point of reference regarding the status, needs and problems of ecology and environmental health in America, compels a broad view of the agency's role." Testimony by William K. Reilly before the Committee on Governmental Affairs, U.S. Senate (July 24, 2001). This is a view far better captured by a cabinet level department.

Not Getting There and Unintended Consequences

There is ample reason to be concerned that, however lofty this goal, it may not be attained if the effort to secure cabinet elevation is also seen as an opportunity for adding new restrictions on EPA's operations. The history of efforts to elevate EPA to a cabinet agency could not be clearer. In 1988, 1991, 1993-94, and again in 2001, these efforts have stalled because an unencumbered approach became laden with the particular concerns of various Members of Congress. These proved to be controversial enough to halt this important project. Let us not make this same mistake again.

Some of the proposals for changes I have seen --such as housing peer review outside of EPA in the National Academy of Sciences -- do not seem designed to better equip a new Department. Rather, they seem designed to hobble EPA and to prevent it from carrying out its responsibilities.

We should be skeptical when we hear "sound science" being used as the justification for a change. In the late 1990's, during my tenure at the Agency, the poster child for bad science repeatedly cited by Congress and industry was the epidemiological basis for EPA's association of elevated fine particles and premature deaths. These criticisms ignored the extensive peer review that had occurred, both outside the Agency in independent peer reviewed journals and

inside it through a Congressionally mandated review process. Further, the criticisms have since been discredited by subsequent reevaluations by an independent body -- the Health Effects Institute -- as well as by ample newly developing science. These criticisms were discredited as well through the crucible of litigation, ultimately resulting in a unanimous Supreme Court decision in favor of EPA. Too often, claims of flaws in EPA's science have been used by advocates to bolster mere policy disagreements.

Other changes being contemplated to EPA's structure -- while perhaps well-intentioned -- may suffer from perverse unintended consequences. For example, the feature of H.R. 2138, the bill introduced by the Chairman, that has regulatory development supervised by the Under Secretary for Policy and regional permitting activities supervised by the Under Secretary for Implementation (section 7) may lead to the loss of practical and common sense understanding in the on-the-ground consequences of proposed regulatory actions and further separation from state-based capabilities. Would the consolidation of science functions in a new Under Secretary (section 7) lead to its isolation in yet a different "stovepipe", as Administrator Whitman suggested in her testimony before this Subcommittee? Testimony of Administrator Whitman at 247 (July 16, 2002) ("My concern with establishing a Deputy Administrator for Science . . . is that science should be incorporated throughout the Agency. It should be part of every one of the Assistant Administrator's jobs. I don't want anyone thinking the Deputy Administrator for Science will take care of that.").

When I first came to EPA, in the mid-1990's, its websites received approximately 100,000 "hits" per year. Administrator Browner emphasized expanding citizens right-to-know, and today EPA's internet sites receive over 125 million hits per month. This reveals the central importance of environmental information and the public's thirst for more and better data. I recount this change, though, for a more fundamental and important reason. It is that EPA's charter -- its mission and its authorizing structure -- must remain fluid and nimble to respond to changes that we cannot today possibly forsee. How unfortunate it would have been to have locked the agency into a mission that would have precluded it from moving into the environmental information arena. Likewise, I urge extreme caution with any proposed mission because the unintended consequences of it down the road are far too difficult to fathom. Even today, a mission such as set out in H.R. 2138, limited to some vague notion of "unreasonable risk"(sec. 4(b)(2)), seems unfortunately value-laden and calculated to engender controversy. Would the new Department even be able to pursue some of the very areas of focus recommended by NAPA -- such as addressing climate change and non-point source pollutants -- under this implicit "unreasonable risk" standard?

There are numerous other important questions as well. The loss of Senate consultation in the appointment of the General Counsel (section 6) and the disparity with the approach for the chief financial and science officers of the new Department may instead diminish that official's ability to achieve consistent legal interpretations across offices and regions. Does the Chief Financial Officer really have the competence to address regulatory costs (section 7(g)(1))? Does not the creation of independent enforcement authority for the proposed Bureau of Environmental Statistics (section 8(d)(1)) create the possibility of inconsistent actions and interpretations by the new Department? How can the Bureau's mission of transparency be squared with an approach that withholds from the public any "corporately identifiable data" (section 8(h)(2))? Why should not other important issues be addressed during the reorganization, such as codifying a

commitment to protecting children's health based upon their scientifically demonstrated greater sensitivities and exposures?

Toward Improved Public Health and Environmental Outcomes

That is not to say that H.R. 2138 does not raise important issues about how EPA's operations can be improved. I agree generally with the need to further integrate science into agency resource prioritization and regulatory decisionmaking. I support the concept of an enhanced capacity for independent statistical data as well as for better program evaluation. I believe we need to enhance EPA's ability to move toward creative multi-media approaches, but without undermining the basic tenets of its existing authorities.

Each of these issues, though, is complex and deserves careful analysis and direction. Nor is it to say that Congress, EPA, state regulators, and concerned citizens are starting at the beginning in thinking about these issues, for much work already has been done. The change to cabinet status should provide the impetus for Congress to establish a more focused, high level commission that would report back to Congress for the consideration of changes to enhance the new Department's effectiveness.

Achieving Real Public Health and Environmental Protection

I would be remiss in my responsibility to the Committee if I did not root this discussion in the context in which it currently is occurring. I am very concerned -- and I believe the American people increasingly share this view -- that this effort will be regarded as nothing more than window dressing if we continue down the road the Administration is taking on the environment.

The Administration claims to want to empower states to carry out environmental protection, yet it undercuts them when their interests do not align neatly with its ideological agenda. Within just the last few weeks, EPA compelled states to adopt its controversial New Source Review changes, and the Solicitor General filed a brief in the Supreme Court in the diesel fleet rule case attempting to remove important tools that California uses to protect its citizens from that State's significant air pollution.

The Administration claims to support sound science, yet EPA removed a comprehensive discussion of global climate change from its effort to assess the state of the environment and it continues to ignore the findings made by the National Academy of Sciences -- at the Administration's request -- that climate change impacts are human induced and real. It has issued "gag" orders on perchlorate and not allowed EPA staff to conduct studies of mercury emissions.

The Administration has thwarted Congressional intention and removed any incentive for aging industrial facilities to be replaced by more efficient and better controlled ones through its New Source Review changes. It reversed the opinions of my predecessor and myself as General

Counsel that the Clean Air Act provides the authority to treat carbon dioxide as a pollutant by disingenuously claiming that Congress has effectively precluded consideration of this issue. It has revoked plans to accomplish watershed-based pollution planning through the tool presented by total maximum daily loads.

These are just a few examples of an approach that, seemingly at every turn, belittles environmental and public health protections. Achieving the historic step of elevating EPA to cabinet status -- however worthy -- cannot and will not obscure this most unfortunate record.

I thank the Committee for the opportunity to testify and would be pleased to answer any questions you may have.

Mr. OSE. Mr. Elliott, thank you for your patience. You're recognized for 5 minutes.

Mr. ELLIOTT. Thank you, Mr. Chairman.

I agree with my colleagues that it's important to elevate EPA to Cabinet status. I do disagree with my good friend Gary Guzy. I support the chairman's bill primarily because of its provisions to upgrade the role of science at EPA and make other important organizational improvements.

After 20 years of study of the Agency as an academic, I am convinced that the single most important thing we could do to improve the Agency is to create a high-level advocate for science at the highest reaches of the Agency. I can't improve on the report by a distinguished committee of the National Academy of Sciences in 2000 which said, "Just as the advice of the Agency's legal counsel is relied upon by the Administrator to determine whether a proposal is legal, an appropriately qualified and empowered science official is needed to attest to the Administrator and the Nation that proposed action is scientific."

As I reflect upon my own experiences at EPA as General Counsel, I believe that scientific considerations were, unfortunately, conspicuous by their absence from the high-level dialog at the Agency. This situation has gotten worse rather than better in subsequent administrations.

I respectfully disagree with my friends such as Gary Guzy who think that any kind of changes in Cabinet status legislation will make it unenactable. I think that is a demonstrably mistaken theory that has been really discredited by history. We've had a number of simple elevation bills in the past but they have not been enacted essentially for political reasons. I hope that this time, for a variety of reasons, it will be possible to elevate EPA to Cabinet status. I think the true test is the one that Jim Connaughton articulated, and that is that Cabinet status legislation should be limited to truly organizational or structural issues such as creating an Under Secretary for Science, but there's plenty of room to do that, and it would be an important reform.

The problem in my experience is the triumph of politics at EPA. It's not that EPA lacks scientific information but rather there is a reality or a perception that decisions are based on politics rather than on science. This is a bipartisan disease. We can have abuses and ignoring of science either of the right or of the left.

Adam Smith, the great political philosopher and founder of economics, once wrote, "Science is the great antidote to the poison of enthusiasm and superstition." He should have written that it is a bipartisan antidote, and science is an antidote for the superstitions and enthusiasms of either the right or the left.

In my view, the problem is that we don't have a high-level advocate for science at the top councils of the Agency, and I hope that the committee and the Congress and the Nation will seize this historic opportunity to strengthen the voice of science at EPA.

I thank the committee; and Congressman Shays in particular from my home State of Connecticut. It is a pleasure to be testifying in front of you as well.

Thank you very much, and I'd ask that my written statement be made part of the record.

Mr. OSE. Without objection. The Chair thanks the gentleman.

[The prepared statement of Mr. Elliott follows:]

Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
Committee on Government Reform
U.S. House of Representatives
September 9, 2003

Testimony of E. Donald Elliott[1] on EPA Cabinet Elevation

(H.R. 37 and 2138)

Mr. Chairman and Distinguished Members of the Committee:

It is a pleasure to testify before this distinguished Subcommittee on the important topic of EPA Cabinet elevation. As an academic working in the fields of environmental law, administrative law and law and science, as well as a former EPA General Counsel and a practicing environmental lawyer, I strongly support the bi-partisan proposals to elevate EPA to cabinet status. Creating a Cabinet-level environmental ministry will send a clear signal at home, as well as to our friends in Europe and elsewhere, that we as a nation are second to none in the importance that we give to protecting the environment for future generations. Cabinet status is also a good idea because it will more clearly make the White House responsible for EPA's actions or inactions, rather than reinforcing the mistaken impression that EPA is somehow "independent" of presidential direction and control.

While I would support Mr. Boehlert's bill (H.R. 37), I do prefer Mr. Ose's bill (H.R. 2138) because of its provisions to upgrade the role of

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science within EPA and its other organizational provisions. I do not agree with those who say that it is either inappropriate or infeasible politically for the Congress to deal with organizational issues such as creating a high-level chief science officer when legislating a cabinet-level Department of the Environment. On the contrary, most legislation creating new departments has properly addressed similar organizational and structural issues.

To improve environmental policy over the long term, there are, in my view, two pressing needs for organization improvements at EPA: (1) to create a high level advocate for science, and (2) to make sure that EPA's enforcement office is brought under proper policy control and does not continue to be an independent policy-maker, as I believe that it has been in New Source Review program under the Clean Air Act and other areas in recent years.

In the years since I left EPA, I have worked as an academic primarily on how to improve environmental policy. I am convinced that one of the keys is to strengthen science's voice at the highest levels within EPA. After much study, I am convinced that creating a high-level advocate for science at the highest levels of the Agency is the single most important step that we could take in that direction, and I applaud the efforts of Mr. Ose, as well as Mr. Ehlers and others in the past, to make this good idea a reality. As I testified before the Senate in 2001, I believe that an Undersecretary for Science is the right way to accomplish this objective.

The arguments that we need a high level advocate for science at EPA are admirably made in a report by a distinguished committee of the National Academy of Sciences in 2000. Just as law has a high-level voice through the

General Counsel, science also needs a similar high-level voice, I therefore support the recommendation by the National Academy of Sciences for a high-level chief science officer who would advise the Administrator – hopefully, soon the Secretary --whether proposed policies are consistent with science, just as the General Counsel advises the Administrator whether proposals are consistent with law, just as the advice of the agency's legal counsel is relied upon by the Administrator to determine whether a proposal is 'legal,' an appropriately qualified and adequately empowered science official is needed to attest to the Administrator and the nation that the proposed action is 'scientific'—that it is consistent, or at least not inconsistent, with available scientific knowledge ...."[2] I have published two articles recently explaining at length why I endorse this recommendation based on my own experiences at EPA as well as over 20 years studying the Agency as an academic.[3] Rather than repeat those arguments at length in my prepared testimony, I request that these articles be made part of the record. To sum up my argument, as I reflect on my own experience at the highest levels of EPA, I believe that scientific considerations were unfortunately conspicuous by their absence from the high-level dialogue, and I believe this situation has gotten worse rather than improved in subsequent Administrations.

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[2] National Research Council, *Strengthening Science at the U.S. Environmental Protection Agency* (2000).

[3] E. Donald Elliott, Strengthening Science's Voice at EPA, 66 Law & Contemp. Problems (Autumn 2004, forthcoming). E. Donald Elliott, The Science Debacle at EPA, *in* Science, Agencies, and the Courts: Is Three a Crowd? 31 ELR 10125 (Jan 2001).

I respectfully disagree with my friends who believe that any substantive provisions of any sort will kill EPA Cabinet-status legislation. This is a demonstrably mistaken theory that we came up with when I was at EPA in 1990. Since both parties had endorsed Cabinet-status in principle, we thought that perhaps a simple EPA elevation bill with no other provisions could pass. This was naïve and misguided in 1990 and it is naïve and misguided today. A simple elevation bill didn't pass in 1990 and it didn't pass subsequently. The theory that the key to legislating cabinet status is a simple elevation bill is refuted by history. The reasons that EPA has not been elevated in the past have been largely political, having primarily to do with who gets credit with the American people for putting an environmental agency into the Cabinet. Each party has favored the idea when it is in power, and then quietly finds reasons to oppose it when the other party is power. Perhaps now that we have the unique circumstances of the White House, House and Senate all under the control of a single party, we can finally pass EPA cabinet status legislation. We should not miss this unique historical opportunity, however, to deal with some of the long-standing organization issues at the Agency, such as elevating the role of science.

We all understand that a "clean bill" is more likely to become law if stripped of controversial positions. Each of us would undoubtedly like to see his or her pet project written into Cabinet-status legislation. I, for example, am a long-time supporter of "Next Generation" or "Alternative Compliance" legislation.[4] Such legislation would give environmental

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[4] E. Donald Elliott, Toward Ecological Law and Policy, *in* THINKING ECOLOGICALLY: THE NEXT GENERATION OF ENVIRONMENTAL POLICY 170 (continued...)

regulators flexibility to move beyond "one size fits all" solutions in order to achieve superior environmental performance. I would dearly love to see such authority written into Cabinet-status legislation, but I reluctantly recognize that this is not the time or place for substantive revisions.

Nonetheless, within the principle that Cabinet-status legislation should be restricted to truly organizational issues, I do think there is still room for needed organizational reforms, such as creating an Undersecretary for Science. In other words, I think a bill like the Ose bill that limits itself to truly structural issues IS a "clean bill" that does not deal with extraneous measures. There is plenty of room within the concept of a "clean bill" to designate a high-level "Chief Science Officer" at a new Department of the Environment -- in the same way that pending proposals already designate chief legal officers, chief financial officers and chief information officers. Science is conspicuous by its absence from mention in some of the pending bills.

Perhaps the single greatest failing in the current structure of EPA is the absence of a high-level advocate for good science at the Agency's highest echelons. The role of science must be enhanced and built permanently into the foundations of the new Department of the Environment. My mentor Bill Reilly was fond of quoting a remark Senator Moynihan made to him during his confirmation process: "Young man, do

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(...continued)

(ed. M. Chertow & D. Esty, Yale Univ. Press, 1997); E. Donald Elliott and Gail Charnley, Toward Bigger Bubbles, 13 Forum for Applied Research and Public Policy 48-54 (Winter 1998); E. Donald Elliott, Beyond Environmental Markets: or Three Modest Proposals for the Future of Environmental Law, 29 CAPITAL U. L.REV. 245 (2001).

not allow your programs to become based on middle-class enthusiasms." The greatest danger for the new Environmental Department, as for EPA at some low points in the past, is that it will be taken over by some passing political "enthusiasm" – of either the right or the left -- that is not grounded in science. "[S]cience is the great antidote to the poison of enthusiasm and superstition."[5] wrote Adam Smith, the political philosopher and father of economics.

Of course, science alone cannot make environmental decisions. There are always uncertainties and environmental decisions always involve values and policy judgments as well as science. But the risk today is NOT that we will have too much science and not enough politics in our environmental decisions,[6] but the rather just the opposite. As Georgetown University law professor Steven Goldberg aptly put it: "Regulatory agencies are regularly accused of being 'captured' by industry, consumer groups, members of Congress or bureaucratic inertia. They are never accused, however, of being captured by scientists."[7]

I applaud many recent efforts to upgrade the role of science at EPA, including the development of a world-class Science Advisory Board, the STAR program, enhanced peer review and an enhanced role for scientists on the working groups. These are all good steps forward. The problem that remains, however, is not that EPA lacks accurate scientific information, but

5. Adam Smith, An Inquiry into the Nature And Causes of the Wealth of Nations (1776). CHAPTER I, PART 3 ARTICLE III.

6 Compare Adam Babich, Too Much Science In Environmental Law, 28 Columbia Journal of Environmental Law 119 (2003).

7 Steven Goldberg, The Reluctant Embrace: Law and Science in America, 75 GEORGETOWN L. J. 1341, 1365 (1987).

rather that science is not often heard in the top councils of the Agency when decisions are made.

It is particularly important to create a chief science officer over and above the traditional AA-ships such as the Office of Research and Development (ORD). It is part of the culture that Assistant Administrator's (AA's) are expected to maintain their silence about matters that are within another AA's bailiwick. Thus, in my experience, ORD usually maintained its silence even when its scientists understood that a proposal had little scientific support, or even was blatantly unscientific.

In conclusion, let me thank the subcommittee for this opportunity to testify. I am very proud of my service with EPA, and I strongly support its elevation to Cabinet status. I do believe, however, that science needs a clearer – and yes, a louder -- voice in the highest councils of the new Department. I hope that in one way or another, the legislation reported out by this subcommittee will provide that missing voice.

Mr. OSE. Dr. Moghissi, welcome. Thank you for your patience. You're recognized for 5 minutes.

Mr. MOGHISSI. It appears to me that the three former EPA people have been lumped together and, as usual, we all don't agree.

My perspective is as a former principal——

Mr. OSE. Dr. Moghissi, if you could just take the throat of the mic, the little extender, and straighten it. The mic is like this. Take it and go like that. There you go.

Mr. MOGHISSI. Here we go.

Mr. OSE. We need an attorney for some useful purpose. We welcome you, Dr. Moghissi.

Mr. MOGHISSI. I won't tell my joke on attorneys. I'll leave it for a later date.

My perspective is as a charter member of the Environmental Protection Agency, as a former principal science adviser for radiation hazardous materials, as an academic administrator—I was assistant vice president of University of Maryland and associate vice president at Temple University and as a professor at various universities. I'm a scientist. I'm not a lawyer. I'm not a politician.

Let me briefly say what led to the decision to support the bill under consideration. We at the Institute for Regulatory Science are dedicated to the idea of best available science, and my statement includes details of what constitutes best available science, and I would appreciate if it's made part of the record.

Mr. OSE. Without objection.

Mr. MOGHISSI. My frustration started when I arrived in Washington as a principal science adviser in 1977, worked in the various work groups and recognized how the regulations were written. I was extremely frustrated at that time when I talked about regulatory science, it was considered a joke, these are contradictory terms.

Now, we are in the process—we have two studies in progress. The reason I'm bringing them up is because my conclusions are derived from those two studies. One, the study of science at the EPA—with all due fairness to my friend on this side on the EPA's science. There's a large consensus within the scientific community that the EPA's scientific—the scientific foundation of EPA's regulations is largely poor.

I have come to the conclusion, as my friend on the right side has come, that the inclusion of politics—I call it ideology—is responsible for the poor science. I believe, like he does, that the EPA scientists, my former colleagues, are outstanding like other scientists are, but I believe the management has done some damage to it.

The second study deals with the objective of environmental laws. Our preliminary study indicates that the objective overwhelmingly is the protection of the human health, and the human welfare is secondary to it. The reason we worry about ecology is because ecology can produce products that aren't fit for human consumption.

Now, if I may be permitted, I have some of my friends who heard that I'm supporting the bill—they have contacted me and tell me how could I do that? It is simple. In my judgment, if the EPA is forced to rely upon independent peer review—and the operative word is independent—then the cost of the operation of the EPA, even with the addition of the Under Secretary of Science, even with

the addition of the Bureau of Environmental Statistics, will be reduced rather than increased. I would be happy to elaborate why I believe that.

Second, I would appreciate it if a sentence in my testimony—the written testimony is slightly modified. The section, "What is best available science," the first sentence under "Science versus non-scientific objectives," it should read, "There is ample evidence indicating that the intrusion of nonscientific objectives would jeopardize the objectivity and consequently the acceptability of scientific information."

Let me go now and suggest—I will use my all diplomatic skills and suggest that the H.R. 37 should not be considered. What is the point? The EPA, as the Administrator already said, is already a member of the Cabinet. She participated in all the Cabinet meetings. So why would anybody want to change it? Passing a law with all the changes that need to be done simply to change the name of an agency that is a Cabinet member already to another Cabinet member? I don't see why maybe scientists are not smart enough to know the reason for something like that.

Now, I'm strongly recommending that the word environment in the bill be defined—and I have a definition. "Environment means humans, other living things and environmental media." Environmental media are already defined. Because of the study, as I described, it would meet the objective of the bill.

Second, I'm recommending that the Peer Review Team be renamed to Peer Review Oversight Team and will be given the responsibility to oversee the peer review activities of the Department of Environmental Protection by appointing specific panels. And I would be happy to elaborate on that.

Thank you very much, sir.

Mr. OSE. Thank you, Dr. Moghissi.

[The prepared statement of Mr. Moghissi follows:]

Statement of A. Alan Moghissi, Ph.D.

President, Institute for Regulatory Science
Columbia, MD - Alexandria, VA

Presented at the hearings on H.R. 2138 - Elevating the Environmental Protection Agency to Department of Environmental Protection.

Mr. Chairman, Members of the Subcommittee:

Thank you for the opportunity to provide testimony on elevation of the U. S. Environmental Protection Agency (EPA) to the Department of Environmental Protection. My testimony is based on my perspective as a charter member of the EPA; a research scientist; a science administrator; an editor; and a manager who had to comply with environmental regulations. In addition, for the last two decades I have been actively involved with promotion of the concept of Best Available Science (BAS) because of my concern over the quality of science used in many of our societal decisions notably on matters related to environmental protection.

When EPA was formed, we were most enthusiastic about the prospect of having one agency handling all environmental issues. Although I am proud of our achievements, I am not so proud that opportunities were lost to enhance the quality of the environment. I am even less proud that significant funds were spent on activities that had a relatively small impact on the quality of the environment, while true environmental issues were either insufficiently addressed, addressed late, or not at all. It is true that the EPA was asked to perform a nearly impossible task of promulgating regulations when the necessary data were insufficient or lacking. However, EPA has made numerous decisions that are based on less than Best Available Science regardless of the availability of scientific information. This accusation is made not only by those who had to live with the often stringent regulations, but also by a rather large number of independent reviews and studies performed by various scholarly organizations.

We at the Institute for Regulatory Science are in the initial phases of performing two studies that would have an immediate impact on the proposed formation of the Department of Environmental Protection. Currently, we are seeking funding to continue these two studies and hope that we can complete them reasonably soon. The basic thrust of these studies is as follows:

1. The first study deals with the criticism of the quality of science used at the EPA. We are evaluating studies performed by scholarly organizations such as the National Research Council (the research arm of the National Academy of Sciences, National Academy of Engineers, and the Institute of Medicine); the General Accounting Office; and various professional societies. We are also evaluating relevant decisions by the courts, and information published in peer-reviewed journals. Although this study is in its initial phases, the evidence is overwhelming that the mainstream scientific community has significant reservations regarding EPA's science. The key reason for the science problems at the EPA is the lack of recognition that the foundations of acceptability of scientific information is independent peer review. Precisely because EPA's decisions are often highly contested, one would have expected that the EPA would attempt to err on the side of caution and rely upon independent peer review. Instead, the evidence is overwhelming that most relevant scientific documents used in regulations are not independently peer reviewed. The situation is even less favorable for guides.

2. The second study covers environmental laws. In this study we are trying to evaluate Congressional Findings in various environmental laws. We are particularly interested to determine the emphasis of Congress relative to the protection of humans versus the protection of other living things, including the ecosystem. Again here initial results clearly indicate that Congress has given high priority to protecting humans.

A closer look at the reason for the relatively poor scientific performance of the EPA indicates that the management notably the political leadership of the EPA has traditionally accepted and sometimes favored the intrusion of ideology, societal objectives, and numerous other non-scientific issues into the science underlying regulatory decisions. This tradition has resulted in a culture at the EPA which is

responsible for the negative view of the scientific community notably those in the regulated community on the science of EPA. By far the most serious accusation is that EPA has been selective in using scientific information by choosing the information that supported its preconceived views and disregarded the information that did not. There are significant potential dangers in the continuation of such a culture. The impact of such a culture is not only economical, but at a minimum it includes the development of a potentially deep-seated mistrust in all decisions related to environmental protection. Please note that the history is littered with remnants of those societies that tried to infuse ideology, societal objectives, and other non-scientific desires into science.

I want to be sure that my criticism of science at the EPA is not construed as questioning the competency or dedication of scientists and engineers at the EPA. Based on my personal experience, I am convinced that the competency and dedication of EPA's scientists and engineers compare favorably with those in other federal agencies and elsewhere.

Precisely for reasons described above, I believe that the structure of the Department of Environmental Protection as included in H.R. 2138 is reasonable. I hope that the Congress can impress upon the science part of the Department of Environmental Protection the significance of reliance upon Best Available Science. This includes the following core requirements:

1. The science must be entirely separated from societal objectives. Scientific facts should be provided to the regulators; and the regulators are the ones to introduce societal objectives in applying science.

2. All scientific information that is used in promulgating regulations or in preparing guides must be subjected to independent peer review. Obviously, there are minor decisions that can be exempted from such a requirement. In contrast to scientific information, societal decisions cannot be judged by scientists. Scientists are no more qualified to decide societal issues than members of any other profession or trade.

3. The Management of the Department of Environmental Protection must formally respond to the findings and recommendations of peer review panels, and must make the response available to the public. The publication of such a response does not need to violate requirements to protect proprietary information and protection of human subjects. There is a well-established process to do so.

4. The scientists and engineers at the science side of the Department of Environmental Protection should be encouraged to publish the results of their activities in peer-reviewed journals, and should actively participate in the professional societies of their respective disciplines.

5. The program offices of the Department of Environmental Protection should be discouraged from intruding in the scientific deliberations of the science side. This requirement should not be interpreted as discouraging interaction between the two groups. Instead, this requirement should prohibit the program offices from dictating or asking the science side to provide evidence for a preconceived outcome.

6. The Department of Environmental Protection should be encouraged to revisit its decisions and correct decisions based on poor science or new information. Although many laws require such a revision, in practice, EPA has been reluctant to do so.

I have no illusion that it will take some time to restructure the tradition and the culture of an agency that is accustomed to ideologically-processed science. However, H.R. 2138 provides a mechanism to reduce the problem and hopefully initiate a new tradition.

I do have some comments for consideration by the Subcommittee. For the sake of simplicity, I am dividing my comments into two groups. The first group consists of those comments that I strongly urge the Subcommittee to consider, as they are critical to the success of the Department of Environmental Protection. The second group consists of those comments that are desirable.

Let me address the first group which I **strongly urge**:

1. As stated above, it appears that the primary focus of the majority of environmental laws is the protection of humans. The protection of other living things is based not only on ethical concerns but also on the recognition that medicine has benefited from the availability of a vast pool of biologic materials. Obviously, there are numerous other reasons for protecting other living things. Consequently, it is imperative that the word environment is defined in the bill. I am suggesting that under section 3 definitions after item (2) the word environment is defined and the remainder of that section is renumbered accordingly as follows:

(3) Environment means humans, other living things, and environmental media

2. In several instances the bill included wordings such as humans and the environment. Consistent with the definition described above, it should be changed to **environment and particularly humans**. The affected sections include 4 (b) (3); 4 (b) (4); 7 (d); and 7 (g) (1).

The **desirable** modifications are as follows:

1. Section 8 (j) establishes a Bureau of Environmental Statistics. The formation of this Bureau and its functions is appropriate and long overdue. Section (8) (j) (2) establishes a Peer Review Team. I am suggesting that the title of the Team be changed to **Peer Review Oversight Team** and its function be changed to oversee the peer review of a variety of information managed by the Bureau. This recommendation is based on many years of my experience with independent peer review of various projects many of them related to environmental protection. The **Peer Review Oversight Team** would have the ability to appoint independent peer review panels to review various aspects of the highly-complex topics covered in the responsibilities of the Bureau. At a minimum, the text must include provisions that the **Peer Review Oversight Team** can appoint panels for specific reviews in support of the Team's efforts.

Mr. Chairman and members of the Subcommittee, you have undertaken an important task of converting a cabinet agency to a department. During this process, you have attempted to correct the most important shortcoming of that agency. I believe that the chosen approach is sound. I hope that my comments will help to improve the bill. Those of us who have dedicated our professional lives to protection of the environment hope that you will be successful in your efforts.

Attached to this testimony are three documents:

1. A description of Best Available Science which constitutes the foundation of the Institute for Regulatory Science.

2. Fundamentals of Independent Peer Review as practiced by the Institute for Regulatory Science and many other scholarly organizations.

3. A biographical summary describing my professional qualifications.

Attachment 1: What is Best Available Science?

A. Alan Moghissi, Ph.D.

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WHAT IS BEST AVAILABLE SCIENCE?

The public is often provided with contradictory scientific information. The news media are often accused of selecting scientists who support their preconceived notions. Advocacy organizations, certain regulatory agencies, and even certain members of the legislative branch of the government seem to follow the same path. The result is confusion, mistrust of science, scientists, and many important societal institutions. Those frustrated with the current situation have coined words such as sound science and junk science to identify the acceptability of scientific information. Meanwhile, the phrase Best Available Science or BAS is increasingly used to describe the level of acceptability of scientific information. The BAS concept is based on three important elements as follows:

1. Status of science
2. Selection process
3. Science vs non-scientific objectives

Status of Science

The status of scientific knowledge can be categorized into three classes, each having two subgroups as follows:

Class IA - Confirmed science: This class is equivalent to scientific law. It is scientific information that has been unequivocally confirmed and generally accepted. Note that each scientific law or scientific fact has its limitations and conditions for its validity. For example, the validity of the law of gravity has been well established including the fact that it does not apply to atomic nucleus. Similarly, the speed of light is known with a given accuracy. The differences in its measurement are within the generally-accepted accuracy.

Class IB - Applied science: This class consists of application of scientific laws to various branches of commerce and industry. Engineering and other applied sciences fall into this class.

Class IIA - Extrapolation: This class includes scientific information obtained by extrapolation from observations beyond its scientific validity. Most predictive models and a large segment of contested scientific information fall into this class. These include predicted changes in the global climate, and cancer assessment as performed by the U.S. Environmental Protection Agency (EPA). Data resulting from exposing rodents to high levels of chemicals (occasionally so high that a fraction of animals die of acute poisoning) are extrapolated by EPA to humans for exposure levels that are sometimes a million-fold lower.

Class IIB - Scientific judgement: In many cases, decisions must be made without having the needed scientific information. The methodology for expert judgement is reasonably well developed and consists of asking a number of individuals to give answers to specific questions and statistically assess the results. However, in absence of this rigorous system, the scientific judgement is no more than an educated guess.

Class IIIA - Speculation: This class consists of information that is not based on any scientific information or judgement. Ethical consideration dictates that the nature of the information be clearly indicated. This requirement is mandatory for any scientist who engages in speculation. Furthermore, it is imperative that the scientific community develop unambiguous rules of conduct to ensure that speculation is identified as such.

Class IIIB - Pseudo-science: Sometimes called junk science or politically-processed science, this information has the sole purpose of promoting someone's ideology. The champion of this class of science was

Lysenko, a Soviet geneticist who claimed a new form of genetics. The result of implementation of his system was the destruction of genetics research in the Soviet Union and disastrous agricultural production in that country. Pseudo-science is by no means limited to the past or the Soviet Union. A large segment of information disseminated by certain advocacy groups can be classified into this category. Often the dissemination of pseudo-science is justified on the basis that it is necessary to exaggerate or scare people in order to move the democratic system. What is being overlooked is the long-term damage that misinformation causes.

Selection Process

There are rational and reasonable uncontested methods to resolve scientific controversies. Briefly, the scientific information is divided into the following four distinct categories:

Group 1 - Personal Opinions: Expression of views by individuals regardless of their training, experience, and social agenda, are included in this group. Personal opinions are seldom if ever BAS. At best, this category can be used to initiate the study of a scientific issue. Note the standard process of news media is reliance upon this category in its reporting of scientific issues.

Group 2 - Gray Literature: Written information prepared by government agencies, advocacy groups, and others that has not been subjected to an independent peer review is included in this category. This is the favorite category of government agencies, advocacy groups, and individuals who want to promote an idea. In fact, this category is the more organized and written form of personal opinions. Again here, at best, this category should be used to initiate a study. Experience shows that in the overwhelming majority of cases this category does not meet the requirements of scientific acceptability.

Group 3 - Peer-Reviewed Science: Information subjected to an independent peer review constitutes this category. Peer review is the foundation of scientific acceptability. There are numerous requirements for acceptability of peer review. Briefly, the individual who is chosen as a reviewer must be a peer to the author of the study, and must have no conflict of interest. In addition, the author of the study must respond to the criticism by the peer to the satisfaction of an uninvolved person or organization.

Group 4 - Consensus-Processed Science: This category consists of information resulting from a process used to resolve scientific disputes. The prerequisite for this process is the formation of a group of peers under the auspices of an organization that is uniquely qualified to do so. Professional societies are primary candidates for this activity. There are, however, certain limitations to such an approach as follows:

1. Professional societies are qualified to manage the consensus process in their respective disciplines. For example, engineers cannot authoritatively speak on medical practice, and chemists cannot judge the validity of issues related to electrical engineering.

2. Management of the consensus process must exclude parochial interests of the profession represented by the professional society. Many professional societies represent their parochial interests and should disregard these interests during the consensus process.

3. Organizations established by Congress for the purpose of reaching scientific consensus must meet certain requirements. For example, the National Research Council (the research arm of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine) is uniquely qualified to

evaluate interdisciplinary scientific issues. In contrast, the National Academy of Public Administration is qualified to address administrative issues, and the National Council on Radiation Protection and Measurements is qualified to evaluate issues related to radiation.

Science vs Non-Scientific Objectives

A key area on acceptability of scientific information is the intrusion of non-scientific objectives in science. It is true that scientific investigation is performed because society wants to solve a problem or otherwise enhance the knowledge of humanity. In effect, the initiation or continuation of scientific activities are based on a societal objective. However, the inclusion of ideology, beliefs, or any other non-scientific objective in assessing the validity of scientific information is inconsistent with the foundation of BAS. Scientists have no monopoly on deciding what is good for society. Consequently, once the science is evaluated using the peer review or consensus process, members of other professions such as lawyers, accountants, or book sellers are as qualified to decide what is good for society as are members of the scientific community.

Attachment 2: Fundamentals of Independent Peer Review

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Fundamentals of Independent Peer Review

INTRODUCTION

The need to provide scientific advice to the nation was recognized as early as the administration of Abraham Lincoln who established the National Academy of Sciences which resulted in the formation of the National Academy of Engineering and the Institute of Medicine. Recognizing the need for a joint research organization, the academies formed the National Research Council (NRC). More recently, Congress has found it necessary to establish the National Council on Radiation Protection and Measurements and the National Academy of Public Administration to supplement the activities of the NRC. The development of science, engineering, and technology has reached a level whereby it is not only desirable but mandatory to ensure that societal decisions rely upon the Best Available Science (BAS). Inherent in the BAS concept is independent peer review. For a number of reasons, including the passage of several laws by the Congress, it has become fashionable among federal agencies to claim that they perform peer review of many of their activities. Numerous reports of the NRC, along with those from the General Accounting Office (GAO) and many other organizations, indicate the deficiency of these claims. The fact is that several federal agencies notably the U.S. Environmental Protection Agency (EPA) have a long way to go to embrace the concept of BAS, including the independent peer review.

PRINCIPLES OF INDEPENDENT PEER REVIEW

The formation of the Institute for Regulatory Science (RSI) was a direct consequence of the recognition that a large number of our regulations are based on poor science. The expressed mission of RSI is the promotion of BAS. The concept of BAS separates scientific from societal aspects of a decision that include value judgements. In recent years, RSI has teamed up with the American Society of Mechanical Engineers (ASME)Cone of the largest and oldest professional societies in the world to formulate clear and unambiguous criteria guiding the performance of independent peer review. Based on the experience of ASME/RSI, the following principles were identified as the most important requirements for an independent peer review program:

Principle 1: *The selection of reviewers and the outcome of the peer review are the result of the consensus of a group rather than the decision of an individual.*

This principle implies that all decisions dealing with selection of reviewers and the review must be made collectively by a group of qualified individuals rather than a single individual. Consequently, the ASME/RSI process uses a committee appointed by a duly organized entity of ASME. This committee appoints Review Panels (RPs) who in turn perform the review.

Principle 2: *Clear and unambiguous policies ensure that conflict of interest is avoided or at least minimized.*

The issue of conflict of interest is normally addressed by having each reviewer sign a conflict of interest form implying that the individual has no conflict of interest. However, such an approach leaves the judgement entirely to the reviewer. An independent peer review process requires clear policies indicating what constitutes a conflict of interest. The policy guiding the conflict of interest should be: *Those who have a stake in the outcome of the review may not act as reviewer or participate in the selection of reviewers.*

Principle 3: *The findings and recommendations of the review panel address unambiguous and clear*

questions (sometimes called review criteria or lines of inquiry) identified by the sponsoring organization.

The past experience of many federal agencies has resulted in skepticism indicating that reviewers appeared to have had a free reign in addressing any issue. A properly-managed independent peer review must be based on clearly identified questions (review criteria or lines of inquiry). To be sure, questions (review criteria in lines of inquiry) must be technically reasonable. However, they must be based on the needs of the manager and must be responsive to those needs.

Principle 4: *The findings and recommendations responding to the review criteria are constructive and helpful rather than being adversarial.*

This important and hereto under-emphasized principle is an integral part of independent peer review. As the review is intended to assist the managers in their decision process, it should be helpful to the decision makers rather than being confrontational.

Principle 5: *The participation of appropriately selected stakeholders significantly enhances the credibility and acceptability of the results of peer review.*

The participation of stakeholders in an independent peer review is an asset. In the context of this principle, stakeholders are those who are personally impacted by a decision; those who must deal with it during the course of their occupation; and all others who have an interest in the outcome of the peer review or the peer review process. Experience indicates that a properly-managed program of stakeholder participation can avoid the sometimes disorderly and chaotic conditions that can result from such participation. Also, the experience indicates that a properly-designed and properly-conducted peer review will enhance the acceptance of the decision that is based on the results of the peer review.

DEFINITION OF INDEPENDENT PEER REVIEW AND RELATED ACTIVITIES

Independent peer review is often confused with other processes notably internal reviews, technical advice, and many other forms of reviews. It is also confused with an important process called independent technical assessment. Although there are similarities among these processes, they are not identical.

Independent Peer Review

Independent peer review consists of a critical evaluation of a project. The project may consist of a study; the scientific foundation of a regulation; a program; competing submissions such as grants; scientific claims; or any other technical document. It is performed by an RP consisting of individuals who by virtue of their education, experience, and acquired knowledge are qualified to be peers of the investigators who participated in the performance of the project. A peer is an individual who is able to perform the project, or the segment of the project that is being reviewed, with little or no additional training or learning.

As indicated in the ASME/RSI principles described above, there are several critical criteria defining requirements for the appointment of members of an RP and the peer review process as follows:

1. Qualifications of the reviewers.
2. Independency of the reviewers from individuals, agencies, or organizations who may be impacted by the outcome of the review.
3. Evaluation of criteria on qualifications and independency of each proposed reviewer by a group with the

functional title Peer Review Oversight Committee (PROC) whose members, in the judgement of an uninvolved technical organization, meet both the requirements on qualifications and independency.

4. Transparency of the peer review and its process.

Independent peer review constitutes the core of acceptability of scientific and engineering information; thus it is performed virtually by all professional societies of scientists and engineers in their publications and other activities. They are uniquely qualified to establish PROCs for peer review of specific subject areas.

Independent Technical Assessment

Independent technical assessment consists of a critical evaluation of a topic. There are significant differences between an independent peer review and an independent technical assessment. The independent peer review consists of rendering judgement on existing information. In contrast, the results of an assessment consist of information gathered, developed, or synthesized by the Assessment Panel (AP). The requirements for appointment of members of an AP are identical to those for independent peer review. Accordingly, the three criteria described under independent peer review apply equally to APs. In this case, the PROC is referred to as Technical Assessment Oversight Committee (TAOC).

Other Forms of Review

There are numerous other forms of reviews that do not qualify as either independent peer review or independent technical assessment. A large number of peer reviews performed by federal agencies fall into this category. In many cases, an individual within the federal agency evaluates the qualifications of the reviewer and assesses the reviewer's independence. Clearly, such an approach does not meet the three criteria identified above.

Examples

There are numerous examples of the three categories of reviews. The following examples are intended as illustrations of each category of reviews.

1. **Independent Peer Review:** The U.S. Department of Energy (DOE) and its predecessor organizations had used the Nevada Test Site for testing nuclear weapons. Approximately 900 explosions took place above ground, above groundwater, at groundwater, and below groundwater. A strategy had been developed by the DOE for remediation of groundwater contamination at that site. The DOE asked the team of ASME/RSI to establish an RP to independently review its strategy. The DOE in cooperation with certain stakeholders identified 11 questions dealing with the validity of the approach, and several other specific questions on how DOE intended to address the problem. The RP was asked to respond to each question with yes or no with appropriate qualifications, and describe its response in its Findings. Subsequently, the RP provided 11 Findings responding to the 11 review criteria. The RP also provided eight recommendations that were directly derived from these Findings. Note that the sole responsibility of the RP was to review DOE's strategy.

2. **Independent Technical Assessment:** The EPA was instructed by the U.S. Congress to initiate an independent study to be performed by the NRC to identify the most important research relevant to setting particulate matter standards, to develop a conceptual plan for particulate matter research, and over five years, to monitor research progress toward improved understanding of the relationship between particulate matter and public health@. In 1998, the NRC prepared its first response to the Congressional mandate. The structure of the report, its content, and the distribution of information among its various chapters were entirely decided by

the committee established by the NRC.

3. **Other Forms of Review:** There are too many examples of other forms of review. For example, on numerous occasions managers of a laboratory or an office seek technical advice from a group of individuals whom they appoint to review a specific project. Such an activity is appropriately referred to as technical advice.

STRUCTURE OF INDEPENDENT PEER REVIEWS

A properly-designed independent peer review process is based on a tiered system. A peer review oversight committee (PROC) establishes policies and ensures that they are followed. The peer review of each project is performed by an RP established by the PROC. The elements of the program include the following:

1. Oversight of Peer Review
2. Review Panels
3. Review Criteria
4. Technical Peer Review Reports
5. Requirements for Transparency of the Process

Peer Review Oversight Committee

The oversight of the peer review is the responsibility of a PROC to be established preferably by a relevant professional society of scientists and engineers. There is a tradition of cooperation among the professional societies to ensure coverage of the necessary disciplines among member of the PROC for the review of multi-disciplinary projects. The functions of the PROC include the following:

1. As the overseer of the entire peer review process, the PROC should enforce all professional and ethical requirements.
2. The PROC evaluates the qualifications and independency of members of each RP and approves those that it deems acceptable.
3. It reviews and approves reports resulting from peer review for compliance with professional and ethical requirements.
4. On occasion the sponsoring organization responds to the recommendations of the RP. In these cases, the PROC renders a judgment on the responsiveness of the sponsoring organization to the recommendations of the RP.

Review Panels

Criteria for acceptability of members of an RP are as follows:

1. **Education:** A minimum of a B.S. degree, preferably an advanced degree in a relevant discipline is required. In rare cases, this criterion may be waived if the candidate is so outstanding, as demonstrated by the other three technical criteria.

2. **Experience:** In addition to education, the reviewer must have significant experience in the area that is being reviewed.
3. **Peer recognition:** Election to an office of a professional society; serving on technical committees of

scholarly organizations; and awards by recognized technical groups similar activities are considered to be a demonstration of peer recognition.

4. **Contributions to the profession:** Contributions to the profession may be demonstrated by publication, primarily in peer-reviewed journals. In addition, patents; presentations at meetings where the papers were peer-reviewed; and similar activities are considered to be contributions to the profession.

5. **Independence:** One of the most complex and contested issues in peer review is a set of subjects collectively called conflict of interest. The ideal reviewer is an individual who is intimately familiar with the subject and yet has no monetary interest in it. The guiding principle for conflict of interest is as follows: *Those who have a personal stake in the outcome of the review may not act as a reviewer or participate in the selection of reviewers.*

Peer Review Criteria

Sometimes referred to as lines of inquiry, peer review criteria are questions provided to the RP to be answered. In a properly-performed independent peer review, the RP responds to review criteria affirmatively or negatively and explains the rationale for the response. In addition, the RP may decide to respond to more than one criterion or the totality of criteria. Responses to questions that were not asked or descriptions outside the scope of peer review are seldom if ever helpful.

Review reports

The *Technical Peer Review Report* with the subtitle *Report of the Review Panel* contains the results of the peer review. Typically the report should consist of the following items:

1. Introduction describing activities that led to the preparation of the report, including a listing of submitted documents.
2. Executive Summary.
3. Summary of the subject that was reviewed.
4. Peer Review Criteria.
5. Findings of the Panel consisting of shortcomings and meritorious aspects of the project. Note that often Review Criteria and Findings are combined.
6. Recommendations of the Panel.
7. References.
8. Appendix containing significant comments of one reviewer which were not shared by others, or those that were considered to be beneficial to the Project Team, but were not important enough to be included in the main body of the report.
9. Biographical Summary of the members of the RP and the PROC and others who had significant technical impact in preparing the report.

Note that for competing submissions or other reviews containing proprietary information, provisions must be made to modify the process. Such a process is in place in the ASME/RSI independent peer review process.

Ideally the *Technical Peer Review Report* is not completed with the *Report of the Review Panel.* It should be incumbent upon the sponsoring organization to respond to the recommendations of the RP. If such a procedure is followed, the addition of the response of the sponsoring organization converts the subtitle to *Interim Report.*

The *Interim Report* is converted to *Final Report* after the PROC reviews and approves the *Report of the Review Panel* and accepts the response by the sponsoring organization.

Transparency of Peer Review

One of the major reasons for mistrust of the scientific foundation of many regulations is the lack of transparency of the peer review process. Transparency of peer review implies that members of the public notably the stakeholders are as informed about the entire peer review proceedings as is the sponsoring organization. This requirement implies that information which is provided to the RP is made public at the same time that it is provided to the RP. It also implies that meetings of the RP, except its executive sessions when the RP writes its report, are open to the public. It also implies that any information about the review process, members of the RP, and any other information which is provided to the sponsoring organization is also provided to the public. The only exception to the transparency requirement is the distribution of proprietary and classified information to the public.

Public participation is a legally-mandated process and often requires a public hearing where every entity individual or corporate can participate. In contrast to public participation, stakeholder participation if properly managed is significantly more structured by identifying and addressing stakeholders' concerns about the issue at hand. On more than one occasion, arguments have been heard by stakeholders who consider their participation as window dressing. Conversely, many decision makers are often concerned by some stakeholders who believe that their recommendations *must* be adopted by the decision makers.

Stakeholder participation is particularly important in issues involving scientific decisions. Most stakeholders are highly critical of those organizations responsible for making scientific decisions, particularly U.S. agencies and industry. Consequently, stakeholder participation in independent peer reviews is a key to the acceptability of the final decision.

OTHER RELEVANT SUBJECTS

Management of an independent peer review requires attention to many more details than is described in this document. For example, in a large-scale project, no reviewer should be used more than two to three times during the life of that project. If so, the Project Team tends to pander to idiosyncrasies of individual reviewers. Similarly, members of the RP should include senior individuals who may have broad knowledge, as well as junior investigators who have detailed knowledge of a specific subject, but may not have the experience and wisdom of more senior investigators. Finally, maintenance of the integrity of the review requires that members of the RP avoid private interactions with members of the Project Team.

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Mr. OSE. Now, this is our fifth hearing on this concept of elevation of the EPA. In our June 6th hearing, this committee heard testimony regarding problems with EPA's operations and science, with the effectiveness of its regulations and its impact on the regulated community, with problems States have with EPA's regional and program offices, with the lack of cross-media research, in addition to a number of other issues. The sum and substance of that was that many of our witnesses believe that, after 30 years of what they describe as seeking piecemeal improvements, EPA needs to be reformed structurally.

I'm going to go from my left to my right here. Mr. Chisum, should Congress make improvements to EPA's organizational structure concurrent with its elevation?

Mr. CHISUM. Absolutely. I think that Congress could instruct EPA or the new Cabinet-level position to work more——

Mr. OSE. Move that microphone closer to you, if you would, please, because we bought a whole bunch of new mics. So everybody gets one.

Mr. CHISUM. Absolutely, Mr. Chairman.

I believe that the EPA could work closer with the States on new innovative programs in a way to comply with the EPA's mandated policies, and I think that could be written into the legislation and be a great assistance to the State in meeting the requirements under EPA.

Mr. OSE. Mr. Roitman.

Mr. ROITMAN. I think there's no question that there are structural improvements that could address a lot of the concerns that you raised and that we also echo. I think the challenge is going to be how to best integrate those goals across whatever organizational structure Congress ends up enacting, because—say, with the regions, which is where we have our most direct impact, it's important that they have—they're coordinated across the functional areas that you've addressed here so that, whatever the structure is, I think it's going to be important to have ways into the process from the policy and innovation part, from the science part as well as from the implementation part.

Mr. OSE. Dr. Hammerschmidt, should Congress make improvements to EPA's organizational structure concurrent with elevation?

Mr. HAMMERSCHMIDT. As usual, I find myself in agreement with my neighbor, Mr. Roitman. The short answer is yes, and I think we need to focus from our concern as States on science and the ability for us to work across all portions of the Agency.

Mr. OSE. Mr. Elliott.

Mr. ELLIOTT. Yes, I would agree that's a very appropriate role for Congress.

I'd go even farther. If you think about it, there are very few other ways that the culture of an existing agency like EPA can be changed to become more scientific other than types of organizational reforms you're talking about. So I think it's crucial that the Congress assume that responsibility; and when you study the field, there are very, very few other things that can be done to change the culture of an agency other than the type of organizational changes you're talking about. So I think it's very important.

Obviously, the challenge is not to micromanage, but I think the bill has struck a good balance, giving the Agency flexibility for the future, but in a few areas where there is a broad consensus, bipartisan consensus of the need for improvement, I think the Congress is doing an excellent job of sending a signal, and I think it will improve matters for the future.

Mr. OSE. Dr. Moghissi.

Mr. MOGHISSI. Yes, I agree with the statement of my friend, Mr. Elliott, here. Yes, the bill does provide a reasonable balance. As a member of the work groups, I saw what was going on in these work groups. Changing the culture by letting the scientists be scientists and take the science and draw conclusions from it—that culture—would be extremely important.

Mr. OSE. Mr. Guzy.

Mr. GUZY. I agree that it essentially is Congress's prerogative and role to make those changes should it desire to do so. I have two kinds of concerns about doing that in this instance, as I tried to outline in my testimony.

First, there are just the practical concerns of whether or not in so doing the various competing proposals engender controversy that takes us off course of ever reaching elevation of EPA to Cabinet status. Because that's the goal I think we all agree on. Then, second, the substance of any of those proposed changes, are they in fact potentially counterproductive?

What I would recommend instead is that with straightforward Cabinet elevation that you create and charge and give a timeframe for the consideration of changes by an independent high-level body or commission as well as by the Agency and that they report back here and then Congress have the opportunity to take that information into account in order to come up with the appropriate changes after the Agency is already operating as a department.

Mr. OSE. Thank you all.

The gentleman from Connecticut.

Mr. SHAYS. I thank the gentlemen for being here. I missed the testimony from the first panel, and I regret that.

I just really have a comment in general that—probably not so enlightened, but I'd like your response to it. If Mr. Ose can get this bill passed, he deserves to be President, because——

Mr. OSE. Just a minute now. Wait a minute. I'm trying to go home.

Mr. SHAYS. Bottom line is, though, it is such a logical thing to do and yet it seems so difficult. I have the view that the administration has worked hard to convince people that the environmental community is mad at it and wants the environmental community to be mad at it, because there's no other logic for me to understand why they have done some of what they've done.

I agree with this administration on a whole host of issues, but when it comes to enforcement of environmental law, I can't even explain why we have taken some of the positions we've taken. So my only conclusion is that they have wanted the environmental community to be mad and express that they're mad so that our so-called base is pleased with it.

Tell me, what tells you that—first, all of you support this legislation, is that correct? I mean, in general, you want to see a Depart-

ment of Environmental Protection. Correct? So, nodding of heads, there's a basic agreement.

What tells you that this administration is inclined to support this legislation? Mr. Elliott.

Mr. ELLIOTT. Well, one thing that tells me that is that the two administration witnesses, Jim Connaughton and Marianne Horinko, said that the administration supported this, as the administration's representatives. I think there was an important breakthrough in the sense that they both said that the administration specifically supported the idea of an Under Secretary for Science. They were both very articulate in explaining how that would improve the functioning of the Agency. And I must say I was very pleased to hear it, having been a long-time advocate of that position.

So I don't believe that any of these provisions are killer amendments or unreasonable or will increase the political vulnerability of this bill at all. I think they're very, very modest and have been really needed for a long time. I mean, Gary Guzy's idea of a high-level body making recommendations, that's what the National Academy of Science did in the year 2000.

Mr. SHAYS. So if we could get this legislation passed without other things being added like risk assessment and so on, then you think that we would have a shot?

Mr. ELLIOTT. Yes, I do. I've been a long-time advocate of a concept of unreasonable risk, but I do believe that's the one provision that goes over the line and could be cited as having a substantive rather than organizational component.

But I really disagree very strongly, as I've indicated in my testimony, with the idea that what has prevented EPA Cabinet status from being enacted in the past are the substantive provisions of the bill. I think that's a canard, and I think it's just demonstrably false.

What has happened is that, politically, neither party has wanted the other party to get credit for EPA Cabinet status. Now that we have a situation of Republican control of both the House and the Senate and the administration, I think we have a historic opportunity to get this done. I don't think we should be greedy. I don't think we should have substantive provisions, but as long as we're talking truly organizational structure on a bipartisan basis, I think it's a unique opportunity.

The other side of that coin is I think it's a unique opportunity to make some long-needed reforms, and that opportunity should not be missed.

Mr. SHAYS. Is it Mr. Guzy?

Mr. GUZY. Yes.

Mr. SHAYS. Mr. Guzy, or Attorney Guzy, from what I understand of your position, that the camel's head under the tent, you'll see a lot more—you want to keep the bill as clean as possible.

Mr. GUZY. Well, that's correct. In addition—or to amplify on that, if I may, Mr. Shays, I very much agree with Mr. Elliott's comments that by far and away the greatest concern that I have in H.R. 2138 is the mission statement itself, because I do believe that moves beyond purely structural changes to the Agency to potentially addressing some very significant substantive issues. But there is a

way in which the substance—I'm sorry, the structure itself can have an impact on the Agency's ability to carry out its mission, and I have an independent degree of concern about—aside from whatever anyone—whatever someone else may add down the road—whether this bill has it just right.

I'd just point out that Administrator Whitman testified when she was last here that "my concern with establishing a Deputy Administrator for Science is that science should be incorporated throughout the Agency. It should be part of every one of the Assistant Administrators' jobs. I don't want anyone thinking the Deputy Administrator for Science will take care of that."

There's a way in which isolating or creating a new stovepipe for science can potentially isolate it and remove it from the responsibilities of other parts of the Agency. There's a way in which taking the science function away from the program offices could in fact have regulatory development even have a harder time in achieving a sound scientific basis.

Mr. SHAYS. I can't imagine if you could achieve a Department of Environmental Protection that you would oppose the bill based on that.

Mr. GUZY. I'm sorry.

Mr. SHAYS. Based on having a separate Under Secretary for Science?

Mr. GUZY. I believe that there should be the enhancement—the further enhancement of science at the agency for——

Mr. SHAYS. That is not what I asked. In other words, if this bill—disregarding the mission statement, which needs to be changed a bit, in spite of the former Director of EPA—Administrator of EPA saying we didn't need a separate Under Secretary, you would not oppose this legislation if it could go through the House and Senate pretty much this way without the mission statement or you would? What would you do?

Mr. GUZY. And there are a few other issues that I think are worth talking about as well. But if your suggestion is a structural change that is designed to enhance science as part of this legislation and that's it, then—and that would be the ultimate result of the legislation—of the legislative process, then it's likely something I would support.

Mr. SHAYS. Thank you. Thank you all very much.

Mr. OSE. Thank you, Mr. Chairman. Thank the gentleman. Mr. Elliott, on pages 2 and 5 of your written statement, you point out that most legislation creating new departments properly addresses similar organizational structural issues; in other words, the debate on one pretty is much the same for the next one after that, so on and so forth. You state that H.R. 2138 is truly structural and therefore in your words a clean bill without extraneous measures, which I appreciate your definition. Does the fact that H.R. 2138 proposes the elevation of an already existing agency alter your conclusion as to whether or not this is a clean bill?

Mr. ELLIOTT. No, not at all. I think the fact that it is an existing agency is really all the more reason that these types of organizational issues ought to be addressed. First of all, we have a 30-year track record here, so I think it's entirely appropriate for the Congress at the time of EPA Cabinet elevation to be reacting to the

agency's record and culture and history and trying to make a mid-course correction. And I would cite, for example, the Food and Drug Modernization Act, which was passed almost unanimously by both House and Senate a few years ago, as an example of similar structural changes being made to an existing agency.

So I really think there is a good record of Congress successfully changing the culture of agencies through legislation. Second, I think it's important to bear in mind, as Jim Connaughton referred to briefly, that the Under Secretary level, which is where you're doing most of the work organizationally, doesn't exist today at EPA as an agency. And so in EPA Cabinet status elevation, we have an opportunity to address what cross-program functions ought to be addressed at the Under Secretary level. That's an issue that doesn't really arise under the existing organizational structure because you don't have that position.

There were some problems with the idea with a Deputy for Science at EPA because of the conflict between two deputies, and that was vented in the past. With elevation, the Under Secretary level, I think, is the appropriate place to have not only an Under Secretary for Science, but also some of the other cross-program integration functions.

Mr. OSE. And one of the things that I have had the pleasure of hearing is the claims from all directions in the political spectrum that EPA does not use or properly use sound science. This gets to the establishment of an Under Secretary for Science and Innovation as detailed in section 7 of my bill.

Mr. Chisum, do you support the centralization of science at the new Department and an Under Secretary for Science and Innovation?

Mr. CHISUM. Yes, I do, Mr. Chairman, and science combined with statistical data will be the best way to make policy.

Mr. OSE. Dr. Hammerschmidt, what's your position on it? Do you support the centralization of science?

Mr. HAMMERSCHMIDT. Yes, I do. I have commented that that is one of the better aspects of the bill, one I am quite enthusiastic about. In addition, I think a personal concern I have within EPA now is we need to do a better job of educating EPA staff who are not scientists in scientific concepts and that could also be an important function of this particular part of the organization.

Mr. OSE. Mr. Roitman, one of the major irritations I have is this cross-media analysis which I don't know of a more timely example than our struggle with MTBE in California. We are worried about the air and now we've got water, but there was no cross-media analysis that satisfactorily analyzed that. Would an Under Secretary for Science and Innovation promote the cross-media studies that you advocate throughout your written testimony?

Mr. CHISUM. I believe it would, Mr. Chairman, because as you well know when we talked about MTBE it was mandated and it seemed to be the best alternative for it, but now that we've looked at it a little closer we find out we can do other things in order to reach clean air. So I think it would help.

Mr. OSE. Mr. Roitman, do you agree with that?

Mr. ROITMAN. Yes, I do. Having an Under Secretary for Science would very much promote our ability to be smart about cross-media

impacts of decisions that are being made. What we need is good science and good data so that we're looking at the full picture when we're making decisions, and I think this would very much help that.

Mr. OSE. I apologize for being very direct on these questions and not asking everybody their collective wisdom. I'm just out of time here and I see my red light. Mr. Elliott, on page 2 of your testimony, you note support to Congressman Ehler's approach to elevating science in H.R. 64 and for the approach laid out in H.R. 2138, which is my bill. Why do you believe that an Under Secretary for Science and Innovation is the right way to elevate science at EPA?

Mr. ELLIOTT. I think you need to change the culture of the agency so that science is heard on all issues. Science needs a representative at the highest levels in the policy debates at the agency. When I was at the agency a decade ago, there were only three people in the agency that really had a mandate across all the areas of the agency. They were the Administrator, the Deputy Administrator and the General Counsel. There was a strong norm that scientists should not speak unless spoken to, that the Office of Research and Development would not interfere with proposals that were being advanced by another AA ship. So I think the concept of turf had grown up rather strongly. I had one incident where the scientists had been in a room at a briefing for the Deputy Administrator. They didn't say anything or object and then came up to me in the hall afterwards and said, "Don, how could you let this happen. You know this is unscientific." When the scientists are coming to the General Counsel saying you ought to do something to stop this, we have a structural problem at the Agency. We need somebody like the General Counsel but a General Counsel for Science who can be an advocate for a scientific point of view. I think an Under Secretary for Science and Innovation is the best way to do that. I think we have a structural problem at the Agency and we need a structural solution to counterbalance the other forces. We have a strong high level advocate for policy or politics at the Agency, a strong high level advocate for law, and we need to balance those forces with a strong high level advocate for science.

Mr. OSE. Dr. Moghissi, on page 3 of your written statement you make several suggestions that you break out into two groups to improve the scientific credibility of EPA, including removing scientific deliberations from the program offices. Would you please explain that a little bit further or elucidate us?

Mr. MOGHISSI. For the sake of simplicity, I'm going to invent a new compound called dimethyl chicken wire. The dimethyl chicken wire comes on the market and the department is asked to evaluate what the risks are, what the limitations are to be placed on it and so forth. The science side of the EPA would decide: one, it is a carcinogen, is it a reproductive toxin, is it neuro toxic material, what else is there, whatever toxicity is there. It determines those response functions; would determine what the potential risk may be accurate, with the appropriate arrow bars; and that information would go to the program offices. They may have scientists. But the peer review—the independent peer review science is not provided by the program offices. The program offices are qualified to say what is an acceptable risk, what is the economics, what is this and

that, and they come to a conclusion to an appropriate regulation. That is the only way in my judgment the ideologically processed science which, as of now or has been at least in my time, was prevalent at the EPA will disappear.

Mr. OSE. Under the scenario you have drawn with the dimethyl chicken wire, you're suggesting that the lack of access to the independent peer review is perhaps a significant negative in current process?

Mr. MOGHISSI. Yes, sir.

Mr. OSE. You apparently feel very strongly that an independent peer review is an integral part of what we ought to be doing?

Mr. MOGHISSI. Yes, sir.

Mr. OSE. Now do you support the statutory mandate for peer review?

Mr. MOGHISSI. Yes, I do.

Mr. OSE. During the subcommittee's prior hearings during a discussion on the functions of the Under Secretary of Policy, Planning and Innovation, some of our witnesses testified that most of our environmental laws delegate implementation and compliance efforts to the States. Now some of you have firsthand experience with that. As a result of that delegation, the States play an enormous role in the success of EPA's environmental pollution control and prevention. On top of that States have their own environmental laws and regulations and yet at previous hearings witnesses testified that regional offices inconsistently interpret EPA's regulations, their nonbinding guidance and our laws. States, as many of you testified, require both flexibility and predictability to address environmental challenges.

Now H.R. 2138, which is my bill, provides oversight of the regional offices and consolidates the implementation, compliance and enforcement functions under a single Under Secretary. Mr. Roitman, Representative Chisum in particular, and then I want to come to Dr. Hammerschmidt, do you support the consolidation of this implementation, compliance and enforcement under a single Under Secretary?

Mr. CHISUM. Mr. Secretary, I would support that. However, the delegation of implementation of EPA rules and regulations needs to stay with States that have agreements with the Federal Government in order to do that because we're the one who can best identify the bad actors and innovative programs that could meet the compliance with EPA rules.

Mr. OSE. From your position as a member of the State of Texas Legislature does H.R. 2138 incorporate such flexibility?

Mr. CHISUM. I believe it does.

Mr. OSE. Do you support the consolidation of the implementation, compliance and enforcement?

Mr. ROITMAN. I think it's important that we have consistent program implementation among the regions across the country, and that is based on a lot of years of experience in talking with my colleagues across the country in the implementation of these programs. There does need to be flexibility. There is no question that there are different issues in Colorado than there are in Delaware, for example. But I think you can have consistent approaches while still maintaining flexibility.

The only other comment I would like to make is that I think we do need to make sure that the prominence of innovation, as you have addressed in the bill also is integrated into the program implementation because really the places where we need to innovate are in the States and in the regional offices who are dealing with the public and dealing with the regulated community all the time.

Mr. OSE. Does H.R. 2138 incorporate sufficient flexibility on that standpoint?

Mr. ROITMAN. I believe it can.

Mr. OSE. You believe it can or it does?

Mr. ROITMAN. I believe the way it is written allows sufficient flexibility.

Mr. OSE. So if we send you a question, you could expand on that?

Mr. ROITMAN. Yes.

Mr. OSE. Thank you. Dr. Hammerschmidt, same question, from your perspective in Kansas do you support H.R. 2138's consolidation of implementation, compliance and enforcement?

Mr. HAMMERSCHMIDT. Yes. This is part of H.R. 2138 that I thought the most about and have actually early on had questions about, but I think it does work. What we are looking for as States is a spectrum of solutions. Just tell us what the boundaries of that particular universe is so that we can make the State level decisions and I think the bill does create that ability. It's going to have to be charged to that Under Secretary to make it happen. And bureaucracies are often in the business of implementing what laws are passed by Congress and State legislatures, and I think it is going to be very incumbent upon the administration to make it happen with their appointees.

Mr. OSE. Regardless of the administration it seems implicit in your remarks that the Under Secretary for Science says OK, here's the science bounds, parameter x, opposite of x. You have to be between these poles here and then the Under Secretary for Implementation and Compliance and Enforcement works with the States for solutions between those poles, is that the way you see it?

Mr. HAMMERSCHMIDT. That's the way I see it. And if I can maybe preempt Governor Leavitt on the en Libra process which western Governors and Governor Leavitt have developed, they make it a very explicit statement that science is for facts and process is for making those boundaries.

Mr. OSE. Mr. Roitman, has your State experienced challenges working with regional offices and, if so, do you have suggestions as to how to improve that tradition of interaction between the State and the Federal EPA?

Mr. ROITMAN. I think so much relies on the individuals with whom you are dealing with at any particular time. I think right now we enjoy a very good relationship with our regional administrator and his senior management team. Where you tend to run into challenges are farther down in the organization, where I think it was Ms. Horinko who talked about the 20,000 employees at EPA and not everyone necessarily marching to the exact same drummer. And it is true in any organization and true in mine as well. I'm not sure that there's a structural change that would really improve that, although I very much like the idea of championing both good

science and innovation at the senior levels. I think that can only help.

Mr. OSE. I am very sensitive to everybody's time. That's one of the reasons we started exactly at 2, and I know what the baggage requirement is at the airport and with what the traffic is.

Does the gentleman from Connecticut have further questions? I am going to go ahead and wrap this up with the caveat that we have additional questions we are going to submit to you in writing. We would appreciate timely responses. The record will stay open for 10 days, and that way everyone can make their planes and get home.

I want to thank each of the witnesses today on the second panel for their testimony. This is our fifth hearing on the subject of EPA elevation. Frankly, most people support elevating EPA to the Cabinet, where environmental protection for this country and the rest of the world belongs. We have had three consistent themes emerge from these five hearings and it's very interesting how this has happened.

First, EPA's organizational structure must be modified away from the structure first created in the 1970's, which is not addressing adequately the cross-media issue that we confront in most regulatory climates today.

Second, the regulatory science conducted at EPA must be a priority within the new department. The science must be of its highest quality, must be respected by other scientists and must be independent of the EPA regulators or policymakers.

And finally, EPA deserves to have the benefit of a Bureau of Environmental Statistics, much as the Department of Labor has with the Bureau of Labor Statistics and the Department of Energy has with the Energy Information Agency. A statistical agency is not a novel idea. We're not recreating the wheel. We are just not creating a novel idea, and that's not news to anybody.

I do look forward to working with the witnesses individually, both on this panel and on our previous one and my colleagues and the administration to create a strong Department of Environmental Protection. We're on the road here, gentlemen, and I do appreciate your participation in this. We will work through these issues as best we can and hopefully come up with a product that we can all be proud of.

I appreciate you all taking the time today. This hearing is adjourned.

[Whereupon, at 4:20 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

Questions for the Record
Hearing Held on September 9, 2003
Elevation of EPA to Department Level Status: Federal and State Views
for Marianne L. Horinko, Acting Administrator, U.S. EPA
from Ranking Member Henry A. Waxman and Ranking Member John F. Tierney

Mission Statement

1. The "mission statement" for EPA in H.R. 2138 appears to narrow EPA's purpose, limiting it to protecting against "unreasonable environmental risks."[1] In contrast, key EPA authorities lay out much broader goals for the agency. For example, the Clean Air Act states that its purpose is "to protect and enhance the quality of the Nation's air resources." The Clean Water Act's goal is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." These comprehensive goals aim to protect the integrity of the environment that we inherited and will pass on to our children.

   Do you agree that protecting against "unreasonable risks" is a narrower mandate than the goals laid out for EPA in the Clean Air Act and Clean Water Act?

2. Unlike the Clean Air Act and the Clean Water Act, which direct EPA to protect entire environmental media from a variety of different threats, the Toxic Substances Control Act (TSCA) focuses on the impacts of toxic substances across media. TSCA employs an "unreasonable risk" standard, which has been interpreted by the Fifth Circuit as sharply limiting EPA's regulatory authority under section 6 of TSCA.[2] Specifically, the court found that the unreasonable risk standard requires EPA to "balance the costs of its regulations against their benefits."[3] The court emphasized the role of cost-benefit

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[1] H.R. 2138 also provides that EPA's mission is to "protect and improve the quality of the environment." However, given the relative specificity of all of the following paragraphs discussing EPA's mission in the context of "unreasonable risks," there is a strong argument that the specific language could have the legal effect of setting the boundaries for EPA's authority.

[2] *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) applies a similar standard of protecting against "unreasonable adverse effects on the environment." 7 U.S.C.A. § 136a. EPA determines whether something is an "unreasonable adverse effect" by balancing the "economic, social, and environmental costs and benefits" of allowing the pesticide to be used. 7 U.S.C.A. § 136. As one commentator notes, "[a] significant historical factor limiting FIFRA's success in protecting public health and the environment is the cost-benefit analysis built into the statutory 'unreasonable risk' standard." Michael W. Graf, *Regulating Pesticide Pollution in California under the 1986 Safe Drinking Water and Toxic Exposure Act (Proposition 65)*, 28 Ecology Law Quarterly, 686 (2001).

[3] *Id.* at 1222.

analysis in identifying regulatory approaches that are least costly to industry.[4] The court also opined on the importance of discounting costs and benefits over time, including the benefits of saving human lives.[5] In addition, the court emphasized its preference for quantified costs and benefits, stating that "[u]nquantified benefits can, at times, permissibly tip the balance in close cases. They cannot, however, be used to effect a wholesale shift on the balance beam."[6] As a result of the analytical burdens imposed by the unreasonable risk standard, as interpreted by the Fifth Circuit, it is extremely difficult for EPA to issue an environmentally protective rule under section 6 of TSCA. EPA has regulated only a handful of toxic substances under this provision, and it is widely regarded as a failure.[7]

a. Does the Administration believe that the "unreasonable risk" language should be interpreted consistently when it is used in H.R. 2138 and TSCA?

b. If so, does the Administration believe that under this language in H.R. 2138, EPA's mission would be to protect only against those threats to human health and the environment for which it has been shown that the costs of such protection are "reasonable?"

c. If not, please lay out a detailed legal rationale for differentiating between the interpretation of this language when used in these different contexts. Please also provide the Administration's alternative interpretation of the meaning of "unreasonable risk" under H.R. 2138. Please explain in detail how EPA would determine whether a risk is reasonable for the purpose of defining the scope of EPA's mission.

3. The Fifth Circuit also held that in making the determination of "unreasonable risk" under TSCA, EPA must apply "discounting" to reduce the benefits of environmental protections (or costs of environmental harms) that would occur in the future.

a. Does the Administration believe that under the "unreasonable risk" language in H.R. 2138, EPA's mission would be to protect only against those threats to human health and the environment for which it has been shown that the costs of such

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[4] *Id.* at 1216–1217.

[5] *Id.* at 1218.

[6] *Id.* at 1219.

[7] *See, e.g.*, William Boyd, *Controlling Toxic Harms: The Struggle over Dioxin Contamination in the Pulp and Paper Industry*, Stanford Environmental Law Journal, 357 (June 2002); Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, Environmental Lawyer, 114–115 (Sept. 1999); Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, Texas Law Review, 548 (Feb. 1997).

protection are reasonable in light of the benefits of such protection, and only if such costs and benefits have been quantified, monetized, and discounted?

b. Should EPA's mission be limited to protecting against threats to the environment that can be quantified? That can be monetized?

4. Under the Fifth Circuit's interpretation of unreasonable risk, it appears that if EPA's mission were limited to protecting against unreasonable risk, it would no longer include addressing most long-term threats to the environment. For example, EPA is required under the Energy Policy Act of 1992 to set public health and safety standards to protect the public from exposures to radioactivity from the Yucca Mountain high-level radioactive waste disposal site.[8] These standards are designed to set limits for human exposures to releases of radioactivity from the site for a period of over 10,000 years. Applying a 7% (OMB's preferred rate) or 3% (EPA's preferred rate) discount rate over such a long period of time would make negligible almost any projected monetary level of benefits of the regulation, assuming that such benefits could even be quantified and monetized. Certainly the near-term (and therefore minimally discounted) costs of making the repository more secure would necessarily exceed such benefits. Similarly, problems such as tropospheric ozone depletion and global warming will also have impacts over decades and possibly hundreds of years, which makes the benefits of addressing such problems particularly vulnerable to discounting.

   Does the Administration believe that EPA's mission should include investigation of and protection against long-term environmental problems? How would such activities be encompassed within EPA's mission if it is limited to protecting against "unreasonable risks"?

5. H.R. 2138 section 4(b)(3) states that a mission of the Department of Environmental Protection is to "identify, analyze, monitor, and report on existing and potential unreasonable risks to humans and the environment." As discussed above, however, EPA would have to conduct a risk assessment and a cost-benefit analysis before EPA could differentiate between "reasonable" and "unreasonable" risks. Thus limiting EPA's analytical mission to unreasonable risks only seems entirely unworkable.

   a. Does the Administration believe that EPA's analytical and monitoring activities should be limited to those environmental problems that EPA has identified as unreasonable risks? If so, please explain how this requirement would be practicable.

   b. Does the Administration support the inclusion of language referencing "unreasonable risk" in a mission statement for the Department of Environmental Protection? If so, please explain why.

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[8] Energy Policy Act of 1992, § 801.

c. Would the Administration support adopting EPA's existing mission statement, developed by the agency, which reads: "The mission of the U.S. Environmental Protection Agency is to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends"?[9]

d. Does the Administration propose any alternative language for a mission statement for a Department of Environmental Protection?

Bureau of Environmental Statistics

6. At the hearing, Rep. Tierney raised concerns about the prohibition on EPA releasing any "corporately identifiable" information collected by the proposed Bureau of Environmental Statistics. Specifically, Rep. Tierney asked whether the language in H.R. 2138 section 8(h)(2) could limit the release of any information that EPA otherwise has authority to collect and release. You indicated that you did not believe the language would have that effect, but that you would look at the provision again and respond to Rep. Tierney with a more thorough answer.

   a. Could the language in H.R. 2138 section 8(h)(2) limit the release of any information by EPA that EPA otherwise has authority to collect and release?

   b. Specifically, could this language limit release of such information by an EPA office other than the Bureau of Environmental Statistics?

   c. Could this language limit release of information that EPA otherwise has authority to collect and release if the collection and/or release is by the Bureau of Environmental Statistics?

   If the response to question 10.c is yes, it is unclear why the Bureau of Environmental Statistics should be prohibited — much less by statute, preemptively, and without exception — from releasing information that EPA has the authority to collect and release, and in many instances is required to make available to the public under current law.

   For example, under section 114(a) of the Clean Air Act, EPA has broad authority to obtain information for the purpose of "carrying out any provision of this Act." Specifically, EPA has authority to obtain information from "any person who owns or operates any emission source, who manufactures emission control equipment or process equipment, who the Administrator believes may have information necessary for the purposes set forth in this subsection, or who is subject to any requirement of this Act." EPA may require such persons to "establish and maintain such records," "make such reports," "install, use, and maintain such monitoring equipment," "sample such emissions," and "provide such other information as the Administrator may reasonably

[9] U.S. EPA, *Agency Mission Statement* (available online at: http://www.epa.gov/history/org/origins/mission.htm).

require." Section 114(c) provides that "[a]ny records, reports, or information obtained under subsection (a) shall be available to the public," with the exception of information entitled to protection as "trade secrets." However, the exception for "trade secrets" does not apply to "emission data," which therefore must be made available to the public, with no exceptions.

"Emission data" is defined broadly under 40 CFR 2.301(a)(2)(i). It includes:

> [i]nformation necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source . . . [i]nformation necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including, to the extent necessary for such purposes, a description of the manner or rate of operation of the source); and . . . [a] general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

Thus, under the CAA, EPA currently has very broad authority to obtain information from sources of air pollution, and all information deemed to be "emission data" must be made available to the public. Section 308 of the Clean Water Act provides EPA similarly broad authority to obtain and make available to the public information "required to carry out the objective of [the Clean Water Act]."

It seems unwieldy and impractical for the Bureau of Environmental Statistics to rely largely or solely upon data collected by other portions of the agency. But if the Bureau collects data directly, this raises the issue of duplicative reporting requirements. There will likely be strong pressure from sources to consolidate information collections in order to reduce reporting burdens. If data collected by the Bureau is prohibited from release in corporately identifiable form, either EPA will have to conduct dual information collections for the same data, or data that is now required to be made available to the public under the CAA and other statutes will be mandated to be kept secret.

d. Does the Administration support prohibiting the Bureau from releasing information that if collected under existing law is required to be made available to the public? Or prohibiting the Bureau from releasing information that EPA currently has authority to make available to the public?

e. If yes, how would you address the issue of duplicative reporting raised above?

f. If no, does the Administration support addition of a "savings clause" to H.R. 2138 that would clarify that the bill would not bar any entity within EPA from releasing

"privately or corporately identifiable data" that EPA has authority to collect and release under other authority?

7. The provisions of the DOE Organization Act, which establish the Energy Information Administration, do not include any prohibition on release of data collected by the EIA. In fact, section 205(g) of this act requires that "upon request, any [information collected by EIA] shall be promptly made available to the public in a form and manner easily available for public use," except that this does not require disclosure of information that can be withheld from disclosure under the Freedom of Information Act.

   In section 205(i), EIA is specifically required to conduct and publish the results of a survey of energy consumption in the manufacturing industries, and for this publication EIA must present the results "in a manner designed to protect the confidentiality of individual responses." However, this specific requirement for one particular mandated data collection is far from a blanket prohibition on the release of *any* corporately identifiable data collected by an agency's statistical office.

   Does the Administration support providing the Bureau of Environmental Statistics at least as much discretion to release information as is provided to EIA in its authorizing legislation? If not, why not?

Structural Proposals

8. Section 7 of H.R. 2138 lays out a new organizational structure for the Department of the Environment. Under section 7(d), the Assistant Administrators who run the national programs and conduct EPA's nationwide rulemaking activities would report to the Under Secretary for Policy, Planning, and Innovation. Section 7(e) places the Regional Administrators under the Under Secretary for Implementation, Compliance, and Enforcement.

   Much of EPA's nationwide guidance activities relate to the state programs implementing federal environmental laws. The Regional offices often provide Headquarters with valuable and extensive feedback from the states on both rulemaking and guidance. In addition, EPA conducts many state-specific rulemaking activities through the EPA Regions, and many of these require coordination with the national rulemaking programs.

   The separation of the Regional Administrators from the Assistant Administrators responsible for rulemaking and guidance seems likely to diminish critical coordination between these entities. The probable result is the emergence of issues at the under secretary level that should and could have been worked out between Regional Administrators and Assistant Administrators, had they reported to the same person. It is to be expected that this will cause delays in issue resolution. In addition, it appears that this structure will act to insulate the rulemaking programs from the state perspective provided by the Regions, particularly with respect to implementation concerns.

Does the Administration have any concerns about the structures proposed in 7(d) and 7(e)? Please address whether and to what degree you anticipate that each of the problems identified above would occur under the structure established by H.R. 2138. Please also provide any recommendations you have to improve the proposed organizational structure or to otherwise avoid or address the identified problems.

9. H.R. 2138 does not explicitly address the enforcement functions currently contained in the Headquarters Office of Enforcement and Compliance Assistance. However, it appears, based on the Under Secretary's title, that the enforcement functions would join the Regional offices in reporting to the Under Secretary for Implementation, Compliance, and Enforcement. Separating government policy and enforcement functions is critical to ensuring non-politicized independent enforcement.

   a. Does the Administration agree that it is appropriate and necessary to preserve the independence of the enforcement office?

   b. Would the Administration support keeping the enforcement functions as a separate office that does not report to the same Under Secretary as the Regional Offices?

10. Section 7(g)(1) makes the Chief Financial Officer responsible for "[e]nsuring that the budget, human resources, and regulatory costs imposed by the Department accurately reflect environmental and human health risks."

    Please detail the extent to which the CFO currently exercises these responsibilities. Do the CFO and the CFO's staff currently have any responsibility for or expertise in estimating or evaluating the costs of a regulation?

11. Allocating EPA's budget and resources among EPA's multiple areas of responsibility, and determining EPA's regulatory priorities are several of the Administrator's most critical responsibilities.

    Is the CFO the appropriate entity to oversee implementation of the Secretary's decisions regarding regulatory priorities?

12. Section 7(c) establishes an Under Secretary for Science and Information, to be responsible for the Bureau of Environmental Statistics, research and development, and the Department's laboratories. When Governor Whitman testified before the Energy Policy, Natural Resources, and Regulatory Affairs Subcommittee last Congress, she emphasized that science should be integrated throughout the Department and not just the job of one official who is the "science person."

    Do you agree with Governor Whitman's position? If not, what has changed since Governor Whitman testified?

13. You and Chairman Connaughton testified that the Administration supports establishing an Under Secretary for Science and Information. Currently, many of the EPA program offices outside of the Office of Research and Development carry out extensive scientific activities. For example, EPA's National Vehicle and Fuel Emissions Laboratory is located organizationally in the Office of Transportation and Air Quality, in the Office of Air and Radiation. NVFEL staff test vehicle emissions, fuels, and vehicle control technologies. They also write and implement the highly technical rules to control motor vehicle emissions. Under section 7(c), it appears that the NVFEL, as a laboratory, would report to the Under Secretary for Science and Information.

    a. Under H.R. 2138, how would EPA propose to separate out the science and rulemaking functions in NVFEL? Do you agree that the quality of the motor vehicle emissions regulatory work is enhanced by the concentration of in-depth technical expertise among the staff of the NVFEL?

    b. Given the need for technical scientific expertise in developing regulations, how specifically would EPA ensure that this need continues to be met under the organizational approach proposed in H.R. 2138?

14. Currently, the General Counsel and the Assistant Administrators for Air, Water, etc. are Senate-confirmed appointees. H.R. 2138 would eliminate this requirement for all of these positions.

    a. Does the Administration oppose continuing the requirement for Senate confirmation for the General Counsel? Please explain.

    b. Does the Administration oppose continuing the requirement for Senate confirmation for the Assistant Administrators? Please explain.

15. Please provide any other recommendations or concerns regarding the proposed structural reorganization of EPA.

16. Agency reorganizations inevitably require expenditure of agency resources.

    a. Has EPA analyzed the costs — including direct spending (e.g., to relocate staff and hire new staff), staff time, and indirect costs — of conducting the reorganization that would be required by H.R. 2138? Has EPA identified the delays in any currently planned activities that could result from this reorganization?

    b. If so, please provide those estimates.

    c. If not, does EPA intend to conduct that analysis, and if so, by when? If EPA does not intend to conduct that analysis, why not?

Questions for the Record
Hearing Held on September 9, 2003
Elevation of EPA to Department Level Status: Federal and State Views
for Marianne L. Horinko, Acting Administrator, U.S. EPA
from Ranking Member Henry A. Waxman and Ranking Member John F. Tierney

Mission Statement

1. **The "mission statement" for EPA in H.R. 2138 appears to narrow EPA's purpose, limiting it to protecting against "unreasonable environmental risks."[1] In contrast, key EPA authorities lay out much broader goals for the agency. For example, the Clean Air Act states that its purpose is "to protect and enhance the quality of the Nation's air resources." The Clean Water Act's goal is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." These comprehensive goals aim to protect the integrity of the environment that we inherited and will pass on to our children.**

   Do you agree that protecting against "unreasonable risks" is a narrower mandate than the goals laid out for EPA in the Clean Air Act and Clean Water Act?

Answer:

The mission statement in section 4(b) sets out several objectives that are different from the goals and objectives of the various environmental statutes, each of which is unique. However, the savings provision in Section 11(a) of the H.R.2138 would prevent any change, directly or indirectly, to any law that refers to or provides authorities or responsibilities for, or is administered by, EPA. It is EPA's interpretation that the mission statement included in H.R. 2138, if it were to remain, would have no effect on the goals or objectives of the environmental statutes EPA currently administers and would continue to administer as a department.

Nevertheless, the mission statement as drafted in Section 4(b) of H.R.2138 could lead to uncertainty and is unclear in regard to its relationship with the broad and varied mandates in existing environmental laws. To limit uncertainty, and to provide for

[1] H.R. 2138 also provides that EPA's mission is to "protect and improve the quality of the environment." However, given the relative specificity of all of the following paragraphs discussing EPA's mission in the context of "unreasonable risks," there is a strong argument that the specific language could have the legal effect of setting the boundaries for EPA's authority.

flexibility in the future as its mission potentially evolves and laws change, EPA supports striking Section 4(b) from H.R.2138.

2. **Unlike the Clean Air Act and the Clean Water Act, which direct EPA to protect entire environmental media from a variety of different threats, the Toxic Substances Control Act (TSCA) focuses on the impacts of toxic substances across media. TSCA employs an "unreasonable risk" standard, which has been interpreted by the Fifth Circuit as sharply limiting EPA's regulatory authority under section 6 of TSCA.[2] Specifically, the court found that the unreasonable risk standard requires EPA to "balance the costs of its regulations against their benefits."[3] The court emphasized the role of cost-benefit analysis in identifying regulatory approaches that are least costly to industry.[4] The court also opined on the importance of discounting costs and benefits over time, including the benefits of saving human lives.[5] In addition, the court emphasized its preference for quantified costs and benefits, stating that "[u]nquantified benefits can, at times, permissibly tip the balance in close cases. They cannot, however, be used to effect a wholesale shift on the balance beam."[6] As a result of the analytical burdens imposed by the unreasonable risk standard, as interpreted by the Fifth Circuit, it is extremely difficult for EPA to issue an environmentally protective rule under section 6 of TSCA. EPA has regulated only a handful of toxic substances under this provision, and it is widely regarded as a failure.[7]**

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[2] *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) applies a similar standard of protecting against "unreasonable adverse effects on the environment." 7 U.S.C.A. § 136a. EPA determines whether something is an "unreasonable adverse effect" by balancing the "economic, social, and environmental costs and benefits" of allowing the pesticide to be used. 7 U.S.C.A. § 136. As one commentator notes, "[a] significant historical factor limiting FIFRA's success in protecting public health and the environment is the cost-benefit analysis built into the statutory 'unreasonable risk' standard." Michael W. Graf, *Regulating Pesticide Pollution in California under the 1986 Safe Drinking Water and Toxic Exposure Act (Proposition 65)*, 28 Ecology Law Quarterly, 686 (2001).

[3] *Id.* at 1222.

[4] *Id.* at 1216–1217.

[5] *Id.* at 1218.

[6] *Id.* at 1219.

[7] *See, e.g.*, William Boyd, *Controlling Toxic Harms: The Struggle over Dioxin Contamination in the Pulp and Paper Industry*, Stanford Environmental Law Journal, 357 (June 2002); Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, Environmental Lawyer, 114–115 (Sept. 1999); Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, Texas Law Review, 548 (Feb. 1997).

a. Does the Administration believe that the "unreasonable risk" language should be interpreted consistently when it is used in H.R. 2138 and TSCA?

Answer:

As noted in the response to question 1, due to the savings clause in section 11(a) of H.R. 2138, the statement of the Department's mission in section 4(b) would have no effect on the environmental statutes currently administered by EPA. Consequently, the interpretation of the term "unreasonable risk" as used in the mission statement would have no bearing on the standards for implementing the other environmental statutes. Again, to reduce uncertainty, EPA supports striking section 4(b) from H.R. 2138.

b. If so, does the Administration believe that under this language in H.R. 2138, EPA's mission would be to protect only against those threats to human health and the environment for which it has been shown that the costs of such protection are "reasonable?"

Answer:

As a result of the savings clause, the statutory goals, objectives, and authorities of the various environmental statutes would remain unchanged if EPA were redesignated the Department of Environmental Protection. The scope of protection of each statute would remain as currently written.

c. If not, please lay out a detailed legal rationale for differentiating between the interpretation of this language when used in these different contexts. Please also provide the Administration's alternative interpretation of the meaning of "unreasonable risk" under H.R. 2138. Please explain in detail how EPA would determine whether a risk is reasonable for the purpose of defining the scope of EPA's mission.

Answer:

As a result of the savings clause provision in H.R. 2138, the approaches, levels of protection, the nature of any analysis of costs and benefits, and other aspects of the various environmental statutes would remain unchanged after passage of the bill. Nevertheless, any confusion resulting from the mission statement could be eliminated by deleting section 4(b) entirely.

3. The Fifth Circuit also held that in making the determination of "unreasonable risk" under TSCA, EPA must apply "discounting" to reduce the benefits of environmental protections (or costs of environmental harms) that would occur in the future.

a. Does the Administration believe that under the "unreasonable risk" language in H.R. 2138, EPA's mission would be to protect only against those threats to human health and the environment for which

it has been shown that the costs of such protection are reasonable in light of the benefits of such protection, and only if such costs and benefits have been quantified, monetized, and discounted?

Answer:

Due to the savings clause in section 11(a) of the bill, EPA's responsibilities for implementing each of the environmental statutes would continue unchanged if EPA is redesignated as a department.

b. Should EPA's mission be limited to protecting against threats to the environment that can be quantified? That can be monetized?

Answer:

Due to the savings clause, EPA's responsibilities for protecting the environment under each of the environmental statutes would be unchanged if EPA is designated as a department.

4. Under the Fifth Circuit's interpretation of unreasonable risk, it appears that if EPA's mission were limited to protecting against unreasonable risk, it would no longer include addressing most long-term threats to the environment. For example, EPA is required under the Energy Policy Act of 1992 to set public health and safety standards to protect the public from exposures to radioactivity from the Yucca Mountain high-level radioactive waste disposal site.[8] These standards are designed to set limits for human exposures to releases of radioactivity from the site for a period of over 10,000 years. Applying a 7% (OMB's preferred rate) or 3% (EPA's preferred rate) discount rate over such a long period of time would make negligible almost any projected monetary level of benefits of the regulation, assuming that such benefits could even be quantified and monetized. Certainly the near-term (and therefore minimally discounted) costs of making the repository more secure would necessarily exceed such benefits. Similarly, problems such as tropospheric ozone depletion and global warming will also have impacts over decades and possibly hundreds of years, which makes the benefits of addressing such problems particularly vulnerable to discounting.

Does the Administration believe that EPA's mission should include investigation of and protection against long-term environmental problems? How would such activities be encompassed within EPA's mission if it is limited to protecting against "unreasonable risks"?

Answer:

To the extent required and authorized by the various environmental statutes, EPA takes action to protect the full range of threats to public health and the environment. Due to

[8] Energy Policy Act of 1992, § 801.

the savings clause in section 11(a) of H.R. 2138, the goals, objectives, and authorities of the environmental statutes would remain unchanged.

5. **H.R. 2138 section 4(b)(3) states that a mission of the Department of Environmental Protection is to "identify, analyze, monitor, and report on existing and potential unreasonable risks to humans and the environment." As discussed above, however, EPA would have to conduct a risk assessment and a cost-benefit analysis before EPA could differentiate between "reasonable" and "unreasonable" risks. Thus limiting EPA's analytical mission to unreasonable risks only seems entirely unworkable.**

   a. **Does the Administration believe that EPA's analytical and monitoring activities should be limited to those environmental problems that EPA has identified as unreasonable risks? If so, please explain how this requirement would be practicable.**

Answer:

Due to the savings clause in section 11(a) of H.R. 2138, EPA's responsibilities for assessing and protecting the environment under each of the environmental statutes would be unchanged if EPA is designated as a department.

   b. **Does the Administration support the inclusion of language referencing "unreasonable risk" in a mission statement for the Department of Environmental Protection? If so, please explain why.**

Answer:

While the mission statement currently included in section 4(b) of H.R. 2138 would not change the goals, objectives, and authorities of the various environmental statutes that EPA administers due to the savings clause in section 11(a), retaining section 4(b) could perpetuate confusion, uncertainty, inflexibility, and controversy and could lead to unnecessary litigation. For these reasons, EPA supports removal of section 4(b) from the bill.

   c. **Would the Administration support adopting EPA's existing mission statement, developed by the agency, which reads: "The mission of the U.S. Environmental Protection Agency is to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends"?[9]**

Answer:

On September 30, 2003, EPA submitted its *2003-2008 Strategic Plan* to Congress and OMB as required under the Government Performance and Results Act. The Strategic

[9] U.S. EPA, *Agency Mission Statement* (available online at: http://www.epa.gov/history/org/origins/mission.htm).

Plan will guide the Agency's planning over the next five years, and is built around five goals, centered on the themes of air and global climate change, water, land, communities and ecosystems, and compliance and environmental stewardship. These themes reflect EPA's current mission, "to protect human health and the environment."

EPA's mission statement is a useful, general summary of EPA's responsibilities under the various environmental statutes the Agency administers. As with most government agencies, EPA's mission flows from the goals, objectives, requirements, and authorities of all the statutes it administers and may change over time. To provide for flexibility in the future as its mission potentially evolves and as laws change, and to prevent confusion, EPA does not support including a mission statement in the departmental legislation.

d. Does the Administration propose any alternative language for a mission statement for a Department of Environmental Protection?

Answer:

For the reasons set out above in response to questions 1 through 5, EPA does not support including a mission statement in the departmental legislation.

Bureau of Environmental Statistics

6. At the hearing, Rep. Tierney raised concerns about the prohibition on EPA releasing any "corporately identifiable" information collected by the proposed Bureau of Environmental Statistics. Specifically, Rep. Tierney asked whether the language in H.R. 2138 section 8(h)(2) could limit the release of any information that EPA otherwise has authority to collect and release. You indicated that you did not believe the language would have that effect, but that you would look at the provision again and respond to Rep. Tierney with a more thorough answer.

Answer:

EPA used several principles to assess confidentiality provisions when considering creation of a Bureau of Environmental Statistics (BES) in the context of the September 9 hearing. The extent to which confidentiality should be protected depends on the authority under which it is collected, the agency that collects it, and the purpose for which it is collected. These principles are clarified below:

- EPA opposes modification of existing provisions of environmental statutes dealing with information collection and dissemination to the extent that they provide new authorities to, or modify existing authorities of, units within EPA other than the BES.

- The BES needs to be able to give enforceable assurances of confidentiality, i.e., to be able to guarantee that information collected under a pledge of confidentiality would not be released in identifiable form. "Identifiable form"as defined in the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002, Pub.L. 107-347, Title V (44 U.S.C. § 3501 note), means "any representation of information that permits the identity of the respondent to whom the information applies to be reasonably inferred by either direct or indirect means." The exception to this general rule would be that information in identifiable form could be released to other statistical agencies for statistical purposes (also defined by CIPSEA).

- The BES must be able to convince other agencies that the BES pledges of confidentiality, as they extend to information collected by other agencies, would be effective, in order to achieve efficiency in gathering environmental and related statistics.

- The non-statistical functions of the BES, the authorities under which they are to be performed, and the status of such activities with respect to confidentiality promises should also be addressed.

a. Could the language in H.R. 2138 section 8(h)(2) limit the release of any information by EPA that EPA otherwise has authority to collect and release?

Answer:

H.R. 2138 contains seven provisions that mandate, authorize, or prohibit disclosure of information:

- Section 8(g)(2) **would require** the BES to disclose "any information reported or obtained" to any jurisdictional committee of Congress, **"subject to otherwise applicable law."** (Emphasis added.)

- Section 8(h)(1) **would require** the BES to disclose to the public, upon request, all information obtained by the Bureau, **"except that this subsection shall not require disclosure of matters exempted from disclosure pursuant to [8(h)2]..., or section 552(b) of title 5, United States Code, the Homeland Security Act of 2003 (Public Law 107-296), or other applicable law."** (Emphasis added.)

- Section 8(h)(2) **would prohibit** disclosure by the BES of information that is personally or corporately identifiable.

- Section 8(h)(5) **would provide the BES authority to disclose information "notwithstanding paragraphs (1) and (3)"** (of 8(h)), to the GAO, the Inspector General of EPA, and any department or statistical agency of the federal government that requests it for use in carrying out lawful functions, **but would not require such disclosure, at least to other agenci s, nor would it revoke the requirement in 8(h)(2) to protect information that yields personal or corporate identity.**

- Section 8(h)(6) states that information disclosed by the BES to organizations named in 8(h)(5) would continue to be subject to restrictions on use and disclosure of the information that would apply to the Department, including BES.

- Section 8(j)(4)(B) **would require the BES to make available all information** deemed necessary by the Peer Review Team to the Team, **"notwithstanding any other provision of law."** (Emphasis added.)

- Section 8(j)(5) states that all confidentiality standards would apply to the peer review group.

Section 8(h)(2), the prohibition of disclosure of information that is personally or corporately identifiable and "collected by the Bureau," is the key provision. The only explicit exception is in section 8(j)(4)(B), information requested by the Peer Review Team. (We do not favor a statutory requirement for peer review of statistical methodologies used by the BES.)

We do not read the confidentiality provisions of section 8 as potentially applying to, or changing, the confidentiality status of any information obtained by EPA, or offices in the new Department other than the BES, under existing authorities. This is particularly true when read together with the Savings Provision found in section 11(a).

We support changes to section 8(h)(2) to simplify and improve the clarity of appropriate confidentiality protections to information acquired for statistical purposes by BES without impacting the availability of information under EPA's existing legal framework.

b. Specifically, could this language limit release of such information by an EPA office other than the Bureau of Environmental Statistics?

Answer:

Because section 8 of H.R. 2138 is entitled, "Bureau of Environmental Statistics" and deals only with the creation and operation of the Bureau, we do not believe it would affect implementation of existing laws by any other office in the new Department, including disclosure of information by such offices. This reading is reinforced by the Savings Provision at section 11(a), which states that nothing in the bill is to alter, affect, amend, modify, or otherwise change, directly or indirectly, other laws implemented by EPA.

c. Could this language limit release of information that EPA otherwise has authority to collect and release if the collection and/or release is by the Bureau of Environmental Statistics?

Answer:

If the BES were to collect information under existing EPA authorities for statistical purposes, or if it were to obtain from another part of the new Department data collected

by an EPA program office before the legislation becomes law or by another office in the new Department after it becomes law and use it for statistical analysis, the BES would not be able to disclose the information in identifiable form under section 8(h)(2). As discussed in the answer to 6b, the other offices in the new Department would still be able to disclose the information they obtained for other purposes in accordance with existing EPA statutes. We believe these protections for information in the possession of the BES would be both appropriate and warranted, given the necessity of separating statistical functions from regulatory and enforcement functions, and the practical requirement that respondents be assured confidentiality of their identities to gain cooperation with any voluntary surveys independently conducted by the BES.

To better explain this distinction, consider a scenario in which the BES obtains data that another office in the new Department has collected from 10,000 respondents for the purpose of developing regulations. The BES is unlikely to use data from all original respondents; it would more likely sample the database, taking say, data from 1,000 respondents. When data in the sample are analyzed, the BES draws its conclusions. There is no reason that the 1,000 respondents whose answers were analyzed are any more or any less likely to fit into the patterns revealed in BES's analysis, if any. Why should they, therefore, be subject to more public scrutiny? Particularly considering that the entire database of the 10,000 respondents generally is public information, we believe the continuing availability of the underlying database elsewhere in the Department, a statement by the BES on the statistical methodologies used, and the BES's conclusions are sufficient. It would be helpful to clarify this outcome in the language of H.R. 2138.

d. If the response to question 6.c is yes, it is unclear why the Bureau of Environmental Statistics should be prohibited — much less by statute, preemptively, and without exception — from releasing information that EPA has the authority to collect and release, and in many instances is required to make available to the public under current law.

For example, under section 114(a) of the Clean Air Act, EPA has broad authority to obtain information for the purpose of "carrying out any provision of this Act." Specifically, EPA has authority to obtain information from "any person who owns or operates any emission source, who manufactures emission control equipment or process equipment, who the Administrator believes may have information necessary for the purposes set forth in this subsection, or who is subject to any requirement of this Act." EPA may require such persons to "establish and maintain such records," "make such reports," "install, use, and maintain such monitoring equipment," "sample such emissions," and "provide such other information as the Administrator may reasonably require." Section 114(c) provides that "[a]ny records, reports, or information obtained under subsection (a) shall be available to the public," with the exception of information entitled to protection as "trade secrets." However, the exception for "trade secrets" does not apply to "emission data,"

which therefore must be made available to the public, with no exceptions.

"Emission data" is defined broadly under 40 CFR 2.301(a)(2)(i). It includes:

[i]nformation necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source . . . [i]nformation necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including, to the extent necessary for such purposes, a description of the manner or rate of operation of the source); and . . . [a] general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

Thus, under the CAA, EPA currently has very broad authority to obtain information from sources of air pollution, and all information deemed to be "emission data" must be made available to the public. Section 308 of the Clean Water Act provides EPA similarly broad authority to obtain and make available to the public information "required to carry out the objective of [the Clean Water Act]."

It seems unwieldy and impractical for the Bureau of Environmental Statistics to rely largely or solely upon data collected by other portions of the agency. But if the Bureau collects data directly, this raises the issue of duplicative reporting requirements. There will likely be strong pressure from sources to consolidate information collections in order to reduce reporting burdens. If data collected by the Bureau is prohibited from release in corporately identifiable form, either EPA will have to conduct dual information collections for the same data, or data that is now required to be made available to the public under the CAA and other statutes will be mandated to be kept secret.

Does the Administration support prohibiting the Bureau from releasing information that if collected under existing law is required to be made available to the public? Or prohibiting the Bureau from releasing information that EPA currently has authority to make available to the public?

Answer:

The Administration is not seeking, and does not support legislative changes to alter confidentiality protections or disclosure requirements currently found in environmental statutes implemented by EPA. We do not believe that section 8 of H.R. 2138 would affect implementation of existing laws by offices in the new Department other than the BES. This is reinforced by the Savings Provision at section 11(a), which states that nothing in the bill is to alter, affect, amend, modify, or otherwise change, directly or indirectly, other laws implemented by EPA.

As discussed above, if the BES were to apply statistical techniques to analyze data obtained by the BES from other offices in the new Department, we believe the underlying data that would remain in the other offices in the Department should continue to be subject to applicable provisions of the statutes under which it was collected by EPA or the new Department concerning its confidentiality status. However, with respect to the BES's use of the information, it would be inappropriate to identify the specific companies or individuals and their responses that were selected in the sampling process for analysis. The BES should indicate which public data were used in its analysis, explain its sampling techniques, and provide its statistical results.

e. If yes, how would you address the issue of duplicative reporting raised above?

Answer:

There may be situations where the BES would need to collect information directly from respondents that would be similar to the information another office in EPA would seek, although we anticipate that these situations will arise infrequently. This is because the BES Director would need to exercise the authority under Section 8 judiciously and in cooperation with the Department's other offices, given the statutory imperative of reducing unreasonable paperwork burdens on respondents. However, when these situations do arise, the BES would not be permitted to release data it collected in identifiable form, even to another office within the Department, such as the enforcement office or to the Department of Justice for enforcement purposes. But BES' exercising direct collection authority should not have the effect of limiting authority of the enforcement office to collect directly the data it would require for enforcement purposes. The data collected by the enforcement office should not be construed as "unnecessarily duplicative of information otherwise reasonably available to the Agency" under the Paperwork Reduction Act because the data the enforcement office could obtain from the BES would be incomplete. We are eager to work with the Committee to ensure this result.
We would suggest that the Subcommittee include report language to address the potential for duplicative reporting in which both the BES and another office might seek to collect similar information. If the BES or another office within the new Department were to use data collected by the other then there would be no significant duplicative collection because both collections would be subject to the Paperwork Reduction Act and the OMB process for authorizing information collection requests.

However, while the BES would be bound to strict requirements of confidentiality in sharing data with other offices within the Department or other federal agencies, EPA would like to ensure that information or data collected by offices other than BES

consistent with the requirements of the Paperwork Reduction Act, would continue to be shared for law enforcement purposes. As stated above, we believe that the continuing availability of the underlying BES database elsewhere in the Department, along with a statement by the BES on the statistical methodologies used, and the BES's conclusions are sufficient.

f. If no, does the Administration support addition of a "savings clause" to H.R. 2138 that would clarify that the bill would not bar any entity within EPA from releasing "privately or corporately identifiable data" that EPA has authority to collect and release under other authority?

Answer:

As discussed above, we believe that the current Savings Provision in section 11(a) would prevent restrictions on public availability of data imposed on the BES from applying to other offices in the new Department. Thus, data collected by EPA program offices using current authorities and data collected by other offices in the new Department under EPA's authorities would remain available to the public to the same extent they are available today. This is true even though the BES would be restricted in terms of what it could disclose if it obtained the information from those offices for its own use.

For BES analyses of information previously collected by EPA or other offices in the new Department, we prefer that the BES would: identify the source of the information source used in its analysis; explain how that information may be obtained by the public from another office in the Department; identify the sampling or other analytic methods used; and review the analytic results without revealing, in identifiable form, particular respondents selected for a statistical sample. Since the underlying database would remain public in another part of the Department, we do not believe public access to information would be impeded. Therefore, we do not believe an additional savings provision is necessary. Similarly, if the BES collects information directly from respondents for statistical purposes, we believe that it should not release it in identifiable form, consistent with practices of other statistical agencies.

7. The provisions of the DOE Organization Act, which establish the Energy Information Administration, do not include any prohibition on release of data collected by the EIA. In fact, section 205(g) of this act requires that "upon request, any [information collected by EIA] shall be promptly made available to the public in a form and manner easily available for public use," except that this does not require disclosure of information that can be withheld from disclosure under the Freedom of Information Act. In section 205(i), EIA is specifically required to conduct and publish the results of a survey of energy consumption in the manufacturing industries, and for this publication EIA must present the results "in a manner designed to protect the confidentiality of individual responses." However, this specific requirement for one particular mandated data collection is far from a blanket prohibition on the release of *any* corporately identifiable data collected by an agency's statistical office.

Does the Administration support providing the Bureau of Environmental Statistics at least as much discretion to release information as is provided to EIA in its authorizing legislation? If not, why not?

Answer:

This question specifically refers to sections 205(g) and section 205(i) of the DOE Organization Act. (Pub.L. 95-91; 42 USC 7135(g) and (i)). We defer to DOE in interpreting its own statute; nevertheless, section 205(g) appears to require that data collected by the EIA be promptly made available to the public in a form and manner easily available for public use, except it does not require disclosure of information that is protected under the Freedom of Information Act. Also, the prohibition against divulging trade secrets under 15 USC 796(d) would remain in effect. Section 205(i) appears to mandate that for one specific study conducted by EIA, data be presented in a manner designed to protect the confidentiality of individual responses.

However, these sections must be read in conjunction with section 504(d) of CIPSEA, which
provides that "Data or information acquired by the Energy Information Administration under a pledge of confidentiality and designated by the Energy Information Administration to be used for exclusively statistical purposes shall not be disclosed in identifiable form for nonstatistical
purposes under . . . section 205 . . . of the Department of Energy Organization Act. . . ."

EPA supports clear public access and confidentiality protections. In particular, EPA supports language on confidentiality that is consistent with CIPSEA. In this regard, also see CIPSEA § 512 (b).

Structural Proposals

8. **Section 7 of H.R. 2138 lays out a new organizational structure for the Department
of the Environment. Under section 7(d), the Assistant Administrators who run the national programs and conduct EPA's nationwide rulemaking activities would report to the Under Secretary for Policy, Planning, and Innovation. Section 7(e) places the Regional Administrators under the Under Secretary for Implementation, Compliance, and Enforcement.**

   Much of EPA's nationwide guidance activities relate to the state programs implementing federal environmental laws. The Regional offices often provide Headquarters with valuable and extensive feedback from the states on both rulemaking and guidance. In addition, EPA conducts many state-specific rulemaking activities through the EPA Regions, and many of these require coordination with the national rulemaking programs.

   The separation of the Regional Administrators from the Assistant Administrators responsible for rulemaking and guidance seems likely to

diminish critical coordination between these entities. The probable result is the emergence of issues at the under secretary level that should and could have been worked out between Regional Administrators and Assistant Administrators, had they reported to the same person. It is to be expected that this will cause delays in issue resolution. In addition, it appears that this structure will act to insulate the rulemaking programs from the state perspective provided by the Regions, particularly with respect to implementation concerns.

Does the Administration have any concerns about the structures proposed in 7(d) and 7(e)? Please address whether and to what degree you anticipate that each of the problems identified above would occur under the structure established by H.R. 2138. Please also provide any recommendations you have to improve the proposed organizational structure or to otherwise avoid or address the identified problems.

Answer:

EPA does not support the organizational structure as currently defined in Section 7. The Administration supports a new Department that is given sufficient flexibility to establish an organizational structure that would enable it to manage the relationship between Headquarters and Regional Offices as effectively and efficiently as possible. Under Administrator Whitman's leadership, the Agency made several improvements in coordination and communication between Headquarters and Regional Offices. The Agency has completely revamped its Strategic Plan and goals, eliminating much of the old single media structure, and establishing a structure that facilitates integration across all programs. The new integrated structure is the basis for all Agency planning, budgeting and evaluation of performance. Teams of senior Regional and Headquarters managers hold joint responsibility for progress on the goals. This has resulted in increased communication and cooperation throughout the Agency.

The Regions have a major role in both the regulatory/policy development of the Agency and implementation of the national environmental programs. The vital importance of the regional structure of EPA in dealing directly with the states and tribes in performing their delegated duties through their governors, tribal leaders, environmental department directors, and other officials is critical to the ultimate success in addressing the needs and interests of the people. The Regional Administrators' role in Agency-wide rulemaking, policy, and management decisions is integral to the success of the Agency, and will not be diminished regardless of the regional reporting structure.

9. **H.R. 2138 does not explicitly address the enforcement functions currently contained in the Headquarters Office of Enforcement and Compliance Assistance. However, it appears, based on the Under Secretary's title, that the enforcement functions would join the Regional offices in reporting to the Under Secretary for Implementation, Compliance, and Enforcement. Separating government policy and enforcement functions is critical to ensuring non-politicized independent enforcement.**

a. Does the Administration agree that it is appropriate and necessary to preserve the independence of the enforcement office?

Answer:

It is important to preserve the independence of the enforcement function in a new Department; however, it should be informed by the media offices.

b. Would the Administration support keeping the enforcement functions as a separate office that does not report to the same Under Secretary as the Regional Offices?

Answer:

Enforcement must be informed by the program offices in a way that allows for a cross-media approach to enforcement. The Administration supports language that allows for the greatest amount of flexibility in establishing an organizational structure that would enable the Department to manage as effectively and efficiently as possible.

10. Section 7(g)(1) makes the Chief Financial Officer responsible for "[e]nsuring that the budget, human resources, and regulatory costs imposed by the Department accurately reflect environmental and human health risks."

Please detail the extent to which the CFO currently exercises these responsibilities. Do the CFO and the CFO's staff currently have any responsibility for or expertise in estimating or evaluating the costs of a regulation?

Answer:

The Office of the Chief Financial Officer performs the following functions:

- Develops, manages, and supports a goal-based management system for the Agency that involves strategic planning and accountability for environmental, fiscal, and managerial results; and,

- Manages the Agency-wide budget, resources management and financial management functions including program analysis and annual planning, budget formulation, preparation and execution; controls and systems for payroll and disbursements.

Currently, EPA's Office of Policy, Economics and Innovation (OPEI), within the Office of the Administrator, is responsible for estimating or evaluating the costs of a regulation. OPEI serves as EPA's Economics Advisor: as such, helps ensure that the Agency relies on sound economic science to support its activities and advises the Administrator on all economics issues as they relate to EPA policies, regulations, procedures and decisions. OPEI also provides critical economic analyses to augment and support the Agency's understanding of the financial and societal impacts of environmental policies and

regulations. OPEI conducts economic research that leads to the development of analytic tools used by Federal, State and local governments.

11. Allocating EPA's budget and resources among EPA's multiple areas of responsibility, and determining EPA's regulatory priorities are several of the Administrator's most critical responsibilities.
Is the CFO the appropriate entity to oversee implementation of the Secretary's decisions regarding regulatory priorities?

Answer:

The CFO connects EPA's budget with the Agency's strategic planning; however, the national program managers in the media offices oversee implementation of the Agency's regulatory priorities.

12. Section 7(c) establishes an Under Secretary for Science and Information, to be responsible for the Bureau of Environmental Statistics, research and development, and the Department's laboratories. When Governor Whitman testified before the Energy Policy, Natural Resources, and Regulatory Affairs Subcommittee last Congress, she emphasized that science should be integrated throughout the Department and not just the job of one official who is the "science person."

Do you agree with Governor Whitman's position? If not, what has changed since Governor Whitman testified?

Answer:

EPA has taken steps to promote the integration of sound science throughout the Agency, and continues to maintain that such integration should also take place if the Agency is elevated to departmental status. One of these steps was the appointment, by then Administrator Whitman, of an Agency Science Advisor to champion science throughout the Agency. Whether as a Science Advisor in an agency or an Under Secretary in a department, having an individual responsible for ensuring sound science informs policy decisions both promotes the integration of science and is consistent with the position of Administrator Whitman.

Additionally, we believe that the Director of the Bureau of Environmental Statistics should report to the Secretary to ensure that statistical information is communicated directly to the Secretary, independent from any assessment of potential regulatory or enforcement program interests. A direct reporting relationship would enhance the independence and credibility of the Bureau's Director, and would be consistent with the reporting arrangement for several other Federal statistical agencies.

We look forward to working with the Subcommittee to ensure that sound science principles continue to be integrated throughout the programs.

13. You and Chairman Connaughton testified that the Administration supports establishing an Under Secretary for Science and Information. Currently,

many of the EPA program offices outside of the Office of Research and Development carry out extensive scientific activities. For example, EPA's National Vehicle and Fuel Emissions Laboratory is located organizationally in the Office of Transportation and Air Quality, in the Office of Air and Radiation. NVFEL staff test vehicle emissions, fuels, and vehicle control technologies. They also write and implement the highly technical rules to control motor vehicle emissions. Under section 7(c), it appears that the NVFEL, as a laboratory, would report to the Under Secretary for Science and Information.

a. Under H.R. 2138, how would EPA propose to separate out the science and rulemaking functions in NVFEL? Do you agree that the quality of the motor vehicle emissions regulatory work is enhanced by the concentration of in-depth technical expertise among the staff of the NVFEL?

b. Given the need for technical scientific expertise in developing regulations, how specifically would EPA ensure that this need continues to be met under the organizational approach proposed in H.R. 2138?

Answer:

The Administration supports an organizational approach that ensures that sound science informs policies and enhances the efficient operation of EPA. We do not believe that H.R. 2138 should include reporting structures for science. When developing its regulatory and other policy decisions, the Agency draws upon science both conducted by the Agency and work published by others in the scientific literature. Scientific activities conducted by, and for, the Agency include scientific studies and analyses conducted by EPA's program and regional offices (e.g., NVFEL), research performed in ORD's laboratories and centers, and EPA-funded work conducted by academic researchers, state/local governments, Tribes, and non-governmental entities. The expertise of EPA's scientists and engineers is a valuable resource to the Agency's policymakers.

Making environmental decisions with sound science requires relevant, high quality research; sound economic and other scientific analyses; peer review of the scientific products used to inform decisions; proper characterization of scientific findings; and the appropriate use of science in the decision process. While it is critical that sound science inform Agency policy decisions, it is equally important that policy objectives not be allowed to influence scientific results. The ability for scientists to both independently conduct research and "call it as they see it" as they participate in environmental decision-making is vital to the credibility of Agency decisions, and must be maintained in any organizational structure.

14. Currently, the General Counsel and the Assistant Administrators for Air, Water, etc. are Senate-confirmed appointees. H.R. 2138 would eliminate this requirement for all of these positions.

a. Does the Administration oppose continuing the requirement for Senate confirmation for the General Counsel? Please explain.

Answer:

No, we do not oppose continuing the requirement for Senate confirmation for the General Counsel. This position currently is Presidentially-appointed and Senate-confirmed and should remain so. Continuing the requirement for Senate confirmation would keep the General Counsel at the same level as those of other Departments.

b. Does the Administration oppose continuing the requirement for Senate confirmation for the Assistant Administrators? Please explain.

Answer:

No, we do not oppose continuing the requirement for Senate confirmation for these positions. These positions currently are Presidentially-appointed and Senate-confirmed and should remain so. Continuing the requirement for Senate confirmation would put the Assistant Secretaries at the same level as those of other Departments.

15. Please provide any other recommendations or concerns regarding the proposed structural reorganization of EPA.

Answer:

H.R. 2138, with some modification, would provide the basis for better integrating existing policy with the Agency's components, and would provide us the opportunity to better organize in order to provide better environmental protection. While the legislation as currently written may be too prescriptive with regard to writing detailed structural requirements into law, some of the key structural reforms, with certain adjustments, could help EPA overcome organizational challenges consistent with the Agency's overall direction as embodied in its 2003 Strategic Plan for the next five years.

For example, in order to elevate the stature of science in Departmental decision-making, we support establishing an Under Secretary for Science, who would also be the Secretary's Science Advisor. However, the information management function should be separated from the science organization. The legislation should also establish a Chief Information Officer who would report directly to the Secretary, and follow the Clinger-Cohen Act of 1996 that created the position of Chief Information Officer with primary duties for information resources management as a direct report to the Department head.

Additionally, while we support the creation of a Bureau of Environmental Statistics (BES) to recognize the importance of providing independent and expert monitoring and reporting of environmental conditions, the role and authority of EPA's BES should be consistent with the structure and authority of other Federal statistical bureaus. Additionally, the BES Director would report directly to the Secretary to promote independence and credibility.

H.R. 2138 includes a statutory requirement that each of the ten Regional Administrators report to a newly-created Under Secretary for Implementation, Compliance and Enforcement. While the regional offices need to implement goals and policies that are set nationally, they also need sufficient flexibility to implement these goals to reflect local conditions. We believe that EPA's regional offices should have close coordination and communication with the leadership of the new Department. I would urge the Congress to allow the Executive Branch to have sufficient flexibility in establishing a management structure that would enable the Department to manage the regional office functions as effectively and efficiently as possible.

16. Agency reorganizations inevitably require expenditure of agency resources.

a. Has EPA analyzed the costs — including direct spending (e.g., to relocate staff and hire new staff), staff time, and indirect costs — of conducting the reorganization that would be required by H.R. 2138? Has EPA identified the delays in any currently planned activities that could result from this reorganization?

b. If so, please provide those estimates.

c. If not, does EPA intend to conduct that analysis, and if so, by when? If EPA does not intend to conduct that analysis, why not?

Answer:

The Agency has not conducted an extensive analysis of the costs of potential reorganizations, but we have considered the implications of H.R. 2138 and found it would involve only minimal administrative costs for restructuring EPA's current offices. However, the statistical activities to be undertaken by a new Bureau of Environmental Statistics are not within the scope of EPA's current mission. Resources for the BES would depend on the scope of the its work and the extent to which early activities can be part of a clearly defined, focused, stepwise progression to a full-fledged statistical agency. When the scope and activities are identified, we will be able to project resource needs.

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NEWS & ANALYSIS

Science, Agencies, and the Courts: Is Three a Crowd?

by E. Donald Elliott, Alan Charles Raul, Richard J. Pierce Jr., Thomas O. McGarity, and Wendy E. Wagner (moderator)[1]

WENDY WAGNER: Welcome to the Panel on Science, Agencies, and the Courts. This panel is sponsored by the Environmental Natural Resources Regulation Committee of the Administrative Law and Regulatory Section of the [American Bar Association (ABA)], and also co-sponsored by the Standing Committee on the Environment of the ABA.

My name is Wendy Wagner. I'm going to moderate the panel, and as the title of the panel implies, we're going to talk about judicial review of agency science. This isn't a new topic in administrative law, but over the past few years there have been some different developments in the courts that may ultimately change the way the courts review agency science in the future.

We have convened four panelists whom I consider to be the nation's top experts on the issue of judicial review of agency science. I'm sure all of you are familiar with these panelists, each of whom is extraordinarily distinguished, not only in this narrow area, but also in administrative and environmental law more generally.

E. Donald Elliott is our first speaker. He is currently a partner at Paul, Hastings, Janofsky & Walker LLP, Washington, D.C. He was a tenured professor at Yale Law School until 1993, but he continues to serve in an adjunct role there. Mr. Elliott was general counsel of the [U.S.] Environmental Protection Agency [(EPA)] from 1989 through 1991. His practice currently specializes in environmental and toxic torts areas, but he seems to find time still to participate in a number of academic conferences and continues to be prolific, writing more than 60 articles on various issues of environmental and administrative law. So with that, I will turn the microphone over to Don Elliott.

DONALD ELLIOTT: Thank you, Wendy. I want to talk about what I call the "science debacle" at EPA.

I think the central conundrum of U.S. administrative law has been how to meld politics and expertise. As recently as the 1960s and the 1970s, thoughtful people were concerned that experts might overwhelm democratic decisionmaking in a technocratic society. My old mentor, Judge Bazelon, called this threat "the perils of wizardry,"[2] or the notion that expertise might dominate our public decisionmaking. Now, a decade or two later, no thoughtful person could possibly think that we've got too much science in environmental decisionmaking. As Georgetown University law professor Steven Goldberg aptly put it: "Regulatory agencies are regularly accused of being 'captured' by industry, consumer groups, members of Congress or bureaucratic inertia. They are never accused, however, of being captured by scientists."[3]

The so-called endocrine destructor issue is a good example of too much politics and not enough science in our environmental decisions. The theory that low doses of certain chemicals might mimic hormones and disrupt the functioning of our bodies is frightening, but is based on experimental results that many scientific laboratories have tried and failed to replicate.[4] Nonetheless, this poorly supported speculation is taken very seriously at EPA, and the Congress has even legislated about it.

Our public discourse in administrative law is increasingly dominated by politics and increasingly excludes science and expertise from playing an important role. I like the title of David Stockman's book, *The Triumph of Politics* (even though it was about another area of policy). What

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Every October, the Administrative Law Section holds a three-day conference in Washington, D.C., with more than a dozen panels, workshops, and other events that focus on issues arising in administrative and regulatory law. To learn more about the section's activities and publications (including its "Annual Developments in Administrative and Regulatory Practice" series), contact the Administrative Law Section's office at (202) 662-1528 or visit the section's website at <http://www.abanet.org/adminlaw>.

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2. *See, e.g.*, David L. Bazelon, *Coping With Technology Through the Legal Process*, 62 CORNELL L. REV. 817 (1977).

3. Stephen Goldberg, *The Reluctant Embrace: Law and Science in America*, 75 GEO. L.J. 1341, 1365 (1987).

4. *See, e.g.*, J. Ashby et al., *Lack of Effects for Low Dose Levels of Bisphenol A and Diethylstilbestrol on the Prostate Gland of CF1 Mice Exposed in Utero*, 30 REG. TOXICOLOGY & PHARMACOLOGY 156 (1999).

we're experiencing in environmental law is really "the triumph of politics," or conversely, the "rout and retreat of science" in environmental decisionmaking.

The decline of science as an important determinant in environmental decisionmaking is in many ways the underlying subtext of Justice Stephen Breyer's book, *Breaking the Vicious Circle: Toward Effective Risk Regulation*.[5] In case after case, the book shows how decisionmaking, particularly in the environmental area, has become political and science has been precluded from playing its rightful role.

My belief is that what we're seeing in terms of the recent court decisions setting aside many agency decisions, particularly in the environmental area, is not the result of more stringent standards of judicial review or of judicial activism. Rather, I think it's a symptom of a more fundamental problem: science is being increasingly marginalized and is playing less of a role in the decisionmaking process, particularly at my old agency, EPA. In short, the courts are stepping in more because the agencies are ignoring science more.

Throughout my career I've been very skeptical of the role of courts in reviewing scientific and technical information. I have written a lot about that, and been active as an adviser to the Carnegie Commission and the Federal Courts Study Committee. I worked with Judge Bazelon on the lower court opinion in *Vermont Yankee*.[6] All of this has led to skepticism about the ability of judges to penetrate to the merits of scientific and technical controversies. But I do have to admit there is a role for the courts when agency abuses become too extreme. Judge Wald got me to admit that a few years ago when we were on another ABA panel together. After hearing my spiel about how judges can't really understand the scientific issues, [she] said: "Well, you will agree with me, won't you, Don, that we're better off with [courts] reviewing [agencies], to really get at the extreme abuses." I had to admit that she was right. What we're seeing now is that a string of court decisions that are setting aside EPA decisions because the Agency has really gone too far in disregarding science.

I want to talk a bit about what I think may underlie some of those developments, and potentially what we might be able to do to return science to its rightful role.

I am somewhat skeptical about claims that the stringency of judicial review is changing because of the empirical study that Peter Schuck and I did of judicial review that was published in 1990.[7] What our data showed was that the affirmance and reversal rates tended to be relatively durable over time, and that affirmance rates were actually higher during the so-called hard look era of supposedly stringent judicial review. We concluded that one can't judge the actual stringency of judicial review by looking at a few "leading cases" because they are really just the tip of the iceburg.

Nonetheless, I believe that some of the decline in the role of science in environmental decisionmaking experienced in recent years is a consequence of a highly deferential standard of judicial review on scientific and technical information. I trace this deferential standard back to the *Baltimore Gas*[8] case, which was a decision by the U.S. Supreme Court on the merits of the *Vermont Yankee* litigation.

After the *Vermont Yankee* case went back on remand, and the D.C. Circuit tried a second time to say that the Nuclear Regulatory Commission [(NRC)] had not given proper consideration to the long-term disposal of nuclear waste, this time on substantive grounds.[9] The Court reversed a second time, essentially throwing Judge Bazelon's words back at him and stating that the Court's deference is highest in areas in which cold war agencies are making decisions at the "frontiers of science."

The high level of deference that courts give to agencies in technical areas has produced distorted incentives. It is an open invitation to agencies to make decisions on political grounds but rationalize them on technical grounds. Wendy Wagner calls this the "Science Charade" in her very important piece in the *Columbia Law Review*.[10] Professor Wagner has correctly identified the incentives that the courts have created for agencies to distort the actual basis of their decisions by rationalizing them on technical grounds. This is simple to analyze as a matter of law and economics; if one creates a standard that is highly deferential in one area, i.e., there are lower costs for agencies if they ground a decision on scientific grounds, one would expect that the incentives created would warp their decisions.

In my experience at EPA—where I was in many meetings with the Administrator or Deputy Administrator when options were presented to them for decision—I cannot remember a single case in which there was a significant discussion of the underlying scientific emphasis.

Now, that doesn't mean science was irrelevant to Agency decisionmaking; that conclusion would be too extreme. Perhaps science sets the outer parameters of discourse, the range of options that are considered.

But there is no doubt in my mind that our public discourse is distorted by the "science charade" as a result of the greater deference that courts give agencies if they rationalize their decisions on technical rather than policy grounds. As a result of the more deferential standards for technical decisions, the written opinions that state the "basis and purpose" for Agency decisions often end up justifying a policy outcome based on a discussion of science.

Wendy's insight is that we've got a fundamental disconnect in American administrative law between the real reasons for Agency decisions—as reflected by the policy debate within the Agency and within the government about

5. STEPHEN G. BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993).

6. Natural Res. Def. Council v. NRC, 547 F.2d 633, 6 ELR 20615 (D.C. Cir. 1976), *rev'd sub nom.* Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, 435 U.S. 519, 8 ELR 20288 (1978).

7. Peter H. Schuck & E. Donald Elliott, *To the* Chevron *Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J 984.

8. Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, 462 U.S. 87, 13 ELR 20544 (1983).

9. Natural Res. Def. Council v. NRC, 685 F.2d 459, 12 ELR 20465 (D.C. Cir. 1982), *rev'd sub nom. Baltimore Gas*, 462 U.S. at 87, 13 ELR at 20544.

10. Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

why we make a decision—and the quite different rationale that ends up in the written statement of reasons to justify the Agency's decision. And, of course, it is the Agency's contemporaneous statement of reasons that usually becomes the sole basis for judicial review.[11] What ends up in the statement of reasons to justify it, in turn becomes a subject of judicial review.

In general, at EPA, the decisions are written by people who weren't even in the room when the Administrator made his or her decision. I would usually go back and give the lawyer in the General Counsel's office who was going to write up the decision one or two sentences on what I took to be the essence of the Administrator's decision, in the hopes that it might kind it [sic] into the written statement of the Agency's reasons for purposes of judicial review. But there is a massive disconnect between what agencies think about internally and what they say in justifying their decisions. This disconnect should be very troubling for proponents of judicial review. In my view, judicial review has almost become a form of literary criticism, focusing on the skill of the Agency's lawyers in writing up opinions, rather than the rationality of the actual basis of Agency decisions, because the courts rarely see the actual basis for the Agency's decisions.

In a sense, the culprit is the *Morgan*[12] rule, the notion that you can't go behind the agency's statement of reasons, because that has created a distance between the actual grounds of the decision and the stated basis. Courts should not defer to agency decisions on the grounds of scientific expertise if all of the scientists within the agency dissented from the decision.

There are a lot of costs to the "science charade." Public dialogue and peer review of agency decisions are stifled if agencies misstate the true basis for their decisions. Many environmental scientists criticize EPA for misunderstanding the science. That's rarely the problem. In my experience, someone within EPA understands the science quite well. If the science gets mangled along the way, it is because the scientists aren't writing up the Agency's rationale; the lawyers are, and the lawyers perceive their role as that of advocates who must justify the Agency's decision on the grounds that are most likely to be sustained in court. Thus, the "science charade" creates pervasive confusion, and a warping or distortion of public dialogue about environmental issues.[13]

Nonetheless, despite the growing disconnect between real reasons and stated reasons in Agency decisionmaking, judicial review does, to some extent, constrain the Agency. Let me mention just one example, the recent chloroform decision.[14] EPA had for many years maintained that there were no thresholds for the activity of carcinogens, i.e., there are no "safe" levels of exposure. As science developed, the mechanisms of carcinogenesis became better and better described, and the mechanisms of repair at the cellular level also were better understood. Science reached the conclusion that, at least with certain chemicals, there were levels of exposure below which there would not be a significant effect, and this became a broad scientific consensus, at least for some substances.

Chloroform is one of the substances for which thresholds had been demonstrated scientifically and broadly accepted by scientists, including EPA's scientists. Despite widespread recognition of that consensus, EPA stuck with its policy of setting maximum contaminant levels (MCLs) at zero under the Safe Drinking Water Act (SDWA). That decision was, of course, then set aside by the D.C. Circuit as capricious and arbitrary and not supported by the record.

But this is to me an example of EPA systematically disregarding, if not defying, the science. I remember one incredible meeting at EPA that crystallizes my conclusion that science is not playing the role that it ought to within the Agency. There's a separate office at EPA called the Office of Research and Development (ORD), which is really the science office. The name is interesting—Office of Research and Development. In my opinion, it should really be called the "Science Office." Nonetheless, it's where pure science is housed at the Agency. During a "red border review," in which a program office circulated its proposal for comment by all the other offices, we were in a meeting with the Deputy Administrator. The specific subject of the meeting doesn't matter. Following the meeting, the representative of ORD, who had not said anything during the meeting, came up to me in the hall and said, "Don, how could you let that happen? You know that this decision is not supportable at all from a scientific basis." My thought in reply was "Why does the representative of the science office not dare to say anything in the meeting, and then beats on me, as the general counsel, afterwards to carry the ball for science." To me, this vignette illustrates how cowed science has become in the internal debates at the EPA.

When I left EPA one of my biggest priorities was to try to figure out how we could increase the role of science at EPA. I believe that this should be the highest priority for the incoming Administration, to restore science to its rightful role at EPA.

The challenge is to get more science and better science into EPA decisions. I tried to look around for some success stories. I believe that as a research academic strategy one should ferret out cases in which things work reasonably well, and then figure out how to replicate success. It struck me that we have an agency that's quite similar to EPA, but whose decisions are very credible scientifically—the Food and Drug Administration (FDA). There are a lot of criticisms of the FDA—that it's too slow, that it doesn't get drugs on the market soon enough—but it's very rare that FDA's decisions get attacked for disregarding the science,

11. *See, e.g.*, Citizens to Preserve Overton Park v. Volpe, 332 U.S. 402, 1 ELR 20110 (1971).

12. United States v. Morgan (Morgan IV), 313 U.S. 409 (1941). *See also* Daniel J. Gifford, *The* Morgan *Cases: A Retrospective View*, 30 ADMIN. L. REV. 237 (1978).

13. For a parallel argument that legal fictions in toxic tort cases are distorting public perceptions of risk, see E. Donald Elliott, *The Future of Toxic Torts: Of Chemophobia, Risk as Compensable Injury and Hybrid Compensation Systems*, 25 HOUS. L. REV. 781 (1988).

14. Chlorine Chemistry Council v. EPA, 206 F.3d 1286, 30 ELR 20473 (D.C. Cir. 2000).

or for not being science-based. EPA has a lot to learn from FDA about how to create an agency culture that is more science-based.

Now, admittedly, there are some important structural differences between FDA and EPA. For one thing, FDA doesn't have environmental groups, at least to the same extent, involved in making policy. But I don't actually blame the environmental groups for the low level of scientific discourse at EPA. I think that they, like industry, have simply adapted to the current nature of the discourse.

When my friend Fred Krupp became the executive director of the Environmental Defense Fund [(EDF)] a number of years ago, we were riding back on the plane from New Haven together. He said, "well, what do you think I should do?" I replied, "Hire some scientists and economists," and he did. I'm sure other people gave him that same advice, but EDF (now ED) has been very successful at using more scientists and economists as environmental advocates. So I disagree with those who would say that "good science" is inherently biased in favor of industry.

One of the reasons that environmental groups and companies do not invest more in scientific discourse at EPA is that it is not the coin of the realm. It is simply not the basis on which decisions are made. So they're in a sense adapting to the culture of the place.

There are three quick points that I would like to make about what we might learn from the FDA example, how we might improve the role of science at EPA. First, consider the personnel. We've never had a scientist as the Administrator of the EPA. That's quite remarkable. My boss, Bill Reilly, was a lawyer, but he also had an M.A. in city planning from Columbia, so that's about as close, I think, that we have gotten to a scientist. Meanwhile, David Kessler, who is both an M.D. and a lawyer, was the head of FDA and is now the dean at Yale Medical School. Carol Browner was formerly a congressional aide, and I didn't actually hear Carol make this point, but she is reputed to have said in a meeting that she regards science as just another pressure group. If science is regarded as just another interest group, that partially explains the problems that we have.

We have had a number of assistant administrators at EPA, such as Lynn Goldman, Bernie Goldstein, and Jack Moore, who have had a scientific background, and I think their background shows in the quality of their decisions. I don't agree necessarily with the decisions that they have made, but their decisions have been science-based and serious about the evidence, in a way that I don't see many other decisions at EPA as being.

But the personnel issue is obviously not just concerned with the political appointees at the top. When EPA was formed in the 1970s there were 360 public health officers at the Agency. There are only a handful, if any, today.

The second major thing I think that needs to happen is that the ORD needs to be reinvigorated. It ought to be reorganized, and renamed as the "Science Office," not just the Office of Research and Development, but the Science Office, and they ought to put somebody in charge of it who is a vigorous policy advocate as well as a scientist.

The Science Office at EPA ought to have a veto over the Agency's decisions on scientific grounds in a way that the economists had a veto over decisions in the past.[15] And until there is a group that is serious about science, that has the ability to stop decisions that are not respectful of science, I don't think things are going to change.

The third point is we need to find ways to build science into the decisions, rather than tacking them on at the end as a judicial review measure. The Clinton Administration took a very useful and courageous act in its Executive Order mandating peer review,[16] but one of the problems with peer review, like Office of Management and Budget (OMB) review or judicial review, is it comes at the end of the line, and tries to knock out bad decisions, rather than building in good decisionmaking from the beginning. Elsewhere[17] I've argued—building on the "total quality management" literature by Demming and others—that you can't inspect quality at the end of the line; you have to build it in from the beginning. While it would be helpful to have better peer review, and to have a reinvigorated Science Office, we also have to change the culture of EPA so that decisions are science-based from the beginning.

An irony here is that one of the significant differences between EPA and [the] FDA is that at EPA, science decisions are institutionally separated from political decisions. They're kind of tacked on at the end. This, I think, comes in part from Bill Ruckelshaus' famous distinction between risk assessment and risk management,[18] the notion that we need to separate science and values. I think that's an entirely valid point, as an analytical one, but it doesn't follow, in my view, that a separation between science and policy ought to be reflected in the internal organization of the Agency. By separating the scientists from the policy process, we've marginalized them. One example of that is when Bill Reilly asked the Science Advisory Board (SAB) to make recommendations for risk reduction. There was a big debate within the SAB as to whether or not the board would be willing to make a policy recommendation, be-

15. The National Academy of Sciences has recently made a similar proposal for a new EPA Deputy Administrator for Science and Technology: "Just as the advice of the agency's legal counsel is relied upon by the Administrator to determine whether a proposal is 'legal,' an appropriately qualified and adequately empowered science official is needed to attest to the Administrator and the nation that the proposed action is 'scientific'—that it is consistent, or at least not inconsistent, with available scientific knowledge . . . ." NATIONAL RESEARCH COUNCIL, STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY (2000).

16. Exec. Order No. 12866, Regulatory Planning and Review, 58 Fed. Reg. 51735 (Sept. 30, 1993), ADMIN. MAT. 45070. *See also* PRESIDENTIAL/CONGRESSIONAL COMM'N ON RISK ASSESSMENT AND RISK MANAGEMENT, RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISIONMAKING 103 (1997).

17. E. Donald Elliott, *TQM-ing OMB: Or Why Regulatory Review Under Executive Order 12,291 Works Poorly and What President Clinton Should Do About It*, 57 LAW & CONTEMP. PROBS. 167 (1994).

18. *See* William D. Ruckelshaus, *Stopping the Pendulum*, ENVTL. F., Nov./Dec. 1995, at 26.

cause there was such a strong culture of separation of science and values.

Now, contrast that with the FDA where, rather than having a program office that's political, and then tacking on science by "peer review," science is an integral part of the process. Many of the agencies that use science successfully integrate it into the policy process by creating "advisory committees" of outside experts that recommend policy to the Agency, such as the Advisory Committee on Reactor Safeguards at the NRC. In contrast, it merits noting that one of the ways that peer review is conducted at EPA under the Executive Order is to hire a consulting firm.

Let me close by saying that I don't believe judicial review is the complete answer. We also need to change the internal culture and structure of the Agency. And I would respectfully disagree with my friend and colleague from the last Bush Administration[19] about *Daubert*[20] being the solution. I don't think courts can solve the problems of administrative agencies, but I do believe that the recent spate of court decisions setting aside EPA decisions on scientific and technical grounds is a symptom of a fundamental regulatory disease, which reflects the diminished role of science at EPA.

I very much hope the next president will correct the situation. Thank you.

WENDY WAGNER: Thank you very much.

Our next speaker is Alan Raul. He is a partner at Sidley & Austin, and has written a number of influential and provocative briefs, congressional testimony, and articles on the subject of the judicial review of agency science.

Before becoming a partner in Sidley & Austin, Mr. Raul had quite an impressive career inside government. He first served as an associate in the Office of White House Counsel under President Reagan. He then served as General Counsel at OMB from 1988 to 1989, and subsequently was General Counsel at the [U.S.] Department of Agriculture (USDA) for another four years, from 1989 to 1993.

Perhaps equally impressive is the fact that Mr. Raul is not only a formidable force in the environmental law area, he also specializes on issues of the Internet, and coordinates the E-commerce practice group at the Washington office of Sidley & Austin. So welcome, Alan.

ALAN RAUL: Thanks, Wendy.

I propose the use of what I will call "regulatory *Daubert*" as a principle for judicial review of agency decisionmaking in the scientific realm—not as a solution, but as a reform to enhance agency decisionmaking, to refine judicial review, and to promote accountability, which I think really is the most significant aspect of the issue.

I think in part there is a fallacy of the degree of effectiveness of presidential and congressional oversight with regard to agency rulemaking in general, and perhaps environmental decisionmaking in particular. The principle that has been articulated in the *Chevron*[21] decision of the Supreme Court and many other decisions, namely that policy decisions, including those of bureaucrats in the executive branch, should be left to the political branch and not displaced by the preferences and policy choices of judges, is quite correct, quite appropriate. But it is grounded in the notion that there is political accountability for the regulatory decisions made by agencies such as EPA, and that premise can be dissected and challenged and determined to be not entirely substantiated.

For some of the very most important regulatory decisions that an agency like EPA makes, you will get interest of the White House, although their ability to affect the outcome is limited; you will get some congressional oversight, through the Congressional Review Act,[22] which specifically empowered Congress to enact legislation to overturn rules.

Of course, Congress has the power under the Constitution to reject regulations, whether or not it utilizes a specific statute such as the Congressional Review Act. But while Congress has established procedures through the Act to review regulations, not a single rule has been taken to a vote in either House. There have been some measures introduced regarding final regulations, but not once has a measure come upon to a vote in either chamber.

So while the *Chevron* notion of deference assumes there is political accountability for policies that are adopted by regulatory agencies through the legislative and executive branches, the assumption does not withstand close scrutiny.

What, then, is the problem that a regulatory *Daubert* solution would solve? As Don indicated, EPA is subject to rather intensive judicial review, in the D.C. Circuit in particular, and in other courts of appeals and district courts as well. That review has resulted, perhaps recently to an even greater extent, in reversals of the Agency's decisions at a remarkably high rate.

Jonathan Adler has documented[23] an appellate reversal rate of EPA that is much higher than would be expected under the *Chevron* deference that is, at least in principle, accorded to the Agency. EPA is reversed frequently on scientific grounds, regardless of the courts' references to "extreme" deference, on scientific questions. The agency is reversed in the D.C. Circuit a lot, and is not treated with kid gloves.

By importing *Daubert*-type principles into judicial review under the Administrative Procedure Act (APA),[24]

19. *See* remarks of Alan Raul, hereinbelow.

20. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 23 ELR 20979 (1993).

21. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 14 ELR 20507 (1984).

22. Congressional Review of Agency Rulemaking Act, 5 U.S.C. §801(a)(1)(B).

23. Jonathan Adler, *Environmental Performance at the Bench: The EPA's Record in Federal Court*, Reason Pub. Pol'y Inst. (2000), *available at* <http://www.rppi.org>.

24. *See* 5 U.S.C. §706, *available in* ELR STAT. ADMIN. PROC.

we can better define the principles of judicial review, make them more consistent, and better advise the Agency, the public, and the Congress of the standards EPA, as well as the Supreme Court, should apply in the review of regulatory science.

The Court, as we're all well aware, in four decisions that began with *Daubert*, followed by *Joiner*,[25] *Kumho Tire*,[26] and most recently *Weisgram v. Marley Co.*,[27] has empowered federal judges to take a more influential role in assessing the methodologies and principles that are at stake in civil litigation under the Federal Rules of Evidence. Now certainly the APA, but not the Federal Rules of Evidence, applies to judicial review of agency decisions. Trials are not conducted, and agency decisions are reviewed by courts based on the administrative record produced by the agency itself. Under *Chevron* and other decisions, there is great deference that is accorded to the agency decisions; judges are specifically enjoined from substituting their own preferences and choices in place of those of the agency.

So an agency that is merely wrong on the law, or merely wrong on the science, will not be reversed pursuant to the APA. Instead, an agency needs to be "really, really wrong" in order to be reversed, a standard that is often called "plainly erroneous" or otherwise "arbitrary and capricious." But I think that the legal test really boils down to whether the agency is "really, really wrong," and, as Don Elliott has noted, there is ample evidence in EPA's track record that they are often really wrong—really, really wrong.

The *Chlorine Chemistry Council*[28] decision is indeed an example of the disconnect between science and the Agency's ultimate decision. There, the D.C. Circuit overturned an SDWA regulation of EPA. The preamble to the Agency's rule, a statement of basis and purpose, made it perfectly clear that the science supported the existence of a threshold in the carcinogenic properties of chloroform, but nonetheless the Agency said that it was going to stick with its old policy, instead of going with the available science. The EPA rule which ignored the best available science was struck down.

It would be interesting to consider whether the D.C. Circuit would have struck down that disconnect between the Agency science and its decision, but for the fact that the SDWA has a specific statutory "good science" mandate. The Agency had been specifically directed by Congress to apply the best available science, subject to objective peer review.

In the absence of such a specific science mandate, would the court have said, "well, you know, you've told us what the science is, you've told us what your policy is; what are we going to defer to, your scientific view or your policy view"?

I think that Wendy would argue, although she can speak for herself, that where the policy preferences are fully disclosed, and the assumptions are fully disclosed, there ought to be deference to the Agency. I believe that position is largely sound. So what would *Daubert*-type principles accomplish when Congress has not mandated specific scientific principles for agencies and reviewing courts to apply?

Applying regulatory *Daubert* would promote the full disclosure of all of the Agency's underlying principles, assumptions, and facts and obligate the Agency to come completely clean on the foundation for its scientific decision. Following that full disclosure, the Agency is entitled to policy deference on the scientific foundation for its decisions.

The question has to be asked about how *Daubert*-type principles would function in the judicial review context, given the distinction between the Federal Rules of Evidence and the APA. I submit that under Supreme Court and D.C. Circuit and other appellate court precedents, in particular *Motor Vehicle Manufacturers v. State Farm*,[29] regulatory *Daubert* can easily be imported into judicial review under the APA. Reasoned decisionmaking, the requirement for sound documentation and substantiation, and the important role of judicial review in maintaining accountability, all point in the direction of a need for more probing review of the Agency's scientific methodologies and principles.

The goal for incorporating a regulatory *Daubert* approach would be not only to encourage less deference and more probing judicial review but also to establish more consistent standards. That way, it wouldn't always be a roll of the dice as to which judicial panel you get, or what appellate or district court you're before, as to how intensive the judicial review of agency science will be.

If the agencies, EPA in particular, know that reviewing judges are empowered with *Daubert*-type inspiration to look closely at the science underlying the decisions, agency decisionmaking will improve. The documentation will be better, the explanations will be better, the defaults, the policy choices, and the uncertainties will all necessarily be disclosed and subjected to greater scrutiny, because the agency will know that it's not going to survive in court if it doesn't come clean on those factors.

And of course, if it comes clean on those factors, the opportunity for public accountability—public scrutiny through Congress, through the media, the White House—will all be enhanced at the same time.

At this juncture I would like to respond to Don Elliott's point that there is a distinction between the EPA and FDA statutory frameworks; a distinction that is relevant to the perception that science at [the] FDA is superior to science at EPA. Many of the EPA statutes either specifically preclude the consideration of cost-effectiveness and efficiency in decisionmaking, or have been interpreted as precluding consideration of a cost-benefit balancing. So this leads in many cases to a charade, where the Agency, as Don

25. General Elec. Co. v. Joiner, 522 U.S. 579, 28 ELR 20227 (1997).

26. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 29 ELR 20638 (1999).

27. 120 S. Ct. 1011 (2000).

28. Chlorine Chemistry Council v. EPA, 206 F.3d 1286, 30 ELR 20473 (D.C. Cir. 2000).

29. Motor Vehicle Mfrs. Ass'n of the United States v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 13 ELR 20672 (1983).

indicated, is not making a decision based on the factors that it claims to be making the decision on, because consideration of cost is essential to any public policy decision. If there were no real consideration of cost then the only democratic and moral alternative would be to set health protections, to set pollution levels, at a level stringent enough to protect every last American from every last adverse health or other environmental impact.

The fact of the matter is that in real life there has to be balancing. In the FDA context, with regard to the approval of new drugs, the balancing is perfectly manifest. Every new drug is going to have some adverse side effects. There are going to be some risks. And in exchange for incurring those risks and imposing them on a statistically anticipated—although hopefully small—percentage of the population, there will be benefits that will be accorded to the much greater percentage of the population, who will benefit from the approval of the new drug.

That same type of analysis ought to be appropriate, I would submit, in the environmental context, but because of the way the statutes have been interpreted, the opportunity for balancing overtly has been denied to EPA. As a result, the Agency needs to dance around the true bases for its decisions. So with regard to my proposal that *Daubert*-type principles be incorporated into administrative law, one of the beneficial results would be to promote EPA disclosure of the true bases for its decisions.

What would a *Daubert* regulatory standard specifically do? It would ensure that the reviewing court looks at the science that the agency has relied on to assure that it's relevant and reliable for the matter at hand. That would, in a nutshell, promote reasoned decisionmaking, which is what the APA is all about.

The reviewing judges wouldn't substitute their own conclusions, so there would be no conflict with either what the Supreme Court has articulated as *Daubert* principles, or with what the Court has required under the APA in *Chevron*, *State Farm*, and many other APA cases.

Now, why is this important? It is because the science that underlies the decisions, and the decisions that EPA and other agencies make based on science, are crucially important to society. If getting science right, or increasing the likelihood that the science is relevant and reliable, is an important objective in the case of litigation between two private litigants who are adjudicating a product liability or other tort action, if that's important, surely it's also important what science EPA relies on when it imposes tens of billions of dollars of cost on society under the Clean Air Act rules, and protects thousands or millions of people under those rules, as well.

So it's arguably much more important that the regulatory science be as good as possible, and that the public appreciate the relevant weaknesses in the Agency science, than the science used in civil litigation.

Does the EPA have a problem on the science front? I think that, as Don Elliott indicated, there is a problem with science. He spoke of being in meetings at the highest levels during which science was not even discussed as a basis for the decision.

In 1992, EPA Administrator Reilly received a report from an expert commissioned panel. The report was called *Safeguarding the Future: Credible Science, Credible Decisions*.[30] The report said that "EPA is not always assured that contrasting reputable scientific views are well explored and well documented from the beginning to the end of the regulatory process."[31] It went on to note that "EPA science is perceived by many people, both inside and outside the agency to be adjusted to fit policy. Such adjustments could be made consciously or unconsciously by the scientist or decisionmaker."[32]

So in 1992 the Agency itself recognized that it had a problem with regard to the objective nature of its own science. Wendy Wagner has documented the problem brilliantly, and the courts have recognized this, as well.

The D.C. Circuit in the 1994 *Chemical Manufacturers Ass'n v. EPA*[33] case concluded that EPA demonstrated a "let them eat cake" attitude towards science, by disregarding the question of whether the pollutant in question was a science or gas in its findings in its dispersion model. The court basically said, "well, of course, models are not going to fit precisely, that's why they're just models, and you fit the facts, the science, as best you can to your model. But if your model is not taking account of whether the pollutant in question is a solid or a gas, and you've been put on notice that it's one, to act as though it were the other really demonstrates a 'let them eat cake' attitude."

But having said that there are some courts that have taken the Agency to task for scientific inadequacies, there are numerous other panels, including some in the D.C. Circuit, where "extreme" deference has been the conscious principle for judicial review. In light of the Agency's problematic relationship to science, and the Supreme Court's comfort level in the *Daubert* line of cases in empowering judges to evaluate scientific methodologies and principles, this "extreme" deference is clearly inappropriate, and results in inadequate accountability of the Agency for its scientific decisions.

I should note two developments with regard to the *Daubert* analogy in administrative law; two cases specifically decline to apply the rationale in regulatory litigation. A Seventh Circuit case[34] and a district court case[35] declined to apply *Daubert* in the APA context, indicating that even though *Daubert* could result in better decisionmaking and better agency documentation, the standard would be too intrusive and inconsistent with the degree of deference that the

30. U.S. EPA, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS (1992).

31. *Id.* at 36.

32. *Id.* at 37.

33. 28 F.3d 1259, 24 ELR 21210 (D.C. Cir. 1994).

34. Sierra Club v. Marita, 46 F.3d 606, 25 ELR 20514 (7th Cir. 1995).

35. Stewart v. Potts, 983 F. Supp. 678, 28 ELR 20574 (S.D. Tex. 1997).

agencies are entitled to. On a more favorable note, however, in the *American Trucking Ass'n* (*ATA*) case[36] the D.C. Circuit did, in fact, cite *Daubert* in the context of the Clean Air Scientific Advisory Committee's [(CASAC's)] advice to the administrator on the role of science.

One last point on the Supreme Court's likelihood of accepting *Daubert* in the administrative law context. In *Daubert* itself, the Court cited a book by Sheila Jasanoff[37] regarding peer review of agency science in the federal decisionmaking process. The citation occurred in a context of the Court considering the importance of peer review in reviewing science in civil litigation. The Court's reliance on a regulatory science book in *Daubert* suggests that the Court would not be hostile to the notion that *Daubert*-type principles ought to have a role in judicial review of agency decisionmaking. Thank you.

WENDY WAGNER: Thank you Alan.

Professor Richard Pierce is our third panelist. Professor Pierce is the Lyle T. Alverson Professor at George Washington University (GW) Law School. Before joining the faculty at GW, Professor Pierce already enjoyed a distinguished career as an academic. He has been a professor at the Columbia Law School, the University of Virginia Law School, Southern Methodist University Law School, Tulane University Law School, and the University of Kansas Law School, and has served as the Dean of the University of Pittsburgh Law School.

Professor Pierce has written several books and many dozens of influential articles that raise critical insights about a variety of topics in the areas of regulation, administrative law, torts, and judicial decisionmaking. While he is clearly one of the nation's top experts on the judicial review of agency rulemakings, he is also a top expert on a number of other topics as well.

RICHARD PIERCE: Thank you, Wendy. I'm going to use the *American Trucking* case to illustrate some of the problems that I see with the current uses of science in agencies and courts.[38] As many of you know, the Court has, in effect, agreed to review two different D.C. Circuit decisions in the *ATA* case.

The first is the 1999 decision of the D.C. Circuit in which the court held that EPA's interpretation of §109(b) of the Clean Air Act (CAA)[39] is unconstitutional. The Court also has agreed, in effect, to review the 1980 decision of the D.C. Circuit in which the court, ironically, adopted the interpretation of the CAA that it held to be unconstitutional in 1999. In that 1980 decision, *Lead Industries Ass'n v. EPA*,[40] the court interpreted §109(b) to require EPA to focus exclusively on health concerns in setting primary ambient air standards, and precluded EPA from considering cost.

Now, looking at this case, and starting at the beginning with the Agency actions, I can identify a couple of problems I see in the Agency actions themselves. The EPA actions consisted of two rules: a rule that established a new primary ambient standard applicable to ozone,[41] and a rule that established a new primary ambient standard applicable to particulate matter.[42] EPA, in the thousands of pages of explanations that it provided for those rules, made two basic points that trouble me.

First, it said we don't consider the cost of setting standards, and we haven't in this case. Second, it said "we set these primary ambient standards solely to protect public health, and they do." Well, both of those assertions are just demonstrably false. They are just absolute fibs. They cannot be true, and here is some of the evidence to support that.

First of all, EPA prepared a 718-page cost-benefit analysis of the two rules.[43] It says it didn't read it, and didn't consider it, okay? Well, come on. That's ridiculous. I mean, I got it with three clicks off of the Internet. Nobody can convince me that not a soul in a decisionmaking capacity at EPA, on its advisory committee, in OMB, or in the White House bothered to hit the three clicks on their computer to get that 718-page document. That's not credible.

To support that conclusion, let me tell you that I have had numerous, both past and present, EPA decisionmakers tell me off the record, well, of course we look at those things. Would you ignore something that tells you $20 billion here, $10,000 over here? No. You would look at it, and indeed they did.

The second piece of evidence: EPA couldn't possibly have chosen the standards it chose without considering costs. EPA's announcements of benefits shows, among other things, that if it had chosen a more stringent particulate standard, a tougher particulate standard, it would save several thousand more lives per year, and they estimate the health benefits of a more stringent standard at $4 billion per year. Now, assume that it costs nothing to establish a more stringent particulate standard. Any human being would say, I will choose the more stringent standard. The only way you can get from the data before the EPA to the standard they chose is through the consideration of costs.

Of course they considered costs. Unfortunately, they aren't going to say that. They have to disguise the actual basis for their decisions because of some combination of the language in §109(b) and the D.C. Circuit's 1980 decision interpreting that language.

36. American Trucking Ass'n v. EPA, 175 F.3d 1027, 29 ELR 21071 (D.C. Cir. 1999), *panel opinion modified & reh'g en banc denied*, 195 F.3d 4, 30 ELR 20119 (D.C. Cir. 1999).

37. SHELIA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICYMAKERS 61-76 (1990).

38. *See* Richard J. Pierce Jr., *The Inherent Limits on Judicial Control of Agency Discretion: The D.C. Circuit and the Nondelegation Doctrine*, 52 ADMIN. L. REV. 63 (2000).

39. 42 U.S.C. §7409, ELR STAT. CAA §109.

40. 647 F.2d 1130, 10 ELR 20643 (D.C. Cir.), *cert. denied*, 449 U.S. 1042 (1980).

41. National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38856 (July 18, 1997).

42. National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38652 (July 18, 1997).

43. U.S. EPA, EPA REGULATORY IMPACT ANALYSES FOR THE PARTICULATE MATTER AND OZONE NATIONAL AMBIENT AIR QUALITY STANDARDS AND PROPOSED REGIONAL HAZE RULE (1997).

Now, turn to the *ATA* decision itself, the 1999 decision. The first thing—I'm sure most of you know this, but I want to make sure everybody does—the court did not hold that §109(b) is unconstitutional as a standardless delegation of power to an agency. That would be certainly an unusual decision, only the third time any court had ever done it in 200 some years, but that isn't what the court did.

It couldn't possibly do that, because the standard in §109(b) is actually much more precise than scores of standards that the Supreme Court has upheld under the nondelegation doctrine. In fact, the problem with §109(b), at least as it was interpreted by the D.C. Circuit in 1980, is exactly the opposite. It is not too broad a delegation of powers, it's far too *narrow* a delegation of powers. The court in *Lead Industries* said you can't consider cost; that is the opposite of the problem that arises and is responded to by the nondelegation doctrine. So what did the court in *ATA* do? It held that EPA cannot set primary air standards unless and until it adopts "determinate binding standards" that both it and reviewing courts can apply to say how much pollution is too much.

I've got three basic problems with that holding. First of all, it obviously is a complete disconnect with the nondelegation doctrine, the purpose of which is to force Congress to establish meaningful standards in statutes. The court's approach doesn't do anything in that regard. Second, there is simply no standard that would satisfy the court's mandate. With respect to both the effects of pollutants on human health, and the social value of human health, there is no way to implement a determinate binding standard that will tell us how much pollution is too much. Third, the only standard that would come close to satisfying both the criteria identified in *ATA*, and in *Lead Industries*, would require complete deindustrialization of the United States.

To the extent that we have data relating to the health effects of these two pollutants, the presently available data indicates that there is a spectrum of health responses at every level of exposure, every level of concentration of these pollutants, all the way down to, and some of the data suggest, even below, the baseline level of these pollutants produced from nonanthropogenic sources.

I'm not a big fan of that opinion, as you can tell, but even with those big flaws, I think the D.C. Circuit makes a really good point—a point that EPA really was not in a position to address effectively given its role in government, but one that the Supreme Court can address in a constructive manner. EPA does not, and cannot, provide a rational explanation for its choices of primary air standards. I think one of the reasons the Agency had 3,000 pages of explanation is that if they provided the short explanation, it would be patently silly; EPA needed 3,000 pages to cover up the fact that it wasn't doing what it said it was doing. That is a true problem. In order to figure out what can be done about this constructively, the first step is to figure out exactly what EPA *is* doing in cases of this type.

EPA is making policy decisions by making trade offs between public health goals and economic goals, in conditions in which the relevant relationships and values are so uncertain that it necessarily has a great deal of discretion to choose where to draw the line in making those trade offs. That's what it is doing. Now, that's an entirely appropriate function for an agency to perform, and the Supreme Court has said so in at least a dozen cases. Indeed, the Court legitimated that practice in *Chevron* by attributing the Agency policy decisions to the politically accountable president.

Now, you really can't take that attribution seriously in the case of all agency policy decisions. The president undoubtedly is unaware of the vast majority of them. But when it comes to a decision of this magnitude, where you're talking about scores of billions of dollars on one side and tens of thousands of lives on the other, you bet the president is involved. I'm quite certain that President Clinton was involved in this decisionmaking process. I hope he was, and I'm quite certain that he did what the D.C. Circuit has referred to in a complimentary fashion as "jawboning," namely to induce the Agency to act in a manner that is consistent with the values and preferences of the president.

That's 100% legitimate. The problem is, EPA can't say that's what it's doing. If it did so, it would be admitting that it has acted in a manner inconsistent with the D.C. Circuit's 1980 interpretation of §109(b). EPA must instead say that it is doing something that it cannot possibly be doing, choosing standards that achieve public health goals in some absolute sense without any consideration of cost.

So what can be done about this? The Supreme Court is in a position not necessarily to solve the problem, but certainly to reshape it in a very constructive way. I think the Court should reverse *both* the 1999 *ATA* decision and *Lead Industries*. It should base its reversal of the 1980 decision on the canon of construction the D.C. Circuit has applied in four cases in the last two years. That canon is that it will not attribute to Congress an intent to forbid an agency from considering the cost of its actions absent "clear congressional intent . . . to preclude consideration of cost."[44]

Most recently, the D.C. Circuit announced and applied that canon in *Michigan v. EPA*[45] just a few months ago. That canon makes very good sense. We all consider the cost of our decisions in everything we do in life every day. Ignoring cost is so irrational, and so contrary to basic human nature, that courts should be extremely reluctant to conclude that Congress has prohibited an agency from considering the costs of its action.

That kind of decision would then free EPA to say what it is really doing, and to describe why it is doing what it is doing; why it has chosen this standard rather than that standard, instead of being forced to lie. Now, once EPA has the freedom to do that, then the courts can turn that freedom into an obligation through application of the arbitrary and capricious provision of the ATA. That's what I hope the Su-

44. Natural Res. Def. Council v. EPA, 824 F.2d 1146, 1163, 17 ELR 21032, 21038 (D.C. Cir. 1987) (en banc).

45. 213 F.3d 663, 30 ELR 20407 (D.C. Cir. 2000).

preme Court is going to do for all of us some time in the next few months. Thank you.

WENDY WAGNER: Thanks so much. Professor Thomas McGarity is our last panelist. He holds the W. James Kronzer Chair in Trial and Appellate Advocacy at the University of Texas School of Law. He also has written two books and many, many dozens of articles that have made a tremendous impact on our understanding of environmental and health regulation. His path-breaking work on the causes of regulatory "ossification" and his critical analysis of regulatory fine-tuning are just two examples of the kind of work he has produced.

Professor McGarity has also served on a number of prominent national panels and task forces that were convened to better understand and identify avenues for improving upon regulatory processes, particularly in the area of environmental and workplace protection. So with that, we'll turn it over Professor McGarity.

THOMAS MCGARITY: Thank you, Wendy. She mentioned I'm the Kronzer professor at University of Texas Law School. The University of Texas Law School is fortunate now to have joined its faculty Wendy Wagner. I'm very, very pleased about that, as are all the members of the faculty, and we are looking forward to her actually winding up in Austin here pretty soon.

Most of you out there probably know my views about at least substantive judicial review of agency rulemaking involving science. I'm the advocate not of the hard look doctrine, but rather of a much more deferential standard for judicial review.

I think that substantive judicial review has played a major role in what Don Elliott has called the ossification of the rulemaking process. I give credit to Don; I give him full credit for that term. What I did was, 10 years ago, at the very same conference at which he delivered his OMB piece, accept his challenge to think and write about the ossification of the rulemaking process,[46] and one of the things that I discovered in doing so was that agencies do see the courts peering over their heads, especially the personnel rather deep in the agency, and that can have a real impact as to the obligation of coming up with long, long explanations sufficient to satisfy a reviewing court.

I want to say a few words about Don's presentation before I move on to my general remarks. First of all, I was a little surprised at his use (and Alan's, too) of the word "science" as if that were a "something." That there is the science, and then there is the policies or the politics, and the agencies are ignoring the "science" so often.

The science is just data, and interpretations of the data, are admittedly exceedingly important, especially for decisionmaking at EPA. But to say there is the science of something, as if it were the agreed-upon interpretation of the data, or that there would be a database sufficient and adequate to support a conclusion, and that anyone with scientific training who looked at that data would reach the same conclusion, is in most contexts in which it comes up—and certainly in judicial review—highly misleading. There are situations in which it is true, of course. Nobody disputes Newton's laws, and we don't see much litigation about them. Where you do see the litigation is where there are disputes (increasingly important these days) over interpretations of data.

So often where one comes out on those disputes depends on whose ox is being gored, as to whether you want a lot of data and a whole lot of analysis, or you are anxious to proceed ahead with a new technology or policy without a whole lot of data and analysis.

There are two major problems here. One is in identifying genuine scientific disputes, and isolating the ones that have been conjured up by folks. Maybe endocrine destructors is one of those. It's entirely possible that it may be a false dispute. Maybe the scientific community is really totally in agreement on that topic, and maybe it isn't. The difficult question is which ones are the real, legitimate scientific disputes and which ones aren't.

The other problem is that, in resolving science policy disputes, when we recognize that there is a legitimate dispute, we try to segregate the science from the policy. I couldn't agree more with Alan in that regard that it is desirable for agencies to be very explicit about the uncertainties they're encountering, be very explicit about the policies, the risk assessment inferences.

One final point with respect to Don before I move on is that he didn't mention the SAB. I was a little surprised by that. There are scientists in the EPA. The [ORD] hasn't in practice been the science office, but there are scientists in all the program offices, and the SAB has played, in my experience over the years, an increasingly important role as a kind of distiller and "weeder-outer," if you will, of the illegitimate disputes. It is, of course, by statute, composed of scientists from across the range of scientific viewpoint.

Now, I do agree with Alan, also, that the D.C. Circuit has been fairly aggressive in reversing EPA decisions in the past few years, and I think that's entirely inappropriate. I think that there are three real reasons why we should have very deferential judicial review of the sort that Alan doesn't like. First, respect for the court and its branches—this is nothing new, by the way. The second, which doesn't get talked about much but really should, the appropriateness of judicial policymaking in the guise of judicial review. Finally, and this does get talked about a lot, judicial competence.

With regard to the respect for the executive and legislative branches, unelected judges ought to show proper respect for the other elected branches. This is especially true, I think, when the judges are lobbying the atomic bomb of the delegation doctrine, where they can trump legislation. A court that invokes the delegation doctrine to invalidate a

46. *See* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385 (1992).

law, or even an agency's construction or interpretation of the law, is itself engaging in a discretionary exercise of institutional power. Under what has been called "conservation of discretion," there is discretion being exercised, it's just now the judges that have the discretion. That is a power that is not exclusively granted to the courts by the Constitution.

When a court invalidates a law or an interpretation on the ground that it is not supported by an intelligible principle, I think it owes an obligation to the citizens to at least be prepared to articulate an intelligible principle for determining whether the principles that the agency has applied are intelligible. I believe that the *ATA* opinion failed to do so.[47] Conspicuously missing from the court's application of the delegation doctrine was any legal analysis of that doctrine, or the relevant Supreme Court precedence. The dissent made note of that absence. In fact, I don't see any serious legal analysis of the language of the statute or its legislative history.

The reader of *ATA* comes away from that opinion with the sense that the analysis is, in essence, "I know intelligible when I see it, and this isn't it." The problem with that approach, of course, is that it doesn't give much guidance. The EPA is invited to try to come up with an approach to satisfy the majority, or to seek specific legislation from Congress. The reader doesn't get any sense of why the Agency's approach failed, and very little guidance as to what might work in the future.

Moreover, even when performing the ordinary substantive judicial review function outside the sort of atom bomb of the delegation doctrine, a single unsympathetic or confused court can bring about dramatic shifts in focus of a program, or sometimes even the complete destruction of a regulatory program.

I will take a moment to argue with Dick Pierce on whether EPA needed to engage in cost-benefit analysis in order to be intelligible. I do think that one can, admittedly being a little charitable, defend the Agency's statement about why it chose an ozone level of .08 over .07. The court said, well, there are effects all the way down conceivably to zero. That may be true, but with increasing degrees of uncertainty—and I think that's the balance that the Agency was striking, not so much against the cost of more stringent standards, but the balance of how confident it was in the conclusions that sensitive populations would, in fact, be affected.

In the ozone rulemaking EPA predicted transient and uncertain effects at .07. At .08, the effects were more likely to be serious and reversible, although there was a good deal of uncertainty about that. As you get to .09 the Agency was much more confident that there would be serious and irreversible effects. So that's a line-drawing exercise, and it's a line drawing that can appropriately be governed by a sort of balancing of your confidence level against the seriousness of the effect.

Finally, I'd like to speak to judicial competence, and this is where I join with Alan on the *Daubert* point. Most judges don't have the education necessary to deal with complex scientific issues, but I don't draw the line there. I don't say that's the point. Most of us don't—most litigators don't, most lawyers don't, and yet we litigate about complex scientific issues all the time.

The one thing that we do have that the judges don't is time. That is, we have the time to educate ourselves. Most of the issues, especially to the extent that the science and the policy are intertwined, as they so often are, are matters that intelligent people who work and strive hard enough can get their hands around. Now, it requires work. It requires more than sort of ivory tower stuff that we sometimes see coming out of the academic discipline; it requires reading the *Federal Register* documents, reading the background documents, reading the scientific studies themselves.

And that is hard, time-consuming, and the sort of thing that we really can't expect judges to do, nor should we expect even their law clerks to be doing this, either. Even well-intentioned judges who are not attempting to expand their institutional turf, and are not trying to legislate judicially their own policy preferences, are going to have trouble separating the science from the policy. I simply do not trust a federal district judge to tell me that what EPA has concluded is bad science. A beautiful example of that is the *Flue-Cured Tobacco*[48] case, involving EPA's extensive risk assessment of environmental tobacco smoke.

Again, it takes a lot of work. I spent two years on it, and I'm not nearly done. But we have 33 million documents from the tobacco industry that you can look at and you can see the process really work. In that case, you can watch the conscious obfuscation of science. It is explicit and very, very clear.

I'm writing about this. It's going to be a while, but I'll just give you some previews. In 1981, a professor in Japan published the first epidemiological study of Japanese wives with smoking husbands that showed, he believed, statistics that environmental tobacco smoke (ETS) caused lung cancer. Within days after it became known that the study was available, the tobacco industry had already commissioned 15 or 20 scientists to write critiques for prominent scientific publications. When one of those scientists said he thought the Japanese study was a pretty good one, the head of the tobacco industry dropped him. That's how, apparently, it works in the real world.

At great expense, the industry assembled a symposium at McGill University, loaded it up with tobacco company consultants, and then published the proceedings. Those proceedings were cited to the courts, and they're cited to the courts today. This is not to say that the scientists at the McGill conference were lying, but I would suggest that what is going on here is a conscious attempt to interpret the data in one way, and in a way that is very much driven by particular politics.

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47. *See* Thomas O. McGarity, *The Clean Air Act at a Crossroads: Statutory Interpretation and Long-Standing Administrative Practice in the Shadow of the Delegation Doctrine*, 8 N.Y.U. ENVTL. L.J. (forthcoming 2000).

48. Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 857 F. Supp. 1137, 25 ELR 20089 (M.D.N.C. 1994).

Finally, days before EPA was to publish its risk assessment, a public relations firm for the tobacco industry created out of whole cloth a controversy over a study by a graduate student at Yale named Mr. Morella, who was by that time deceased. Morella's work wasn't even a dissertation; it was a master's thesis that an industry scientist found in a file. A public relations consultant for the tobacco industry pulled together reams of paper about Mr. Morella's research, sent the material to 300 reporters throughout the country, and went to extraordinary efforts to have press conferences, press releases, and so forth. It claimed that EPA was guilty of such "bad science" that it ignored the biggest epidemiological study undertaken in the United States, or had simply pushed it under the table.

It turned out that virtually all of those charges were wrong. EPA had seen the "study," had talked to the major professor at Yale who was an adviser to the graduate student, and the major professor said, "I plan to publish this data." He allowed Mr. Morella to pick through it for his master's thesis, but planned to publish the study, and ultimately did publish it. The published study basically agreed with EPA. But that study was cited in the industry's challenge before the Middle District of North Carolina, a district that was obviously chosen for the purpose of obtaining a reversal, and that court threw out EPA's risk assessment.

There were legal grounds upon which the court acted, in that the statute itself talked about a scientific advisory entity, and EPA relied upon its own SAB. Interestingly, the tobacco industry lawyers, back when EPA was preparing the risk assessment, leaned on EPA very heavily to do it through the SAB. When the SAB found the risk assessment to be supported by the data, the industry argued that the statute required a differently composed board. I suppose this argument might have provided a legitimate reason for reversing EPA, but the court didn't stop there. Instead, it wrote a 40- or 50-page point-by-point scientific critique of EPA's risk assessment. That went way beyond the pale. Maybe this is as *Flue-Cured Tobacco* is an outlier, but the point here is that the judge really wasn't competent to be critiquing EPA's science. In fact, it appears that the judge was attempting to destroy this report so that it wouldn't be used in litigation elsewhere, as for example, private litigation, and that sort of thing.

My conclusion, or to sort of sum it all up, is that federal judges should, to the extent possible, be neutral arbiters of particular disputes, and should carefully avoid the public perception that they're acting as part of the political process. If they don't, I think the public is not going to have much trust for that institution. There's sufficiently little trust for governmental institutions these days, as it is. The judiciary is the repository of a great deal of that remaining trust, but as it becomes more and more apparent that the judges are acting as politicians, the public will show less respect, and unpopular judicial opinions remain unenforced and generally disregarded. Thank you.

WENDY WAGNER: Thank you. You were an absolutely terrific panel. Perhaps we should take a few minutes for the panelists to respond before we take questions from the audience.

ALAN RAUL: I would like to respond to a couple of points.

While it's true that *Lead Industries* read consideration of costs out of CAA §109, the fact of the matter is that Congress has passed numerous statutes, some of which are part of the Contract With America, and some of which were not, that specifically embrace consideration of costs and risk assessment, and cost-benefit balancing.

The Unfunded Mandates Reform Act (UMRA) of 1995[49] required the EPA to engage in a cost-benefit analysis, and to choose the most cost-effective, least burdensome regulatory alternative consistent with law. And the SDWA is considered a model for new and more enlightened statutes. As Professor Pierce indicated, the reality is that life compels us all to consider costs and balance costs and benefits, and to consider risk assessment, and risk balancing.

So we've got the UMRA, which is an overriding statute requiring agencies to consider and act on cost-effectiveness and efficiency grounds; the Toxic Substances Control Act[50] and the Federal Insecticide, Fungicide, and Rodenticide Act,[51] both of which involve cost-benefit analysis; the SDWA, which imports risk assessment and cost balancing, and, perhaps most significantly in the *ATA* context, the 1990 Amendments to the CAA, which brought many cost considerations into the Act. Those amendments require the Agency to publish an analysis of the cost-benefit implications of national ambient air quality standards. There are numerous other provisions that clearly signal congressional adoption of cost-benefit balancing and cost-effectiveness as a necessary principle in environmental regulatory decisionmaking.

I believe the Supreme Court will and should take all these factors into account in deciding whether *Lead Industries* is correct, whether it was correct when decided in 1980, or whether it remains correct in light of the substantive congressional enactments that should be read in pari materia with §109 of the CAA, as previously interpreted by the D.C. Circuit.

Professor McGarity made good and effective points with regard to the ozone rule that EPA issued, and the applicable uncertainties and lack of confidence in various outcomes. What is important to remember there is that the [CASAC] advised EPA that there is no bright scientific line that distinguishes among any of the alternatives—the status quo, the slightly more stringent standard of .07, the slightly less stringent standard of .09—there is basically not a scientific distinction that can help you decide among these alternatives. So as Professor Pierce said, it's got to be something else.

On *Flue-Cured Tobacco*, it is important to know that the deciding judge was the same one who ruled that the [FDA] had authority to regulate tobacco, a decision that was

49. Pub. L. No. 104-4, 109 Stat. 48 (codified at 2 U.S.C. §1501).

50. 15 U.S.C. §§2601-2692, ELR STAT. TSCA §§2-412.

51. 7 U.S.C. §§136-136y, ELR STAT. FIFRA §§2-34.

ultimately reversed by the Supreme Court in *Food & Drug Administration v. Brown & Williamson Tobacco Corp.*[52] Obviously, the judge was more than willing to decide against the interests of the tobacco industry. But what the judge found in *Flue-Cured Tobacco* was that EPA had actually manipulated the science in numerous egregious ways. Indeed, he was not as scathing in his criticism of EPA as the Congressional Research Service (CRS) was in testimony it delivered before Congress. The CRS used terms to chastise and criticize EPA that one doesn't say in polite company, even in congressional testimony, because EPA had changed the so-called confidence level for statistical analysis from the traditional 95% confidence interval to a 90% confidence interval, thereby artificially boosting the apparent association between cancer and secondhand smoke. EPA changed it not only from what is traditional in this type of analysis, but in fact, EPA relaxed the standard from what was used in the Agency's own draft study. The CRS, and the court, found a problem with that.

EPA also excluded some studies. Professor McGarity talked about the possibility of industry influencing the studies, and referenced tobacco industry documents. But it's also the case that the Agency dropped studies that it didn't want to look at, and lowered the traditional analytic standards that it typically applies and other scientists apply to judge the strength of correlations and statistical association.

RICHARD PIERCE: I wanted to respond to one of Alan's points. I agree with a lot of Alan's points, but I wanted to urge caution about going very far with the regulatory *Daubert* idea. Initially, I think it's important to note the very different institutional context that we're talking about here.

Daubert arose in the context of whether a federal judge should act as a filter as to what kind of evidence lay jurors can consider. I think *Daubert* makes a lot of sense in that context. Federal judges don't know that much about science, but they know a lot more than do lay jurors, and so it makes sense to assign them that task. Transposing that into the regulatory context, however, is quite doubtful. Federal judges don't know much about science. They know a lot less about science than do agencies. My favorite illustration concerns a passage in a Supreme Court plurality opinion, a wonderful passage—Tom knows it well—in which the Court, in an attempt to be helpful after holding that the [Occupational Safety and Health Administration (OSHA)] must find that a substance poses a significant risk before it gets regulated, gives an illustration of a risk it considers real bad, and a risk it considers trivial.[53] Anyone who has had Toxicology 101, even if they got a D in it, can see that the risk that the court calls trivial is much larger than the risk the court calls plainly unacceptable. I don't want fools like that messing around with science, and that's the *best* of our judiciary.

Another reason for skepticism is that most agencies are already applying *Daubert*. *Daubert* arose in the context of a bendectine case. [The] FDA considered the evidence about bendectine. In fact, considered exactly the same evidence that was at issue in *Daubert* on two different occasions—there were elaborate studies—and it said what the Supreme Court said. The Agency never considered the kind of really "junk" science that is routinely excluded throughout the *Daubert* line of cases.

One final point. At one point both Alan and Don made reference to the D.C. Circuit's high reversal rate of EPA to prove that EPA is doing a lot of bad things. Well, I'm not a big fan of EPA. I have no doubt that EPA does a lot of bad stuff, but I urge caution in terms of using the D.C. Circuit reversal rate to prove that an agency is doing a bad job. I would urge anybody who hasn't yet done so to read Ricky Revesz's study[54] in which he goes through the political statistics, and shows that on the D.C. Circuit in particular, Republican appointees almost invariably find flaws with Agency decisionmaking, while Democratic appointees hardly ever do.

This is just politics that has gone from the Agency level to the judicial level. That's all that is. And you can't draw an inference from that as to anything except that Republicans continue to maintain a majority of the members of the D.C. Circuit.

RANDY HILL: I'm Randy Hill, and I'm sort of a spy here. I'm actually from EPA. Let me say that right off.

My question is primarily for Mr. Raul, and I would really love to engage you on *Chlorine Chemistry Council*, but having worked on the case I may drift into making privileged statements, so instead, what I want to ask you a two-part question about your thesis about *Daubert*. The first part is, do you think it's actually necessary? I've been sort of working myself on a hypothesis, and I think Professor McGarity in some ways endorsed it, that maybe the standard of review has already changed.

I think if you look at *Chemical Manufacturers Ass'n*, at *Flue-Cured Tobacco* case, and a 1994 case from the the D.C. Circuit, *Leather Industries*,[55] the courts were, in fact, taking a harder look at Agency science, and basically giving the Agency a lot less deference than they used to get. So I'm wondering whether, in fact, even if there's a problem, is there a necessary cure, or have the courts already sort of taken it on themselves?

The second part of the question is, assuming that we do need a cure, and this maybe follows up on Professor Pierce's points, how would you, in fact, carry it out; would it be simply a higher standard of review, or would you expect the courts to engage in some sort of evidentiary fact-finding in order to decide which of the studies to take?

52. 120 S. Ct. 1291 (2000).

53. Pierce, *supra* note 31, at 72 (discussing Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 10 ELR 20489 (1980) (*Benzene*)).

54. Richard L. Revesz, *Environmental Regulation, Ideology, and the D.C. Circuit*, 83 VA. L. REV. 1717 (1997).

55. Leather Indus. of Am., Inc. v. EPA, 40 F.3d 392, 25 ELR 20158 (D.C. Cir. 1994).

My concept of judicial review is that if the Agency has seven studies, and they're sort of equally balanced, and the Agency says, "well, there are reasons to think that these four studies are better than those three," the courts ought to get out of the way, yet they really haven't been doing that. So how would a *Daubert* principle change that kind of review?

ALAN RAUL: I think you make a good point that the standard, to some extent, may have changed. The D.C. Circuit has not been, in my view, particularly hospitable to EPA, perhaps for the reasons that Professor Pierce has indicated. So I think in part the standard has changed, at the D.C. Circuit in particular. Other courts have also been willing to take a hard look, but it's not uniform. One of the principle objectives of my regulatory *Daubert* proposal is to attempt to achieve a more uniform level of judicial review of science, with the interest of enhancing the predictability of review itself, as well as to send a signal to the Agency that it needs to provide better and more honest scientific substantiation and documentation.

But I would note that there are a couple of court decisions in which the notion of extreme deference continues to hold sway. In a 1992 decision, which you might say was long enough ago that it is before the de facto standard of review changed, *International Fabricare Institute v. EPA*,[56] the D.C. Circuit was very deferential to agency decisionmaking. More recently, in the May 2000 decision in *Environmental Defense Fund v. EPA*,[57] the D.C. Circuit said that EPA's reasons and policy choices are subject only to minimal standards of rationality, and that courts must show considerable deference to an agency.

Again, these are not terribly controversial propositions, but they reflect a tension in the standard of scientific review that the D.C. Circuit, and other courts, are trying to apply to EPA. Is the standard "extreme" deference, is it merely "some" degree of deference? I would suggest that by bringing analogous *Daubert*-type principles into administrative law and judicial review, you would get a more uniform, reliable level of judicial review. So as to whether the cure is "necessary" or not, I would suggest that if the objective is to achieve more predictability and reliability, yes, it is necessary.

One last point on whether the standard has changed. Last term's decision in *Christensen v. Harris County*[58] has been cited by many courts as evidence for the continued vigor of *Chevron* in applying deference. In fact, Justice Thomas' decision really scales back the degree of deference that is accorded to agency actions that are not issued pursuant to notice-and-comment rulemaking. Justice Scalia took great issue with Justice Thomas' opinion in that case. I think the case, properly understood, reflects a scaling back of the extent of *Chevron* deference under certain circumstances.

I would suggest *Daubert*-type principles ought to be applied in administrative law to empower and encourage reviewing judges to remove the barrier of extreme deference standing between them and a review of the methodologies and principles that agencies rely on. Courts would not substitute their own political or policy preferences for those of the Agency, but would make the Agency come clean on what the key scientific factors are, what the key uncertainties and assumptions are. I think that can be done without substituting judicial policies for administrative policies, which would be an unfortunate result.

THOMAS MCGARITY: I think sometimes what you see is extreme deference when the petitioner is [the EDF], and not so much deference when it's American Trucking Associations, so just pulling verbiage out of an opinion may depend again on whose ox is being gored. Also, I would just suggest to you that, in the area of genetically modified foods, when people talk about the FDA, that's a very controversial business these days. The fact of the matter is there is virtually no science to support the safety of genetically modified food, but under the reasonable certainty of no harm test that the FDA applies it basically allowed it all to go through as generally recognized as safe. There's no science to base that on. But we don't hear a lot of fighting about that. Now, we may, as soon as [the] FDA is sued, see how deferential they are to that.

ALAN RAUL: The District Court in D.C. actually affirmed the FDA biotech policy, just a week or so ago.

PETER STRAUSS: There was an awful lot in the panel's wonderful presentation that struck me as being quite familiar in a really long term sense. I can remember an opinion writer for the old Civil Aeronautics Board (CAB), back in the days when there was a CAB, talking about how he wrote opinions. "Well, they tell me Delta gets the route from Atlanta to Chicago. Now you go write the opinion." This is not a new kind of problem. What you were arguing for, Alan, sounds to be very much like what the Supreme Court at least said it thought it had accomplished in *Baltimore Gas*, that because the agency was open about its uncertainties, deference is owing to them.

And one can also remember Bill Pederson's remarks about the utility of giving those within the EPA who care about reasonable decisionmaking process tools with which to work against those within the Agency who do not. That's from 1977, as I recall, and seems to be very much in the way of the dispute that we're talking about today.

I have two general propositions on which I'd like any of you to respond. For me, Justice Stevens' greatest error in *Industrial Union (Benzene)*, and for that matter, Judge Williams' greatest error in *ATA*, was to fail to credit a device that Congress had provided for bringing science to bear on regulatory decisions. In *Benzene* it was the National Institute of Occupational Safety and Health [(NIOSH)] which had advised, as it was statutorily directed to do, OSHA about what

56. 972 F.2d 384, 22 ELR 21385 (D.C. Cir. 1992).

57. 210 F.3d 396, 30 ELR 20550 (D.C. Cir. 2000).

58. 120 S. Ct. 1655 (2000).

its priorities ought to be. Stevens writes his opinion as if that advice wasn't there, as if OSHA didn't have a reason for going after Benzene regulation because NIOSH, this scientific panel, had told them Benzene ought to be a priority. His opinion paid no attention to this congressionally mandated device for setting priorities.

Similarly, in *ATA*, the CASAC was involved, and while it's certainly true, as Alan remarked a few moments ago, that it didn't resolve the science issue, it bracketed it, and its doing so makes wholly illegitimate Judge Williams' remark that about EPA being "free to pick any point between zero and a hair below the concentrations yielding London's Killer Fog."[59] He pays no attention at all to this useful bureaucratic, structural device; so that's question one this panel. Does the panel think that these are the kinds of devices that ought to get more judicial attention as an appropriate means for bringing science to bear on regulatory processes?

And the second is a question about *ATA*. If I take the word "delegation" out of *ATA*, which I will admit is hard to do, what I read is a judicial insistence that the explanation EPA writes has to have one important quality to it; it has to be sufficient to tell the court what the Agency's reasoning process will be the next time this kind of issue arises, so as to permit the court to assess whether the Agency would used that process consistently, or explain there was a departure from it. Put that way, the opinion seems to express a very standard and, I would suppose, desirable principle of administrative law.

RICHARD PIERCE: I'll take a stab at that; my answers are yes and yes. I agree completely with your first point. Those do seem to be extremely useful devices, and I think the courts should acknowledge them, credit them, use them. On your second point, I would agree with that, too. If the D.C. Circuit had written *ATA* as a standard *State Farm* arbitrary and capricious reversal, well, of course, it never would get to the Supreme Court. The Court might take one of those kinds of cases every 10 years, and the decision wouldn't be getting this kind of attention from us, and might or might not have been right.

There is, however, another point that logically follows from that. If the D.C. Circuit had taken that approach, then I think it would have been obliged to treat these not as one rulemaking, but as two, as they were, of course. As has already been illustrated, I think these really were quite different rulemakings. I've talked to members of the advisory committees on both rulemakings; the two rulemakings were worlds apart. And so the D.C. Circuit, having taken that approach, would have been obligated then to say that one was fine and the other was not; it might have said a whole lot of things, but we would have learned a lot more about its reaction to the quality of the Agency's reasoning process.

THOMAS MCGARITY: I agree with Peter on both points.

ALAN RAUL: Well, I think we are in unanimous agreement, because my answers would be yes and yes, too. I would offer just a couple of observations. I think that in *ATA* the court was so deferential to the Agency's science that it accepted it without any real question or analysis. The ozone and particulate matter rules were indeed very different rules. There were scientific issues and questions about both of them, and the D.C. Circuit certainly had an opportunity to get into the scientific issues but decided not to, accepting the Agency's scientific conclusions and judgments through complete deference.

The point that Professor Strauss makes—that if you take nondelegation out of *ATA*, and express the requirement as to whether the Agency's reasoning process has been consistently applied—I think that's exactly right, and would certainly be one of the goals that I would propose for the regulatory *Daubert* approach. That's exactly what is intended to be accomplished. That is to say, smoking out what the Agency is really basing its decisions on, the basis of its reasoning process, and determining whether the Agency is applying that process consistently.

With regard to the SAB and the CASAC in the ozone rulemaking, they certainly did bracket what the scientific range would be, and they indicated that there was no bright scientific line, thereby making clear that the ultimate decision was a policy judgment, as opposed to a scientific one. One caution I would note on reliance on SAB-type reports regards how those reports end up being drafted. I think it is possible, and I have seen instances in my review of Agency activity with regard to these reports, that SAB members express comments, and an EPA staff writer writes up the comments in a draft. It then goes back out and is circulated to the SAB. The SAB members say "no, that's not right, I didn't say that." Comments go back the staff writer, the staff writer puts out another draft, the SAB again says "no, that's not what I said, that's not right." Ultimately, in the drafting of the report an Agency official is in control of the final product. Sometimes it's important to verify that the report actually correctly reflects the deliberations of the SAB members themselves.

PETER STRAUSS: I should confess that in my earlier guise as general counsel of the [NRC], I had a lot to do with a similar type of advisory board that works there, and worked, I thought at the time, tremendously well in part because you could bring in professors in the relevant subjects from MIT, from Cal Tech; from wherever in the country you could get people who were willing to do a bit of service. Now, it follows from that those professors will not write their reports. And so it does come down to an integrity of process issue, but they're getting in early, and they're having an opportunity to give candid advice. It was so for the NRC, as I'm confident that in the CASAC context the Commission is a really good outrigger for what can otherwise be a politics-driven process.

59. *American Trucking*, 175 F.3d at 1037, 29 ELR at 21073.

THOMAS MCGARITY: On Peter's first point, one difference would be had the court simply treated in *ATA* the matter as a standard substantive judicial review, if the court felt the Agency's actions were arbitrary and capricious, all that would have happened would have been a remand to the the Agency, not a reversal and a throwing out of the standard. The throwing out of the standard, in fact, threw the entire regulatory program totally out of kilter. It's still not back together again, and may never be.

WENDY PACHTER: I'm both a scientist and a lawyer, and from a legal point of view, I found this fascinating and wonderful.

From the scientific point of view, what I do is interpreting science for policymakers, and sometimes for lawyers. What I found a little troubling was the discussion of do jurors understand science, no; judges understand science better than jurors, but lawyers have more time to do it than even judges, and who should be doing this.

I think the idea of bracketing the science is one that I really like. What you do with the process once you bracket the science is an important question, but once you bracket the science I think the scientists are in the best position to determine what is the most credible science.

I don't think lawyers and judges should be doing that, except in consultation, and the American Association for the Advancement of Science in the Federal Judicial Center is currently—I don't know a lot about this project, but they're trying to implement some procedures for *Daubert* litigation, such as having scientific masters, impartial experts, who would advise the court, rather than partisan experts. I know that in some state law cases, also, the American Psychological Association has made the same kind of recommendation, namely that there be science experts to the court rather than partisan experts. Likewise, the National Research Council is doing some reports specifically for agencies, so that questions can be sent to the National Research Council, which is seen as somewhat more impartial.

WENDY WAGNER: Thanks to a marvelous panel.