THE ROLE OF SCIENCE IN REGULATORY REFORM

HEARING

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

APRIL 30, 2009

Serial No. 111–23

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April 30, 2009

THE ROLE OF SCIENCE IN REGULATORY REFORM

THURSDAY, APRIL 30, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:06 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chair of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

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Subcommittee on Investigations and Oversight

Hearing on

The Role of Science in Regulatory Reform

Thursday, April 30, 2009
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witness List

PANEL I

Dr. Rick Melberth, *Director of Regulatory Policy, OMB Watch*

Ms. Caroline Smith DeWaal, *Director, Food Safety Program*
Center for Science in the Public Interest

Mr. Wesley Warren, *Director of Programs*
National Resources Defense Council

Dr. Cary Coglianese,
Director, Penn Program on Regulation
Associate Dean and Edward B. Shils Professor of Law and Professor of Political Science,
University of Pennsylvania

Ms. Rena Steinzor, *Jacob A. France Research Professor of Law*
University of Maryland School of Law

HEARING CHARTER

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

The Role of Science in Regulatory Reform

THURSDAY, APRIL 30, 2009
10:00 A.M.–12:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Thursday, April 30, 2009, the Subcommittee on Investigations and Oversight of the Committee on Science and Technology will hold a hearing regarding President Obama's call for updating the federal regulatory review process. In one of his first orders, Mr. Obama withdrew the Bush Administration's controversial Executive Order 13422 and also directed the Office of Management and Budget (OMB) to develop a set of recommendations for a new approach to regulatory review within 100 days.[1] The new Executive Order would replace the Clinton-era Executive Order 12866, published on September 30, 1993 and currently in force, which provides guidance to agencies for submitting proposed regulations to OMB for pre-approval.

In his Memorandum, the President noted that "a great deal has been learned" about regulation, its uses and the process of regulatory review since the publication of E.O. 12866. In what he called "this time of fundamental transformation," the President said that the regulatory review "process—and the principles governing regulation in general—should be revisited." OMB issued a request for public comment regarding regulatory reform that would:

- "offer suggestions for the relationship between [the Office of Information and Regulatory Affairs ("OIRA")] and the agencies;
- "provide guidance on disclosure and transparency;
- "encourage public participation in agency regulatory processes;
- "offer suggestions on the role of cost-benefit analysis;
- "address the role of distributional considerations, fairness, and concern for the interests of future generations;
- "identify methods of ensuring that regulatory review does not produce undue delay;
- "clarify the role of the behavioral sciences in formulating regulatory policy; and
- "identify the best tools for achieving public goals through the regulatory process."

E.O. 13422 required that agencies identify in writing to OIRA the specific market failure or problem that warranted the proposed regulation or guidance; that a Presidential appointee in each agency be designated as Regulatory Policy Officer; and that that officer approve each regulatory undertaking by the agency. The Subcommittee held two hearings on E.O. 13422 in the previous Congress, on February 13, 2007 and on April 26, 2007, and Chairman Miller sponsored an amendment aimed at blocking OIRA from using funds in its 2008 appropriation to implement the Order.[2]

This hearing marks the third by the Subcommittee to examine the role of the Office of Information and Regulatory Affairs (OIRA), the office at OMB that has evolved into the center for Executive review of regulations. Prior hearings focused

[1] 74 FR 5977 (2009).

[2] H.AMDT. 461 to H.R. 2829, Making appropriations for financial services and general government for the fiscal year ending September 30, 2008, and for other purposes. The amendment was accepted by voice vote and was in the version of H.R. 2829 that passed the House, but it was removed in the Senate and was not included the final legislation, H.R. 2764, the *Consolidated Appropriations Act,* 2008.

on how the Bush Administration was using OIRA to block, hinder or weaken regulatory proposals from statutory agencies. This hearing will receive testimony from experts in the public interest and academic world who track the activities of OIRA or the results of its interventions. In particular, it will look at the following issues:

1. The nature of OIRA's role in the regulatory process, particularly in the way it uses or challenges scientific information, and its relationship to federal regulatory agencies;
2. The standard of transparency that should be expected of OIRA in the regulatory process; and
3. The role of cost-benefit analysis in the regulatory process.

Witness List

Caroline Smith DeWaal: Director, Food Safety Program, Center for Science in the Public Interest

Rick Melberth, Ph.D.: Director, Federal Regulatory Policy, OMB Watch

Wesley Warren: Director of Programs, National Resources Defense Council

Cary Coglianese, Ph.D: Associate Dean and Edward B. Shils Professor of Law and Professor of Political Science, University of Pennsylvania Law School

Rena Steinzor: Professor of Law, University of Maryland.

Key Issues

Regulatory authority is the main tool Congress has used to charge Executive agencies with responsibilities to protect the environment, public health, the safety of the workplace, the use of public lands and myriad other good purposes. Congress obviously cannot pass a new law every time a new threat to the environment or to human health emerges. Instead, Congress puts into place general purposes, general authority and a set of values that the agency should use in carrying out the law.

When OIRA injects itself into the regulatory process, it can become unclear whether the Office is acting to guarantee that a proposed regulation is convincingly demonstrated and efficient in its likely outcome, or is simply substituting the President's values and preferences for the goals and purposes Congress wrote into law. The line between the former and the latter can be crossed either in the guidance to agencies from OIRA or by the way OIRA conducts itself.

OIRA has quietly grown into the most powerful regulatory agency in Washington. The Reagan Administration used OIRA to push further and further into the process of vetting regulations. A string of Executive Orders in the 1980s, many issued during David Stockman's tenure at OMB, forced agencies to let OIRA be a full partner—some thought dominant partner—in moving regulations forward. Several House Chairs fought a very bitter struggle to push OIRA back out of the business of interfering with the conduct of agencies as they carried out the law. That fight met only mixed success.

E.O. 12866, discussed in greater detail below, was a Clinton-era effort to retain Reagan-initiated White House oversight of agency regulatory processes balanced against the recognition that agencies must have primacy in the regulatory process. The thrust of E.O. 12866 was to pare back the array of regulatory actions that would be swept up into OIRA's review, and it was estimated that the reviews done by OIRA fell from approximately 2,000 to approximately 500. Clinton's OIRA, while still assertive, was cognizant that it was ultimately the agencies that were charged by Congress with carrying out public purposes and that OIRA's assertions of authority had to be tempered by that legal reality.

The Bush Administration moved very aggressively to supplant the agencies' authority with a centralized command-and-control system whereby OIRA acted as a very stingy gatekeeper on what proposed regulations could see the light of day. In tone, OIRA returned to the Reagan era, using its privileged position as "the President's voice" in regulatory matters to push agencies into rethinking everything they were doing on regulation.

Critics of the role OIRA began in 2001 to assert that the values and judgments of OIRA's small staff—which is dominated by economists—trumped the judgments of technical experts in the agencies and supplanted the values in statute designed to guide agency regulatory activities. OIRA used its circulars to force agencies to analyze and reanalyze the information underlying and supporting proposed regulations.

Additionally, under the now-revoked E.O. 13422, OIRA put in place very clear economic criteria for regulation and guidance that, depending on the case, may have

had nothing to do with the values established in statute. Finally, having neither consulted nor received input from Congress, the Bush Administration made the Regulatory Policy Officer a more empowered gatekeeper, with direct political allegiance to the President.

Many (including staff of regulatory agencies) assert that the cumulative effect of OIRA's behavior under the Bush Administration was to intimidate agencies into running away from their statutory responsibilities in order to avoid getting caught up in the political struggles that were associated with moving regulation forward. Supporters of the Bush-era approach, happy to see an office moving to slow agency actions, argued that the net result of OIRA's actions was, at the end of the day, more defensible regulation.

The question facing the President and the country is: What kind of OIRA should we have? If the Clinton era order is dated and not as transparent as it could be, and the Bush era approach is too much "centralized command-and-control" and raises questions about whether the Executive is undermining agencies' abilities to carry out the law, what should the new Administration do with OIRA? Getting the answer to this question right is the difference between a government that follows the law—acting effectively and efficiently to protect the public's health and safety—and crippling the ability of agencies to carry out the laws passed by Congress.

Background

Brief History of OMB: What is now known as the Office of Management and Budget ("OMB") was originally created in the *Budget and Accounting Act of 1921.*[3] The Act created the Bureau of the Budget ("BOB") in the Treasury Department. Congress created BOB to unify the budget process and enable the Executive branch to send a single budget to Congress. Previously, the Executive branch transmitted budgets to Congressional committees independently of one another, and the budget process was consequently highly fragmented. Created at the same time, the Congress's General Accounting Office (now the Government Accountability Office) was to give Congress an ability to independently check the budgetary information from the Executive as well as to examine the way programs were being funded and managed.

In 1939, Congress moved BOB from the Treasury Department to the Executive Office of the President.[4] FDR, largely through executive order, expanded BOB's functions to include broad management oversight of federal operations.

In 1970, BOB went through another major reorganization, which saw it transformed into OMB.[5] At this time, the federal management oversight functions of OMB were expanded, and they have continued to be expanded until the present day.

The next major change to OMB occurred with the 1980 *Paperwork Reduction Act.*[6] This act created the Office of Information and Regulatory Affairs ("OIRA") within OMB.[7] OIRA's original charge was primarily to reduce the government paperwork burden on the public and to develop policies and standards with regard to information management. One focus of this was to eliminate duplicative or unnecessary paperwork and information collection.

Other major laws affecting OMB are the *Congressional Budget Act of 1974,* and the *Budget Enforcement Act of 1990.* The *Budget Enforcement Act* expired in 2002.

OIRA and Executive Order 12866: The Office of Information and Regulatory Affairs was created with the 1980 *Paperwork Reduction Act.*[8] Under the enabling Act, OIRA was charged with reducing the government paperwork burden on the public and developing policies and standards with regard to information management. Throughout the years, OIRA's functions have been expanded through legislation and executive action. The major surviving changes include the *Paperwork Reduction Act of 1995*[9] and Executive Order 12866 (1993). In addition, during the Administration of George W. Bush, OIRA came to oversee implementation of the Data Access Law[10] and the Data Quality Law,[11] including the peer review practices of agencies.

The effect of these and other changes to OIRA was to guarantee OIRA the central role in the promulgation of virtually all federal regulations.

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[3] 42 Stat. 22, Ch. 18, Sec. 207. OMB currently resides at U.S.C. Title 31, Chapter 5 (31 U.S.C. Sec. 501).
[4] 53 Stat. 1423, Sec. 1.
[5] 84 Stat. 2085, Sec. 102(a), restated 88 Stat. 11, Sec. 1.
[6] 44 U.S.C. Chapter 35, P.L. 96–511, restated P.L. 104–13, 109 Stat. 163.
[7] 44 U.S.C. Sec. 3503.
[8] 44 U.S.C. Chapter 35, P.L. 96–511, restated P.L. 104–13, 109 Stat. 163.
[9] 44 U.S.C. Chapter 35, P.L. 104–13, 109 Stat. 163.
[10] P.L. 105–277, 112 Stat 2681.
[11] P.L. 106–554, Sec. 515, 114 Stat. 2763.

Executive Order 12866 requires the following from all agencies:

1. Assess the economic costs and benefits of all regulatory proposals;
2. Complete a Regulatory Impact Analysis ("RIA") for all major rules (any rule that will have an impact of $100 million or more, or that OMB designates as major). The RIA must describe the costs and benefits of the proposed rule and alternative approaches, and then justify the chosen approach;
3. Submit all major proposed and final rules to OMB for review;
4. Wait until OMB reviews and approves the rule before publishing proposed and final rules;
5. Submit an annual plan to OMB to establish regulatory priorities and improve coordination of the Administration's regulatory program (this requirement also applies to independent agencies);
6. Periodically review existing rules.

Most of these requirements actually originated in earlier administrations (particularly the Reagan Administration). The initiatives of the Reagan years had turned OIRA into a kind of "gatekeeper" that stood between the agencies and the ability to put regulations out for comment, or to finalize them. However, the Clinton Administration intended to set a different tone and, drawing on what it felt to be the best of the ideas of the Reagan years, drafted a new Executive Order to organize and guide the work of OIRA.

Sally Katzen, an attorney by training with experience in the Carter Administration's management system, took the lead in drafting E.O. 12866. That process involved comment and review from all the agencies, as well as participation by OMB General Counsel, White House Counsel and Domestic Policy Staff, and even the President himself. What Katzen attempted to do has been described as the "hot tub theory" of managing regulation: Rather than being a gatekeeper, OIRA would work with agencies to put out the best regulations possible. The economics of a proposal were important, but not to the exclusion of other values. Indeed, there was recognition that not everything valued by society could have a dollar value assigned to it. In addition, some statutes require agencies to consider economic costs only in choosing among alternatives for achieving the goal of a regulation, not in deciding whether to issue the regulation or not.

Clinton's approach changed regulatory oversight. First, it set up a 90-day period for OMB review of proposed rules and created a mechanism for the timely resolution of disputes between OMB and agency heads. There would be no "paralysis by analysis" if these commitments were kept. Second, it created new public disclosure requirements which mandated that all documents exchanged between OMB and the agency during regulatory review be made available to the public at the conclusion of the rule-making. Last, the Order created a process for meetings between OMB officials and people outside the Executive branch regarding pending reviews that attempted to shine a more public light on such meetings.

These aspects of E.O. 12866 made the OMB regulatory review process much more transparent and limited OMB's ability to "kill" agency rule-making by endless OMB review. The E.O. also focused OMB review to include only major rule-making instead of all rule-making, reducing the number of regulations reviewed each year from more than 2,000 under Reagan to about 500 under Clinton.

Bush Amendments to E.O. 12866: The Bush Administration amended this Executive Order twice. The first amendment, in 2002, simply removed the Vice President from the process, replacing that office with that of the White House chief of staff. The second occasion for amendment, the now-revoked Executive Order 13422, came with limited warning and little discussion, and it carried much broader implications. Below is a summary of the major changes.

1. Elevating "Market Failure":

First, the amendment established a new standard that had to be met by any proposed guidance or regulation. Originally, the first principle guiding submissions to OIRA seeking approval of a proposed regulation was: "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."

The amended language read, "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the signifi-

cance of the problem, to enable assessment of whether any new regulation is warranted."

Critics of OIRA alleged that this new standard of "market failure" supplanted the values that exist in statute for regulatory action. They also felt that OIRA could use this standard to summarily dispense with proposals it deemed to be unconvincing in their articulation of a market failure. However, there was permissive language allowing for other kinds of analysis.

2. Presidential Appointees as Regulatory Policy Officers

The amendment directed each agency to name a Regulatory Policy Officer who would be a Presidential appointee. While Regulatory Policy Officers had been required in the Executive Order as originally propounded in 1993, the notion that the officer must be a Presidential appointee took the expert staff of agencies out of the picture. The language of the amendment charged this officer with being "involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in [the] Executive order."

This political appointee appeared to have the function of a kind of gatekeeper's gatekeeper. The officer was to compose an annual plan and "no rule-making [was to] commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office." Previously such officers were to be involved in the rule-making process; with the amendment, they were to have total discretion over the initiation of work that could lead to a regulation. (The Congressional Research Service, reporting on the amendment, stated that these regulatory officers had largely been drawn from political appointees already, so that the change might not be a notable one; however, the source of this assertion was OIRA itself, and because OIRA kept no master list of these officers, evaluating the assertion was problematic.)

3. Aggregate Regulatory Costs and Benefits

The original E.O. 12866 required a "summary of planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of anticipated costs and benefits." E.O. 13422 amended it to expand this requirement by directing that each agency provide the "best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities."

Critics alleged that this would elevate cost-benefit analysis in the regulatory process. Cost-benefit analysis is an analytical tool that is very controversial in guiding regulatory behavior. While the call to make sure that the benefits of a regulation exceed its costs has a simple appeal, the reality is that many of the benefits regulations are designed to capture (the survival of a species, protecting the lives and health of citizens, the quality of the air or water) are impossible to place an accurate value on. The costs of steps to implement a regulation, however, are usually easy to specify with precision. The result is a process that tends to be very complete in its enumeration of costs and incomplete in its ability to set values on the benefits. Retrospective studies have found that the estimated costs of a regulation turn out to be overstated. And, of course, using "dollars" to estimate costs provides the illusion of a precision that does not—perhaps cannot—exist.

Critics also viewed this as a potential first step towards a regulatory "budget" whose capping might be used to stop future regulations.

4. Review of Significant Guidance Documents

Under E.O. 13422 each agency was obliged to provide OIRA with advance notice of all proposed significant guidance documents. OIRA could then decide which guidance it deemed "significant" from its perspective and ask for the proposed guidance and a brief explanation of need, as provided in: "The OIRA administrator shall notify the agency when additional consultation will be required before issuance of the significant guidance document." There was no time limit on how long OIRA could take in moving on these guidance proposals.

The potential impact on agency conduct appeared very, very significant in that it might sweep up thousands of such proposals each year. The amendment required that guidance be issued to communicate to an affected public how an agency intended to interpret or enforce statutory directions. The business community relies on such guidance to ensure that conduct will comply with agency intentions for application of law.

Conclusion

With his decisions to revoke Executive Order 13422 and to initiate a thoroughgoing review of the federal regulatory process, the President has called into question

the direction in which that process was going during the previous administration. During a public comment period that was announced on February 26, 2009[12] and closed on March 31, 2009, OMB received 187 comments on "how to improve the process and principles governing Federal Regulatory review" from industry, nonprofit advocacy groups, academics and academic institutions, labor unions, trade associations, State and local officials, a foreign government and private individuals.[13] It is apparent that the President's action has rekindled debate on such basic issues as the role of science versus that of economics in regulation and the role of Congress versus that of the White House in setting the parameters of the regulatory process.

[12] 74 FR 8819 (2009).

[13] Links to these comments were available at *http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp* as of April 24, 2009.

Chair MILLER. Good morning and welcome to this hearing to examine our options for regulatory reform. That has been something this subcommittee has worked on. Dr. Melberth, your organization has played an important role as well.

Today's discussion is a sequel to two hearings that this subcommittee held in the last Congress on the role of the Office of Information and Regulatory Affairs, or OIRA. Although rarely in the headlines, OIRA has in the last few years since its creation under President Reagan quietly become the most powerful regulatory office in the Federal Government.

This fact was highlighted when an Executive Order promulgated by the Bush Administration, Executive Order 13422, gave OIRA even greater powers, powers that could be exercised behind closed doors. In changing the review process, it strengthened the influence—the Executive Order strengthened the influence of OIRA, which is staffed mainly by economists, over the final content of regulations first drafted by regulatory agencies, scientific and technical experts. The order had the effect of placing in the hands of the President, OIRA and a faceless political operative at each agency, power over regulatory efforts that was consistent neither with statute nor with the Constitution.

This subcommittee last met to discuss—since we last met, the regulatory landscape has changed. There is a new President. You probably read about it in the papers. Within 10 days of his inauguration, President Obama withdrew that Executive Order and gave the Office of Management and Budget, of which OIRA is a part, 100 days to develop a set of recommendations for a new approach to regulatory review.

President Obama said that far more is now known about regulation than when the Clinton Administration issued Executive Order 12866, the predecessor Executive Order, which set out the fundamental principles and structures that currently govern regulatory review. He said that a great deal has been learned not only about when regulation is justified but also what works and what does not. He has ordered that a successor to Executive Order 12866 be drafted.

From eight points that the President directed OMB to address in its recommendations, we have chosen three today with the help of our panel of experts in this topic that we will explore. One is the relationship between OIRA and the agencies. We will give special attention here to the way OIRA uses or challenges scientific information. Second, disclosure and transparency. Today's focus will be on the standard of transparency that should be expected of OIRA and up and down the regulatory process in issuing new regulations. And the third, the role of cost-benefit analysis in the regulatory process.

The President's action has rekindled debate on such basic issues as the role of science in economics and regulation and the role of Congress and the White House in deciding how regulations are issued and the discretion that the underlying law and the Constitution allows the executive branch. The Constitution does not say the President shall faithfully execute the laws that he likes. From 183 responses, many of them long and detailed, that OMB has gotten already under that proposed change in the Executive Order, it ap-

pears that the debate on how rule-making should proceed from here will be vigorous and it should be vigorous.

The questions facing the President and the Nation are weighty. What kind of OIRA should we have? Should it be one that, as has often has been the case, acts as a gatekeeper, often in secret, hindering the regulatory process through delay and the application of extralegal criteria? Or should it be the one that sees itself as a partner with the agencies, sharing the goal of timely, sensible and effective regulation?

Coming up with the right answer to those questions could be the difference between a government that follows the law, acting effectively and efficient to protect the public health and safety and one that cripples the ability of its own executive branch agencies to carry out the laws passed by Congress. I look forward to the testimony and to the discussion following the testimony.

I now recognize Dr. Broun for his opening remarks.

[The prepared statement of Chair Miller follows:]

PREPARED STATEMENT OF CHAIR BRAD MILLER

Good morning. I want to welcome all of you to this hearing on to examine options for regulatory reform.

Today's discussion is a sequel to two hearings that this subcommittee held in the last Congress on the role of the Office of Information and Regulatory Affairs, or OIRA. Though rarely in the headlines, OIRA has, in the years since its creation under President Reagan, quietly become the most powerful regulatory office in the Federal Government.

This fact was highlighted when an Executive Order promulgated by the Bush Administration, E.O. 13422, gave OIRA even greater powers, powers that could be exercised behind closed doors. In changing the review process, it strengthened the influence of OIRA, which is staffed mainly by economists, over the final content of regulations first drafted by regulatory agencies' scientific and technical experts. The order had the effect of placing in the hands of the President, OIRA, and a faceless political operative in every agency, power over regulatory efforts that was consistent neither with statute nor with the Constitution.

Since this subcommittee last met to discuss OIRA, the regulatory landscape changed. Within ten days of his inauguration, President Obama withdrew E.O. 13422 and gave the Office of Management and Budget, of which OIRA is a part, 100 days to develop a set of recommendations for a new approach to regulatory review.

Mr. Obama said that "far more is now known about regulation" than when the Clinton Administration issued Executive Order 12866, which set out the fundamental principles and structures that currently govern regulatory review. He said that "a great deal has been learned . . . not only about when [regulation] is justified, but also about what works and what does not." He has ordered that a successor to E.O. 12866 be drafted.

From eight points that the President directed OMB to address in its recommendations, we have chosen three that, with the help of our panel of expert witnesses, we will explore today:

1. "The relationship between OIRA and its agencies." We will give special attention here to the way OIRA uses or challenges specific scientific information.
2. "Disclosure and transparency." Today's focus will be on the standard of transparency that should be expected of OIRA in the regulatory process.
3. "The role of cost-benefit analysis" in the regulatory process.

The President's action has rekindled debate on such basic issues as the role of science and economics in regulation, and the role of Congress and the White House in deciding how regulations are issued and the discretion that the underlying law allows the Executive Branch. From the 183 responses—many of them long and detailed—that OMB received to its request for public comment on the matter, it appears this debate will be vigorous.

And well it should be. The questions facing the President and the Nation are weighty: What kind of OIRA should we have? Should it be one that, as has so often been the case, acts as a gatekeeper, hindering the regulatory process through delay and the application of extra-legal criteria? Or should it be one that sees itself as a partner with the agencies, sharing the goal of promoting timely, sensible, and effective regulation?

Coming up with the right answer to these questions could be the difference between a government that follows the law—acting effectively and efficiently to protect the public's health and safety—and one that cripples the ability of its own Executive agencies to carry out the laws passed by Congress. I look forward to our testimony and discussion.

I now recognize Mr. Broun for his opening remarks.

Mr. BROUN. Thank you, Mr. Chair. I want to congratulate you for staying within five minutes, but as you know, I will always——

Chair MILLER. When I hear congratulations, I assume it is about basketball.

Mr. BROUN. I will always go with you to take as long as you want, Mr. Chair. Thank you, Chair Miller. I want to thank you for holding this hearing and I want to welcome the witnesses here today.

The regulatory process is an important topic for this committee to address as regulations affect the lives of every citizen, whether it is through public health, economic stability or public safety. Science is central to this process and provides a foundation of knowledge. It informs policy-makers. Unfortunately, this connection is often manipulated by those who claim their policy decisions are indisputably required by science and those who question the quality or interpretation of that science. We probably won't be able to resolve this tension today, but hope the panelists can at least shed some light on the conflict so that future decisions are made transparently without shrouding policy and science or denigrating the findings.

While science plays an enormous role in providing regulators, policy-makers and legislators with the best information possible, it does not absolve those individuals of their responsibilities to make hard choices. As Dr. Coglianese points out in his testimony, "Science speaks to what is rather than what should be." This is an extremely important concept to understand and elegantly highlights the issues we are facing today. All too often controversies arise over issues that are not questions of science but of policy. For example, when decisions are made based on values or ethics, this is seen as an affront to science but it shouldn't be as long as the decision isn't sold under the banner of science.

With that in mind, I look forward to the Subcommittee's third hearing on this topic. The previous two focused on President Bush's Executive Order 13422. This amendment to President Clinton's Executive Order 12866 created consternation amongst advocacy groups because, as they argued, it gave too much control over the regulatory process to the Administration and would prevent agencies from protecting public health and safety. What it really did was simply require agencies to report to OIRA work that the Clinton Administration had already required agencies to do and address issues that were being ignored. In the end, the consternation over this Executive Order was more likely about who was issuing the order rather than what it directed. Because of this, it will be interesting to see what the current Administration does with the

authorities it inherited from the previous Administration. While President Obama rescinded Executive Order 13422, many of the same principles may find their way back into a new order but probably with less outrage.

Similarly, the Administration recently nominated Cass Sunstein to head OIRA. His nomination has come with mixed reviews from advocacy groups because of his support for cost-benefit analysis, but this concern is far less than the previous nominees. How Mr. Sunstein intends to run OIRA will also be interesting to follow, given previous criticisms from outside groups regarding centralized authority and review. Every new Administration since Reagan has chosen to organize and oversee the regulatory process differently, and this Administration certainly will not be an exception.

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

[The prepared statement of Mr. Broun follows:]

PREPARED STATEMENT OF REPRESENTATIVE PAUL C. BROUN

Thank you Chairman Miller. I want to thank you for holding this hearing and welcome our witnesses here today.

The regulatory process is an important topic for this committee to address as regulations affect the lives of every citizen, whether it is through public health, economic stability, or public safety. Science is central to this process and provides a foundation of knowledge that informs policy-makers. Unfortunately, this connection is often manipulated by those who claim their policy decisions are indisputably required by science, and those who question the quality or interpretation of that science. We probably won't be able to resolve this tension today, but I hope the panelists can at least shed some light on the conflict so that future decisions are made transparently without shrouding policy in science, or denigrating findings.

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Thank you, Mr. Chairman. I yield back.

CPR CENTER FOR PROGRESSIVE REFORM

FOR IMMEDIATE RELEASE
Thursday, April 30, 2009

Contact: Matthew Freeman, 202.747.0698, ext 2
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Obama Administration Should Redefine Role of 'Regulatory Czar' to Help Protect Citizens, Not Weaken Regulation, CPR President Tells Congressional Committee

(Washington) -- The White House should reshape the role of the "Regulatory Czar" to be a defender of federal regulatory agencies and their missions, not to be an impediment to regulation, Rena Steinzor, President of the Center for Progressive Reform, told members of Congress Thursday morning. Steinzor, a professor of law at the University of Maryland, testified before the House Science and Technology Committee's Subcommittee on Investigations and Oversight.

"The Obama Administration and Congress should define a new mission for the regulatory czar," Steinzor said in her prepared testimony. "The American people need more, not less regulation on every front, from mortgage lending to workplace hazards. The regulatory czar's mission should be to rescue struggling regulatory agencies by helping them to obtain more resources and stronger legal authority."

The hearing came on the heels of President Obama's April 20 nomination of Cass Sunstein to be the director of the Office of Information and Regulatory Affairs (OIRA), known as the "regulatory czar." Sunstein's confirmation hearing in the Senate has not yet been scheduled. Professor Sunstein's predecessor, John Graham, used OIRA to expand control over regulatory policy to an unprecedented extent, blocking and watering down protective regulations, and hindering the effectiveness of the nation's regulatory system. Steinzor called on Sunstein and the Obama Administration to reverse course and use OIRA as a tool to strengthen, not weaken, regulation.

Steinzor's testimony argues:

- **The Obama Administration and Congress should define a new mission for the regulatory czar**. OIRA should not work to diminish rules made by the EPA and other regulatory agencies The regulatory czar should instead be instructed to work to ensure that agencies are able to fulfill their regulatory missions in a vigorous, timely, effective, and wise manner.
- **OIRA should stop reviewing individual regulatory proposals.** Empirical studies reveal that OIRA has served for more than 30 years as a killing ground for protective regulations. Except during the Clinton Administration, OIRA's threat to target any given regulatory proposal has chilled the development of strong and effective regulation. OIRA should leave the drafting of individual rule regulatory impact analyses and the making of final decisions to agency experts, supervised by appointed agency leaders.
- **OIRA should stay out of science policy.** OIRA is a small office, comprised of approximately 40 to 50 professionals, the vast majority of whom are economists. During

the Bush Administration, several of these positions were set aside to hire scientists, who proposed radical changes in the way research would be used to make regulatory policy. OIRA is not competent to propose science policy in the regulatory arena and should abandon this role.

The Center for Progressive Reform (www.progressivereform.org) is a nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. Visit CPR on the web at www.progressivereform.org and read the blog at www.progressivereform.org/cprblog.

Related Documents:

- CPR's white paper on regulatory review in the Obama Administration, *Reinvigorating Protection of Health, Safety, and the Environment: The Choices Facing Cass Sunstein* (1/26/09): http://www.progressivereform.org/articles/SunsteinOIRA901.pdf
- Rena Steinzor's letter (written together with CPR Member Scholar Wendy Wagner) to John Holdren, President Obama's top science advisor, on policy recommendations for "clean science" reforms (4/3/09): www.progressivereform.org/articles/Holdren_CleanSci_Letter_040309.pdf

# # #

Chair MILLER. Thank you, Dr. Broun, and obviously this committee will pursue conversations with Mr. Sunstein in addition to whatever role he may be as an advocate for cost-benefit analysis. He is a distinguished legal scholar and I hope he would not take the view that laws passed by Congress can be treated by the President as free advice.

I ask unanimous consent now that all additional opening statements submitted by Members be included in the record. I don't know that we have any of those but they may be. Without objection, so ordered.

I also ask unanimous consent to enter a set of documents in the record that have already been provided to the Minority, and without objection, so ordered.

[The information follows:]

The Union of Concerned Scientists. "Federal Science and the Public Good: Securing the Integrity of Science in Policy Making." Cambridge, MA. December 2008. Available online at *http://www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/federal-science-and-the.html* as of May 28, 2009.

Chair MILLER. It is my pleasure now to introduce our witnesses. Dr. Rick Melberth is the Director of Regulatory Policy at OMB Watch, and again, my office and this subcommittee had worked closely with OMB Watch and with Dr. Melberth over time on this specific issue. Ms. Caroline Smith DeWaal is the Director of the Food Safety Program at the Center for Science in the Public Interest. Mr. Wesley Warren is the Director of Programs at the Natural Resources Defense Council and a former Associate Director of Natural Resources, Energy and Science at the OMB. And Dr. Cary——

Dr. COGLIANESE. Coglianese.

Chair MILLER. Coglianese is the Director of the Penn Program on Regulation and the Associate Dean and Edward B. Shils Professor

of Law at University of Pennsylvania Law school as well as Professor of Political Science at U. Penn. I don't know if Edward Shils was himself a lawyer, but I think if my name were Shils I probably would have either chosen or a different profession or changed my name. And Ms. Rena Steinzor is the Jacob A. France Research Professor of Law at the University of Maryland and the President of the Center for Progressive Reform.

As our witnesses should know, you each have five minutes for your spoken testimony. Your written testimony will be included in the record for the hearing. When you all have completed your spoken testimony, we will begin with questions and each Member will have five minutes to question the panel. It is the practice of this subcommittee to receive testimony under oath. We don't really think perjury is a particular concern here but it is our practice. Do any of you have any objection to taking an oath? Okay. You also have the right to be represented by counsel. Do any of you have counsel present? Well, now that you are at ease, if you would please stand and raise your right hand? Do you swear to tell the truth and nothing but the truth? The record will reflect that every—each of the witnesses did take the oath, did say "I do," and we will begin with Dr. Melberth. Dr. Melberth.

STATEMENT OF DR. RICK MELBERTH, DIRECTOR OF REGULATORY POLICY, OMB WATCH

Dr. MELBERTH. Good morning, Mr. Chair, Dr. Broun. Thank you for this opportunity to present some recommendations for ways to reform the regulatory process.

In April 2007, OMB Watch initiated a project called Advancing the Public Interest through Regulatory Reform, and we asked a diverse group of experts in regulatory policy and policies that are highly regulated to take part in the project. Their work resulted in a report released in November 2008 that contains 49 recommendations for reforming the regulatory process. While the authors of the report had varying perspectives on the issues they examined during the project, they all agreed that the current regulatory process is in need of substantial reform. I want to confine my brief remarks to one very critical area of reform discussed in the report, and that is the relationship between the Office of Information and Regulatory Affairs and the federal agencies responsible for protecting the public.

The relationship between OIRA and the agencies has been defined, as you indicated, Mr. Chair, by a series of Executive Orders that outline that regulatory process. The current Executive Order 12866 is under review by President Obama and they have begun that process of looking at and reexamining that Executive Order. The report calls for the restructuring of that relationship between OIRA and the agencies, placing a greater priority on agency expertise and statutory authority. The report notes, "The locus of decision-making authority should reside in the federal agencies given the legal mandate to promulgate regulations." That is, the agencies should possess the decision-making authority when promulgating regulations because they, not OIRA, are given the statutory mandate from Congress.

The role the authors suggest for OIRA is consistent with Congressional designs for the administrative state. Congress mandates regulatory authority to the agencies which have the expertise to address the highly complex issues that are before them. OIRA does not have this range of expertise and should not be approving or rejecting individual rules. Instead, OIRA's role should be focused on a larger picture rather than on individual rules. For example, OIRA desk officers could help facilitate comments from other agencies, convene interagency dialogue about rules in which multiple agencies have an interest and identify government-wide management issues that may improve rule-making.

OIRA could turn its attention to the general performance of agencies and to coordination at the point where agencies are setting their priorities and planning their activities. This coordinating role would provide the opportunity for OIRA to see that agency actions are consistent with Presidential policies through some mechanism like agencies' annual regulatory plans and agendas. OIRA could then identify gaps in regulatory responsibilities and hold agencies accountable for addressing those gaps, and this approach would permit the prospective coordination of actions across agencies rather than individual retrospective reviews of specific rules after an agency has expended considerable time and resources. When conflicts arise over substantive regulatory issues, for example, between the President's policies and agency actions, or between two or more agencies, then OIRA should consult with agency heads, those who have been appointed by the President and have the legal responsibility to implement Congress's mandate to Congress—mandates to the agencies. OIRA would be able to carry out this function much more evenhandedly if it were not simultaneously approving or rejecting agency rules. This changed rule recognizes that regulatory agencies are very different and have statutes that require very different things of them. OIRA cannot and should not have the expertise that resides in the agencies and therefore should not be making decisions about the content of individual rules.

Lastly, Congress has established OIRA to administer federal information resource policies and to review agency requests to collect information from the public. The report urges the President to appoint to OIRA someone well versed in information resource management policies. Information management is the statutory responsibility of the office. By focusing so heavily on controlling regulatory decisions, OIRA has strayed from this statutory responsibility. OIRA could help agencies accomplish their Congressional mandates by carrying out its information management responsibilities in ways that do not unduly burden agencies or slow down agency efforts to collect important information.

The report's 49 recommendations are aimed at creating a regulatory process that is open, inclusive, effective and efficient. One factor critically important to reforming that process to meet these goals is a restructuring of the relationship between OIRA and the agencies based on the recognition that agencies' expertise in statutory authority that Congress has delegated to them.

Thank you, Mr. Chair.

[The prepared statement of Dr. Melberth follows:]

PREPARED STATEMENT OF RICK MELBERTH

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify before you today. I am Rick Melberth, Director of Regulatory Policy for OMB Watch. OMB Watch is a nonprofit, nonpartisan research and advocacy center promoting an open, accountable government responsive to the public's needs. Founded in1983 to remove the veil of secrecy from the White House Office of Management and Budget, OMB Watch has since then expanded its focus beyond monitoring OMB itself. We currently address four issue areas: right to know and access to government information; advocacy rights of nonprofits; effective budget and tax policies; and the use of regulatory policy to protect the public.

My testimony today focuses on the recommendations for reforming the regulatory process. These recommendations are the product of a process in which 17 regulatory experts with diverse perspectives on regulatory issues came together because of their basic agreement that the current process is broken. In November 2008, these experts issued 49 recommendations in a report, *Advancing the Public Interest through Regulatory Reform: Recommendations for President-Elect Obama and the 111th Congress.* A copy of the report is included with my comments for the hearing record.[1]

I. Recommendations and Principles

This testimony summarizes the most important of these recommendations in six areas: 1) the relationship between the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) and federal agencies, 2) the need to restore scientific integrity to agency decision-making, 3) the importance of restoring desperately needed resources to federal regulatory agencies, 4) regulatory transparency, 5) how to improve the timeliness and responsiveness of the rule-making process, and 6) the use of cost-benefit analysis.

The executive summary of the report identified the principles that guided the authors in developing their recommendations (p. 2):

1. **Regulatory decisions should be timely and responsive to public need.** Timely action is a benefit to the public and all stakeholders. Government must actively assess public needs, identify where regulatory gaps exist, and act to address such gaps. Regulatory decisions should be based on the best available information, balanced with the need to act in a timely manner.
2. **The regulatory process must be transparent and improve public participation.** Openness, from pre-rule-making to the publication of final rules, is essential to meaningful accountability in the process. The Internet age affords new ways of fostering meaningful public participation.
3. **Regulatory decisions should be based on well informed, flexible decision-making.** There needs to be a premium placed on authority within regulatory agencies to decide what information is critical to effective regulations and to ensure those decisions reside with agency scientists and experts.
4. **Authority to make decisions about regulations should reflect the statutory delegation granted by Congress.** Federal agencies are given the responsibility to implement legislation and have the substantive expertise necessary to develop effective standards. That expertise should be recognized and provide the foundation for sound regulatory decisions.
5. **Agencies must have the resources to meet their statutory obligations and organizational missions.** Resources are needed for addressing regulatory gaps, providing accountability and transparency mechanisms, and meeting regulatory compliance and enforcement functions.
6. **Government must do a better job of encouraging compliance with existing regulations and fairly enforce them.** In order to strengthen public protections and provide regulated communities with fair and predictable compliance approaches, agencies must be enabled to meet more effectively both current and new demands and work to improve or create regulatory compliance programs.

[1] OMB Watch initiated the project in April 2007. The recommendations are those of the 17 authors not OMB Watch although we staffed the project. I was the project manager and, with my colleague, Matt Madia, drafted the report under the guidance of the authors.

The recommendations were finalized in the fall of 2008. The vision the recommendations express were supported by all the authors, although not all of them agreed on every recommendation or characterization.

II. The Relationship between OIRA and Agencies

The relationship between OIRA and federal regulatory agencies is critically important to the regulatory process. The report stated: "[T]here needs to be a fundamental restructuring of the interaction between OIRA and the agencies, placing greater priority on agency expertise and statutory authority for decision-making." (p. 16) The agencies should possess the decision-making authority when promulgating regulations because they, not OIRA, are given the statutory mandate from Congress.

The modern-day structure of executive orders that began with President Reagan has placed significant power in OIRA to review regulations. The degree to which OIRA has exercised this centralized control varied somewhat from administration to administration, but there was one constant throughout the years: OIRA was in control and had the *de facto* presidential authorization to approve, amend, or kill rules developed by agencies. With a new administration entering office and planning to revise the regulatory executive order, there is an opportunity to try a different approach, one that emphasizes OIRA's role as coordinator and facilitator of sound agency practices rather than second-guessing agency decisions on individual rules.

The role the authors suggested for OIRA is consistent with congressional designs for the administrative state. Congress mandates regulatory authority to the agencies. The agencies have the technical, scientific, economic, and social expertise to address the highly complex issues before them. OIRA does not have this range of expertise and should not be approving or rejecting individual rules.

On December 22, 2008, some of the authors met with the presidential transition team to discuss the report's recommendations. At that meeting, the authors were asked specifically about what they believed should be the relationship between OIRA and the agencies. Subsequently, the authors sent to the transition team a memo outlining their proposal for the role of OIRA. (A copy of the memo is submitted with this testimony for the record.) The portion of the memo that addressed this question reads:

> Our recommendations call for a fundamental restructuring of the interaction between OIRA and the agencies, placing greater priority on agency expertise and statutory authority for decision-making. While we had differing views on the unitary executive theory that underlies centralized regulatory review, we did reach consensus on pragmatic approaches for constructive changes to OIRA's role. The role for OIRA would focus on three key functions: (1) implementation of its own statutory responsibilities; (2) transparent resolution of interagency disputes on regulations; and (3) implementation of presidential policies, where those are clear.
>
> We emphasize the need for clarity on the last role to avoid the tendency of OIRA, or an organization of its nature, to engage in mission creep based on implied presidential policies. OIRA should be concerned with agency structures and general regulatory performance. Just as in budgetary matters, coordination at the stage of priority setting is a pivotal occasion for the implementation of presidential policies. Whether reviving the Regulatory Working Group is appropriate or not, we are clear that priority setting requires greater transparency and public involvement, which OIRA should facilitate. But it is also necessary to make clear that OIRA's role is limited and does not usurp the role of the political leaders who lead the agencies with direct statutory responsibility for regulatory decisions. We believe this approach recognizes that the White House (a collection of various offices that often may be involved in reviewing agency rules) does not, nor should it, have the expertise that resides within the agencies; it acknowledges that the White House has the ability to identify government-wide management issues that should be raised with agencies that may improve the rule-making process, and to see the big picture of what rules and activities agencies are undertaking.
>
> In implementation of this split in responsibility, the role of the OIRA desk officers changes, shifting them away from making "Yes/No" decisions on individual rules. Instead, the desk officer can assist an agency in regulatory priority setting; in the context of particular rule-makings, the officer may help facilitate comments from other agencies, pose questions about the regulatory proposal or the underlying research, or convene interagency dialogue as a collegial effort, but should not be acting as a person with an implied right to make final deci-

> sions on the substance of a rule or the regulatory priorities within an agency. This would create a new type of relationship between OIRA and the agencies, respecting the delegation of congressional rule-making decision-making authority to the agencies.[2]

This position highlights the important role OIRA could play in overseeing the regulatory big picture and helping agencies to do their work more effectively and efficiently. It also acknowledges OIRA's responsibility to help agencies establish policy priorities, just as OMB does in budgetary matters, and to hold agencies accountable. But it recognizes that regulatory agencies are very different and have statutes that require very different things of them. OIRA cannot, and should not, have the expertise that resides in the agencies, and therefore, should not be making decisions about the content of individual rules.

The authors reiterated this position on the agency-OIRA relationship in comments submitted to OMB on a new regulatory executive order that President Obama is expected to issue. It is time for a different relationship, one "that places greater priority on agency expertise and statutory authority for decision-making."[3]

In the comments and in the report, the authors recommended that OIRA return to its statutory mission under the *Paperwork Reduction Act* (PRA). OIRA was created to manage federal information resources and to approve agency information collection requests.[4] If OIRA was more focused on helping agencies manage more effectively information important to regulatory decision-making, the relationship between the agencies and OIRA could be substantially more cooperative and productive than the current relationship. The authors concluded their comments on a new executive order with this note:

> In conclusion, a healthy relationship between rule-making agencies and OIRA is critical to a well-functioning regulatory system that adequately responds to public need. We believe this relationship would be improved if OIRA engaged less in rule-by-rule review and instead focused on assisting agencies in gathering the opinions of other agencies and contributing to regulatory priority setting. The Obama Administration has an opportunity to redefine federal regulatory policy for the better—not just for itself, but for future administrations.

III. Restoring Scientific Integrity

Timely and accurate information is essential to setting regulatory policy. The information considered in the regulatory process is a function of legislative direction and agency processes designed to meet the problem an agency addresses. These processes must generate independent and credible information. To generate this high quality information, agencies must have access to the most reliable information available from the scientific community. Both the process and the information in the process need to be free from political interference.

The report's nine recommendations in this area focused on restoring scientific integrity to the process. "Agency experts, federal advisory committees, peer reviewers, and other experts involved in the design, conduct, and analysis of government research and regulations should be free from interference from political appointees within the agency and within White House offices. They should be free from political harassment and censorship and free to disclose information considered relevant to the recommendations they forward to policy-makers." (p. 30)

The recommendations emphasized two points: 1) how the public can hold government officials accountable for their actions, and 2) ways to ensure that information used in policy decisions is independent and the best available. President Obama has taken a valuable first step in issuing a memorandum to agency heads regarding the

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[2] Memorandum from Gary Bass on behalf of those endorsing the recommendations from the Advancing the Public Interest through Regulatory Reform to Sally Katzen, Cass Sunstein, Dan Chenok, and Mike Fitzpatrick on Follow-up to Questions Raised Regarding our Recommendations, December 24, 2008.

[3] Comments submitted by the authors of *Advancing the Public Interest through Regulatory Reform* on OMB's request for comments on Federal Regulatory Reform, March 31, 2009, available at *http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp*

[4] The authors recognized in these comments that OIRA has statutory responsibilities that it must follow. They wrote, "Other statutory responsibilities, such as those in the *Unfunded Mandates Reform Act,* need to be followed. But even those regulatory review requirements are significantly smaller in scope than OIRA's current approach to regulatory review."

importance of scientific integrity, thus meeting the first of the report's recommendations in this area.[5]

The memo's first paragraph reads:

> Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health, protection of the environment, increased efficiency in the use of energy and other resources, mitigation of the threat of climate change, and protection of national security.

It goes on to call on political officials to refrain from suppressing information, making information developed and used by agencies transparent, and selecting professionals for executive branch positions based on their scientific and technical qualifications. Lastly, the memo assigns to the director of the White House Office of Science and Technology Policy the responsibility for creating a process to result in recommendations for guaranteeing scientific integrity in the executive branch.

Advancing the Public Interest addressed many of these issues in some detail. For example, the report recommended strengthening federal advisory committees and conflict of interest procedures for those serving on the committees. These committees are essential mechanisms for providing expert advice and analysis. The political independence of the committees has often been compromised, calling into question the independence of the advice they provide to agencies.

Restoring scientific integrity requires increased transparency. The report recommended that agencies disclose scientific, technical, economic, and social analyses used in the regulatory process. Making this information available for public scrutiny and replication enhances the quality and integrity of the information used and the policy decisions that flow from the process. Creating policies by which agency scientists can discuss their scientific findings with the public, their colleagues, and the media is part of this emphasis on transparency in the report. These recommendations should be read in the context of the other transparency recommendations in the report, including making information considered in the process part of the rulemaking docket. (See the transparency section below.)

Finally, secretive interagency reviews and vetoes of other agency actions should end. If agencies are impacted by the work of an agency mandated to address a problem, the agencies should make their interests and the potential impacts known to the primary agency and OIRA in an open and transparent process. When conflicts arise, OIRA could mediate these conflicts. This conflict resolution role is an appropriate one for OIRA to play when the actions of one agency potentially impact another. Other agencies should not be able to terminate or hinder actions through inappropriate interagency review. OIRA should not provide impacted agencies with the multiple opportunities to delay or alter scientific assessments and processes behind closed doors.[6] Interagency reviews and expressions of concern should be publicly disclosed.

IV. Restoring Resources to Federal Agencies

By far the biggest problem facing regulatory agencies is the dire need for financial and human resources. Agencies are experiencing a drain of expert scientists, engineers, and trained inspectors at the same time they are facing increased regulatory responsibilities and new challenges. Budgets have not kept pace or have been cut. As we have seen with both the financial crisis and the surge in imported goods, the dangers to the public are real and can be serious. The report noted, "Federal agencies responsible for regulating these financial and consumer products, and for regulating public health risks from environmental hazards, are plagued by declining resources and authority, making it more difficult to ensure the safety and soundness of consumer products." (p. 39)

In the 100-day recommendations to both the new President and the 111th Congress, *Advancing the Public Interest* called for an increase in funding for regulatory implementation and enforcement. The authors recognized that agency resources cannot be restored all at once, but wrote that there should be a multi-year efforts to bring agencies to the point where they can meet their organizational missions. Congress and the President should provide agencies the resources to help identify

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[5] Memorandum for the Heads of Executive Departments and Agencies, Subject: Scientific Integrity, March 9, 2009, available at *http://fdsys.gpo.gov/fdsys/pkg/DCPD-200900137/pdf/DCPD-200900137.pdf*

[6] The example the authors cite is the interagency review process, recently amended by OIRA, for toxicological assessments performed by the Environmental Protection Agency for its Integrated Risk Information System (IRIS). The revised process allows agencies such as the Department of Defense to have multiple opportunities to stop IRIS assessments of certain chemicals.

data gaps, build or restore information collection programs, and enhance enforcement programs. The recommendations called for helping the agencies build comprehensive compliance initiatives and develop modern enforcement tools for deterrence.

In summarizing the implementation and enforcement recommendations, the authors wrote:

> Effective implementation of many financial, public health, worker and consumer safety, and environmental quality regulations require a complex mix of Federal, State, and local government actions, as well as third party involvement. This mix relies substantially on the leadership of federal agencies: setting priorities, providing technical and financial assistance, and ultimately enforcing compliance with regulations. Without sufficient financial and human resources, clear enforcement goals, and sound evaluation tools, the problems identified and addressed in law cannot effectively be solved. (p. 41)

V. Regulatory Transparency

The report cited three reasons why transparency is critical to ensuring a well-functioning regulatory process: transparency improves the legitimacy of regulations, increasing acceptance within both the public and the regulated community; it serves as a check on misconduct by exposing decisions to the public; and it improves both the quality and quantity of public participation.

All of the transparency recommendations are based on the notion that government should adopt a presumption of openness. The authors believed that the public has a right to know how regulatory decisions are made.

It should be noted that while the report goes to great lengths to avoid recommending the imposition of new requirements on agency employees, the authors believed imposing transparency requirements to be a worthy exception. While they were mindful of the increased workload associated with new disclosure requirements, they also recognized that advances in technology have made disclosure easier and that the government should embrace those advances to mitigate the burden and increase and improve public accessibility. The report stated, "The Internet age has also redefined the concept of government transparency: Information should be available online in a timely fashion and in searchable formats to be considered truly transparent in modern society." (p. 45)

The report recommended that agency rule-making dockets be expanded to include more relevant information and that dockets be more accessible to the public. In addition, agencies should include in their dockets "all studies in their possession related to a rule-making, regardless of whether the study was used to inform the policy option the agency chose." (p. 47)

The report called on the Obama Administration to make *Regulations.gov,* the central location for online access to rule-making dockets, more user-friendly by expanding search capabilities and other features. The report also recommended that these dockets be opened and made available online as soon as possible, preferably before the agency publishes a notice of proposed rule-making.

Within those dockets, the report recommended expanding disclosure of communications made by or to federal officials during the rule-making process. Keeping these communications hidden, as officials have generally done, often obscures the true rationale behind a decision or the true decision-maker. Accordingly, the report recommended improving disclosure along three common paths of communications:

- "Agencies should disclose online all written communications among federal officials from different agencies, including the White House, regarding rules under development or under review" including draft proposed and draft final rules sent to the White House for review, if such review continues; (p. 47)
- "Agencies should disclose online all substantive communications, written or oral, between any White House office and any non-governmental entity regarding rules under development or under review;" and (p. 48)
- "Agencies should disclose online all substantive communications between the agency and non-governmental entities regarding regulations." (p. 49)

The report also recommended a series of reforms about how the *Freedom of Information Act* should be interpreted and implemented. The authors recognized, "Although FOIA's reach extends beyond rule-making and into other areas of government information, improved access to a broad class of records can contribute to a better public understanding of how government works, including rule-making." (p. 50)

Leading the FOIA recommendations was a call for the Administration to interpret FOIA liberally and to make government information public whenever possible. To

accomplish this goal, the report recommended President Obama instruct his attorney general to repeal the Ashcroft memo of Oct. 12, 2001, which urged agencies to exercise caution when disclosing government information, and replace it with a memo that promotes a climate of disclosure and openness. The authors chose this recommendation as one of seven that should be implemented in the first 100 days of the Obama Administration.

VI. Improving the Timeliness and Responsiveness of the Rule-making Process

Delay in writing new rules is one of the most obvious and serious flaws inherent in the current rule-making process. The authors agreed that any reform agenda must include a serious effort to reduce delay.

A common complaint is that the regulatory process is burdened with too many analytical requirements, some of which may add little value to regulations or their underlying rationale. These requirements are set out in various laws, executive orders, and cross-cutting administrative policies (often formulated by White House offices).

The report did not evaluate each of these requirements but called for a broad assessment of regulatory process requirements. "Although many people have different opinions about which of these requirements are burdens and which are necessities, we agreed that serious reform should start by considering the removal of all such requirements from the process and then the addition of requirements deemed essential to efficient, effective, and timely rule-making," the report noted. (pp. 14–15)

Accordingly, the report recommended that President Obama establish a blue-ribbon commission to analyze all the potential sources of delay in the rule-making process. The President should use the results of the commission's study to consolidate executive-imposed requirements and urge Congress to consider repealing any statutory requirements deemed unnecessary or counterproductive. The report recommended that President Obama establish this commission within the first 100 days of his Administration.

In other cases, the points of delay are less easily identifiable. Agency leaders may lack the political will to complete regulations in a timely manner, or institutional barriers may slow the process within an agency.

Scientific uncertainty is one issue that has been used to push rule-makings into an analytical maze. Claims, whether real or manufactured, that the evidence underlying a policy option is not certain enough to warrant action can force agencies into a loop of reanalysis and research. Meanwhile, the public may continue to be harmed by poorly regulated products and practices.

To address this problem, the report called on federal officials to "stop using claims of uncertainty to delay or avoid regulation." The report cited three reasons in support:

- "Pushing for certainty may result in completely stopping regulation in policy areas that rely on scientific information;"
- Waiting for some level of certainty may not be required by law, especially those laws that emphasize the prevention of harm; and
- Because "regulation is not an irreversible course of policy [. . .] As evidence grows, standards can be made more or less stringent if necessary." (p. 25)

VII. Cost-benefit analysis

The role of cost-benefit analysis in regulatory decision-making is consistently one of the most controversial issues in modern debates over the rule-making process. The authors chose not to endorse or foreclose cost-benefit analysis either as it is currently used or any variation thereof. However, the authors agreed that agencies should maintain flexibility over how they conduct cost-benefit analysis, and rebuked one-size-fits-all requirements like those found in OMB's Circular A–4.

Instead, the authors recommended six principles for the practice of cost-benefit analysis, should it be used:

a. Cost-benefit analysis should only be used in ways consistent with the values expressed in statutory or judicial provisions;

b. Cost-benefit analysis is an analytical tool and should not be determinative in regulatory decision-making unless specifically required by statute (i.e., it should be a source of information, not a decisional standard);

c. Information and assumptions used in cost-benefit analysis should be transparent and allow for the analysis to be replicated. The analysis should include statements of uncertainty about the assumptions;

d. Cost-benefit analysis should disclose both quantitative and qualitative aspects—and utilize both when interpreting results;
e. Cost-benefit analysis should include an explicit statement about who benefits and who bears the costs; and
f. While it may be appropriate to have methodological questions about cost-benefit analyses conducted by federal agencies, the White House or other regulatory reviewing agencies should never manipulate or alter results. (p. 24)

Most importantly, the authors recognized that the statutes underlying regulations should be the preeminent criteria for decision-making and should not be usurped by any form of regulatory analysis unless mandated by statute.

VIII. Conclusion

Federal regulations are critical to implementing public policies and protecting the health and safety of the public and the quality of our natural resources. Producing effective and efficient regulations is an essential governmental function. The process by which regulations are promulgated has been increasingly burdened with analytical and procedural hurdles. The result is that it takes years for most major regulations to be completed; it now takes a decade for some agencies to produce these protections. It is neither an open nor accessible process meaning the public is largely shut out of participating in meaningful ways.

As we have seen too often recently, the current regulatory process no longer adequately protects the public. Most students of the process agree that it is in need of serious repair. The Advancing the Public Interest through Regulatory Reform project was designed to address problems that exist in the current process and recommend changes to Congress and a new presidential administration. The authors of the report believed that it was necessary to address these problems and that the arrival of a new administration and Congress provided a great opportunity to reform the regulatory process.

The Obama Administration and Congress have taken the first steps on some of the recommendations outlined above. For example:

- the FY 2009 omnibus spending bill contains significant budget increases for the Consumer Product Safety Commission and the Food and Drug Administrations;
- the President has initiated a process to revise a new executive order and, for the first time, has created a process that considers both agencies' opinions and public opinion;
- on March 9, 2009, the President issued a memo on the importance of maintaining scientific integrity throughout the Executive branch and the Administration is taking public comment on ways to implement the principles in the memo; and
- on his first full day in office, the President issued a memo on FOIA instructing the Attorney General to include a presumption of openness regarding information disclosure. On March 19, Attorney General Holder issued a memo consistent with the President's direction. Holder wrote, "I strongly encourage agencies to make discretionary disclosures of information," adding, "An agency should not withhold records merely because it can demonstrate, as a technical matter, that the records fall within the scope of a FOIA exemption." [7]

Thank you for the opportunity to appear before the Subcommittee today as you continue to address these important issues. I'm happy to answer your questions.

Reference

Bass, Bird, et al. *Advancing the Public Interest Through Regulatory Reform: Recommendations for President-Elect Obama and the 111th Congress.* Washington, D.C. OMB Watch, November 2008. Website: *http://www.reginfo.gov/public/jsp/EO/fedRegReview/regulatoryreformrecs.pdf*. Available as of May 27, 2009.

[7] Memorandum for Heads of Executive Departments and Agencies from the Attorney General on the *Freedom of Information Act,* March 19, 2009, available at *http://www.usdoj.gov/ag/foia-memo-march2009.pdf*

MEMORANDUM

TO: Sally Katzen, Cass Sunstein, Dan Chenok, and Mike Fitzpatrick

FROM: Gary Bass on behalf of those endorsing the recommendations from Advancing the Public Interest Through Regulatory Reform

DATE: December 24, 2008

RE: Follow-up to Questions Raised Regarding our Recommendations

This is in follow-up to questions raised during our meeting of December 22 to discuss recommendations from Advancing the Public Interest Through Regulatory Reform.[1]

1. When it comes to regulatory activity, we believe that behavioral change within OMB and the agencies is essential, but not the sole issue that needs to be addressed. The free market ideology of the last eight years has created a culture and attitude throughout government that devalues the role of regulatory solutions and revealed loopholes in the regulatory framework. Appointing key personnel within OMB and the agencies that understand regulation is an important government tool to protect the public and our natural resources and will be a powerful step in changing this anti-regulatory culture. However, our recommendations are intended to reach beyond selecting "good guys" or "bad guys" for key political appointments, to leave a legacy of institutional, systemic change that extends beyond behavioral conversions and prevents these sorts of abuses in the future including after the Obama administration leaves.

   Since it was created by the Paperwork Reduction Act, OIRA has functioned largely on the basis of the personality of the administrator, creating a ping-pong style of regulatory policy shifting from administrator to administrator and from administration to administration. While some of this is inevitable, our recommendations acknowledge the importance of these behavioral changes, but also try to change underlying factors that influence the role regulation plays in government, extending beyond the Obama administration. We think now is the moment for institutionalizing through law a relationship stressing OIRA's role as a coordinator or facilitator of sound agency process rather than a second-guesser of particular rulemaking actions.

2. Our recommendations call for a fundamental restructuring of the interaction between OIRA and the agencies, placing greater priority on agency expertise and statutory authority for decision-making. While we had differing views on the unitary executive theory that underlies centralized regulatory review, we did reach consensus on pragmatic approaches for constructive changes to OIRA's role. The role for OIRA would focus on three key functions: (1) implementation of its own statutory responsibilities; (2) transparent resolution of inter-agency disputes on regulations; and (3) implementation of presidential policies, where those are clear.

   We emphasize the need for clarity on the last role to avoid the tendency of OIRA, or an organization of its nature, to engage in mission creep based on implied presidential policies. OIRA should be concerned with agency structures and general regulatory performance. Just as in budgetary matters, coordination at the stage of priority setting is a pivotal occasion for the implementation of presidential policies. Whether reviving the

[1] There were several types of questions asked of us, including: (a) are our concerns limited to the actions (or inactions) taken by the Bush administration; (b) would we be satisfied if OIRA and agencies pursued a regulatory agenda we liked; (c) why should OIRA function differently than other parts of OMB; and (d) what specifically should be the role of OIRA and regulatory agencies?

Regulatory Working Group is appropriate or not, we are clear that priority setting requires greater transparency and public involvement, which OIRA should facilitate. But it is also necessary to make clear that OIRA's role is limited and does not usurp the role of the political leaders who lead the agencies with direct statutory responsibility for regulatory decisions. We believe this approach recognizes that the White House (a collection of various offices that often may be involved in reviewing agency rules) does not, nor should it, have the expertise that resides within the agencies; it acknowledges that the White House has the ability to identify government-wide management issues that should be raised with agencies that may improve the rulemaking process, and to see the big picture of what rules and activities agencies are undertaking.

In implementation of this split in responsibility, the role of the OIRA desk officers changes, shifting them away from making "Yes/No" decisions on individual rules. Instead, the desk officer can assist an agency in regulatory priority setting; in the context of particular rulemakings, the officer may help facilitate comments from other agencies, pose questions about the regulatory proposal or the underlying research, or convene interagency dialog as a collegial effort, but should not be acting as a person with an implied right to make final decisions on the substance of a rule or the regulatory priorities within an agency. This would create a new type of relationship between OIRA and the agencies, respecting the delegation of congressional rulemaking decision-making authority to the agencies.

3. OMB's review of regulations is a significantly different process than its review of agency budgets or proposed legislation. Budgets and legislation end up in public congressional venues; OMB's role is not controlling in those situations. Regulations are rarely debated in open congressional formats, such as hearings, and are rarely voted on by elected leaders. Unlike the budget process where examiners generally have similar expertise to agencies, OIRA desk officers do not have the technical skills of rule-writers or agency scientists. Hence, regulations take on a special situation for OMB that is different than the review of other governmental essentials. Moreover, Congress has already delegated regulatory authority to the agencies. This provides a rational reason to try a new role for OMB, one that is less transactional and more focused on assisting agencies in setting regulatory priorities through interactive, transparent means. In changing this role, the actions will implicitly support other recommendations we have made to strengthen the integrity of science in the rulemaking process at the agency level.

4. OIRA should hold agencies accountable for their regulatory actions. After an agency's priorities have been set through its regulatory plan and identified in the Unified Agenda, OMB should track whether the agency is meeting its plans and seek explanations when it is not. Thus, "prompt letters" may be appropriate, but should be focused on holding the agencies accountable for activities that are part of their work plans.

   OIRA should be cautious in raising issues that an agency should address beyond those identified in the Unified Agenda. Letters and calls from OIRA cause agency wheels to spin, often altering planned activities, even if that was not OIRA's intent. To the extent that an agency shifts its agenda as a result of OIRA's inquiries, it means the agency is displacing work on other priorities. When the White House wants an agency to shift priorities from the regulatory plan, the proper method is a vehicle that ensures public engagement.

MEMORANDUM

TO: Michael Fitzpatrick, OIRA Associate Administrator, and Kevin Neyland, OIRA Deputy Administrator and Acting Administrator

FROM: Authors of *Advancing the Public Interest through Regulatory Reform:* Gary D. Bass, Michael Bird, Caroline Smith DeWaal, N. Bruce Duthu, David J. Goldston, Mark Greenwood, Francesca Grifo, John Irons, Edwin S. Jayne, Sylvia Johnson, David Michaels, Richard W. Parker, Beryl Radin, Reece Rushing, J. Robert Shull, Peter W. Strauss, Wesley Warren

DATE: March 23, 2009

RE: Comments on the relationship between OIRA and federal agencies

Thank you for meeting with us on March 6th and for the opportunity to comment on ways to reform the current state of the federal regulatory system.

On Jan. 30, President Obama issued a memorandum to the heads of executive departments and agencies calling for recommendations on regulatory reform. The President's memo identified eight aspects of the regulatory process which he believes should be addressed during executive review. On Feb. 26, the White House Office of Management and Budget (OMB) published a notice in the *Federal Register* calling for public comments on "how to improve the process and principles governing regulation." OMB's notice reiterated the eight issues identified in the President's memo.

We believe the first issue, the relationship between federal rulemaking agencies and OMB's Office of Information and Regulatory Affairs (OIRA), is critically important to the regulatory process and a key issue to address in the regulatory executive order. Restructuring this relationship is equally critical to reforming the process.

Our report, released in November 2008, calls for such a restructuring. The report states, "There needs to be a fundamental restructuring of the interaction between OIRA and the agencies, placing greater priority on agency expertise and statutory authority for decision-making." It goes on to state, "The locus of decision making authority should reside in the federal agencies given the legal mandate to promulgate regulations."

On Dec. 24, we submitted to then President-Elect Obama's transition team a memo providing more detail on our joint views on the OIRA-agency relationship. Similarly, these comments emphasize and elaborate on some of the report's recommendations as they relate to the OIRA-agency relationship. In each communication we have tried to convey the core first principle that rulemaking authority, including decisions about its content, should reside with the agencies, not OIRA.

Since it was created by the Paperwork Reduction Act, OIRA has reflected the personality of the administrator. As a result, regulatory policy has shifted from administrator to administrator and from administration to administration. While some shifting is inevitable, we acknowledge the importance of reforms which will change underlying factors that influence the role regulation plays in government – reforms which must extend beyond the Obama administration. The modern-day regulatory executive orders that began with President Reagan gave significant power to OIRA. Depending on the administration, there have been different degrees of centralization and control over the agency regulatory decision-making. However, throughout the years, there was one consistent theme: OIRA, either by perception or reality, was in the driver's seat. We think now is the moment to try a different approach, stressing OIRA's role as a coordinator or facilitator of sound agency process rather than a second-guesser of particular rulemaking actions.

Congress delegates regulatory authority to the agencies. Moreover, agencies possess substantive expertise relevant to the regulatory matters before them – expertise sometimes seldom found elsewhere in government. Taken in tandem, these provide a rational reason for the Obama administration to craft a new role for OIRA, one that is focused on assisting agencies in setting regulatory priorities through interactive, transparent means rather than on the review of each significant rule. Actions undertaken in this new role will implicitly support other recommendations made in our report to strengthen the integrity of science in the rulemaking process at the agency level.

Our report calls for a fundamental restructuring of the interaction between OIRA and the agencies, placing greater priority on agency expertise and statutory authority for decision-making. While we have differing views on the unitary executive theory that underlies centralized regulatory review, we reached consensus on pragmatic approaches for constructive changes to OIRA's role. The role for OIRA would focus on three key functions: (1) implementation of its own statutory responsibilities, (2) transparent resolution of interagency disputes on regulations; and (3) implementation of presidential policies, where those are clear.

First, Congress created OIRA to administer policies for strengthening federal information resources and to approve agency requests to collect information from the public. OIRA should carry out these responsibilities in a way that does not unduly burden agencies and should be especially mindful that protracted approval periods slow agency efforts to gather valuable information. OIRA and agencies should also work together to consider alternative approaches to the paperwork clearance process that would provide agencies flexibility especially in regard to requests needed to address emerging problems. Other statutory responsibilities, such as those in the Unfunded Mandates Reform Act, need to be followed. But even those regulatory review requirements are significantly smaller in scope than OIRA's current approach to regulatory review.

Second, the role of the OIRA desk officers would change, shifting them away from making "Yes/No" decisions on individual rules. Instead, in the context of particular rulemakings, the officer may help facilitate comments from other agencies, pose questions about the regulatory proposal or the underlying research, or convene interagency dialog as a collegial effort. The officer should not act as a person with an implied right to make final decisions on the substance of a rule or the regulatory priorities within an agency. By embracing a role in which it assists agencies, OIRA would exhibit more respect for both the congressional delegation of authority to the agencies and those agencies' relevant expertise. It would also change the perceived role of OIRA, which may help OIRA in implementing the statutory requirements under the Paperwork Reduction Act.

Third, we emphasize the need for clarity on the last function to avoid the tendency of OIRA, or an organization of its nature, to engage in mission creep based on implied presidential policies. OIRA should be concerned with agency structures and general regulatory performance. Just as in budgetary matters, coordination at the stage of priority setting is a pivotal occasion for the implementation of presidential policies. Whether reviving the Regulatory Working Group is appropriate or not, priority setting requires greater transparency and public involvement, which OIRA should facilitate. But it is also necessary to make clear that OIRA's role is limited and does not usurp the role of the political leaders who lead the agencies with direct statutory responsibility for regulatory decisions. We believe this approach recognizes that the White House (a collection of various offices that often may be involved in reviewing agency rules) does not, nor should it, have the expertise that resides within the agencies; it acknowledges that the White House has the ability to identify government-wide management issues that should be raised with agencies that may improve the rulemaking process, and to see the big picture of what rules and activities agencies are undertaking.

In addition to priority setting, OIRA should focus on holding agencies' accountable. After an agency's priorities have been set through its regulatory plan and identified in the Unified Agenda, OMB should track whether the agency is meeting its plans and seek explanations when it is not.

Thus, "prompt letters" may be appropriate, but should be focused on holding the agencies accountable for activities that are part of their work plans, not reinventing their work plans.

OIRA should be cautious in raising issues that an agency should address beyond those identified in the Unified Agenda. Letters and calls from OIRA cause agency wheels to spin, often altering planned activities, even if that was not OIRA's intent. To the extent that an agency shifts its agenda as a result of OIRA's inquiries, it means the agency is displacing work on other priorities. When the White House wants an agency to shift priorities from the regulatory plan, the proper method is a vehicle that ensures public engagement.

Much like OIRA ought to respect the will of Congress in delegating authority to agencies, both OIRA and agencies ought to respect congressional prerogatives on the preemption of state law. As our report states, "Too often, agencies have used federal regulation to inappropriately preempt state positive law (proscriptive requirements enacted by legislatures or set by regulatory bodies) and, in some cases, state tort law." The report recommends, "The president should instruct agency heads to avoid preemption of state laws when there is no express authority to do so."

The President, OIRA, and agencies should also pay attention to the issue of scientific uncertainty and emphasize the value of having the best information possible available in decision making. Using the absence of certainty as a pretext for avoiding or delaying regulation must stop. Our report identifies three reasons to avoid such inaction:

- "Pushing for certainty may result in completely stopping regulation in policy areas that rely on scientific information."
- "Federal laws often recognize that the government has a responsibility to protect citizens from harms they cannot control. Some statutes explicitly call for some margin of protection."
- "Regulation is not an irreversible course of policy…As evidence grows, standards can be made more or less stringent if necessary."

In conclusion, a healthy relationship between rulemaking agencies and OIRA is critical to a well-functioning regulatory system that adequately responds to public need. We believe this relationship would be improved if OIRA engaged less in rule-by-rule review and instead focused on assisting agencies in gathering the opinions of other agencies and contributing to regulatory priority setting. The Obama administration has an opportunity to redefine federal regulatory policy for the better – not just for itself, but for future administrations.

BIOGRAPHY FOR RICK MELBERTH

Rick Melberth joined OMB Watch in November 2006 as the Director of Federal Regulatory Policy, the program which works to protect and improve the government's ability to develop and enforce safeguards for public health, safety, environment, and civil rights. He directs all activities related to policy advocacy, analysis, research, monitoring, and public education. Dr. Melberth comes to OMB Watch from Vermont Law School where he was Director of Internal Planning and formerly the Associate Director of the Environmental Law Center. He helped design the curriculum and taught courses in the Master's program.

Melberth has written several pieces about decision-making in government and environmental issues during his academic career and while working as an independent consultant and policy analyst. He also worked in the solid waste management field as the manager of a solid waste division and a program to implement a waste-to-energy facility in county government in Ohio. This led to the opportunity to co-author a book for local governmental officials, *Decision-making in Local Government: The Resource Recovery Alternative.*

Melberth completed his doctorate in public administration and public policy at the University of Cincinnati in 1982. His Master of Environmental Science (M.En) and AB in political science are from Miami University.

Chair MILLER. Thank you, Dr. Melberth. That was very close to five minutes.

Ms. Smith DeWaal.

STATEMENT OF MS. CAROLINE SMITH DEWAAL, DIRECTOR, FOOD SAFETY PROGRAM, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Ms. SMITH DEWAAL. Thank you. I will see if I can do the same.

Thank you very much for inviting me to testify, Chair Miller, and also Ranking Member Broun. It is a privilege. I haven't been yet before this subcommittee. My name is Caroline Smith DeWaal. I direct the Food Safety Program for the Center for Science in the Public Interest. Our organization was founded nearly 40 years ago and focuses primarily on nutrition and food safety. We accept no government or industry funding so our views can be very, very independent.

As one of the contributors to advancing the public interest through regulatory reform, I was privileged to work with a group of diverse regulatory experts in identifying the failures of, and the fixes to, the regulatory system, and we commend President Obama on his revocation of the Executive Order 13422 earlier this year. But much more remains to be done, much of it centered on reforming the regulatory review process at the Office of Management and Budget's OIRA.

My written testimony has identified and illustrated a number of problems with OIRA's review of regulations. The meat and poultry HACCP regulations showed how science is not well advanced and public health improvements can be thwarted when regulations are tied up in multi-year regulatory reviews. This case showed that the burden of review has really provided incentives for federal agencies to find creative ways to avoid going through the OMB process.

The proposed egg regulation, which has been in the works for 10 years and is supported by two separate scientific risk assessments, illustrated the problem inherent in unlimited reviews that add years to the development of a regulation. It also illustrated that scientific uncertainty cannot overcome the confusion of having multiple agencies in charge of food safety.

The bioterrorism rules that came about after Congress enacted the *Bioterrorism Act of 2002* showed that OMB reviews can open the door to industry to lobby for changes to regulations without the transparency requirements required by law for the federal agencies under the *Administrative Procedures Act.* This allows OMB to override policy decisions best left to the agencies.

These problems did not originate in the Bush Administration, nor will they necessarily disappear just by having different people in charge. Fundamental changes are needed to reduce the breadth of oversight and the time lags that result. When it comes to food safety, the goal must be a rapid-paced and flexible regulatory structure that can accommodate constantly changing science and even, on occasion, imperfect science. As regulations and policies evolve, regulators must be allowed to bring new science to bear in preventing food-borne illnesses and outbreaks.

Unfortunately, the review process has become a barrier to agencies' efforts to rapidly translate new science into better regulation for protecting public health. OMB, through its lengthy reviews, has diminished the role of science in crafting federal regulations. CSPI recommends that a new Executive Order rewrite the OMB mandate for OIRA to accomplish the following.

They should update the definition for significant rules to narrow the number of regulations requiring prior approval by OIRA and to limit the review to economic issues raised in the proposed rules. They should give OIRA a rapid timeframe for review that ensures that agencies can produce timely federal agencies to protect public health and social welfare. They should require OIRA to defer to federal agencies on the scientific and technical questions and OIRA should operate with transparency that is comparable to that required by the federal agencies.

The real costs of regulatory delay are felt by everyday Americans when they experience an avoidable food-borne illness from peanut butter or peppers, from salad makings or spices. The food industry can do better, but it needs a level playing field and that's what regulations provide. Our nation's food safety program can also improve, but not without reform of the OMB process as well. Thank you.

[The prepared statement of Ms. Smith DeWaal follows:]

PREPARED STATEMENT OF CAROLINE SMITH DEWAAL

Good morning Mr. Chairman, Ranking Member Broun and Members of the Subcommittee on Investigations and Oversight. My name is Caroline Smith DeWaal, and I am the Director of Food Safety for the Center for Science in the Public Interest (CSPI). Founded nearly 40 years ago, CSPI is a nonprofit health advocacy and education organization focused on nutrition and food safety. We are supported principally by the 950,000 subscribers to our *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you for inviting me to provide testimony today on the role of science in regulatory reform. As my expertise is food safety, I have not had an opportunity to testify before this subcommittee before, largely because issues I am commonly called on to testify on reside within the jurisdiction of the Energy and Commerce and the Agriculture Committees. But food safety owes a debt to one of the signature agencies under the Science and Technology Committee's jurisdiction. The premier process control system, known as Hazard Analysis and Critical Control Points (HACCP), was developed in the 1960s by Pillsbury for the National Aeronautics and Space Administration (NASA).[1] NASA had an understandable concern over astronauts contracting food-borne illnesses in the confines of a space capsule at zero gravity. Today this space-age program is being used widely to reduce the risks from contaminated food and improve food safety for all Americans, not just astronauts.

Advancing the Public Interest Through Regulatory Reform

As one of the contributors to *"Advancing the Public Interest Through Regulatory Reform,"* I was privileged to work with a group of diverse regulatory experts on identifying failures and fixes to the regulatory system. In my testimony, I will address some of the issues discussed in that report, together with other issues that we have identified based on long experience working on food safety regulations during the Clinton and Bush presidencies. I will provide case studies of how the failures in our regulatory review system can place the publics' health at risk.

We commend President Obama's revocation of Executive Order (E.O.) 13422 on January 30, 2009.[2] The rescinded order contained a number of flawed provisions that greatly diminished the deference that should be given to agency experts and scientists in rule-making decisions. This is a start to implementing the recommendations in *"Advancing the Public Interest Through Regulatory Reform."*

But more remains to be done, much of it centered on reforming the regulatory review process at the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). The process and principles governing the review of agency regulations give OIRA undue discretion to override policy decisions

[1] Pan American Health Organization, HACCP: Essential Tool for Food Safety, 2001.

[2] Letter to Mabel Echols, Office of Management and Budget, from Kirsten Stade, Program Manager, Integrity in Science, and Illene Ringel Heller, Senior Staff Attorney, CSPI, Re: Request for Public Comment on Improving the Process and Principles Governing Regulations; 74 *Fed. Reg.* 8819, Feb. 26, 2009 (March 19, 2009).

that are based on sound science and the exhaustive work of federal agency experts.[3] The new Administration's commitment to ensuring the integrity of the administrative process is a welcome change.

I have worked with both the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) on identifying effective regulatory approaches to address food safety problems since the early 1990's and have met periodically with the OIRA staff during their consideration of federal regulations, usually at the request of the agencies. Over this period, I have seen the regulatory process extend to a multi-year process—often taking five or more years to complete a single regulation. I have also observed the agencies shy away from using regulations at all, and opting for alternative approaches that either don't involve or lessen OIRA review. I will discuss this more during the case studies presented later in my testimony.

If you look at OIRA's function like that of a regulatory agency, the OIRA staff perform a "prior approval" function for most federal actions, even those like voluntary surveys or consumer focus group research.[4] This type of data gathering is often important to help agencies set the parameters for improving their regulatory approach. Conversely, without doing the necessary research and consultation, the agencies may adopt less effective regulatory approaches. Yet the requirement for review by OIRA of even voluntary surveys can trigger long delays. For documents submitted to OMB as a courtesy, agencies have told me that they factor in a 90-day "wait time" for a response.

Cost-benefit analysis has played an overly significant role in rule-making, an exercise heavily weighted towards the estimation of industry costs. In fact, it can become "mission impossible" for an agency to prove prospectively the benefits that might accrue from a regulation. Instead, federal agencies should be encouraged to identify well-defined public health goals and develop metrics to measure the effectiveness of regulations over time, rather than requiring them to prove with a high degree of confidence that preventative measures will work before initiating the rule-making process.

In order to increase OIRA's effectiveness and minimize the long-standing delays in the regulatory process, any new executive order on regulatory review should be based on a more narrowly focused role for OIRA in regulatory review, one better suited to its economic expertise. Instead of performing an open-ended review of every "significant" regulation with an economic cost or benefit of $100 million (a figure not updated for decades),[5] OIRA should issue guidance to the agencies and then audit agencies' compliance with the guidance, focusing primarily on rules with high costs and low benefits. This would allow agencies to develop regulations more easily and quickly and avoid the burden of OIRA review of each action. OIRA audits that disclosed problems with the cost/benefit analysis in specific regulations could be discussed with the agency chiefs and if needed, technical amendments to regulations could be used to make modifications.

A new executive order should update the definition for "significant" rules to narrow the number of regulations requiring prior approval and limit OIRA's review to the economic issues raised in the proposed rules. As OIRA is staffed by economists, it should avoid a scientific and technical review of regulations. Such questions should be deferred to the expertise of the federal agencies. Finally, OIRA should have a rapid time frame for review that balances thoughtful review with the need to produce timely federal agency actions, particularly to protect public health and social welfare.

Recent history has well documented that, as a nation, we are suffering more from the lack of appropriate regulation than from too much regulation. Perhaps if OIRA is freed up from this burdensome review of the minutia of agency action, its skilled economists could focus more on the gaps in regulation, such as those that led to major disasters in the financial sector, as well as the continuing crises in health care and food safety, among others.[6] Identifying regulatory gaps or analyzing regulatory approaches in other nations to ensure that our systems are not falling behind could ensure that future crises are averted.

To whatever extent that OIRA retains a role in agency rule-making, it should operate with greater transparency. Agencies must be instructed more forcefully to doc-

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[3] Gary D. Bass, et. al, *Advancing the Public Interest Through Regulatory Reform,* OMB Watch, Nov. 2008.

[4] The *Paperwork Reduction Act of 1980* gives OIRA authority to review and approve information collection by federal agencies. 44 U.S.C. § 3501 et seq.

[5] The very broad definition of "significant" allows OMB to review almost any rule that it chooses. President Ronald Reagan established the $100 million threshold for determining a proposed regulation is "major" in 1981. E.O. 12291, Feb. 17, 1981.

[6] OIRA issues prompt letters to suggest areas in which agencies could improve regulation.

ument any changes to their draft rules or pre-rule framework made at OIRA's suggestion at whatever point in the rule-making process those changes occurred. In 2003, the Government Accountability Office (GAO) found that the documentation required by E.O. 12866 was present for only about one quarter of the regulations it reviewed.[7] Documentation of all communications should clearly indicate which regulation is the subject of those communications, as well as the name and affiliations of all parties to the communication.

A complete public docket, which is updated regularly and documents when and by whom all suggestions to modify a rule are made, will be a strong deterrent to the kinds of political and corporate interference in agency rule-making that have too often prevailed during the previous Administration and which are documented in the case study below.

At its worst, OIRA today is considered a "black box" for regulation, where non-experts review rules and meet with outside parties, often the very industries covered by the regulations, to discuss changes. Public health improvements should not be delayed by a lengthy regulatory oversight process that attempts to second guess agency experts and gives the regulated industries an "off the record" opportunity to get provisions changed at OMB.

Role of Science in Public Policy: Food Safety Case Studies

New challenges, such as emerging pathogens or chemical hazards, and new technologies to address them are a fact of life for modern food production. Regulatory systems must be capable of providing the flexibility to allow the rapid recognition of emerging hazards and the rapid implementation of tools to address them. Let me discuss the theory that underpins efforts to modernize today's food safety regulatory system, which is an antiquated system built on a 1906 legal foundation.

Process control systems managed by the food industry and regularly reviewed by government regulators are at the heart of a modern food safety system. Such systems are designed to be flexible and to adapt to change. The food industry designs and validates its own safety system and monitors its implementation at the processor level. The government sets performance standards and inspects plants to ensure the systems are designed and managed properly.

Performance standards provide a metric for measuring the success of a facility's food safety controls and allow government inspectors to standardize their evaluation of plants producing similar products. Performance standards can utilize a specific chemical or pathogen limit or a performance measure, such as a standard microbial or "log" reduction. The agency sets the target level, and companies have flexibility in deciding how to reach it. Performance standards allow companies to innovate within the parameters set by the government. Government agencies should regularly update their standards to reflect current conditions. Such a system allows both the food industry and the government programs to achieve continuous improvement.

The government sometimes must rapidly establish a performance standard for an emerging hazard. For example, the findings of melamine in infant formula in China and in some products in global trade provided the immediate need for FDA to set a standard for that chemical in formula quickly, a sensitive issue as this is the single source of nutrition for many infants, who are a high-risk group.[8] Clearly the regulatory system must accommodate these circumstances, but the system we have today forces many agencies to operate outside of the rule-making process in order to set food safety standards.

Unfortunately today more than 10 years into the HACCP era, performance standards are not used effectively. The ones that were developed have become out-dated, and agencies are reticent to develop new ones due to the changing science and the lengthy nature of the regulatory review process. One of the biggest limitations to more effective and responsive regulation is imperfect data. Decision-makers often lack the baseline information required to develop new or improve older performance standards. These gaps in data can delay, or even derail, meaningful regulatory efforts. The regulatory system must accommodate these circumstances where meaningful regulatory action must be progressed even in the absence of perfect data.

When it comes to food safety, the goal must be a rapid-paced and flexible regulatory structure that can accommodate constantly changing science and even imperfect science. As regulations and policy evolve, regulators must be allowed to bring

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[7] Gov. Acct. Off. Rep. No. 03–929, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews,* Sept. 2003.

[8] See, FDA, *Interim Safety and Risk Assessment of Melamine and its Analogues in Food for Humans,* Oct. 3, 2008; followed quickly by FDA, *Update: Interim Safety and Risk Assessment of Melamine and its Analogues in Food for Humans,* Nov. 28, 2008, in response findings of melamine and cyanuric acid in some U.S. manufactured infant formula.

new science to bear in preventing food-borne illness outbreaks. Unfortunately, the regulatory review process has become a moribund, time-consuming and daunting barrier to agencies' efforts to rapidly translate new science into better regulation for protecting the health of the public.

Case Study: Meat and Poultry HACCP

Cumbersome Review Process Means Performance Standards Not Updated; Agency Finds Creative Solutions

An important illustration of the modern food safety system discussed above is USDA's application of HACCP systems for meat and poultry plants. The agency adopted the program by regulation in 1996 and within three years it was in use in every meat and poultry facility in the United States. The agency also utilized performance standards based on the frequency of *Salmonella* in the different species and ground products; these standards have been in use since the program started. Under this program, the agency periodically runs a series of tests for *Salmonella* in individual facilities to evaluate their performance against the standard for that sector of the industry.

The performance standards were established on the basis of a series of baseline studies documenting *Salmonella* and other pathogens and indicator organisms on meat in the early-to-mid 1990's. By the time the program was fully implemented (1999), the standards were already largely out-of-date. In fact, to even approach the "limit," many companies would have to double the amount of *Salmonella* in their products.

In 2006, the agency came up with a creative solution to the obsolete standards adopted in the 1996 Pathogen Reduction regulation. The agency published a notice in the *Federal Register* announcing that it would place meat plants into one of three categories depending on their *Salmonella* testing results.[9] Companies would be placed in category I if their results were 50 percent or less of the published *Salmonella* performance standard. Companies with results between 50 percent and 100 percent of the *Salmonella* performance standard would be placed in Category II. And those plants with results in excess of the *Salmonella* performance standard were placed in Category III, and faced increased enforcement and compliance checks by USDA.

In August 2007, the Under Secretary of Food Safety at USDA announced that the agency would publish the names of plants in Category II and III on the Internet.[10] The release of plant names started in March 2008. While this new approach was published in the *Federal Register,* and the agency solicited public comment, it was not a federal regulation because it required no specific action of the industry.[11] This allowed the agency to move from the concept phase to implementation in about one and a half years. If the agency had chosen to update the performance standards, assuming the data was available to do that, it would likely have taken anywhere from three to seven years from the concept to implementation. So this solution, which effectively reduced the performance standard by 50 percent through the use of a "name and shame" strategy rather than a more classic regulatory enforcement, was implemented much faster simply by avoiding a full OIRA review.

Case Study: Shell Egg Rule

Multiple Risk Assessments and 10 Years is Still Not Sufficient to Achieve Needed Regulations

The efforts to finalize a regulation to control *Salmonella* Enteritidis (SE) in shell eggs shows that even when sound science supports regulation and cost-benefit analysis favors action, the lack of a clear food safety agency that is "in charge" may allow OMB to throw up roadblocks to implementation. Thus OMB can block a regulation that might prevent thousands of illnesses and possibly hundreds of deaths each year,[12] just because it can't decide which federal agency should manage the problem.

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[9] *Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection, 71 *Fed. Reg.* 9772, (Feb. 27, 2006).

[10] Transcript, USDA, Public Health Based Inspection in Slaughter to Address *Campylobacter, Salmonella,* and Other Public Health Concerns (August 7, 2007) at http://www.fsis.usda.gov/PDF/Transcript_*080707_Slaughter_Inspection.pdf*

[11] *Salmonella* Verification Sampling Program: Response to Comments and New Agency Policies, 73 *Fed. Reg.* 4767 (Jan. 28, 2008).

[12] *Salmonella* is estimated to cause 1.3 million illnesses and 500 deaths each year. *Salmonella* Enteritidis is the most common serotype, according to the Centers for Disease Control and Pre-

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In 1997, on the basis of a pilot study conducted in Pennsylvania that showed that on-farm controls could greatly reduce the incidence of SE in eggs and laying flocks, CSPI petitioned the government to require egg producers to implement on-farm process control programs. The approach supported by CSPI's petition was also recommended in the first SE risk assessment. In 1996, after watching an increasing incidence of SE in eggs, the Food Safety Inspection Service (FSIS) and FDA initiated a risk assessment to assess the interventions needed to reduce the risk of illnesses from SE.[13] Published by FSIS in 1998, it provided further support for the need for on-farm controls to address SE in live hens, thereby reducing the incidence of illnesses from SE.[14]

FDA and FSIS issued a joint advanced notice of proposed rule-making in 1998[15] and the issue even merited a Presidential announcement in 1999 by President Bill Clinton, which clearly indicated FDA would take the lead on the food safety regulation.[16] But after that, the issue sat under the Bush Administration while it re-debated internally which agency should handle this issue. FDA did not publish a proposed rule until 2004.[17] At approximately the same time, FSIS released a second risk assessment further documenting the need for regulatory action.[18] After accepting comments in 2004, and in a second extended comment period in 2005, the rule continued to languish. It was not sent to OIRA for final review until 2008.

FDA had cited its intention to finish the Shell Egg rule in numerous documents including the budget[19] and the Food Protection Plan.[20] But it could never seem to get it finalized at OMB. What happened at OIRA once the rule was forwarded to OMB is anyone's guess, though we know OIRA met with industry and consumer groups on the rule in August 2008. All we know is that on Nov. 19, 2008, FDA withdrew a well-vetted final rule citing the need to address comments received during interagency review.[21] Because OIRA's comments were made through an interagency exchange, the public has no way of challenging the decision to withdraw the rule.

So the rule fully supported by science-based risk assessments as being needed to protect public health from an avoidable problem in shell eggs is back at FDA with the start of the Obama Administration, no change from 10 years ago when President Clinton made it the topic of a Presidential radio address.

Case Study: Bioterrorism Act

Interference in Agency Determinations Results in Weak Regulations

In June 2002, Congress passed the *Public Health Security and Bioterrorism Preparedness and Response Act* to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Act gave FDA four new authorities: FDA could detain potentially contaminated foods; register foreign and domestic food facilities; require record keeping in the food industry; and give prior notice of food imports. Congress set an 18-month time frame for FDA to adopt regulations under the new law.

FDA did publish four proposed rules between February and May 2003, with intentions to push forward to get the regulations finalized to meet the deadlines in the Act. But things slowed when the rules arrived at OMB.

Documents reviewed by CSPI showed that during the comment periods, OMB hosted a steady stream of meetings with over 30 food industry representatives who we believe were seeking to influence the final outcome on four proposed anti-bioter-

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vention. CDC, Preliminary FoodNet Data on Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2008, *MMWR Weekly*, April 10, 2009, 58(13); 333–337.

[13] FSIS, *Salmonella* Enteritridis Risk Assessment: Shell Eggs and Egg Products, June 12, 1998.

[14] *Id.*

[15] *Salmonella* Enteritidis in Eggs; Advanced Notice of Proposed Rule-making, 63 *Fed. Reg.* 27502 (May 19, 1998).

[16] Press Release, USDA & FDA, Clinton Administration Announces Ambitious New Plan to Improve Egg Safety, Reduce *Salmonella* Illnesses (Dec. 11, 1999) at *http://www.usda.gov/news/releases/1999/12/0483*

[17] Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Proposed Rule, 69 *Fed. Reg.* 56824 (Sept. 22, 2004).

[18] FSIS, Risk Assessments of *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products, Oct. 2005 (Assessing risk of SE contamination in processed eggs for the purpose of establishing science-based performance standards).

[19] FDA, Foods, FY 2008 Budget Justification Documents located at *http://www.fda.gov/oc/oms/ofm/budget/2008/1-BudgetNarrativeCFSAN.pdf*

[20] FDA, Food Protection Plan, Nov. 2007 (Proposing to issue a final regulation on *Salmonella* in shell eggs by Spring 2008).

[21] Joan Murphy, FDA Withdraws *Salmonella* Enteriditis Shell Egg Rule From OMB Review, *Food and Chemical News,* Dec. 1, 2008.

rorism rules.[22] While these meetings provide an opportunity for OIRA staff to ask questions of outside experts, they are not formally within the notice and comment rule-making process under the *Administrative Procedure Act* (APA).[23] Therefore, the meetings produce few of the hallmarks of transparency that are part of the APA process. OIRA lists participants at the meetings and publishes documents it receives on its web site, but does not follow a public comment process, make a transcript or provide any response to comments it receives. And these meetings with industry seemed to have an impact.

Because FDA does not have inspectors at every port of entry, the purpose of the prior-notice requirement for shipments of imported food was to allow the FDA to dispatch its inspectors to check the riskiest incoming food shipments. FDA proposed a rule on prior notice of food imports that required importers to notify the Agency by noon on the day before a food shipment arrives. However, in July and September 2003, OMB held four meetings with the food industry on this proposed regulation. The regulation that emerged in October 2003 had significantly shorter notice requirements—just two hours notice for trucks, four hours for trains or planes, and eight hours for ships transporting food. Additionally, under the interim final rule importers are permitted to make last minute changes to their notifications. The final rule on prior notice that was required to be completed in late 2003, is slated to go into effect next week, nearly six years past its Congressionally-mandated "due date."[24]

These time frames were clearly not adequate to meet the intention of the statute. FDA could not move inspectors to ports to check high-risk products identified under the shortened notice requirements. While they could potentially hold suspect products on site until an FDA inspector could get there, it clearly undercut the intent and efficacy of the new law.

In another of the proposed rules, FDA sought to require companies to keep records on food shipments and ingredients. Known as "one up/one down," this traceability provision was intended to allow FDA to quickly track food back to its source in an emergency.

During consideration of this regulation, OMB held meetings with 14 food industry representatives, including three meetings in February and March 2004. The industry agenda for one meeting included such topics as "Lot code tracking is unnecessary and costly," and "Four-hour record-keeping retrieval—Unreasonable and unnecessary." The impact: The lot code tracking provision was revised to exempt transporters and distributors and the record retrieval provisions were changed in the final rule from four hours to 24 hours. These changes significantly weakened the final record-keeping provisions, and may have contributed to the long investigative delays in recent outbreaks linked to *Salmonella* in the United States.[25]

As the *Bioterrorism Act* specified that the regulation be finalized within 18 months, the first deadline expired in December 2003. Though FDA announced that it would finalize the rule by the end of March 2004, the final rule was instead published nine months beyond that target date, in December 2004. Compliance with the rule was not required until June 2005 for large companies. Small businesses (fewer than 500 employees) had an additional year to comply.

The two other regulations were finalized as required by the law. In October 2003, FDA issued a final rule requiring domestic food processors and importers to register with the agency. In June 2004, it finalized a rule covering administrative detention procedures for food.

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[22] According to participant lists on OMB's web site, agency officials met with officials from Kraft, ConAgra, Procter & Gamble, the Food Marketing Institute, the Grocery Manufacturers of America, the National Food Processors Association, and the National Coalition of Food Importing Associations, as well as several food packaging and transportation groups. In response to a *Freedom of Information Act* (FOIA) request, CSPI obtained additional information, including handouts and meeting agendas supplied by the industry representatives. There was no evidence that OMB met with any independent food-safety experts or consumer groups during this time. *http://www.cspinet.org/new/200409291.html*

[23] A similar meeting of industry representatives at the agency level would require, at a minimum, a taped transcript.

[24] Prior Notice of Imported Food Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002;* Draft Compliance Policy Guide; "Sec. 110.310 Prior Notice of Imported Food Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*;" Availability; Final Rule and Notice, 73 *Fed. Reg.* 66294, (Nov. 7, 2008).

[25] Julie Schmit, Tracing Tainted Produce Isn't Easy; *Salmonella* Case Highlights Complex Distribution System, *USA Today,* Aug. 14, 2008, at 1B; See, HHS Office of Inspector General Rep. No. OEI–02–06–00210, Traceability in the Food Supply Chain, March 2009 (revealing poor compliance by industry and recommending stronger traceability laws).

Conclusion

This testimony has identified and illustrated a number of problems with the OIRA review of regulations. The meat and poultry HACCP regulation showed how science is not well advanced and public health improvements can be thwarted when regulations are tied up in a multi-year regulatory review process. The case showed that OIRA's burdensome review has provided incentives for the agencies to find creative ways to avoid going through the OMB process. For meat and poultry products, it means that USDA has kept outdated performance standards in place by using newer guidance benchmarked to the old performance standards.

The proposed egg regulation illustrated the problem inherent in unlimited reviews that can add years to the development of regulations. It also illustrates the confusion of having multiple agencies in charge of food safety.

The bioterrorism rules showed that OIRA reviews can open the door for industry to lobby for changes to regulations without the transparency requirements of the APA and also how OIRA can override policy decisions best left to the agencies. We have also heard from agencies about the long delays inherent in trying to do a voluntary survey and how agencies are sometimes asked to predict future benefits with specificity before a rule can progress.

These problems did not originate in the Bush Administration, nor will they necessarily disappear just by having different people in charge. Fundamental changes are needed to reduce the breadth of oversight and the time lags that result from such broad oversight.

The role of science in the regulatory process is very important; however, for the reasons discussed above, OIRA review has diminished the role of science in crafting federal regulations. CSPI recommends that a new executive order rewrite the OIRA mandate to give it more targeted review along with responsibility for identifying gaps in regulatory oversight. A new executive order should update the definition for "significant" rules to narrow the number of regulations requiring prior approval and limit OIRA's review to the economic issues raised in the proposed rules. As OIRA is staffed by economists, they should defer to the federal agencies on scientific and technical questions. OIRA should have a rapid time frame for review that balances thoughtful review with the need to produce timely federal agency actions, particularly to protect public health and social welfare. Finally, to whatever extent that OIRA retains a role in agency rule-making, it should operate with greater transparency. Agencies must be instructed more forcefully to document any changes to their draft rules or pre-rule framework made at OIRA's suggestion at whatever point in the rule-making process those changes occurred.

The real costs of regulatory delay are felt by everyday American's when they experience an avoidable food borne illness. The food industry can improve, but it needs a level playing field to do it. Our nation's food safety program can and will improve, I am confident. But it won't happen without reform of the OIRA review process as well.

BIOGRAPHY FOR CAROLINE SMITH DEWAAL

Caroline Smith DeWaal is the Director of the Food Safety Program for the Center for Science in the Public Interest and co-author of *Is Our Food Safe? A Consumer's Guide to Protecting Your Health and the Environment* (Three Rivers Press, 2002). She represents CSPI in the media, in Congress and in the regulatory arena on a broad range of food safety issues. Ms. DeWaal is the leading consumer analyst on reform of laws and regulations governing food safety. Since 1999, she has maintained and annually published a listing of food-borne illness outbreaks organized by food source that now contains over fifteen years of outbreaks reports. She has presented CSPI's outbreak database at numerous scientific conferences, including the American Public Health Association, International Association for Food Protection and the American Society for Microbiology. She has presented papers on food safety at over 50 scientific and public policy conferences. She has participated in a number of World Health Organization consultations on food safety and is currently an expert advisor on its Intergrated Surveillance of Antibiotic Resistance project. She represents the International Association of Consumer Food Organizations at the Codex Committee on Food Hygiene. She has participated in several national advisory committees to USDA and FDA. She chaired the Editorial Board of the *Food and Drug Law Journal* and is a member of the International Association of Food Protection. DeWaal graduated from the University of Vermont and Antioch School of Law.

Chair MILLER. Thank you, Ms. Smith DeWaal.

Mr. Warren.

STATEMENT OF MR. WESLEY P. WARREN, DIRECTOR OF PROGRAMS, NATURAL RESOURCES DEFENSE COUNCIL

Mr. WARREN. Thank you, Chair Miller and Dr. Broun. I appreciate the opportunity to testify today. I am Wesley Warren, Director of Programs at the Natural Resources Defense Council. NRDC is an environmental organization composed of legal and scientific experts who represent over a million members and activists across the country who are interested in environmental protection.

Just for the record, I would like to note for Chair Miller that I hail from North Carolina, still have family in Raleigh and flew out of the Greensboro Airport just last night on business returning to Washington. So I send my regards from the state.

Chair MILLER. Please feel free to mention my name to your relatives in Raleigh.

Mr. WARREN. I will be sure to do that.

So I have detailed comments and recommendations in the testimony submitted for the record but which I won't repeat. Instead, I would like to take a moment to speak to the Committee to say what I think is at stake in these issues and for these hearings.

The role of science in public policy is really critical and it is critical that we restore its integrity. That means we produce the best quality science and then we put that science to the best possible use. The OMB has a tremendously important role in this process to ensure that scientific standards have been followed, but it is not the role of OIRA to substitute its scientific judgment for the judgment of the expert agencies or to dictate what scientific practices should be. That instead should be determined by independent scientific bodies like the National Academy of Science and other scientific experts who generate standing scientific practices.

Why does this matter in terms of the use of policy? Regulatory policy is environmental policy. If you look at the Bush Administration report on the cost and benefits of federal regulations, you will see that environmental benefits, although there is a big range of the estimates of those benefits, on the upper end of the range have an astonishing $593 billion of benefits to the economy over a 10-year period. This was the Bush Administration OMB. And that on the upper end of the range is 90 percent of all the benefits of social regulations that exist. Why is that? The reason is because of the tremendous number of lives that can be saved from reducing pollution, especially air pollution, and the value that society puts on that life. So when you take a body of information such as this, which is generated through risk assessments by the agencies, the question is, how do you put that to use in policy-making. And what you want to do is insulate the application of that kind of information from political manipulation.

Unfortunately, we discovered under the Bush Administration that it was very prone to manipulation. When the OMB would involve itself in a process, it would often add additional decisional criteria than those contained in the underlying statute that Congress had enacted, sometimes an unreasonable cost-benefit test, and one of the reasons they—one of the ways that they set out to really tilt the scales on cost-benefit analysis was to lower the estimated value that we would put on a human life. This had an extraordinary impact on what the estimated benefits might be from

regulations, and in extreme cases they would say, for example, it was dubbed the "senior death discount" that if older people died from air pollution because they didn't have as many years left to live, that that life wasn't worth protecting as much and would in the extreme case reduce the value of that life from what the standard value of human life is, which is $6.1 million, according to EPA, to as low as $130,000, depending upon how many years left a person might have to live. This has an astonishing impact on what federal policy might be regarding environmental protection.

So our recommendation is that it is very important now to make sure that OIRA doesn't substitute its expertise on science for that of the expert agencies and doesn't impose itself in a decision-making process to add criteria that Congress did not include itself, and as a result I will read our recommendation for OIRA, which is that the government should establish written, publicly available performance requirements and milestones for OIRA review of agency actions to ensure efficient and timely completion of its duties, and there should be an accountability mechanism including transparency to ensure that these performance standards are met. Thank you very much.

[The prepared statement of Mr. Warren follows:]

PREPARED STATEMENT OF WESLEY P. WARREN

Good morning and thank you for the opportunity to testify on *The Role of Science in Regulatory Reform.* My name is Wesley Warren, and I am the Director of Programs for the Natural Resources Defense Council (NRDC). NRDC is a national, nonprofit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Prior to joining NRDC I served in the White House as Chief of Staff at the Council on Environmental Quality and as Associate Director for Natural Resources, Energy and Science at the Office of Management and Budget. I previously worked on the professional staff of the House Science and Energy and Commerce Committees.

The role of science in regulatory reform is an important and timely topic and I commend the Subcommittee for making it an area of focus early in the 111th Congress. As Members of this committee know, science is at the very core of the work many of our agencies do to fulfill their missions, particularly when those missions involve protecting public health and the environment. How scientific analysis is conducted by those experts within federal agencies, and how science fares in relation to other considerations taken in the regulatory process, can make enormous differences in whether laws passed by Congress are implemented as intended, and how effectively those laws protect the public. It is not an overstatement to say that these questions and how they are resolved can make the difference between life and death, or life and health, for many Americans.

Too often in recent years, proposed agency actions based upon the solid scientific work of agency experts that would have improved protection of public health and the environment have been blocked, delayed, watered down or otherwise weakened based upon ideological-imposed criteria that were never authorized by Congress. An important source of this diversion and delay of public health protections has been the Office of Management and Budget (OMB), and specifically the Office of Information and Regulatory Affairs (OIRA).

Under Executive Order 12866, which succeeds previous Executive Orders, OMB is given substantial authority to review agency actions including rule-making, guidance, and even propounding information requests. OMB has frequently used this authority, particularly (but not exclusively) in recent years, to interfere with agency efforts to carry out their science-based missions, and to impose consideration of other factors never sanctioned by Congress. Moreover, OMB has frequently used methods to influence regulatory outcomes that run counter to principles of open government and transparency.

This subcommittee held a hearing last summer that considered some examples of these problems, including OMB's revised process for overseeing and interfering with EPA's development of hazard assessments for toxic chemicals through its IRIS pro-

gram. My NRDC colleague Dr. Linda Greer testified before the Subcommittee on that issue.

Less than a year later, these types of problems are receiving renewed scrutiny, prompted in part by the new Administration's request for public comments on whether and how to amend E.O. 12866. NRDC responded to the Administration's call for comments on how to improve the way our regulatory process functions. Below I provide an overview of the issues raised by the potential revision or replacement of the Executive Order, followed by a summary of the recommendations NRDC submitted to the Administration. I will then outline in some detail the basis for those recommendations.

I. OVERVIEW

On February 26th, the Office of Management and Budget ("OMB") placed a notice in the *Federal Register* that it would be making recommendations for a new Executive Order of federal regulatory review. NRDC submitted comments pursuant to that notice as OMB requested submissions on eight specific areas: the relationship between the Office of Information and Regulatory Affairs ("OIRA") and the agencies; disclosure and transparency; encouraging public participation in agency regulatory process; the role of cost-benefit analysis; the role of distributional considerations, fairness and concern for the interest of future generations; methods of ensuring that regulatory review does not produce undue delay; the role of the behavioral sciences in formulating regulatory policy; and the best tools for achieving public goals through the regulatory process.

In some ways the most significant issue area is the last area listed by OMB for requested comments, namely, identifying the best tools for achieving public goals through the regulatory process. The most important aspect of this issue has to do with the philosophy of government to be used by the Administration.

The previous Administration had an ideological view of the role of government in the economy which held that, on the face of it, government involvement in regulating economic behavior was necessarily undesirable. An extension of this view was that regulatory policy should have review procedures that would work presumptively against approving regulatory actions. The assumption behind this approach is that since government action so often does more harm than good, then it is better to prevent more regulation as a matter of course and to only allow those that pass an overwhelming burden of proof.

As current events indicate, this ideological view is ill-founded conceptually and poorly documented empirically. In contrast, sound public policy should embrace the concept that it is just as undesirable to under-regulate bad market behavior as it is to interfere needlessly with a well-functioning marketplace. Getting the amount of regulation "just right" should be the goal of public policy, with a presumption that having enough of the right kind of regulation was a sought after outcome.

In environmental policy specifically there is considerable amount of empirical evidence that points to the approaches that are most likely to achieve the right amount of regulation. It should be noted that past reports by OMB have amply documented a highly favorable ratio of benefits to costs resulting from environmental regulations. However, it should also be emphasized that using a cost-benefit test is one of the worst methods on which to rely for environmental decision-making.

As my testimony will discuss later in more detail, cost-benefit analysis (CBA) is an analytical tool that intellectually is designed to prevent too much regulation, and which as a result ends up professing much too little. This highly pronounced asymmetry of results is very undesirable from a public policy perspective and argues both for reforms in CBA procedures and for limitations on its use.

Fortunately the public record abounds with successful alternatives to the use of CBA as the decision-making criteria in environmental policy. In contrast to environmental statutes that rely on cost-benefit or risk assessment requirements, the most successful statutes are those that rely on health-based or technology-based standards. The goals of the latter statutes are much more obtainable and the burdens of proof are much more achievable than the former.

In addition, the precautionary principle acts as an ally to environmental policy and a philosophic alternative to CBA. The precautionary principle formalizes the common sense notion that it's better to be safe than sorry. This approach in effect shifts the burden of proof to those who may engage in undesirable social actions to prove that they are acceptable. This shift acts as an antidote to CBA's overly conservative intellectual framework that is preoccupied with preventing too much regulation. Again the empirical record is filled with statutes that have successfully taken a precautionary approach to public policy to provide a level of protection for society that is much more likely to be just right.

As for the issue concerning the relationship between OIRA and the agencies, it is the view of NRDC that OIRA in particular and the Executive Office of the President (EOP) more generally should respect the statutory authority of the federal agencies and their issue expertise during the rule-making process. That means that OIRA should focus its attention on ensuring compliance with statutory requirements, enhancing the efficiency of agency actions, and providing interagency coordination rather than micromanaging the content of agency decision-making in respect to specific policies.

NRDC also strongly supports the principles of transparency and disclosure in government. They provide an essential guarantee to the public that decision-making is conducted through the proper channels and informs the public of the true basis of government actions. Executive branch input on proposed agency regulations should be included in the Administrative record for judicial review of final agency rules, except where prohibited by law. Because such input is considered by the agency decision-maker, it is properly considered part of the "whole record" for judicial review pursuant to the *Administrative Procedure Act,* 5 U.S.C. § 706.

Equally important in a democracy is the role of public participation in the decision-making process. This is one of the most critical means by which the people affected by governmental decisions can make sure that their opinions are adequately taken into account by policy-makers.

Although details vary, many other recent commentaries generally agree with the views stated herein on the proper role of OIRA, the need to improve the use of cost-benefit analysis, and the virtues of greater disclosure, transparency and public participation.[1]

II. SUMMARY OF RECOMMENDATIONS

1. Sound public policy should embrace the concept that it is just as undesirable to under regulate bad market behavior as it is to interfere needlessly with a well-functioning marketplace. Getting the amount of regulation "just right" should be the goal of public policy, with a presumption that having enough of the right kind of regulation was a sought after outcome.
2. It is the view of NRDC that OIRA in particular and the Executive Office of the President (EOP) more generally should respect the statutory authority of the federal agencies and their issue expertise during the rule-making process.
3. NRDC also strongly supports the principles of transparency and disclosure in government. Executive branch input on proposed agency regulations should be included in the administrative record for judicial review of final agency rules, except where prohibited by law. Because such input is considered by the agency decision-maker, it is properly considered part of the "whole record" for judicial review pursuant to the *Administrative Procedure Act,* 5 U.S.C. § 706.
4. NRDC strongly supports increased public participation in the decision-making process, an important component to democracy.
5. NRDC strongly recommends that CBA not replace or supplement the decisional criteria of the underlying statutory authority, and that to the extent it is used as an informational tool, the Administration should work to reduce its serious flaws.
6. NRDC has requested that OMB conduct a review of past estimates of the costs of environmental compliance and compare them to actual costs, and then devise a methodology protocol for adjusting static cost estimates by more accurately adjusting for costs. Additional research can refine this concept over time, but the inclusion of a standard concept for making this adjustment could help to address the overstatement of costs that tends to systematically occur even in government estimates.
7. NRDC has requested that OMB lead a policy process to examine the inherent under-counting of benefits in cost-benefit analysis and to develop a methodology protocol by which decision-makers can systematically compensate for this deficiency in their use of the tool for informational purposes.

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[1] For example, see American Rivers et. al., *Transition to Green: Leading the Way to a Healthy Environment, a Green Economy and a Sustainable Future,* pp. 2-11–2-20, available at *http://www.saveourenvironment.org/assets/transition-to-green-full-report.pdf*; see also Richard L. Revesz & Michael A. Livermore, *Fixing Regulatory Review: Recommendations for the Next Administration,* Institute for Policy Integrity, Report No. 2 (New York University School of Law, Dec. 2008); Gary Bass et. al., OMB Watch, *Advancing the Public Interest Through Regulatory Reform* (2008), available at *www.ombwatch.org/regulatoryreformrecs.pdf*

8. In the interest of both sound regulatory processes and healthful environmental outcomes, NRDC has suggested that OMB review all the Bush Administration changes to Circular A–4 and consider completely repealing all the changes made to the Clinton Best Practices document, especially those related to discount rates, the value of statistical life-years, and false thresholds for analysis. OMB should also raise the current quantitative threshold for a major rule from $100 million and limit review to rules that cost more than this level without regard to qualitative criteria such as novel legal and policy issues.
9. NRDC has asked the Obama OMB to remove the use of these alternative practices from use and the record of analysis, as the whole purpose of these alternative analyses is to put benefit calculations step-by-step on a downward path in part by creating uncertainty about the results of the main analysis.
10. Any new executive order on federal regulatory review should reinforce the Administration's commitment to addressing distributional considerations, especially those that affect minorities, low-income populations, future generations and children. These considerations are particularly important for environmental regulation. NRDC also recommends committed implementation of Executive Order 12898, addressing environmental justice in minority populations and low-income populations, and Executive Order 13045, protecting children from environmental health risks and safety risks.
11. OMB should establish written, publicly available performance requirements and milestones for OIRA review of agency actions to ensure efficient and timely completion of duties, and there should be an accountability mechanism to ensure that OIRA meets these performance standards. As noted in these comments, these performance requirements should more closely and transparently document exchanges among OIRA, the agencies and outside parties, and should follow a formal process that has clear and reasonable deadlines and a manageable appeals process.

III. GENERAL ISSUES CONCERNING COST-BENEFIT ANALYSIS

CBA can be a useful tool for helping to organize information in the regulatory review process. In some fields, where the costs and benefits are fairly well known and are both of a strictly monetary nature, CBA may even serve as the suitable decision-making test. However, in many areas of social regulation including environmental policy, the flaws of CBA are so serious that they make it inappropriate to use as the decisional criteria. Therefore, NRDC strongly recommends that CBA not replace or supplement the decisional criteria of the underlying statutory authority, and to the extent it is used as an informational tool, that the Administration work to reduce its serious flaws.

The limitations on the use of cost-benefit analysis are extensive and in fact quite well known.[2] Of greatest concern is the extent to which CBA has inherent biases that overstate costs and undervalue benefits. OMB should be commended for inviting input on the key question that should be considered in the use of cost-benefit analysis: namely, what if anything can be done to compensate for its limitations and biases?

a. Overstatement of Costs

On the cost side, the most serious source of overstatement of costs is the overly static assumption about technology in government projections that overlooks the ability of innovation to lower costs over time. Again and again, dire predictions by industry about the effects of environmental protection on the economy have been shown after the fact to be greatly inflated. The eventual cost of the acid rain control program required by the *Clean Air Act Amendments of 1990* is a well-documented case in point, as it fell far below the estimates of either industry or government.[3]

The prowess of technology to lower costs over time is really driven by the efficiency of a market economy in responding to a new constraint, in this case a regulatory requirement that internalizes an externality. It is at least ironic that many advocates of the use of cost-benefit tests as decisional criteria in decision-making also have great faith in the reliance on free market behavior; and yet they have little regard for efficient, cost-minimizing progress by the market to respond to these internalized externalities.

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[2] See Lisa Heinzerling and Frank Ackerman, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection* (Georgetown Law Institute, 2002).

[3] *Id.,* p. 30.

To the extent that CBA will continue to be produced for decision-makers, it needs to move to a more systematic treatment of the role of technology in lowering costs over time. Therefore, NRDC has requested that OMB conduct a review of past estimates of the costs of environmental compliance and compare them to actual costs, and then devise a methodology protocol for adjusting static cost estimates by more accurately adjusting for costs. Additional research can refine this concept over time, but the inclusion of a standard concept for making this adjustment could help to address the overstatement of costs that tends to systematically occur in government estimates.

b. Undervaluing Benefits

One of the most troubling aspects of cost-benefit analysis is not simply its tendency to misstate costs and benefits, but to systematically overstate the costs while understating the benefits. This bias stems from the fact that in the search for a "net benefits" answer to the cost-benefit test the ruling practice is to first quantify all costs and benefits, and then to reduce them to a common denominator in the form of dollars. Therefore any term that does not lead itself to quantification, and then monetization, tends to fall out of the equation entirely.

Because the costs of regulations are usually the expense of compliance, costs do not generally suffer from the same "dropping out" effect in the net benefits equation, whereas benefits by their nature are often difficult to quantify, much less monetize. Even when we cannot precisely state certain kinds of benefits in monetary terms, we know the value to society is not *nothing*. The Administration must undertake an effort to rigorously correct this deficiency as noted below.

There are numerous reasons why the many different kinds of benefits that exist are difficult to either quantify or monetize. This difficulty is serious in estimating the benefits of reducing pollution, but it especially skews our ability to sensibly estimate the benefits of protecting natural resources. Values like preventing the degradation to landscapes, extinction of species, or loss of wilderness are notoriously problematic when it comes to assigning dollar values to them. It may be a fundamentally flawed concept to even try in some cases. However, to the extent that CBA is going to be performed, OMB must develop a better approach for presenting these benefits in the analysis.

Therefore, NRDC has requested that OMB lead a policy process to examine the inherent under-counting of benefits in cost-benefit analysis and to develop a methodology protocol by which decision-makers can systematically compensate for this deficiency in their use of the tool for informational purposes.

c. Implications for Environmental Policy

Past annual OMB reports to Congress regarding federal regulations have documented the overwhelming social benefits of environmental regulations compared to the costs. It is noteworthy that even the Bush OMB reports showed this result even though the techniques used to measure benefits have clearly failed to capture them all through proper quantification. The most recent OMB annual report on the costs and benefits of regulations showed once again that environmental benefits by themselves accounted for most of the benefits of social regulations over the last decade. Therefore, it is essential to understand that regulatory review policy is first and foremost environmental policy.

OMB generally divides the regulations it analyzes into three substantive areas: social regulations, tax compliance and economic regulations. Environmental regulations, including those issued by the EPA, fall under social regulations, which in FY 2007 accounted for 45 percent of all the regulation analyzed by OMB.

OMB analyzed 93 regulations over the ten-year period from October 1997 to September 2007, 40 of which came from EPA.[4] Of the EPA rules OMB analyzed 27 implemented by the Office of Air and Radiation and 10 rules from the Office of Water. The monetized benefits of these rules ranged between $83,298 and $529,567 million, with costs ranging from $32,252 and $35,058 million. The majority of large estimated benefits for EPA rules are accounted for the reduction in public exposure to a single air pollutant—fine particulate matter. Overall, OMB estimated that the 97 analyzed regulations in this ten year period garnered between $122,190 and $655,556 million in benefits, compared to $46,219 and $53,894 million in costs.[5]

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[4] Office of Information and Regulatory Affairs, Office of Management and Budget, *2008 Report to Congress on the Benefits and Costs of Federal Regulations, and Unfunded Mandates on State, Local, and Tribal Entities,* 2008, p. 4 (hereafter the OMB 2008 report). These were analyses of major rules, or rules that generated costs or benefits of at least $100 million. All amounts are stated in 2001 dollars.

[5] *Id.,* pp. iii–5.

For the most recent fiscal year, ranging from October 2006 to September 2007, OMB analyzed the benefits and costs of 40 major final rules. Of these, 18 final rules were categorized as 'social regulations,' with benefits estimated to range between $122,190 and $655,556 million, and costs ranging from $46,219 and $53,894 million. EPA continues to be responsible for the majority of estimated benefits and costs generated by federal regulation, as shown by the three rules promulgated by the EPA. The benefits of the EPA rules range from $21,143 and $170,391 million, with costs estimated between $7,475 and $7,584 million. There were three other environmental regulations promulgated, although two issued by the Department of Interior (DOI) were not monetized and therefore not included. The remaining rule, mandating energy efficiency standards for electric distribution transformers by the Department of Energy (DOE), has estimated benefits of $490 to $865 million, and costs of $381 to $428 million.[6]

Thus, the Environmental Protection Agency (EPA) by itself accounts for as much as 90 percent of the benefits all social regulations from a span of agencies that includes the Departments of Agriculture, Education, Energy, Health and Human Services, Housing and Urban Development, Justice, Labor, and Transportation. In absolute terms the upper end of the range of estimated benefits to society from EPA regulations over this 10-year period is an impressive $593 billion. Furthermore, even by the OMB report's admission, these EPA regulations in the aggregate yield a highly favorable ratio of benefits to costs. Even using the high-end estimate of costs, the ratio of benefits to costs ranges from over 2:1 to an astonishing 17:1.

Keeping in mind that even the lower end of this range is highly beneficial, what explains the large size of this range? The 2008 OMB report points to five factors, but one of the most disturbing is uncertainty about the value to be placed on saving lives.[7] Indeed the greatest contribution by EPA to total social benefits is derived specifically from air pollution controls that reduce such premature mortality. This point is notable not only because of the philosophic importance of preserving life, but also because it underscores the significance of getting the methodology right for estimating the value of protecting it. It also helps to explain the motivation of the Bush Administration in devising new methods for lowering the value attributable to preventing premature mortality, so that it could justify its repeated attempts to weaken air pollution regulations.

d. Bush Administration's Undermining of CBA

The Bush Administration took a multi-faceted approach to warping the use of cost-benefit analysis. Here NRDC would like to highlight two examples which the Administration should consider correcting as part of its review of the regulatory process. One example is the set of "best practices" that the OMB instructs agencies to follow in its calculations of the benefits of regulations (e.g., Circular A–4). The other is distorted estimates of the benefits of air pollution regulations that the Bush Administration left on the books.

In 2003 the Bush OMB revised Clinton Administration regulatory review procedures set out pursuant to Executive Order ("E.O.") 12866. The Clinton procedures were set out in detail in a 1996 OMB document that described best practices for agencies to follow in their calculations of the costs and benefits of regulations, and an OMB 2000 guidance issued to agencies concerning how to implement these practices.[8] The Bush Administration's changes were quite subtle but significant.

Three changes in particular represent the worst changes of the best practices:

- First, OIRA changed the way in which the discount rate is applied for purposes of discounting streams of future benefits.[9]
- Second, OIRA gave greater emphasis to the Value of a Statistical Life-Year (VSLY) as the measure of the benefit of reducing the risk of loss of life, as opposed to the standard Value of a Statistical Life (VSL).[10]

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[6] *Id.,* pp. 7–11.
[7] *Id.,* pp. 7–8.
[8] Office of Management and Budget, Economic Analysis of Federal Regulations Under Executive Order 12866, January 11, 1996; and Jacob J. Lew, Office of Management and Budget, *Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statement,* March 2000.
[9] Office of Information and Regulatory Affairs, Office of Management and Budget, *2003 Report to Congress on the Benefits and Costs of Federal Regulations, and Unfunded Mandates on State, Local, and Tribal Entities,* 2003 (hereafter the OMB 2003 report), pp. 150–153.
[10] *Id.,* p. 147.

- Third, OIRA imposed without justification a completely new set of statistical requirements for rules with impact above a $1 billion threshold.[11]

In making changes to the Clinton Administration's Best Practices guidance, the Bush OMB made two claims in its defense: (1) the changes are not really any different than the policies of the Clinton Administration; and (2) OMB policies are just suggestions and agencies are free to do what they want. If valid, these two arguments taken together would completely obviate the point of making any changes in the first place. The reality was that the changes were specifically meant at least in part to undermine the effectiveness of environmental policy.[12]

The Bush Administration's Circular A–4 demonstrates once again how dramatically the environmental polices and the regulatory approaches of the Bush Administration were entwined. In Circular A–4, of the 35 examples given of how to do a regulatory review procedure or why the procedure is necessary to do, 32 were in the field of environmental policy, and 25 of those were EPA-specific.[13]

Therefore, in the interest of both sound regulatory processes and healthful environmental outcomes, NRDC has suggested to this Administration that OMB review all the Bush Administration changes in Circular A–4 and consider completely repealing all the changes made to the Clinton Best Practices document.

1. The Rate of Discounting Future Benefits

Before the Bush Administration, OMB policy on intra-generational benefit streams regarding the use of a discount rate recommended a seven percent rate based on its claim that seven percent is close to the average before-tax rate of return to capital in the U.S.[14] This directive was plainly out of line with more recent actual rate of return experience and was in need of an update. Even now the 10-year Treasury rate hovers stubbornly below three percent.

The fix of the Bush OIRA, however, was wholly inadequate to the task; it directed agencies to provide net benefits estimates using both the out-of-date seven percent rate and added to it a new three percent discount rate. However, in the past agencies were never really barred from looking at rates other than seven percent as long as they also included an analysis with OMB's seven percent number. As EPA's 2000 guidelines for preparing economic analysis notes after recommending the use of a consumptive rate of interest: "EPA economic analyses therefore should provide estimates of the present values of costs and benefits using both a two to three percent rate and OMB's guidance on discounting [using a seven percent rate]."[15]

Thus, the Bush revision had the effect of further enshrining the dictate that the flawed seven percent rate must be included in agency analysis. Also it puts an implied floor on the lower discount that can be used at three percent, even though one could argue that at times even that rate is too high. OMB should instead take a hard look at what a more reasonable discount rate should be, and allow agencies much greater flexibility in choice of a suitable discount rate for the specific policy under review.

NRDC and many others have profound ethical, pragmatic, policy, and legal concerns about OMB's approach to discounting the value of future lives lost. In particular, OMB should revise the way in which it views the practice of discounting the value of lives that are lost in the future from exposures to hazards in the present. The discounting of future lives (especially if insupportably high discount rates such as seven percent are applied) amounts to an incredible vanishing act where the calculations of such values are concerned.

Not surprisingly, a substantial body of research related to the social rate of time preferences supports the view that individuals discount the value of future lives by a rate far below the seven percent rate set by OMB in Circular A–94. In fact, given

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[11] *Id.,* p. 157.

[12] To rebut fully the first claim above that the Bush changes were not much different from the Clinton policy, one must carefully compare the Bush language to Clinton language that it revised, since changes in context at times altered the meaning of key passages in certain sections. Also, to understand the implications of the Bush changes for environmental regulatory review, one must contrast the revised OMB directives with the existing EPA guidelines on economic analysis from September 2000. (See EPA, *Guidelines for Preparing Economic Analyses* (Sept. 2000)). The EPA guidelines are an outstanding summary of currently accepted approaches to economic analysis. Following a review of the revised guidelines, EPA's Environmental Economics Advisory Committee of the Science Advisory Board described the guidelines as "excellent" and concluded that the guidelines "succeed in reflecting methods and practices that enjoy widespread acceptance in the environmental economics profession."

[13] OMB 2003 Report, Circular A–4, *passim.*

[14] OMB, *Economic Analysis of Federal Regulations Under Executive Order 12866,* Section III.A.3.a. (1996), and OMB, *Special Case: Intergenerational Analysis,* Section A.5.b (2000).

[15] See *supra* note 12, Section 6.3.1.5, p. 48.

the low level of interest rates for the last several years, it would be surprising if up-to-date research on social time preference did not provide a robust endorsement of the view that the discount rate for the loss of future lives should be extremely small if not zero. Therefore, as a way of helping to correct the systematic biases in cost-benefit analysis, NRDC has requested that OMB recommend the use of a discount rate of zero for the value of future lives until the technical and ethical issues related to this practice are satisfactorily resolved.

For issues that have especially long time horizons that are inter-generational in nature, Circular A–4 has suggested a different approach. While still requiring the use of the three percent and seven percent rates as in the case of intra-generational benefits, Circular A–4 would allow rates as low as one percent in certain cases. Although this approach is better than simply limiting the analysis to three percent and seven percent rates, it again falls short of the mark that OMB should set for this analysis. Indeed, it may be worse than current agency practice.

The OMB 1996 best practices document and its 2000 guidelines are somewhat circumspect on the issue of the correct discount rate for inter-generational analysis and allow agencies some leeway. Specifically, these documents allow the agency either to use the same discount rate analysis that it would use for intra-generational benefits while addressing equity issues separately, or to use "a special social rate of time preference." [16] In implementing this advice, the EPA guidance document has recommended that analyses should include a "no discounting" scenario by displaying a stream of costs and benefits over time (which EPA notes is not the same as a discount rate of zero). It also recommends the inclusion of other scenarios beyond the seven percent and three percent rates, namely, those "in the interval one-half to three percent as prescribed in optimal growth models." [17]

Over long time horizons, even the relatively low discount rate of one percent can drive the net present value estimate of benefits down to almost nothing. This statistical obliteration of the value of protecting future lives becomes exaggerated in the extreme when policies with extended timelines like nuclear waste disposal or climate change are involved. The inevitable but insupportable conclusion seems to be that anything the present generation does that adversely effects future generations is acceptable because the value of the benefit to future lives does not amount to much.[18]

2. Shift from Value of a Statistical Life to Life-Years

One of the standard ways for agencies to measure the benefit from reducing the risk of premature mortality is the use of the Value of a Statistical Life (VSL). The estimate for the VSL can be calculated using a number of different kinds of willingness-to-pay surveys, such as those that rely on labor market (i.e., wage-risk) studies or contingent valuation. The standard use of VSL has itself been subject to the criticism that it underestimates the benefit of reducing the risk of mortality because of income, age, and occupational biases that are built into some of the kinds of studies used to construct a value for it.

An alternative to the use of VSL is the concept of the Value of a Statistical Life-Year (VSLY). VSLY in effect measures the benefit of reducing the risk of premature death based on the number of years a hypothetical person has to live, instead of assigning an average VSL to everyone.

VSLY deserves particular attention because it is one of the most controversial proposed changes to the guidelines. Under VSLY, all else being equal, the older a target population is, the lower the calculated benefit of protecting them. Therefore, protections for the elderly would be subjected to a special devaluation under this technique. VSLY also serves as the basis for another technique for lowering the value of life, the Quality Adjusted Life Year (QALY). Once one establishes VSLY as a method for calculating the value of reducing the risk of mortality, then one can take the additional step of adjusting the calculation of the value of remaining life-years by their "quality." Again, since the quality of life of the elderly can be said to be less than younger people, the life of the elderly can be lowered again.

The discussion of the value of a human life and which measure for it is appropriate is at times troubling and often analytically slippery. The troubling aspect comes from the fact that it is an issue that is not economic in nature but rather

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[16] See *supra* note 14, Section III.A.3.c; and OMB 2000, A.5.b. Special Case: Intergenerational Analysis.

[17] See *supra* note 14, Section 6.3.2.4, p. 52.

[18] For a discussion of the implications of discounting on decision-making on climate policy see Richard Newell and William Pizer, *Discounting the Benefits of Climate Change Mitigation: How Much do Uncertain Rates Increase Valuations?* (The Pew Center on Global Climate Change, December 2001).

philosophic. NRDC holds the view that all life is precious and therefore deserves equal protection under the law. This view by itself is a sufficient argument against using VSLY or QALY analysis and NRDC has urged the Administration to adopt this view.

Nonetheless, the value of life as it relates to age is a subject matter of economic study, and therefore it is imperative that the right kind of economic analysis be brought to bear on it. Because the analytical framework for this discussion is so slippery, it is critical to ask the question in the right way so that the thinking about it is also correct.

The supporters of VSLY like to frame the question around a true if partial notion that generally speaking one would rather die later rather than sooner. This notion is so common-sensical that it is the basis of an old joke, in which the robber tells his victim that it's either his money or his life, to which the victim says, "Take my life, I'm saving my money for my old age."

The proposition that one would rather die later than sooner is valid as far as it goes, but one can also stretch it too far. It's true that society has an interest in ensuring that social investments will get younger people to an older age. It's not true that the premise of this conclusion is that the lives of younger people are more valuable to save because they have more years left in them. That incorrect premise leads to following a fair question about when you would rather die with a false one, namely: if you could only save a single person, should it be an older person or a younger person?

There are many wrong premises to this second question as posed, one of which is that society cannot afford to make the investments needed to extend the life of both younger and older people. But the main faulty premise comes about by not asking the right second question after the question about whether you would die sooner or later. The proper follow up question to ask is: now that it's later, are you more willing to die than you were before?

It should not be surprising that the answer that most often comes back to this question is, "Not really." The fact that there is a smaller amount of years left in your supply seems not to have reduced the demand you still have for continuing to use the ones you have left. In some ways it has made the value much higher of each scarce remaining year.

One way economists look at the issue is to consider the social rate of time preference. Reliable empirical data in this field do not support the premise of either QALY or VSLY. One study by some of the leading experts on this subject concluded quite simply that the data do not support discounting the value of life based on the numbers of years someone has remaining to live.[19]

Yes, society has an interest in helping younger people to live longer, so they can "enjoy their money in their old age." However, since individuals continue to want to die later rather than sooner even as they age, it is fundamentally wrong-headed to assume that society can only afford to invest in saving either the young or the old. Once we save the lives of the young, we should not allow ourselves to fall victim to the other side of the robber's choice, telling them as they approach their old-age, there's no more money left to invest in saving them.

3. False Thresholds

E.O. 12866 already requires a regulatory impact analysis (RIA) for major rules above $100 million a year or under certain qualitative conditions. There are several problems with these criteria.

- First, while it is reasonable to have a threshold figure for what is a major rule, the $100 million figure has become out of date and needs to be revised upward based on changes to inflation since the time of the data used to set the original threshold level. A procedure should also be put into place that will automatically allow this figure to rise according to an established price index.
- Second, it is sufficient for the minimum threshold to be limited to costs alone. After all, if the costs are below $100 million and the benefits are above, what difference does it matter how much higher the benefits are above that level?
- Third, the qualitative criteria should be deleted since they are overly vague and put almost no constraints on the potential reach of the review process, whether it makes sense or not. The qualitative criteria that a review can be necessitated by novel legal or policy issues is especially troublesome, and

[19] See Anna Alberini, Maureen Cropper, Alan Krupnick, and Nathalie B. Simon, Resources for the Future, Discussion Paper 02–19, April 2002.

gives OIRA an almost unlimited reach into agency processes in a way not contemplated by Congress. Maximum Available Control Technology proposals are often caught in this net even if they do not exceed $100 million a year in costs and are quite beneficial in their result.

In addition to the threshold for regulatory review contained in E.O. 12866, the Bush Administration required a whole new form of uncertainty analysis for rules costing more than $1 billion a year, even though RIAs under E.O. 12866 already had to address issues of uncertainty in that analysis.[20] This new requirement appears completely arbitrary and serves simply to clog the regulatory process.

No reason was ever given by OMB for why the existing analysis requirement would be deficient for rules of a larger size. Moreover, no justification was given for hinging a formal analysis on the level of cost as opposed to level of cost combined with the ratio of benefits to costs. It is a form of false precision and a waste of resources to do a formal analysis of the exact distribution of the range of uncertainties if you already know the benefits are going to exceed the cost at any level. Finally, no justification was provided for the $1 billion figure being the correct threshold, although it is likely that environmental regulations would be disproportionately impacted by this requirement and therefore it is reasonable to conclude that was the motive.

EPA already had a method for addressing uncertainty analysis. As EPA noted in its 2000 guidelines: "If, however, the implications of uncertainty are not adequately captured in the initial assessment then a more sophisticated analysis should be undertaken . . .. However, these methods can be difficult to implement, often requiring more data than are available to the analyst."[21] Instead of relying on an arbitrary figure to determine whether a higher standard for analysis should apply (e.g., the $1 billion threshold), EPA applied a more reasonable approach by determining first whether the initial assessment passed a test of adequacy in capturing the implications of uncertainty. Where the benefits far exceed the costs and the data are lacking for additional formal analysis, EPA could reasonably decide that the initial assessment was more than adequate.

The effect of the Bush Administration change is to threaten rule-makings with delay by sending the agency back to collect data that may not be available, even if the available data are sufficient to determine the results of the rule would be positive. As OMB ominously notes in its guidelines, "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."[22]

The connection to the potential for tying up environmental controls is not accidental. In its 2003 proposal to change the Clinton guidelines, the Bush OMB explicitly pointed to analysis of air pollution regulations as an example of the problem with uncertainty about future emissions, changes in air quality, resulting health effects, and the "economic and social value of the change in health outcomes." In reality, it was never made clear what other type of rules would even meet this threshold test for extra uncertainty analysis.[23]

The Bush Administration's decision to single out regulations for unfavorable treatment simply on the basis of the size of costs, seems to have been an attempt by the Bush White House to justify after the fact a policy it already had in place. In at least one significant case, EPA's rule to control polluted runoff from construction and development sites, the Bush OMB deleted the most effective and beneficial provision of the rule drafted by EPA simply based on the size of the costs of the provision. The Bush Administration took this indefensible action despite the fact that this action had no basis in the statute as part of its decisional criteria and that even so the provision would have clearly passed any reasonable cost-benefit test.[24] Furthermore some rules like this one may have total costs that seem large in dollars, but that are in fact quite small in comparison to the total size of the industry.

Thus the implication of uncertainty requirements in the hands of a hostile OMB is that arbitrary procedures can be institutionalized as a reason for blocking rules regardless of statutory directives or overall benefits to society. The Obama OMB should avoid new uncertainty concepts that could lead to such results by raising the current $100 million threshold and eliminating the formal uncertainty requirement for rules that exceed $1 billion in costs.

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[20] See *supra* note 8, p. 158.

[21] See *supra* note 12, Section 5.5.1, pp. 27–28.

[22] See *supra* note 8, p. 156.

[23] OMB Draft 2003 Report to Congress on the Costs and benefits of Federal Regulations, 68 *Fed. Reg.* 5,492, 5,524 (Feb. 3, 2003).

[24] For more information on this issue see Dr. Frank Ackerman, *Uses and Abuses of Economic Analysis in Setting Stormwater Regulations,* December 18, 2002.

4. Faulty "Alternative Analysis" Left on the Books

It is instructive to consider the implications of the Bush Administration's changes to the regulatory review process in the context of specific applications during administration policy reviews. Once again, air pollution controls offer a keen illustration of the point of what can happen when the government manipulates the price tag put on human life.

In the fall of 2002 the Bush OIRA insisted that EPA begin to include an "alternative analysis" in its environmental reviews that employed some new techniques to drive down the calculation of benefits. In these alternative analyses, when the entire range of techniques was employed, the estimated benefits of controlling air pollution astonishingly dropped by over an order of magnitude. Three cases in which EPA used a variation of this alternative analysis include the technical justification for the Clear Skies Initiative (CSI), the off-road engine rule (a.k.a. the snowmobile rule), and the off-road diesel rule.[25]

Requiring an alternative analysis by the agency could be a valuable exercise if it were done with the intention of providing a more balanced range of information to policy-makers. Such an effort would be directed to correcting the existing biases of CBA, in this case the underestimation of benefits. There are many ways in which OIRA could direct its efforts to correcting these biases, as has been suggested in prior comments submitted to OIRA by NRDC and others.

Unfortunately, the Bush OIRA made no attempt to produce a set of techniques or alternative analyses that would have the effect of raising estimates of benefits by reducing built-in biases. In fact, OIRA does not even attempt to provide a symmetrical pair of alternative analyses, one that reduces the estimate of benefits in the way OIRA would prefer and one that raises estimates of benefits by correcting anti-benefit biases. Either of these approaches would produce a more complete range of benefit estimates for policy-makers to consider than the Bush OIRA's alternative approach by itself. Of course, the best approach is to simply correct the bias toward underestimation without including OIRA's new analysis, and therefore provide the most honest set of numbers to be used by policy-makers.

In the alternative analysis advocated by OIRA, EPA used three principal steps to lower its own original benefit estimate. In each instance, the approach in the original analysis is a far more reliable calculator of benefits than the alternative analysis. We can see how this process will work over time by going through the alternative analysis in the EPA air pollution proposals step-by-step.

In the first step of both the standard and the alternative analysis, EPA estimates the value of reducing the risk of fatalities in terms of statistical lives. For the standard analysis, this estimate is based on 26 studies, 21 of which are labor market/wage-risk studies and five of which are contingent valuation studies. The alternative analysis, however, only based its estimate on the contingent valuation studies, reducing the VSL almost in half from $6.1 million to $3.7 million. The second step in the alternative analysis adjusts the VSL estimate even further downward based on the fact that many of the people saved by the rule would be elderly, dropping the value to $2.3 million for seniors. The last step shifted the entire analysis from a VSL to a VSLY analysis, which in its worst case scenario can ultimately end up with a valuation of $130,000.

One could also argue that there is no real harm in leaving these alternative analyses and their techniques on the books, since EPA could always ultimately rely on its main analysis. However, the whole purpose of these alternative analyses is to put benefit calculations step-by-step on a downward path in part by creating uncertainty about the results of the main analysis. In addition, it makes no sense to waste staff time and resources performing unhelpful and misleading analyses. Therefore, NRDC has asked that the Obama OMB remove the use of these alternative practices from use and the record of analysis. Indeed, the Bush OMB apparently no longer considered its alternative analysis to be the "alternative," but rather equal or more reliable from their point of view. Proof of this attitude can be seen in the 2003 OMB Annual Report to Congress in the section explaining OMB's method for summing up the cost and benefits of regulations.[26] In most cases, OMB simply accepted the calculations submitted by the agency. However, in the case of EPA

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[25] For references in this section see: EPA, *Technical Addendum: Methodologies for the Benefit Analysis of the Clear Skies Initiative* (September 2002); and EPA, *Final Regulatory Support Document, Final Rule for Cleaner Large Industrial Spark-Ignition Engines, Recreational Marine Diesel Engines, and Recreational Vehicles,* 67 FR 217 (November 8, 2002).

[26] See *supra* note 9.

estimates concerning air pollution benefits OMB created a new lower figure for the range of estimates using its new technique for lowering the value of life.[27]

Thus we can see how the regulatory review procedures adopted by the Bush Administration were meant to set the stage for a more far reaching undermining of environmental protection in general and air pollution controls in particular. It would start by using the Bush OMB alternative analysis to lower benefits and then to argue there is uncertainty about the regulations. Next, the regulation may be subjected to a formal uncertainty analysis for which there would be insufficient data. Then, the agency's rule would be delayed until more data are collected, perhaps endlessly. The approach is an unbalanced trap even for rules that are quite beneficial, with weaker environmental protections one of the results.

IV. ACTION IN THE FACE OF UNCERTAINTY

Because of the inherent biases of CBA, it is a defective tool to use in decision-making on the environment. Regulations that are based on health or technology standards are much more reasonable and effective approaches on which to rely for decision-making.

One of the reasons opponents of regulatory protections often argue for the use of CBA as the decisional criteria in rule-makings is because of its extensive and at times oppressive requirements for information. The CBA technique lends itself readily to the endless argument that more information is needed or that scientific understanding is imperfect. Special interests often try to commandeer the risk assessment process to create an impenetrable labyrinth of procedures or political atmosphere of uncertainty. Ultimately the success of the system requires that opponents of regulation not be allowed to relentlessly demand an unobtainable level of knowledge as a precondition for action.

a. Too Little Precaution, Too Much Time

The desire to have a high degree of certainty in regulatory decision-making prior to taking action builds an overly conservative presumption into the system that is very deep. This presumption is not necessarily reasonable on the face of it. It would be admittedly expensive and inefficient for society to endure a regulatory burden that was not supported by sufficiently positive results. Yet it could also be expensive and inefficient for society not to adopt a level of regulation sufficient to reap all of the positive results potentially available. After all, pollution externalities for example impose a huge and inefficient cost on society in terms of public health and ecological effects, some of which can be irreversible.

Judging from the information provided in past OMB reports on the costs and benefits of regulations, we seem to be in little danger of erring on the side of too much environmental regulation, given the extremely high ratio of benefits to costs that have resulted from existing social regulations. Indeed, the conservative presumption of the system has most likely denied society the benefits that would accompany additional, well-designed regulations to address social externalities like environmental degradation.

One of the principal ways in which the excessively biased nature of the system can be partially offset is through the use of precaution in regulatory policy. The concept of precaution recognizes that knowledge is never perfect, and yet there is often a need to take action before certainty is complete. Precaution introduces into this decision-making process the common sense notion that in some matters it is better to be safe than sorry. The precautionary principle is a statement of the fact that regulatory policy needs to explicitly incorporate a measure of precaution into the decision-making structure in order to reduce risk to society, since that structure left to itself is much more likely to have too little precaution and too much risk.

Another EOP office, the Council on Environmental Quality (CEQ), published a ground-breaking monograph on the subject of risk analysis in 1989, *Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental*

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[27] In the report, OMB notes that it has revised the benefits from reductions in nitrogen oxide ("NO_X") emissions to reflect a range of estimates from these recent EPA analyses. It then acknowledges: "Because of the importance of this endpoint and the considerable uncertainty among economists and policy-makers as to the appropriate way to value reductions in mortality risks, EPA has developed alternative estimates for its 'Clear Skies' legislation that show the potential importance of some of the underlying assumptions . . .. OMB has used this analysis to identify an alternative estimate of the benefits from NO_X reductions, . . . a difference in the estimates of roughly a factor of five." This is a huge reduction in the estimated level of benefits, stated under the guise of uncertainty and submitted to Congress as if it is a figure that should be considered with equal merit as the one relied on by the agency.

Risks.[28] In that publication, CEQ catalogued a long list of different "dimensions" of risk, showing how different the nature of risk can be in different situations. These dimensional traits include severity, potential for catastrophe, reversibility, impact on future generations, voluntariness, and controllability. This catalogue shows that it is not sufficient to focus simply on generic ways that precaution may be used in risk assessment and management; rather it is necessary to start with an understanding of the different kinds of risk that need to be assessed or managed, and then separately analyze the way in which precaution applies in each case.

The failure to appreciate that a one-size-fits-all approach to risk assessment and management does not work well is one of the main ways in which risk policy goes wrong. The Office of Science and Technology Policy (OSTP), yet another EOP office historically active on risk management issues, noted in a 1995 white paper: "[E]ach law establishes somewhat different criteria for making risk management decisions. The extent to which such an analysis is permissible or productive in light of statutory provisions must influence a decision to undertake a risk assessment. There are advantages to having some degree of consistency in the statutory provisions that guide risk reduction activities in the Federal Government . . .. However, the specific methods to be used in evaluating risks are best developed in agencies on a statute-by-statute basis so that the analytical approach is appropriate to the types of risks addressed."[29]

Indeed, the Executive Office of the President (EOP), which includes OMB, CEQ, and OSTP, generally lacks legal power to dictate risk-based decision-making to the agencies. In most cases, such policy is properly rooted instead in the statutory requirements of different agencies. When courts assess whether an agency has acted lawfully, primary consideration is given to whether Congress has already expressed the answer regarding the decision-making criteria through legislation. Agencies interpret this as a mandate to regulate in protection of the public health—even when there is less than absolute certainty as to the probability that a given harm will occur.

Congress and agencies must constantly consider how much precaution to use in regulation. Moreover Congress typically has remedied ineffective health and safety statutes by *increasing* the amount of precaution in a statute. From decades of trial and error, we have learned two important lessons: regulation that accommodates uncertainty succeeds, and regulation dependent upon absolute proof of risk or a rigid cost-benefit test fails to protect the public sensibly.

Congressional mandates to protect health in the face of uncertainty have been consistently upheld in the Supreme Court. In both the *Lead Industries Association* and *American Trucking* decisions, the Court held that the executive may not deviate from the degree of public health protection mandated by congress when implementing a regulation.

b. Case Studies

Many legitimate opportunities to protect public health and safety are hampered by the requirements of *too much* proof of harm, *too much* balancing of environmental risks with "other factors," and *too little* requisite precaution. Examples include the regulation of hazardous air pollutants, lead and other toxics. Based on these case studies, one can see that the alternative to reasonable regulation ends up as inaction, delay, and irreparable harm to the public health and the environment.

As a result of this harsh history lesson, Congress has routinely mandated by statute the standard required for agencies to act under a particular law. Courts have consistently held that a margin of safety adequate to the task of protecting the public health as prescribed by Congress is one that enables an agency to regulate without meeting an unreasonable threshold of certainty.[30]

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[28] Council On Environmental Quality, *Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks,* 1989, pp. 10–11.

[29] See Office of Science and Technology Policy, *Science, Risk, and Public Policy,* March 1995, p. 7.

[30] Examples of Legislated Standards in Environmental Statutes:

Clean Air Act

§ **108** requires NAAQS for pollutants with "an adverse effect on public health or welfare," meaning proof of actual harm before agency action may be taken. *Ethyl Corp v. EPA,* 541 F.2d 1, 14 (D.C. Cir. 1976) (Wright, J.) In other words, demonstration of an effect is required; but demonstrating the *certainty* of the effect is not, as the *Ethyl* case described below proves. The minimum level of certainty required to regulate a chemical was established by the Supreme Court in the so-called Benzene decision. *Industrial Union Department, AFL–CIO v. American Petroleum Institute,* 448 U.S. 607 (1980). The Court held that a mere showing of harm is insufficient cause to regulate a chemical, that the agency, in this case OSHA, must first demonstrate "sig-

In this section, NRDC gives examples as case studies on how to and how not to regulate social risks.

1. Air Toxics: Congress Learns Its Lesson

Before the 1990 amendments to the *Clean Air Act,* EPA was charged by Congress with creating National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the air pollutants listed within the Toxic Release Inventory. Due to the uncertainty about the amount of toxic exposure required to produce harm, EPA assumed the exposure standard to be zero. But EPA was highly reluctant to justify action regarding a zero risk exposure based on risk analysis. As of 1990, only eight of 650 toxic materials had been successfully regulated—this despite reams of data supporting their toxicities. With an unreasonable burden of proof put in place regarding certainty, NESHAPs was a plain failure in practice.

As a result of the agencies' inability to meet its congressional mandate, Congress was compelled to act. Congress took notice of the slow rate of progress, identified the inability to regulate in the face of uncertainty as the problem, and instead mandated toxic standards be generated using technology-forcing requirements. Since the 1990 amendments, 46 air toxics standards have been set for 82 different types of major industrial sources.

The NESHAPs story ends with a happy ending: Congress realized that more action was necessary and responded appropriately. But note that once again it was beyond the scope of EPA (or, for that matter, OMB) to alter the *degree* of precaution mandated by the statute—only Congress could alter the legislated level of risk and uncertainty.

2. Lead: When Agencies Resist Precautionary Regulation

In contrast, neither Congress nor executive agencies were able to regulate environmental exposures to lead before nearly a century of debilitating exposure had taken its toll. The use of lead in gasoline is therefore the single best example of the need for government regulation in the face of uncertainty.[31]

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nificant" risk, and then demonstrate that the proposed alternative would cause a significant risk reduction.

Whitman v. American Trucking Associations, 531 U.S. 437, 465 (2001) (Scalia, J.): "The language, as one scholar has noted, "is absolute." D. Currie, Air Pollution: Federal Law and Analysis 4–15 (1981). The EPA, "based on" the information about health effects contained in the technical "criteria" documents compiled under § 108(a)(2), 42 U.S.C. § 7408(a)(2), is to identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an "adequate" margin of safety, and set the standard at that level."

"Did Congress pass the *Clean Air* and *Clean Water Acts* out of concern that pollution hurts the economy, or out of a fundamental concern for the health of the citizenry?" *Rancho Viejo v. Norton,* 2003 WL 1699326 (2003) (Garland, J.).

See also:

§ 109(b)(1) (codified at 42 USC § 7409): "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."

§ 109(b)(2): "Any national secondary ambient air quality standard . . . shall specify a level of air quality the attainment and maintenance of which . . . is requisite to protect the public welfare from *any known or anticipated adverse effects* associated with the presence of such air pollutant in the ambient air."

Occupational Safety and Health Act § 6(b)(5): requires agency to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer any impairment of health."

Industrial Union Dept., AFL–CIO v. American Petroleum Institute, 448 U.S. 607, 646 (1980): "Congress was concerned, not with absolute safety, but with the elimination of significant harm."

Safe Drinking Water Act

§300g-1(b)(4)(A): "Each maximum contaminant level goal 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.*

Natural Resources Defense Council, Inc. v. E.P.A., 824 F.2d 1211, 1216 (D.C. Cir. 1987): "The *Drinking Water Act,* by contrast, directs the Administrator to establish a recommended level for "each contaminant which, in his judgment . . . *may have any* adverse effect on the health of persons." 42 U.S.C. § 300g-1(b)(1)(B) (emphasis added). This language is inconsistent with a requirement that the Administrator make a threshold finding of significant risk."

[31] Background on lead in gasoline taken from Peter Montague, *Precautionary Action Not Taken: Corporate Structure And the Case Study of Tetraethyl Lead In the U.S.A.,* in Carolyn Raffensperger and Joel Tickner, Eds., *Protecting Public Health and the Environment: Implementing the Precautionary Principle,* at pp. 294–303 (Washington, D.C.: Island Press, 1999).

Lead in gasoline was hazardous from the get-go: within a year of first producing leaded gasoline in 1923, eighty percent of workers at DuPont's New Jersey factory were poisoned, resulting in more than three hundred cases of death or severe nerve damage. Although lead production was temporarily halted in 1925 due to overwhelming opposition from the scientific community, production of lead gasoline resumed the following year after the Surgeon General declined to restrict its use, citing the need for more definite proof.

A half-century later, even after lead was regulated as a hazardous fuel additive because lead was "reasonably anticipated to endanger the public health or welfare," EPA nevertheless resisted classifying lead as an air pollutant until NRDC successfully sued to compel its phase-out.[32] Now, lead is accepted by the agency as a significant environmental threat, including especially to the health of children.

Regulation of lead provided the watershed legal challenge to uncertainty in environmental regulation. This challenge culminated in two separate appeals by the lead industry to the D.C. Circuit, each attempting to require EPA to provide more definite causality before lead could be regulated.[33]

In *Ethyl Corp. v. EPA,* Judge Skelly Wright warned that effective regulation would be "impossible" if courts demanded a "rigorous step-by-step proof of cause and effect." As a result, agencies may now regulate in the face of uncertainty if they use "available evidence to make rational assessments" concerning potential risks.[34] The threshold question was NOT what quantity of lead caused the harm, nor what percentage of that quantity was from gasoline, but whether the lead posed a "significant risk of harm" to the public health.[35]

The requirement to follow statutory mandates for precautionary regulation found further support in *Lead Industries Association v. EPA.*[36] Here, Judge Wright again agreed with EPA that setting a standard under the *Clean Air Act* with "an absence of adverse effects" does not require showing that "the effects on which the standards are *clearly* harmful or *clearly* adverse" (emphasis in original).[37]

3. Toxics: Failing to Protect Public Health

In theory, the *Toxic Substances Control Act* ("TSCA") authorizes the EPA to obtain information on the risks of industrial chemicals and to regulate usage of those chemicals that the agency determines present an unreasonable risk to public health and safety. However, EPA has yet to achieve either of these goals due to a severe lack of regulatory authority to carry out these tasks. There have been approximately 83,000 chemicals currently listed in EPA's TSCA inventory since its implementation in 1979.[38] About 21,000 of these chemicals are new to TSCA's Chemical Substances Inventory since 1976.[39] Of these, 67 percent do not have any test data on file regarding the safety and health effects of the chemical, and 85 percent do not have any data relating to the chemical's effects on public health. EPA has used its authority to test chemicals for unreasonable risk less than 200 times due to the cumbersome process of rule-making required to commence testing.

While the agency has the authority to regulate chemicals under Section 6 of TSCA, the 'unreasonable risk' threshold that the agency must meet is extremely high. The cost-benefit analysis required to meet this standard is extensive, with substantial evidence involved to justify regulation and withstand judicial review. As a result, EPA has only issued regulations to limit the use or production of five existing chemicals to date out of 83,000.[40] This failure to regulate dangerous substances is most pronounced in EPA's effort to regulate and ban asbestos, a known deadly chemical. In *Corrosion Proof Fittings v. EPA,*[41] the Court ruled that EPA did not have sufficient evidence to out-right ban the use of asbestos and therefore did not meet its burden in demonstrating that banning the substance was the least burdensome regulatory action. This was after ten years of data gathering by the agency.[42]

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[32] *NRDC v. Train,* 545 F.2d 320 (2d Cir. 1976).
[33] *Ethyl Corp v. EPA,* 541 F.2d 1 (D.C. Cir. 1976).
[34] *Id.,* at 28.
[35] *Id.,* at 7.
[36] *Lead Industries Association v. EPA.,* 647 F.2d 1130 (D.C. Cir. 1980).
[37] *Id.,* at 1153.
[38] GAO Report, *Toxic Substances Control Reform,* p. 3 (Feb. 26, 2009).
[39] *Id.*
[40] *Id.,* at 10.
[41] 947 F.2d 1201 (5th Cir. 1991).
[42] There is extensive independent research that demonstrates asbestos's high toll on public health and safety. A Rand study estimated that the industry liability costs alone could reach $200 billion. The human costs are considerable. Between 1985 and 2009, 225,000 people are estimated to prematurely lose their lives due to asbestos-related cancers.

In order to remedy these shortcomings, a timetable should be established for all manufacturers to provide chemical data to EPA and other relevant agencies for proper risk assessment. What's more, the burden of proof needs to be shifted so that chemical manufacturers are required to prove the safety of substances, rather than requiring EPA to prove a substance poses an unreasonable risk. Furthermore, the regulatory hurdles EPA faces before being able to take action to address unsafe substances are too high, and must be lowered to allow EPA to protect public health and the environment from unsafe chemicals.

V. DISTRIBUTIONAL CONSIDERATIONS, FAIRNESS AND FUTURE GENERATIONS

Science should play a critical role in reinforcing the Administration's commitment to addressing distributional considerations, especially those that affect minorities, low-income populations, future generations and children. Such considerations are particularly important for environmental regulation. E.O. 12898,[43] adopted in 1994, directs each agency, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Unfortunately, despite the executive policy on environmental justice set forth in this order, it has not been implemented in any meaningful way in recent years.

Under the Bush Administration, the EPA paid only superficial attention to the directive of E.O. 12898. For example, in promulgating regulations pursuant to the *Clean Air Act,* EPA frequently failed to undertake any actual analysis of environmental justice implications and typically just adopted one or two sentences, often boilerplate language, disavowing any distributional impact.[44]

In other cases, such as EPA's 2006 rule-making for the National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry (also called the "HON Rule"),[45] EPA simply ignored significant evidence of environmental justice concerns. In that rule-making EPA opined: "The fact that low-income and minority citizens may represent a larger percentage of the population exposed to HON HAP emissions compared to their percentage within the overall U.S. population does not in itself indicate that there is an environmental justice concern."[46] In declining to impose stricter emissions limitations on chemical manufacturing facilities—facilities that are heavily clustered alongside other industrial facilities in minority and lower-income communities such as New Orleans and the Houston Shipping Channel—EPA relied primarily on "consideration of the additional costs of further control."[47] EPA's decision to ignore scientific, health-based considerations and its attendant failure to adopt additional controls has left poor and minority communities located near the fence lines of chemical manufacturing facilities exposed to cancer risks 300 hundred times greater than the acceptable risk level identified by Congress for toxic air pollution.[48] The new Administration should make a greater commitment, across all agencies, to comply with E.O. 12898 as well as principles of reasoned rule-making and sound science.

Science should similarly be the animating force behind the Administration's concern for the interests of future generations, including today's children. Children face different and more severe health and safety risks than adults:

> "A growing body of scientific knowledge demonstrates that children may suffer disproportionately from environmental health risks and safety risks. These risks arise because: children's neurological, immunological, digestive, and other bodily systems are still developing; children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; children's

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[43] 59 *Fed. Reg.* 7,629 (Feb. 16, 1994).

[44] See, e.g., "Prevention of Significant Deterioration, Non-attainment New Source Review, and Title V: Treatment of Certain Ethanol Production Facilities Under the 'Major Emitting Facility' Definition," 72 *Fed. Reg.* 24,060, 24,077 (May 1, 2007).

[45] 71 *Fed. Reg.* 76,603 (Dec. 21, 2006).

[46] EPA Response to Comments (EPA Doc. ID EPA–HQ–OAR–2005–0475–0164).

[47] *Id.*

[48] Section 112(f)(2)(A) of the *Clean Air Act* states that if, upon completion of an eight-year review, the existing MACT standards for a carcinogenic pollutant do not reduce lifetime cancer risks to less than one-in-one million, then EPA "shall promulgate standards" under § 112(f) for sources emitting that pollutant. 42 U.S.C. § 7412(f)(2)(A). EPA's risk analysis found that hazardous organic emissions from one facility resulted in a lifetime cancer risk of 340-in-one million. SOCMI Residual Risk Assessment (EPA Doc. ID EPA–HQ–OAR–2005–0475–0108) at A–15, N–3, N–4.

size and weight may diminish their protection from standard safety features; and children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves."[49]

With respect to environmental and safety regulations, an existing E.O.[50] provides some guidance. E.O. 13045 declares that "each federal agency: (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks."[51] For regulatory actions that are "economically significant," as defined under E.O. 12866, and that pertain to an environmental health or safety risk that an agency has reason to believe may have a disproportionate effect on children:

> "the issuing agency shall provide to OIRA the following information developed as part of the agency's decision-making process, unless prohibited by law: (a) an evaluation of the environmental health or safety effects of the planned regulation on children; and (b) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency."[52]

Unfortunately, in the same way that agencies have failed in recent years to account fully for the impacts of regulatory action and inaction upon minority and low-income communities, during the Bush Administration they likewise failed to account for the unique vulnerability of children.[53] For example, EPA has previously denied that E.O. 13045 applies to its rule-makings by arguing that a rule does not pose special risk to children, despite contradictory evidence.[54] In light of such recent failures, there is a pressing need for the new Administration to make a greater commitment to the scientific procedures and decision-making guidelines outlined in E.O. 13045.

VI. TRANSPARENCY AND OTHER PROCESS IMPROVEMENTS

NRDC also strongly supports the principles of transparency and disclosure in government. They provide an essential guarantee to the public that decision-making is being conducted through the proper channels and informs the public of the true basis of government actions. Executive branch input on proposed agency regulations should be included in the administrative record for judicial review of final agency rules, except where prohibited by law. Because such input is considered by the agency decision-maker, it is properly considered part of the "whole record" for judicial review pursuant to the *Administrative Procedure Act,* 5 U.S.C. § 706.

Under historic and ongoing OIRA practices, OIRA desk officers and other officials exercise outsized influence over agency rule-makings and other activities that either never become transparent to the public, or become transparent in rare circumstances where a statute (like the *Clean Air Act,* see CAA 307(d)(4)(B)(ii)) requires OIRA written comments to be disclosed. Even in those latter circumstances, however, the OIRA influence and comments (on proposed or final rules) are made public only when a proposed or final rule is signed, severely limiting and undermining the public's ability to learn about the OIRA influence in a timely and effective fashion.

Under the prior Administration, OIRA even managed to circumvent the minimal transparency safeguards built into the rare statute like the *Clean Air Act* that required documentation of OMB written comments. The surreptitious nature of this conduct makes it difficult to prove, which is precisely the problem, but plenty of reliable if anecdotal information exists of such practices. Rather than provide written comments on EPA rule-makings to the agency, OIRA would insist that their comments be accepted on phone calls or during in-person meetings. In at least one situation OIRA staff reportedly insisted that an EPA political appointee transcribe written edits and notes on a draft *Clean Air Act* rule-making during a phone call. It is impossible to see these steps as anything other than circumvention of statutory

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[49] E.O. 13045, 62 *Fed. Reg.* 19,885 (Apr. 23, 1997).
[50] *Id.*
[51] *Id.*
[52] *Id.,* Section 5, 62 *Fed. Reg.* 19,887.
[53] *Id.,* Section 5, 62 *Fed. Reg.* 19,887.
[54] See, e.g., HON Rule, 71 Fed. Reg. at 76,613. In the HON Rule, EPA found that the rule did not present a disproportionate risk to children despite the agency's admission that some of the chemicals of concern regulated by the rule are potentially carcinogenic by a mutagenic mode of action, necessarily a concern for children.

transparency requirements. These are precisely the types of practices that we have urged this Administration to abandon.

Another objectionable practice by OIRA in the recent past involved an informal, pre-review "review" process, in which OIRA staff pressured EPA officials to adopt OIRA-preferred provisions even before the rule entered the official review. The adverse consequences of this procedure were that (1) OIRA could maintain that it did not make changes during the formal OMB review process (they had already been made); (2) any OIRA staff written comments made during the pre-review period were not included in the administrative rule-making records or the certified record for judicial review, meaning there was no transparency or accountability to the public; and (3) OIRA staff did not consider themselves bound by the deadlines governing OMB's formal review, and these informal reviews sometimes led to rules or proposals being delayed for far longer than the formal review period deadlines would have allowed.

These practices permit OIRA staff to exert hidden and potentially undue influence over EPA rules during these informal review periods and delay important public health and environmental measures. These informal reviews sometimes led OMB's subsequent formal reviews to be mere formalities that lasted no more than a few days after the formal review began; the real work and influence had been accomplished during the improper informal reviews, during which OIRA had already won the changes to the rules it was seeking, so the formal review amounted to rubber stamping a pre-negotiated outcome.

Under the prior Administration, OMB would routinely engage in informal reviews of EPA rules—quaintly dubbed "consultations"—outside of the strictures and deadlines provided under E.O. 12866. In some cases, these informal OIRA "consultations" delayed the EPA rule far beyond the time period provided for under the executive order, delaying the rule's important health benefits. For example, EPA's rule governing "PM2.5 De Minimis Emission Levels for General Conformity Applicability," EPA–HQOAR–2004–0491, underwent an informal OIRA consultation for over six months before the rule was re-submitted to OIRA for formal review under E.O. 12866 on July 6, 2006, OMB completed its formal Executive order review on July 7, 2006, making quite clear that the formal review process was a charade and OMB had effectively substituted a drawn out, unaccountable, non-transparent, and informal "consultation" for the formal review process and strictures.

It is also worth noting that a significant number of the rules subject to informal OIRA "consultation" fell well below the $100 million threshold in E.O. 12866. Indeed, it is our understanding that OIRA has long insisted on reviewing every EPA MACT rule, regardless of whether those rules met the quantitative or qualitative significance criteria in E.O. 12866.

Then there are the numerous instances in which OIRA simply granted itself lengthy and nearly open-ended extensions to formally review EPA rules. See, e.g., EPA–HQOAR–2005–0163 (EPA rule-making proposal sent to OMB for formal review on August 18, 2006, OMB review formally extended on November 16, 2006, and OMB review completed on April 19, 2007). In addition, there are examples of OIRA conducting lengthy informal "consultations," followed by lengthy extensions of its formal review period. See, e.g., EPA–HQ–OAR–2001–0004 (EPA rule provided to OIRA for informal "consultation" on April 11, 2005, submitted for formal review on September 8, 2006, formal review extended on December 7, 2006, and OMB formal review completed on February 28, 2007); see also EPA–HQ–OAR–0173.

These documented abuses just cover EPA rules adopted under the *Clean Air Act,* but we have every reason to believe these same abuses have been practiced by OMB with respect to other EPA rule-makings and actions carried out by other federal agencies. We have urged OMB to abandon these abuses of Executive Order 12866, and to adopt new practices that will provide the expected timely and formal review of agency rules—without resorting to non-transparent and abused informal consultations.

In general terms OMB should establish written, publicly available performance requirements and milestones for OIRA review of agency actions to ensure efficient and timely completion of duties, and there should be an accountability mechanism to ensure that OIRA meets these performance standards. More specifically, these performance requirements should include the following:

- Provide all comments on draft rule-making proposals and draft final rules and other agency actions (e.g., guidance) in writing, and make those writings available to the public *in real time* either on the OMB web site or in the publicly available electronic rule-making record for the underlying agency action(s);

- Avoid to the greatest extent possible oral comments on draft proposals and final rules and other actions that could be seen as an attempt to circumvent the written comment condition above or "fingerprinting" requirements in statutes like the *Clean Air Act*;
- Allow officials *only* at the branch chief level or higher to take actions that have the effect of delaying or blocking the agency action past the formal review period, and then only by making written comments on draft proposals and final rules and other actions. This would remedy or lessen the potential for abuse in which OIRA desk officers exercise effective veto power over agency actions by refusing to release those actions.
- Make the comments and identities of all agencies and departments during the interagency review process on a given agency's rule, publicly available and available to the agency in question in real time. This will provide greater information to the public policy process and offer greater accountability for all of the parties involved.
- Hew to the review deadlines in the Executive Order, and only seek extensions where strictly necessary. If and when the formal OMB review period expires, there should be a presumption that OMB review is complete unless formal written objections are lodged at the branch chief level or above, and those written objections are again made available in real time to the agency and the public. If OMB does need to seek an extension, there should be only one such extension and it should be of limited, specified duration. Both of these conditions are needed to reform the current practices which can unjustifiably hold up agency actions by allowing OIRA to either fail to provide written reasons for refusing to release an agency action, or grant itself open-ended extensions.
- Establish an appeals process in situations in which OMB objections to an agency action may be appealed by the agency. This appeal process should be less draconian than the current process calling for elevation to the Vice President's office, since that process discourages appeals and creates undue leverage on the part of OMB. As part of this alternative it could be helpful to involve formally other EOP offices with special expertise and responsibility over the subjects and source of disagreement, e.g., the Council for Environmental Quality for disputes between OMB and EPA and the other environmental and natural resource agencies.
- Finally, we have urged OIRA to provide better detailed summaries of its meetings with outside stakeholders, whomever they might be, rather than the cursory meeting summaries that OIRA currently provides, in which the meeting participants are listed along with only the briefest mention of the subject of the meeting. Members of the public (or fellow agencies for that matter) would benefit from a more meaningful explication of the discussion of issues affecting them.

CONCLUSION

Thank you again for the opportunity to testify before the Subcommittee. We look forward to working with the Subcommittee and Full Committee, as well as the Administration, to ensure that efforts to protect public health and the environment based upon agency expertise are successful. I would be happy to answer any questions you may have.

BIOGRAPHY FOR WESLEY P. WARREN

Wesley P. Warren is the Director of Programs at the Natural Resources Defense Council. He is a recognized expert on federal budgetary and regulatory procedures, especially as they relate to the environmental programs. As Director of Programs for NRDC, he has responsibility for helping to ensure that NRDC's program work is closely coordinated and effectively directed so that NRDC can succeed at achieving its goal of protecting the environment and human health.

Before joining NRDC, Mr. Warren served in the White House as Associate Director for Natural Resources, Energy and Science in the Office of Management and Budget. In this position he provided oversight for major federal agencies involved in environmental policy, including the Departments of Agriculture, Energy and Interior, the Environmental Protection Agency, and the Army Corps of Engineers. Also during his seven-year tenure in the White House, Mr. Warren held positions as the Chief-of-Staff for the Council on Environmental Quality and the Executive Director of the White House Task Force on Livable Communities.

Prior to his service in the Executive Branch, Mr. Warren worked as a legislative aide in the U.S. House of Representatives for six years, first for the Science, Space, and Technology Committee, and then for the Energy and Commerce Committee. As a legislative aide, he worked on a range of Congressional issues including the *Clean Air Act Amendments of 1990* and the *Energy Policy Act of 1992*. Before that, Mr. Warren worked as an energy and environment analyst for the Northeast-Midwest Institute, a policy center advising Members of Congress on issues of regional importance.

Mr. Warren received a B.A. and double honors in Economics and History from Wake Forest University in 1976 and attended graduate school in Political Science at the University of Chicago.

Chair MILLER. Thank you Mr. Warren.

Dr. Coglianese.

STATEMENT OF DR. CARY COGLIANESE, ASSOCIATE DEAN FOR ACADEMIC AFFAIRS, EDWARD B. SHILS PROFESSOR OF LAW, PROFESSOR OF POLITICAL SCIENCE; DIRECTOR, PENN PROGRAM ON REGULATION, UNIVERSITY OF PENNSYLVANIA

Dr. COGLIANESE. Thank you very much, Chair Miller, Ranking Member Broun and other Members of the Subcommittee. I am pleased to be here and I would like to talk in my remarks about the relationship between science and regulatory policy and specifically about what science can and what science cannot do when it comes to justifying good regulatory policy.

Now, regulatory policy—good regulatory policy solves problems, it aims to solve problems, and to do that and do it well, regulatory decision-makers need to understand the problems that they are aiming to solve as well as be able to assess how different solutions to that problem might fare against decision-making criteria that are applicable. And to understand both the problems and the relative strengths and weaknesses of different solutions, regulators need to rely on science, and by that, I mean the systematic inquiry about how the world works. That is needed to help us understand what is causing problems. If we don't understand that, it is harder to solve them. Science can help in identifying possible solutions. If there are multiple causes of a problem, then science can lead policy-makers to think about different solutions aimed at the different causal pathways. And of course, science can also be very important in assessing the impacts or projecting the likely impacts of different policy options.

So, science plays an important and vital role in regulatory policy, but it cannot do everything. First, it cannot provide the criteria for decision-making. Science explains the world. It provides assessments of empirical reality of what is, but doesn't provide normative judgments, doesn't help tell us how to balance between different criteria, whether they might be effectiveness, efficiency, equity or other policy considerations.

So science describes. It does not prescribe. However, sometimes regulatory agencies tend to blur that distinction and sometimes purport to make decisions where science has told us to go. "We have listened to the science. We are doing what science tells us to do." When they are doing that, they are making a claim that just conceptually can't be sustained.

In 1996, the National Research Council explained in a report that "science alone can never be an adequate basis for a risk decision because decisions are ultimately public policy choices." A legal

scholar, Wendy Wagner, has sometimes referred to the over-emphasis on science as a science charade. I have in my own research chronicled in detail the EPA's rule-makings in the 1990s and they have done it again in 2006, revising air quality standards and claiming to have done so because that is where science has led them. Science again is important, but it is not, and shouldn't be used as, a cloak for policy decision-making because in doing so the public is not aware of the real reasons justifying the fundamental policy choices. So in addition, sometimes the lack of transparency about the fundamental policy choices being made and the reasoning behind them could lead agencies to make inconsistent or sub-optimal decisions.

Congress has some options to try to address this problem of a science charade. They could take a look at various laws that create incentives for agencies to claim science is doing more than it can do. They could also look at legislative requirements to compel agencies to clearly demarcate what science is telling them and what the public policy reasoning is.

Many observers have rightfully called for enhancing the soundness of the scientific basis of agency decision-making, but just as there is always room for improving the quality of the science that regulatory agencies repair to, there are also opportunities to enhance the quality of agencies' policy reasoning, especially in those instances where agencies misleadingly suggest that science has determined their decisions.

[The prepared statement of Dr. Coglianese follows:]

PREPARED STATEMENT OF CARY COGLIANESE

Mr. Chairman, Ranking Member Broun, and Members of the Subcommittee, I am pleased to appear before you today to discuss the role of science in setting regulatory standards. In my testimony, I will seek to offer some conceptual clarity about the contribution of science to the making of regulatory policy, explaining what science can and cannot be expected to accomplish in regulatory decision-making.

Good regulation aims to—and does—solve problems.[1] Making sound decisions about regulation therefore calls for an understanding of the problem a regulator seeks to solve. What is the scope and severity of the problem? Is the problem growing worse? What are the causes of the problem? These kinds of questions call for accurate and relevant information about the current state of the world as well as evidence confirming theories about cause-effect relationships.

In addition to understanding the problem, regulatory decision-making calls for a consideration of solutions.[2] What are the possible ways the problem might be solved (or at least the situation improved)? Against which criteria ought alternative solutions be judged (including the option of doing nothing)? How does each alternative fare when assessed against the chosen criteria? On the basis of answers to these kinds of questions, the regulator can make an informed decision about what ought to be done—namely, whether to regulate and, if so, exactly how to do so.

To understand problems and their potential solutions, regulatory decision-making depends on science in several ways. By science, I mean, in general terms, systematic inquiry aimed at generating evidence about and explanations of how the world operates.[3] Science is needed, first, to measure, track, and explain the cause of problems—although importantly it does not tell us why something is properly considered a problem in the first place. Second, by helping understand what causes a problem,

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[1] John Braithwaite, Cary Coglianese, and David Levi-Faur, "Can Regulation and Governance Make a Difference?" *Regulation & Governance* 1: 1, 4 (2007).

[2] For treatments of policy decision-making, see David Weimer & Aidan R. Vining, *Policy Analysis: Concepts and Practice* (4th ed. 2004), and Eugene Bardach, *A Practical Guide for Policy Analysis: The Eightfold Path to More Effective Problem Solving* (2008).

[3] The Supreme Court has defined science as "'a process for proposing and refining theoretical explanations about the world." *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 590 (1993).

science may help inform the process of generating ideas about possible solutions—namely interventions that address different causal pathways to the problem. Finally, science can also quite usefully inform assessments of how different solutions will fare in terms of at least certain types of policy criteria. For example, scientific knowledge about swine flu viruses is clearly essential in assessing the effectiveness in preventing disease transmission of alternative solutions like washing hands versus avoiding pork products.

Science cannot, though, tell a regulator which criteria should be used to evaluate possible alternatives, nor how to balance or make trade-offs between different criteria, whether effectiveness, efficiency, equity, or other policy considerations. Science also cannot make or direct the ultimate choice about what solution should be selected from the alternatives considered. The ultimate choice of whether, how, and how stringently to regulate is a normative or policy judgment: "Science describes; it does not prescribe."[4]

Regulators may sometimes be justified to take action before scientists can conclude that they understand well a problem's causes or can predict with a high degree of confidence how all possible solutions might fare. At other times, scientists may be able to specify the contours surrounding a problem with a great deal of confidence, but regulators may nevertheless be justified to allow that problem to persist—if other weightier (or at least equally weighty) policy considerations so dictate. Solving one problem could, after all, only create other problems. In the context of regulatory policy, science's role—or what President Barack Obama in his Inauguration Address called its "rightful place"—is to provide a *necessary but not sufficient* input into policy decisions.

Members of the scientific community have long emphasized the need to clarify the role science can and cannot play. As early as 1983, in its well-known *Red Book* report, the National Research Council (NRC) called for maintaining a clear conceptual distinction between scientific judgments and policy judgments in risk regulation. The NRC distinguished between risk *assessment,* which it considered to encompass predominantly scientific analysis, and risk *management,* which it said entails consideration of "political, social, economic, and engineering information . . . to select the appropriate regulatory response."[5] In another report issued in 1996, the NRC explained still more bluntly that "science alone can never be an adequate basis for a risk decision" because such "decisions are, ultimately, public policy choices."[6]

Regulatory agencies have not always acknowledged that their decisions are ultimately policy choices, albeit ones informed by science. Legal scholar Wendy Wagner has characterized as pervasive a practice she has called the "science charade," with regulators confronting "multiple political, legal, and institutional incentives to cloak policy judgments in the garb of science."[7] Professor Gary Marchant and I have chronicled in detail one such charade undertaken by the U.S. Environmental Protection Agency (EPA), when it amended its major ambient air quality standards for ozone and particulate matter in the late 1990s.[8] In explaining its amendments, the EPA Administrator at the time made repeated claims to the effect that "science must prevail in determining the level of protection the public will be guaranteed."[9] When the EPA revised its particulate standard nearly a decade later, in 2006, the agency again exaggerated the role of science, arguing that it "based this decision on an assessment of a significantly expanded body of scientific information" and "[t]he assessment concluded that the standard should be strengthened."[10] Yet science is about understanding or predicting what *is,* not about concluding or justifying what a standard *should* be.

Policy decisions can be based on a variety of principles. For example, in the realm of environmental or health and safety regulation, agencies can set standards that

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[4] Cary Coglianese & Gary Marchant, "Shifting Sands: The Limits of Science in Setting Risk Standards," *University of Pennsylvania Law Review* 152: 1255, 1274 (2004).

[5] National Research Council, National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process* 18–19 (1983).

[6] National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society* 26 (1996).

[7] Wendy E. Wagner, "The Science Charade in Toxic Risk Regulation," *Columbia Law Review* 95: 1613, 1650–51 (1995). See also Thomas O. McGarity & Wendy E. Wagner, *Bending Science: How Special Interests Corrupt Public Health Research* 21 (2008) ("In today's legal climate, science has become the most respected and therefore the most powerful influence on domestic health and environmental policy-making.").

[8] Coglianese & Marchant, *supra* note 4.

[9] *Id.* at 1273 (quoting then-Administrator Carol Browner).

[10] EPA, Fact Sheet Final Revisions to the National Ambient Air Quality Standards For Particle Pollution (Particulate Matter), *http://www.epa.gov/air/particlepollution/pdfs/20060921_factsheet.pdf* (Sept. 21, 2006) (last accesses 4/28/09).

seek to: (1) eliminate all unacceptable risks (the acceptable risk principle), (2) eliminate risk until the costs of doing so reach an unacceptable level (the feasibility principle), or (3) balance the benefits and costs of risk reduction (the efficiency or cost-benefit principle). Each of these principles deserves their own justification.[11] But the point here is that despite the availability of these and other policy principles, regulatory agencies like EPA face incentives and constraints that at times lead them to retreat behind a false veil of science.

One such constraint takes the form of authorizing statutes that preclude or discourage agencies from relying on meaningful policy principles. For example, the courts and EPA have interpreted Section 109 of the *Clean Air Act* to prevent the agency from considering costs in setting ambient air quality standards—so instead the agency purports to rely on science to set a standard at a level that is "not lower or higher than is necessary" to protect public health.[12] EPA must cloak its air quality standard-setting in the "garb of science," without being able to provide a coherent policy justification for why it selects particular standards at the levels it does (and not at levels lower or higher).[13]

When regulators purport to rely on science as the sole basis for their policy choices, the real reasons justifying their choices remain hidden from public view. For example, when EPA rejected the most stringent proposed standards in its ozone and particulate rule-makings, citizens never received an adequate policy explanation for why the agency effectively decided to tolerate some residual, known health effects. Nor did citizens receive a coherent policy reason for why, in rejecting the least stringent option, the agency effectively accepted potential job losses or increases in citizens' utility bills owing to compliance costs.[14]

In addition to detracting from transparency and accountability, when agencies exaggerate the role of science they may create other perverse effects. Wendy Wagner and Rena Steinzor have suggested that "[t]he more emphasis that regulators place on science, the greater the affected parties' incentives to do what they can to control its content and production"—which on Wagner and Steinzor's account includes the veritable harassment of independent scientists by organized interests that do not like the scientists' findings.[15] More globally, in terms of public policy outcomes, if agencies avoid confronting the policy choices inherent in making regulation, they may be much more likely to make inconsistent or sub-optimal decisions.[16]

Legislators have options to consider that could reduce agencies' incentives to retreat behind science. Congress could reconsider and rewrite statutory provisions that the courts have construed in a way that effectively forces agencies into misrepresenting the role of science, such as with Section 109 of the *Clean Air Act*. It could consider options for enhancing oversight of policy reasoning by the White House Office of Information and Regulatory Affairs or the courts, or it could impose requirements or make requests of its own that agencies clearly demarcate the role science has played in their decisions and the role played by policy reasoning.

Many observers of the regulatory process have properly sought to enhance "sound science" in agency decision-making—or to avoid what is variously considered "junk science"[17] or "bent science."[18] But just as there is always room for improving the quality of the science that regulatory agencies must necessarily and properly rely upon, there are also opportunities to enhance the quality of agencies' policy reasoning, especially in those instances where they misleadingly suggest that science has determined their decisions.

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[11] For a discussion of rationales for, and some limitations of, these various principles, see Coglianese & Marchant, *supra* note 4, at 1325–1340. Professors Matthew Adler and Eric Posner have offered a recent book-length justification of the cost-benefit principle. Matthew D. Adler & Eric A. Posner's *New Foundations of Cost-Benefit Analysis* (2006). For a recent exchange about their book, see Amy Sinden, Douglas A. Kysar, and David Driesen, "Cost-Benefit Analysis: New Foundations on Shifting Sand," *Regulation & Governance* 3:48 (2009), and Matthew Adler & Eric A. Posner, "New Foundations of Cost-Benefit Analysis: A Reply to Professors Sinden, Kysar, and Driesen," *Regulation & Governance* 3:72 (2009).

[12] *Whitman v. American Trucking Association, Inc.,* 531 U.S. 457 (2001).

[13] Coglianese & Marchant, *supra* note 4.

[14] *Id.* at 1355–56.

[15] Wendy Wagner & Rena Steinzor, Rescuing Science from Politics: Regulation and the Distortion of Scientific Research 4 (2006).

[16] See Coglianese & Marchant, *supra* note 4, at 1290–1323.

[17] Peter Huber, *Galileo's Revenge: Junk Science in the Courtroom* (1991).

[18] McGarity & Wagner, *supra* note 7.

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BIOGRAPHY FOR CARY COGLIANESE

Cary Coglianese is Associate Dean for Academic Affairs and the Edward B. Shils Professor of Law and Professor of Political Science at the University of Pennsylvania, where he also serves as the founding Director of the Penn Program on Regulation. He specializes in the study of regulation and regulatory processes, with a particular emphasis on the empirical evaluation of alternative regulatory strategies and the role of disputing, negotiation, and business-government relations in regulatory policy-making. His work has appeared in, among other journals, the *Administrative Law Review, Duke Law Journal, Law & Society Review, Michigan Law Review, University of Pennsylvania Law Review, Stanford Law Review,* and the *Yale Journal on Regulation.* His co-edited books include *Regulating from the Inside: Can Environmental Management Systems Achieve Policy Goals?, Leveraging the Private Sector: Management-Based Strategies for Improving Environmental Performance,* and *Regulation and Regulatory Processes.* Prior to joining Penn Law, Coglianese spent a dozen years on the faculty at Harvard University's John F. Kennedy School of Government, where he served as the Chair of the School's Regulatory Policy Program and Director of its Politics Research Group. He is the founder and served for seven years as Chair of the Law & Society Association's international collaborative research network on regulatory governance. He is a Council member of the American Bar Association's Section of Administrative Law and Regulatory Practice and a Fellow of the American Bar Foundation. He has taught as a Visiting Professor at the Stanford and Vanderbilt law schools, and served as a founding Editor of the international, peer-reviewed journal, *Regulation & Governance.*

Chair MILLER. Ms. Steinzor.

STATEMENT OF MS. RENA STEINZOR, JACOB A. FRANCE RESEARCH PROFESSOR OF LAW, UNIVERSITY OF MARYLAND SCHOOL OF LAW

Ms. STEINZOR. Thank you, Chair Miller and Members of the Subcommittee.

My testimony today makes three crucial points. First, the Obama Administration and Congress should define a new mission for the regulatory czar and his staff at OIRA. The American people need more, not less, regulation on every front, from mortgage lending to workplace hazards. The regulatory czar's mission should be to rescue struggling regulatory agencies by helping them to obtain more resources and stronger legal authority.

Second, I could not agree more with Rick Melberth's point that OIRA should stop reviewing individual regulatory proposals.

Third, OIRA must stay out of science policy. As you said, Mr. Chair, OIRA is a small office comprised of approximately 40 to 50 professionals, the vast majority of whom are economists. OIRA is not competent to propose science policy in the regulatory arena and should abandon this role.

Regulatory reform has long been code for the unfounded allegation that agencies have run amok and are galloping across the tundra regulating without common sense at an unaffordable cost to industry. That charge is no more credible than the allegations made shortly before the current economic crisis that an overweening Securities and Exchange Commission was thwarting financial institutions from bringing prosperity to the world. Rather than chiding

regulators for their alleged excesses, OIRA should be helping agencies like the Consumer Products Safety Commission, the EPA, the Food and Drug Administration, the National Highway Traffic Safety Administration and the Occupational Safety and Health Administration to produce smarter, better government. These agencies are responsible for the air we breathe and the water we drink. They police hazards in the workplace, the sale of dangerous products, the purity of our food and the safety of our drugs over the counter and prescription, and yet all together these agencies account for less than .8 percent of the total federal budget. In constant dollars, their budgets are the same as they were in mid-1980s. OIRA must use its influence to rescue these agencies by ensuring that they have adequate resources, political support and legal authority to take decisive and timely actions against real threats from smog to peanut butter, from toppling cranes to lead-coated toys.

Under John Graham, OIRA embarked on two fundamentally misguided projects to change the way regulatory science is analyzed and used. The first involved the peer review of studies used by federal agencies to make decisions and the second, tried to mandate a one-size-fits-all risk assessment policy for the entire government. The documents were so poorly informed and extreme that they provoked a backlash of opposition from the scientific community, the public interest community and this committee. Given this unfortunate track record, OIRA under the Obama Administration must confine its supervision of government to areas within its expertise, leaving to experts such as White House Science Policy Advisor John Holdren the difficult job of restoring the independence and integrity of science throughout the government.

When Barack Obama ran for President, he defined the role of government as helping people when they cannot help themselves. He said we don't need bigger government or smaller government, we need better government, we need a more competent government, we need a government that upholds the values we hold in common as Americans. To deliver real change, OIRA must embrace this mandate and not the false premise that its most important mission is to prevent regulatory agencies from intervening with business. Thank you.

[The prepared statement of Ms. Steinzor follows:]

PREPARED STATEMENT OF RENA STEINZOR

Mr. Chairman, and Members of the Subcommittee, thank you for inviting me to testify today. This hearing could not be more timely because the Senate hearing for Cass Sunstein, President Obama's choice to serve as "regulatory czar," will be held very soon and because the President has directed the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) to rewrite Executive Order 12866, which governs the structure of regulatory review. Mr. Sunstein's predecessor, John Graham, used OIRA to expand control over regulatory policy to an unprecedented extent, delivering a body blow to the effectiveness of the Nation's regulatory system in the name of "reforming" it. Consistent with President Obama's strong plurality in what the pundits call a "change election," Mr. Graham's discredited and destructive approach must be rejected and the role of regulatory czar must be fundamentally redefined.

My testimony today makes three crucial points:

1. **The Obama Administration and Congress should define a new mission for the regulatory czar.** The term "regulatory reform" has become a shorthand reference to the assertion that regulatory agencies—especially in

the health and safety arena and most especially with respect to the Environmental Protection Agency (EPA)—must have a heavy net thrown over them to contain their excessive rules and overzealous staff. This approach was never a good idea and, in any event, is outmoded. *The American people need more, not less regulation on every front, from mortgage lending to workplace hazards. The regulatory czar's mission should be to rescue struggling regulatory agencies by helping them to obtain more resources and stronger legal authority.*

2. **OIRA should stop reviewing individual regulatory proposals.** Empirical studies reveal that OIRA has served for well over 30 years as a killing ground for protective regulations. Except during the Clinton Administration, OIRA's threat to target any given regulatory proposal has chilled the development of strong and effective regulation. *OIRA has plenty of work to do formulating regulatory policy and should leave the drafting of individual rule regulatory impact analyses and the making of final decisions to agency experts, supervised by Obama political appointees.*
3. **OIRA must stay out of science policy.** OIRA is a small office, comprised of approximately 40–50 professionals, the vast majority of whom are economists. During the Graham era of kingdom-building, five or six of these positions were set aside to hire scientists, who proceeded to propose radical changes in the way research would be used to make regulatory policy. *OIRA is not competent to propose science policy in the regulatory arena and should abandon this role.*

A New Mission for the Regulatory Czar and OIRA

Regulatory Killing Ground

The Reagan Administration introduced the requirement—continued by all subsequent presidents—that agencies must produce a cost-benefit analysis for every "significant rule," a term of art meaning requirements imposing more than $100 million in compliance costs. President Reagan and his successors also prohibited agencies from proposing or adopting rules until they are approved by economists at OIRA. This requirement gives this small office an unwarranted choke-hold over regulatory decisions.

Cost-benefit analyses are designed to provide a *quantified*—or numerical—estimate of both the potential costs and benefits of a proposed rule. Potential costs include whatever money companies will be compelled to spend to implement the remedies proposed in the rule, such as installation of pollution control equipment or obtaining and enforcing the use of hard hats and respirators for workers dealing with hazardous conditions or materials. When a rule requires the use of an emerging technology, prices fall as the market expands, lowering compliance costs. But these dynamics are ignored and compliance costs are routinely overstated by industries opposing the new rules, and agencies do a poor job of critically evaluating such claims.

Potential benefits of a regulatory proposal include the harm that will be avoided if the regulation is implemented. Economists also insist on quantifying these benefits in monetary terms, an ostensibly straightforward approach that causes huge problems in practice. "Monetizing" human suffering or the irrevocable loss of natural resources is controversial from an ethical perspective. And much of the harm addressed by health and safety regulation is very difficult to reduce to numbers. An equally important problem is that the economists also insist on treating these figures as if they were any other kind of financial investments. People expect to receive a "return" on investments of money that increase the value of the initial amount over time. In essence, people get paid for allowing others—the banks or the government—to use their money. The economists argue that if someone who is exposed to a hazardous chemical today will not die of cancer for 25 more years, the value of the life saved by a regulatory intervention should be quantified as if it was such an investment. So the question becomes how much money would we need to invest today, at a rate of return of either three or seven percent (numbers specified by OIRA), to come up with $6.8 million (a common estimate of the value of saving one life) in 30 years. This practice is known as "discounting."

Because cost-benefit number-crunching deals with such uncertainty, these analyses can run to hundreds of pages of complex, dense, and highly technical data, projections, modeling, and mathematical formulas that deter any but the most determined stakeholders from challenging these analytical bottom lines. As troubling, distilling the series of arbitrary assumptions that underlie such calculations into a

small set of numbers leaves a misleading impression of objectivity when, in fact, such analyses are notoriously susceptible to manipulation, making them ideal useful political cover for decisions to weaken regulations.

Although this point is rejected by cost-benefit enthusiasts, retrospective examinations of regulatory decision-making shows that the primary impact of such analyses is to weaken the protection of health, safety, and the environment, not strengthen it. Professor David Driesen undertook a comprehensive review of studies and reports documenting the impact of OIRA review, concluding that the process slowed and reduced the stringency of environmental, safety, and health regulation in "dozens of cases." David M. Driesen, "Is Cost-Benefit Neutral?," *University of Colorado Law Review* 77 (2006): 335, 355. He examined 25 rules identified by a Government Accountability Office (GAO) study as significantly affected by OIRA review in 2001–2002. GAO–03–929, *RULEMAKING: OMB's Role in Reviews of Agencies Draft Rules and the Transparency of Those Reviews* (2003). He found that the OMB's recommended changes would have reduced regulatory protections with respect to 24, while the remaining change was neutral.

In a similar vein, Professors Lisa Bressman and Michael Vandenbergh interviewed 35 top EPA political appointees during the first Bush and Clinton Administrations. Lisa Schultz Bressman & Michael P. Vandenbergh, "Inside the Administrative State: A Critical Look at the Practice of Presidential Control," *Michigan Law Review* 105 (2006): 47, 50, 75. These respondents said that the OIRA review "regularly skews rule-making in a deregulatory direction" and that OIRA staff use "cost-benefit analysis to impose its own normative preference for deregulation." Professor Steven Croley's work substantiates these conclusions. Steven Croley, "White House Review of Agency Rulemaking: An Empirical Investigation," *University of Chicago Law Review* 70 (2003): 821, 877.

Lastly, Professors Lisa Heinzerling and Frank Ackerman applied traditional cost-benefit analysis to three regulatory decisions made in the 1960's and 1970's that are widely regarded today as unqualified successes. Frank Ackerman & Lisa Heinzerling, "Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea?," *Admin. L. Rev.* 57 (2005): 155. They concluded that the use of this methodology would have resulted in the reversal of all three decisions: lead would have stayed in gasoline instead of being removed; the Grand Canyon would have been dammed to generate hydroelectric power; and workers would have experienced uncontrolled exposure to vinyl chloride.

OIRA is staffed by approximately 40–50 economists who cannot possibly review every regulatory proposal thoroughly. Nevertheless, the threat of OIRA review is deeply disruptive of rule-making. Because agencies do not know which cost-benefit analysis economists may find objectionable, they must gird up for battle over each regulation they are developing. These elaborate preparations, and the subsequent fights that do break out between OIRA and agency staff, slow rule-making substantially.

Acute Regulatory Dysfunction

As the studies I just mentioned demonstrate, beginning with the first Reagan Administration, OIRA has served mainly to suppress and delay regulation thought to be excessive. This focus is hardly appropriate for the challenges confronting today's regulatory system. The allegation that these agencies have run amok, and are galloping across the tundra regulating without common sense and at an unaffordable cost to industry is no more credible than the argument made shortly before the current economic crisis an overweening Securities and Exchange Commission was thwarting financial institutions from bringing prosperity to the world. Instead, like the SEC, regulatory agencies covering the full spectrum of safety, health, environmental and financial protection of Americans are in a frighteningly dysfunctional state that threatens the well-being of every American.

The place to start in rescuing this failed system is to announce a fundamental re-orientation of the OIRA. Rather than chiding regulators for their alleged excesses, the OIRA should be helping agencies like the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and the Occupational Safety and Health Administration (OSHA) to produce smarter, better government. Rescuing these agencies by giving them adequate resources to fulfill their statutory mandates, helping them to develop strong, proactive agendas, and ensuring that they receive enhanced legal authority to take decisive action should be the top priorities for the regulatory czar and his OIRA staff.

This re-orientation of roles is urgent, as illustrated by the acute and dangerous regulatory dysfunction that makes headlines every day. These incidents inflict real

injury. They occur because these five agencies lack the resources and the political will to carry out their vitally important statutory missions effectively. The ranks of the civil service are decimated. The agencies are overburdened by mischievous Bush Administration "midnight regulations" and illegal regulatory decisions now under challenge in the courts. Congress has not reviewed or refreshed many of their authorizing statutes in at least two decades. Their budget resources are a fraction of what they need to fulfill mandates made infinitely more complex by the importation of foreign products, food, and pollution.

In 2007, for example, CPSC oversaw the recall of millions of consumer products, including Chinese-made toys that were slathered in lead paint and children's art sets that included little beads containing gamma hydroxybutyric acid (GHB), a powerful substance commonly referred to as the "date rape drug. Some toddlers who gummed or swallowed the beads had seizures and went into comas. As the media reacted to these events, it became clear that *80 percent of the toys sold in America* are imported from abroad, primarily from China, which has no meaningful health and safety regulation. The CPSC fields only 15 inspectors to screen such imports. Just last month, *Time Magazine* broke a story about the import of Chinese dry wall laced with sulfurous chemicals and used in thousands of homes in Florida, Texas, Louisiana, and other states. Homeowners and renters who could not afford to live anywhere else were exposed to fumes that caused severe adverse health effects from headaches to respiratory failure. The CPSC was mentioned as an after-thought in most news accounts, with state officials desperate to find a way to stop the imports and extract an explanation from manufacturers. Congress wrote the *Consumer Product Safety Improvement Act* in response to such scandals, but these new mandates remain underfunded and the statute never came to grips with the implications of dangerous imports, instead asking the agency to report back on its recommendations for change in three years.

A few weeks ago, GAO issued a report warning that EPA's capacity to deal with new climate change regulations was fundamentally compromised. GAO also moved EPA's ineffective regulation of toxic chemicals to its list of highest priority problems for government overall. As explained in a landmark series published by the *Philadelphia Inquirer,* Bush-era *Clean Air Act* regulations dealing with conventional pollutants were routinely overturned by judicial panels that ironically included the most conservative Bush appointees, indicating how far the Agency has strayed from implementing the laws as Congress intended. See "Smoke and Mirrors: The Subversion of EPA," *http://www.philly.com/inquirer/front_page/20081207_An_Eroding_Mission_at_EPA.html*. Regulation of mercury is in limbo, at least 15 years overdue. The Bush Administration OMB persuaded the President to overturn the advice of EPA's senior political appointees recommending a more stringent standard for ozone pollution, one that EPA's top scientists said was absolutely necessary to limit damage to crops, forests, and other natural resources. *Clean Water Act* protections are mired in a "no win" debate between point and non-point sources, with federal and state regulators lacking the fundamental tools they need to bring non-point pollution under control. The EPA's Integrated Risk Information System (IRIS) lacks inhalation values—the highest levels of airborne toxics that can be tolerated without adverse health effects—for many common hazardous air pollutants, and without these values, effective regulation is impossible. EPA has years of work ahead of it to correct these mistakes.

The FDA is struggling to come to grips with the resource imbalances and other problems that produced the Vioxx scandal and related failures to protect the public. It must completely revamp its efforts to police adverse effects in approved drugs. Its overall reputation and the morale of its staff suffered a body blow during its consideration of whether Plan B should be sold over-the-counter. All of these problems will require careful and sustained attention if we are to have any hope of restoring scientific integrity and independence to FDA new and existing drug oversight. Recent revelations regarding the apparently criminal conduct of a peanut processing company with facilities in Georgia and Texas reveal gaping holes in the food safety protection net. The company shipped *Salmonella*-contaminated products that sickened 20,000 and caused nine deaths, provoking a recall that cost billions of dollars.

NHTSA has yet to deal effectively with the safety problems posed by Sport Utility Vehicles. Although these hazards are to some extent alleviated by the decreasing popularity of such vehicles, the economic downturn and falling price of petroleum products may well blunt these trends. As Bush appointee Jeffrey Runge, a medical doctor who was NHTSA Administrator during President George W. Bush's first term, told *The New York Times,* "The theory that I'm going to protect myself and my family even if it costs other people's lives has been the operative incentive for the design of these new vehicles, and that's just wrong." The same article described

the research of Michelle White, an economist at the University of California, San Diego, whose calculations show that each accident where an SUV driver remains unhurt means four fatalities for the smaller car's occupants, pedestrians, bicyclists, and motorcyclists. Danny Hakim, "A Regulator Takes Aim at Hazards of S.U.V.s," *New York Times,* December 22, 2002, late edition, sec. 3.

OSHA is equally paralyzed on the regulatory front. As just one headline-grabbing example, the existing standard for crane safety has not been updated since 1971. OSHA staff prepared a consensus standard to update these requirements, but it has been stuck in the Secretary's office for many years. Beryllium, an extraordinarily toxic metal used in a variety of industrial applications, is regulated under a 1949 OSHA standard that is *ten times less protective* than the standard that applies to workers in facilities controlled by the Department of Energy, which updated its own protections in 1999. In fact, OSHA has issued only *two* new standards to control chemical exposures in the workplace over the last ten years. Descriptions of conditions in meat and poultry packing plans by GAO and a superb series of reports in the *Charlotte Observer* are hair-raising. GAO–05–96, *Workplace Safety and Health: Safety in the Meat and Poultry Industry, While Improving, Could be Further Strengthened; Charlotte Observer,* "The Cruelest Cuts, The human cost of bringing poultry to your table," *http://www.charlotteobserver.com/poultry/*. Yet this dangerous industry remains largely unregulated because OSHA lacks both the political will and the resources to attempt credible deterrence-based enforcement.

Solutions

OMB should revamp its Performance Assessment and Ratings Tool to focus on funding gaps.

Rather than view the primary job of a "regulatory czar" as stopping excessive regulation, Cass Sunstein and his OIRA staff should define as revamping the regulatory system to ensure that agencies are able to fulfill their regulatory missions in a vigorous, timely, effective, and wise manner. One critical place to start is for OMB to revamp its Performance Assessment Rating Tool (PART) used to audit the effectiveness of individual government programs to serve a much more crucial function: undertaking an analysis of the resource gap between how much it would cost to implement all of an agency' statutory mandates and the agency's individual budgets. Consider the following charts, tracking the budgets of the five health and safety agencies in *constant dollars* since they were created through 2006:

Figure 1

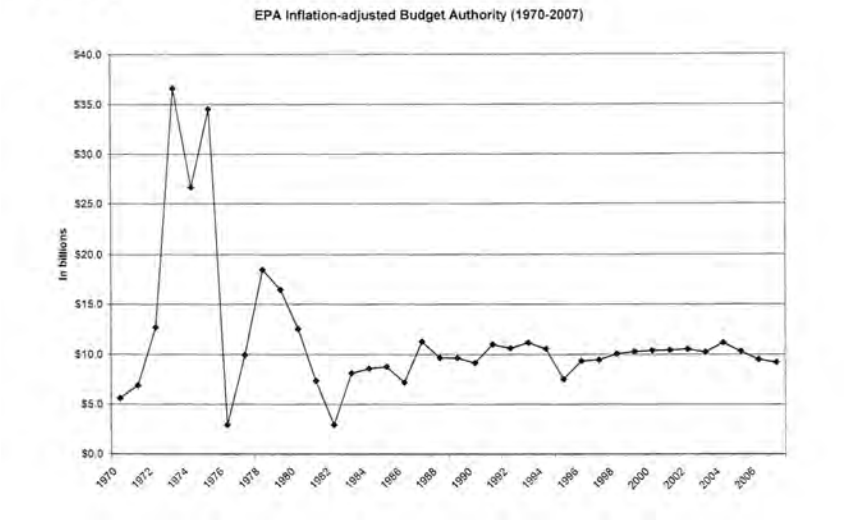
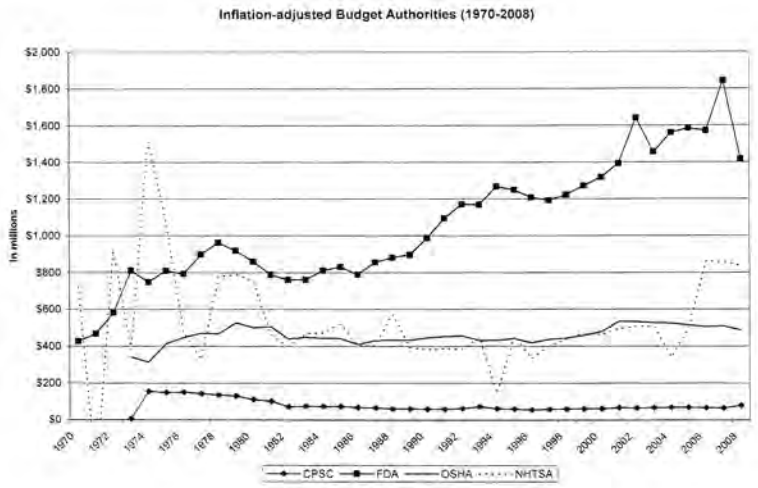


Figure 2



As these figures illustrate, with the exception of FDA, which enjoyed moderate funding increases to accelerate its process for approving new drug applications, these figures show that none of the agencies have received significant increases in their budgets since roughly 1980, approximately a decade after they were created. The EPA budget level set in 1984, which remains roughly the same amount in constant dollars as it is today, preceded passage of a series of ambitious amendments to every major environmental law, including the 1990 *Clean Air Act Amendments.* During this time period:

- The United States population grew 34 percent, from 227 million in 1981 to 304 million in June 2008.
- In 1975, the OSHA was responsible for policing 3.9 million workplaces, which employed 67.8 million workers; it had 2,405 inspectors to do the job. By 2006, the number of workplaces had grown to 8.7 million, worker population to 133.8 million, and the number of OSHA inspectors had fallen to 2,165.
- Between 1987 and 2006, the number of prescriptions filled in the United States came close to tripling, from 1.2 billion to 3.1 billion.
- In 1980, 155,796,000 motor vehicles were registered in the United States. By 2006, that number stood at 244,165,686.

The President should suspend OIRA review of individual rules.

A second crucial reform is to terminate OIRA's responsibility for spot-checking individual regulatory impact analyses. As explained above, this review is far from comprehensive because OIRA has such a small staff. Instead, under Republican presidents, the historical purpose of such reviews was to intimidate agencies into reducing the protectiveness of their own rules in anticipation of potential OIRA disapproval. Apparently, these Administrations did not have confidence that their appointees to head the agencies could exert enough control over career staffs to accomplish presidential goals. Ironically, this fear that agency administrators would "go native" did not really materialize, especially under the Bush II Administration. Furthermore, all of the agencies have ample expertise to prepare such documents, under the supervision of political appointees who have expertise in the matter, and OIRA review is duplicative.

Instead of bogging itself down in the micro-management of specific rule-making, OIRA should spend its time doing work that no other unit of government is set up to accomplish:

- **Resolving interagency disputes over cross-cutting policies.** OIRA should play a central role in convening the principals of warring agencies to

resolve disputes over regulatory policy. In this role, OIRA must avoid the pitfall of hauling one agency (e.g., EPA) before a panel of other agencies and departments that it is assigned to regulate (e.g., the military) to answer for its sins. Instead, OIRA should serve as a neutral broker, well-informed on the legal constraints, especially the requirements of agency statutory mandates that affect the resolution of the dispute, obtaining the assistance of Justice Department experts as necessary.

- **Conducting original research on cross-cutting regulatory issues.** OIRA should spend a significant part of its time exploring important research topics of broad application. For example, as I mentioned earlier, limited research by academics shows that regulatory costs are chronically over-estimated by industries attempting to avoid or weaken regulatory proposals. OIRA's economists, who have at their disposal considerable retrospective data on the government's experience with regulation, could assist greatly in the development of more reliable methodologies for such estimates. Other cross-cutting issues include the efficacy of deterrence-based enforcement, as opposed to compliance counseling and the development of more meaningful "accountability metrics" to ensure that agencies are performing their statutory missions effectively.

OIRA and Science

At various bitter moments in the past, the present, and—I fear—the future, the legal profession is subjected to impassioned attacks for attempting to dominate the Nation's civic affairs. More than once, we have heard the accusation that a piece of legislation is a "lawyers' full employment act" drafted for the primary purpose of making sure that we attorneys always have jobs meddling in other people's affairs. Yet I am afraid that as appropriate as this taunt may be in certain contexts, another profession—namely, economists—has provided the legal profession with serious competition on the power-grabbing front.

Under John Graham, OIRA embarked on two fundamentally misguided projects to change the way regulatory science is analyzed and used. The first involved the peer review of studies used by federal agencies to make such decisions. The second purported to announce a "one-size-fits-all" risk assessment policy for the entire government. These proposals were drafted by a tiny group of scientists hired by Graham to expand his reach into science policy. The documents were so poorly informed and extreme that they provoked a backlash of opposition from the scientific community, the public interest community, and this Committee. A panel convened by the National Research Council condemned the risk assessment bulletin in no uncertain terms. National Research Council, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget,* available at *http://www.nap.edu/catalog.php?record_id=11811.* In the end, OIRA was compelled to drastically revise the peer review bulletin, cutting back severely on its scope. It withdrew the risk assessment guidance.

To give you some sense of these proposals, their flaws, and the trouble they caused, I have attached three documents to this testimony: a May 5, 2006 letter from Chairmen Bart Gordon, John Dingell, Henry Waxman, and James Oberstar to Ralph Cicerone, the President of the National Academy of Sciences regarding the risk assessment proposal; a May 23, 2006 article I wrote about the risk assessment proposal for *Risk Policy Alert;* and the Center for Progressive Reform's December 7, 2003 comments on the peer review proposal .

Given this unfortunate track record, it is vitally important that OIRA under the Obama Administration confine its supervision of government to areas within its expertise, leaving to experts such as White House science policy adviser John Holdren the difficult job of restoring the independence and integrity of regulatory and other science policy issues throughout the government.

Conclusion

When Barack Obama ran for president, he defined the role of government as helping people when they cannot help themselves:

> Now, understand, I don't believe that government can or should try to solve all our problems. You don't believe that either. But I do believe that government should do that which we cannot do for ourselves—protect us from harm; provide a decent education for all children—invest in new roads and new bridges, in new science and technology .. . . Look, if we want get through this crisis, we need to get beyond the old ideological debates and divides between the left and the right. We don't need bigger government or smaller government. We need

better government. We need a more competent government. We need a government that upholds the values we hold in common as Americans.

To deliver real change, OIRA must embrace this mandate, and not the false premise that its most important mission is to prevent regulatory agencies from interfering with business.

The Center for Progressive Reform (CPR) is an organization of 60 academics from universities across the country specializing in the legal, economic, and scientific issues that surround federal regulation to protect public health, natural resources, and worker safety. One component of the Center's mission is to circulate academic papers, studies, and other analyses that promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. We seek to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. We reject the idea that government's only function is to increase the economic efficiency of private markets. For more information, please see *http://progressivereform.org*

ATTACHMENTS:

1. Congressional Letter to NAS President
2. CPR Comments on Peer Review Proposal

Congress of the United States
House of Representatives
Washington, DC 20515

May 5, 2006

Dr. Ralph J. Cicerone
President
National Academy of Sciences
500 5th Street, N.W.
Washington, DC 20001

Dear President Cicerone:

We are writing in regard to the National Academy of Sciences' (NAS) agreement to review the Office of Management and Budget's (OMB) Proposed Risk Assessment Bulletin (Proposed Bulletin). We are concerned that the description of NAS' review does not include important issues raised by the Proposed Bulletin. We urge NAS to define clearly the scope of its review, and either to expand the scope of its review or to articulate the issues raised by OMB's Proposed Bulletin that NAS will not address.

The Proposed Bulletin, which OMB issued on January 9, 2006, would direct agencies to comply with specified requirements when they evaluate risks to public health, safety, and the environment. OMB contracted with NAS, Contract No. 68-C-03-081, for an Ad Hoc Committee of the Board on Environmental Studies and Toxicology (Committee) to review OMB's Proposed Bulletin.

OMB's Proposed Risk Assessment Bulletin raises a number of scientific and technical issues regarding risk assessments. NAS is a logical choice to address such issues in a substantive, constructive critique of the Proposed Bulletin, given the Academy's extensive experience reviewing specific risk assessments for federal agencies and past work summarizing risk assessment techniques and best practices.

However, OMB's Proposed Bulletin also raises serious concerns about its effect on individual agencies' risk assessment practices, including whether it conflicts with statutory directives enacted by Congress. These and other important legal, policy, and budgetary questions would have to be considered in any comprehensive evaluation of OMB's Proposed Risk Assessment Bulletin.

In light of these concerns, the scope of NAS' review is very important. We are writing to inquire as to whether NAS is able and plans to address these concerns, and if not, to urge NAS to make clear in its final report the limited scope of its review. If the Committee's review does not address the full range of issues raised by the Proposed Bulletin, the NAS review cannot be considered a comprehensive review of the Proposed Bulletin.

Charge and Scope of NAS Review

OMB's charge to the NAS and the Academy's proposal produced in response to this charge are ambiguous as to the scope of the Committee's review. It is important that this ambiguity be resolved.

NAS' Plan of Action indicates the Committee will conduct a "scientific review" of the Proposed Bulletin. This suggests that the Committee will confine its review to the scientific and technical aspects of the OMB proposal. However, the specific questions to be addressed by the Committee imply that consideration will be given to issues that go beyond the scope of a scientific review.

Indeed, it appears impossible to provide a comprehensive answer to the questions without reaching beyond the scope of a scientific review. For reasons we will detail below, we believe consideration must be given to questions such as whether this guidance is necessary, and whether the imposition of a single set of rules for the performance of risk assessment across all federal agencies is appropriate.

A comprehensive review of the Proposed Bulletin must address at least the following issues:

1) The necessity of the Proposed Bulletin, given the risk assessment and review procedures already in place;

2) Potential conflicts between the Proposed Bulletin's directives and existing statutory directives;

3) The additional resources that would be needed for agencies to comply with the requirements of the Proposed Bulletin and the effect of these demands on agency operations; and

4) The potential for politicization of science created by the establishment, oversight, and enforcement of requirements for scientific and technical analyses by a White House policy office with little scientific expertise.

- What is the precise scope of NAS' review? Will NAS address each of the issues listed above?

In addition, it is unclear whether the NAS will address the fundamental question of whether the Bulletin should be finalized, or whether the NAS will only recommend improvements to the Proposed Bulletin.

The contract and the NAS proposal describing the review appear to assume that some form of this Bulletin should be finalized and that the only open questions are those pertaining to the specific guidance contained in the Bulletin. For example, in the Purpose, the charge states:

> "It is recognized that a review by NAS would be beneficial and informative as OMB moves forward ***to revise and finalize the Bulletin***." (emphasis added)

It appears that, under this charge, the Committee may offer additions to the guidance, but not consider whether the Proposed Bulletin should be withdrawn. This is emphasized in the description of the task, which states:

> "The NAS shall strive to develop a consensus report ***that contains advice for modifications to the Bulletin.*** ... The expert panel may add ***additional risk assessment issues*** that they determine to be of importance." (emphasis added)

Yet, in light of the issues identified in this letter, we believe that a complete evaluation must consider whether OMB should issue a risk assessment bulletin of this kind.

- Will the Committee consider the threshold question of whether OMB should finalize and issue this Bulletin?

Consistency with Congressional Intent and Existing Law

The introduction section of OMB's proposed Risk Assessment Bulletin provides a brief description of risk assessment and some examples of the agencies that perform these analyses. The introduction also includes a description of the statutes cited as the legal basis for OMB's authority to issue the guidance. There is no mention, however, of the fact that agencies, particularly regulatory agencies, often perform risk assessments in accordance with specific statutes. We also note that the charge does not include legal expertise in the list of "Expertise Required."

Our preliminary analysis of the OMB proposal indicates the analytical approach mandated in these guidelines represents a significant departure from approaches contained in the many statutes governing health, safety and the environment, and from statutory direction to federal agencies to protect human health, safety, and the environment.

We note that although there have been legislative proposals in several Congresses to mandate government-wide criteria for the use of risk assessment and cost-benefit analyses, these bills have never been enacted. Instead, Congress has continued to use a statute-by-statute approach to guide agencies' use of these analytical tools and to set standards for health and environmental protection in the context of discrete issues. OMB's Proposed Bulletin is in conflict with the approach taken in existing law.

The Proposed Bulletin appears to conflict with standard risk assessment practice by combining risk assessment and risk management analyses, and it appears to offer a risk management standard that differs considerably from numerous health, safety, and environmental statutes. The Proposed Bulletin also appears to require cost-benefit and comparative risk analyses to be performed in combination with risk assessments. Cost-benefit analyses are required to be done separately from risk assessments in a number of our health, safety, and environmental statutes, and requirements for comparative risk assessment represent a new analytical requirement that may be inappropriate for many of these statutes.

- Will the Committee undertake an analysis of the degree to which OMB's proposal conflicts or is inconsistent with existing laws?

Existing Agency Risk Assessment and Review Procedures

The ostensible goal of OMB's Proposed Bulletin is to improve the technical quality and objectivity of risk assessments prepared by federal agencies. To determine whether the Proposed Bulletin will achieve this goal requires much more than a technical analysis of the risk assessment procedures contained in the Proposed Bulletin. Among other things, such a determination requires an evaluation of the adequacy of the existing risk assessment

procedures used by federal agencies. It also requires an evaluation of whether the uniform requirements imposed by the Proposed Bulletin would improve current practices, either in some cases or across-the-board.

For a comprehensive review, the Committee must consider the current baseline level of the "technical quality and objectivity" of risk assessments performed by federal agencies. OMB's initiation of this Proposed Bulletin suggests there is some deficiency with current federal risk assessment practices. However, OMB did not provide any evidence of systemic deficiencies in federal agencies' current risk assessment practices. We urge the Committee to be clear in defining the baseline chosen as a basis for comparison and to evaluate carefully those baseline practices.

Agencies currently have numerous mechanisms for review of their risk assessments and other technical work products. Many agencies have one or more Science Advisory Committees made up of outside experts that review agency work. OMB currently mandates interagency reviews of risk assessments at its discretion and uses its authorities to review agency work products. Numerous NAS Committees have reviewed specific agency risk assessments – some of which are underway at this time. When analyses are incorporated into rulemaking procedures, there are opportunities for further review and public comment.

Agencies have traditionally had discretion to determine the type and scope of the risk assessments they need to undertake within the boundaries of their statutory directives and the purpose of the specific risk assessment. The imposition of a one-size-fits-all set of requirements for conducting risk assessments, such as those in this Proposed Bulletin, erodes agency discretion to determine the most appropriate level and type of analysis.

- Is the Committee going to consider all the existing procedures that agencies now use to ensure the technical quality of their risk assessments, including the current OMB review procedures, and then identify what, if any, additional benefits OMB's Proposed Bulletin would provide?

- Will the Committee consider the question of the appropriateness of a one-size-fits-all approach to risk assessment among agencies with very different missions, different scientific bases for analysis and testing, and different statutory directives?

Agency Resources and Timeliness of Agency Action

As procedures in the Proposed Bulletin are expected to require agencies to take additional steps and devote additional time and resources to conducting risk assessments, we have concerns regarding the overall effects of such resource diversions and delays.

It appears the Proposed Bulletin will create additional analytical requirements for agencies. To the extent the requirements of the Proposed Bulletin differ from existing risk assessment procedures, the agencies will be required to include additional information and analyses to comply with OMB's Proposed Bulletin. An estimate of the degree to which the requirements of the Proposed Bulletin will increase analytical burdens on the agencies will be possible only by a comparison between current agency risk assessment procedures and the requirements of the Proposed Bulletin.

The additional time required to comply with the procedures in the Bulletin also should be assessed. As we noted earlier, agencies are required to submit their work to numerous reviews

already. Agencies perform numerous analyses in the course of producing their risk assessments. They also produce cost-benefit analyses, regulatory impact analyses, small business impact analyses, and analyses on potential impacts of regulations on state and local governments. They perform these analyses in accordance with individual health, safety, and environmental statutes, as well as statutes and Executive Orders governing regulatory procedures of all agencies (e.g. the Paperwork Reduction Act, the Unfunded Mandates Reform Act, the Regulatory Flexibility Act, E. O. 12866, etc.).

Any additional requirements for analysis and review should produce a clear and substantial public benefit. This Proposed Bulletin should not become cover for dilatory tactics by special interests. Paralysis by analysis does not serve the interest of science or public policy.

We are also concerned about the potential for this Proposed Bulletin to increase significantly the costs to the covered agencies. Agencies have limited staff and budgets. OMB has supplied no cost estimates for this proposal, and it appears unlikely that any additional resources would be provided to agencies to fulfill their obligations under the Proposed Bulletin.

- Will the Committee assess the potential for and effects of increased costs and increased time to produce agency work products?

OMB's Role and Influence on Science and the Rulemaking Process

We assume the Committee will need to obtain information from the various federal agencies regarding their current risk assessment practices and whether OMB's proposal directs them to perform risk assessments in a manner that is not compatible with their needs, that is burdensome, or that is contrary to their statutory responsibilities.

If so, we have serious reservations about the level of candor the Committee will hear given that it will be asking agencies to offer opinions and information that might directly conflict with a policy proposal from the White House. We note this is not a problem unique to any individual Administration. The nature of the relationship between the Office of Management and Budget and federal agencies does not foster candid evaluations by career agency employees of the policies proposed by the Administration.

For example, *Inside EPA* recently reported that Dr. Nancy Beck, one of the principal OMB authors of this Proposed Bulletin, is now on detail to the Office of the Science Advisor, Dr. George Gray, at the Environmental Protection Agency (EPA). This example illustrates our concern. This Office will play a key role in providing agency comments about the Proposed Bulletin. Dr. Gray, a recent political appointee to EPA, a former colleague of Dr. John Graham, and Dr. Graham's co-author on a number of articles on risk assessment (one of which is cited by OMB in the footnotes in the Proposed Bulletin) is a proponent of the approach outlined in this Proposed Bulletin. Dr. Gray's agreement to have one of the authors of the Proposed Bulletin from OMB on detail to his office during the time period when the comments are being prepared does not give us confidence that the comments provided by EPA will reflect the concerns of EPA career practitioners of risk assessment.

The task of maintaining objectivity and delineating the boundary between science and policy is a difficult one. It is important to have safeguards to protect the integrity of scientific and technical information from political interference. We have concerns that barriers between science and politics would be eroded by involvement of a White House policy office in the establishment and

enforcement of criteria for the production of risk assessments and other scientific and technical work products by federal agencies.

Congress authorized federal agencies to implement statutes in specific areas of public health, safety, and environmental protection. OMB review is not required by any of these statutes. Technical expertise resides within the agencies, not within the Executive Office of the President. Agency actions are required by law to include public processes to ensure transparency. OMB has no such mandate, and its influence over agency actions is significant but poorly understood and documented.[1]

A review that seeks to determine whether OMB's Proposed Bulletin would increase objectivity of risk assessments must consider the fact that the Executive Office of the President, of which OMB is a part, is first and foremost a policy office dedicated to implementing the policies of the President's Administration. As the Government Accountability Office (GAO) found in its 2003 report, "The Office of Information and Regulatory Analysis (OIRA) is part of the Executive Office of the President, and the President is OIRA's chief client."[2] OMB does not approach the review of agency work products from an unbiased perspective.

- Will the Committee address the question of whether it is feasible and desirable to have risk assessment requirements issued, overseen, and enforced by a policy office with little scientific expertise and no public accountability?

Conclusion

At times, risk assessment can be a useful tool to assist the government in decision-making. It is intended, however, to be a decision support tool, a means to the end of implementing laws ensuring public health, a safe workplace, a clean environment, functioning ecosystems, and robust engineered structures, among others. Agency cost and time to implement the Proposed Bulletin's requirements must be considered in light of the goals and requirements Congress has set in these areas. The Proposed Bulletin is not in the public interest if it results in undue delay in achieving the goals Congress established in our laws for public health, environmental, and workplace safety.

We value the expertise the NAS brings to policy deliberations. The Committee's findings regarding the OMB Proposed Risk Assessment Bulletin will carry great weight in this policy debate. We urge the Committee to be as clear as possible about the scope of its deliberations and the specific issues its review will and will not encompass.

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[1] "Our review documented OIRA's direct influence with regard to more than two dozen rules in which it suggested significant changes that were ultimately adopted by the rulemaking agencies. OIRA's presence in the rulemaking process may also have a subtler, more indirect effect on agencies' decision making—discouraging them from submitting rules that OIRA is unlikely to find acceptable and encouraging them to make the case for the regulations that they do submit more carefully. However, the OIRA regulatory review process is not well understood or documented, and the effect that OIRA's reviews have on individual rules is not always easy to determine." P.110. General Accountability Office (GAO); "Rulemaking OMB's role in Reviews of Agencies' Draft Rules and the Transparency of those Reviews." September 2003, GAO-03-929. 217pp.

[2] General Accountability Office (GAO); "Rulemaking OMB's role in Reviews of Agencies' Draft Rules and the Transparency of those Reviews." September 2003, GAO-03-929. 217pp. (page 110)

Thank you for your consideration and attention to these important issues.

Sincerely,

BART GORDON
Ranking Member
Committee on Science

JOHN D. DINGELL
Ranking Member
Committee on Energy and Commerce

HENRY A. WAXMAN
Ranking Member
Committee on Government Reform

JAMES L. OBERSTAR
Ranking Member
Committee on Transportation and Infrastructure

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December 7, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Bldg., Room 10201
Washington, D.C.

Re: Proposed Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

OMB has proposed a Bulletin that would supplement existing procedures under the Information Quality Act (IQA)[1] by requiring peer review of regulatory information and by specifying the procedures under which that review would take place.[2] OMB has also proposed to become intimately involved in the resolution of information quality complaints.[3] The scope of matters covered Bulletin is overbroad and therefore exceeds OMB's legal authority. For the same reasons, the Bulletin will result in duplicative and costly peer review. In its preoccupation with agency-funded scientists, and its omission of comparable rules for industry scientists, the Bulletin will not accomplish the most important reform that could justify its issuance: ensuring that peer review is balanced for bias and therefore is not dominated by regulated industries to the extent it is today.

The Center for Progressive Regulation (CPR) appreciates the opportunity to comment on these proposals. CPR is an organization of academics specializing in the legal, economic, and scientific issues that surround health, safety, and environmental regulation. As our website indicates, www.progressiveregulation.org, CPR's mission is to advance the public's understanding of the issues addressed by the country's health, safety and environmental laws and to make the nation's response to health, safety, and environmental threats as effective as possible. The Center 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. CPR circulates academic papers, studies, and other analyses that

[1] Treasury and General Appropriations Act for Fiscal Year 2001, Pub. L. No. 106, § 515 (2001).
[2] Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (2003).
[3] Id.

promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. CPR seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. We reject the idea that government's only function is to increase the economic efficiency of private markets.

The Center also seeks to provoke debate on how the government's authority and resources may best be used to preserve collective values and to hold accountable those who ignore or trivialize them. We seek to inform the public about ideas to expand and strengthen public decision-making by facilitating the participation of groups representing the public interest that must struggle with limited information and access to technical expertise.

SUMMARY

OMB proposes mandatory peer review even though the IQA says nothing about peer review and contains no directive that agencies must use it before disseminating information. Moreover, OMB proposes to require peer review even though Congress rejected legislation mandating similar peer review procedures just a few years ago.[4] In light of the lack of statutory authority for its proposal, OMB seeks to justify its peer review requirements by noting that scientists and government officials have recognized the importance of peer review in regulatory processes.[5] There is a difference, however, between recognizing in the abstract that peer review can aid regulatory decision-making and developing specific proposals for making peer review useful. When OMB fills in the details, it fails to limit peer review to circumstances where it is best utilized, and it does not provide for an accountable and balanced peer review process in those circumstances.

More specifically, CPR asks that OMB consider the following objections to its proposal:

- OMB's assertion of jurisdiction to require agencies to use peer review regarding the dissemination of information is doubtful. Even if OMB has authority to require peer review for information that the government disseminates in reports and on the Web, it lacks the authority to require peer review in rulemaking because the IQA does not apply to rulemaking. OMB should delete the requirement that agencies undertake peer review with respect to scientific information that is already subject to extensive notice and comment in the context of a rulemaking covered by the Administrative Procedure Act (APA).

- OMB fails to target peer review to those situations in which it might be most useful. In light of the considerable costs of peer review, OMB should limit peer review to circumstances in which the information to be disseminated sets a new precedent or is reasonably controvertible.

- OMB's effort to avoid the Federal Advisory Committee Act (FACA) does not serve its purpose of increasing public confidence in the information that government disseminates.

[4] *See, e.g.*, H.R. 9 (1995).
[5] Proposed Bulletin, *supra* note 2, at 54024.

Contrary to OMB's legal analysis, FACA would apply to any peer review committee mandated by an OMB Bulletin. Even when FACA does not legally apply, OMB should require that agencies comply with the requirements in FACA for balanced peer review committees and a public peer review process when agencies seek peer review of especially significant information.

- OMB's assumption that scientists who receive public funding are more likely to be biased than scientists who receive industry funding is simply wrong, and its plan for appointing scientists with offsetting biases is unworkable. To address potential bias, OMB should require peer review committees to be "fairly balanced," as FACA requires, and should require public disclosures by scientists undertaking peer review of their historical affiliations and sources of research funding. OMB should make explicit its intent to leave in place federal laws and regulations that bar the participation of scientists with demonstrable financial "conflicts of interest," and should encourage agencies to disclose any waivers granted such reviewers.

- OMB rightfully rejected the centralized appointment of peer reviewers, although the reasons expressed by OMB for doing so significantly understate the difficulty of such a process, including the lack of coordination and accountability.

- OMB's decision to exempt information disseminated in adjudication and permit proceedings from its peer review procedures lacks any apparent justification, raising the suspicion that OMB's exemption is based on the fact that the information disseminated in adjudications and permit proceedings is largely information submitted by industry. OMB should require peer review of such studies under the circumstances recommended above.

- OMB's proposal to review each and every request for information correction creates the potential for backroom deals between OMB and the complaining party or other interested parties. To ensure accountability, OMB should issue a concise written explanation for public disclosure indicating that it recommended that an agency modify existing information in light of a complaint, and it should reveal for public disclosure any written communications, and a summary of any oral communications, pertaining to the substance of an information quality complaint received from members of Congress or their staffs or from persons outside of government.

AUTHORITY TO REQUIRE PEER REVIEW

OMB claims the IQA provides authority for its Bulletin, but the text of the Act does not support this claim. The Act does not explicitly require, or even authorize, peer review. Moreover, although the Act imposes a number of duties on OMB, Congress did not include among these duties setting up guidelines for peer review. Further, Congress explicitly rejected the imposition of peer review a few years ago after due consideration and debate,[6] and it is difficult to believe that Congress changed its mind when it passed the IQA. After all, the IQA was a rider hidden in an appropriations bill that no one in Congress other than the sponsor knew was there.

[6] Note 4 & accompanying text.

Moreover, OMB cannot claim other sections of the Paperwork Reduction Act (PRA) as authority for requiring peer review. Although the Act was passed in 1980, OMB has never previously interpreted PRA to authorize the imposition of peer review, and the fact that Congress has several times considered legislation that would expressly require peer review confirms that OMB lacks this power. Although PRA gives OMB authority to "develop and oversee the implementation of policies, principles, and standards to apply to Federal agency dissemination of public information ...."[7] this authority extends only to overseeing how the government "manages" the information that it collects.[8]

Even if the courts hold that OMB can impose a peer review requirement on agencies, this authority does not extend to the dissemination of information in rulemaking because the IQA simply does not apply to rulemaking. Congress indicated that the IQA does not apply to rulemaking when it required that agencies create a new "administrative mechanism" to hear and resolve complaints about information quality.[9] This means Congress intended the rider to apply to contexts where the dissemination of information is not already subject to an administrative mechanism to correct problems. This would not include rulemaking because such a process already exists in rulemaking. Since setting up another process would be superfluous or redundant, it has to be assumed that Congress had no such intention.[10]

SCOPE OF PEER REVIEW

While peer review has a role to play in the regulatory process, OMB's proposal for peer review is too broad in light of the potential benefits that it is likely to generate. OMB errs in assuming that peer review is appropriate or even necessary for all "significant" information because it is likely to have or will have a substantial impact on public policy or private initiatives.[11] Although information may have such an impact, it does not follow that the information is likely to be unreliable or that peer review is necessary to ensure its objectivity. OMB should therefore limit peer review to circumstances where the information to be disseminated sets a new precedent or is reasonably controvertible.[12] In any other circumstance, peer review is wasteful and will unnecessary delay the dissemination of important information.

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[7] 44 U.S.C. §§3504(d)(1).

[8] *See* OMB Circular No. A-130 Revised ("The PRA establishes a broad mandate for agencies to perform their information resources management activities in an efficient, effective, and economical manner."), available at http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html#8.

[9] Information Quality Act, *supra* note 1, §515(b)(2).

[10] The background of the Act also confirms that Congress intended the Act to apply outside the context of rulemaking. Prior to enactment of the Information Quality Act, there was a discussion and debate over how to provide for public input before agencies produce reports or put information on their web sites. *See, e.g.*, 23 Administrative & Regulatory Law News #3 (Spring 2000), at 10 (describing program held by the ABA on the dissemination of reports and information on the Web); White Paper From Industry Coalition to EPA Over Concerns Over Information Programs Submitted May 4, 1999, Daily Env. Rep. (May 4, 1999), at E-1 (discussing the dissemination of reports and information on the Web). There was no discussion, however, of the need to provide mechanisms to improve information quality in the context of rulemaking.

[11] Proposed Bulletin, *supra* note 2, at 54028, §§1-2.

[12] This argument is supported by a formal policy position of the American Bar Association concerning risk assessment. The ABA has recommended that the "nature, significance, and complexity" of a risk assessment should determine "when" agencies use peer review, as well as determining the "nature and scope" of peer review. ABA Resolution on Risk Assessment (October 1999), available at http://www.abanet.org/adminlaw/risk02.pdf. The report accompanying the recommendation, which was not officially adopted by the ABA, explains that peer review

OMB partially concedes this point. Regarding "significant" information, it permits agencies to "select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefit and cost implications, and any controversy regarding the science."[13] The government, however, distributes a wide variety of information, much of which occurs outside of the context of rulemaking, for which peer review may be unnecessary, even though the information has not been previously subjected to peer review. While OMB's flexibility regarding such information may minimize the government's burden in individual situations, the collective time and expense to the government of having universal peer review for significant information is likely to be substantial. Moreover, agencies are not permitted to vary the additional procedures they must use concerning "especially significant" regulatory information,[14] regardless whether the additional procedures are useful and necessary.

FACA

OMB suggests to agencies that they can avoid complying with the Federal Advisory Committee Act (FACA) when they undertake peer review. Congress passed FACA "in large part to promote good-government values such as openness, accountability, and balance of viewpoints."[15] Because these values are vital to ensuring the legitimacy of peer review, OMB should require that agencies conduct peer review of "especially significant information" under FACA.

FACA offers two essential protections necessary to legitimize peer review. First, it mandates a peer review process that is open to the public.[16] OMB does require that an agency provide an opportunity for public comment and that such comments should be furnished to peer reviewers in sufficient time that they can take the comments into account.[17] OMB presumably intends that the comments also be made public, although it does not explicitly so provide. OMB also provides that the report of the peer reviewers and the agency's responses to that report be made public.[18] It is difficult to see why the public should trust a peer review process that operates behind a veil of secrecy. If OMB's goal is to increase public confidence in the information that

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should be "limited to situations in which it is most likely to improve the analysis, such as complex or novel problems, or add authority, such as highly controversial situations." American Bar Association, Section of Administrative Law and Regulatory Practice, Report (August 1999), at 9, available at http://www.abanet.org/adminlaw/risk02.pdf.

[13] Proposed Bulletin, *supra* note 2, at 54028, §2.

[14] *Id.* at 54028, §3.

[15] Steven P. Croley, *Practical Guidance on the Applicability of the Federal Advisory Committee Act*, 10 AD. L.J. 111, 117 (1996); *see also* Jay S. Bybee, *Advising the President: Separation of Powers and the Federal Advisory Committee Act*, 104 YALE L.J. 51, 73 (1994) (noting that Congressional hearings on FACA "focused on the non-representative nature of the advisory committees, and the need to open their proceedings and reports to the President).

[16] FACA requires that peer review minutes are open to the public, 5 U.S.C. App. II §10(a)(1); interested persons are entitled to "attend, appear before, or file statements with any advisory committee," *id.* §10(a)(3), detailed minutes must be kept, *id.* §1010(c), and any records or documents made available to the committee be made available to the public unless the records can be withheld according to one of the exceptions for public disclosure under the Freedom of Information Act (FOIA), *id.* §10(b). An agency can close a meeting only if it determines that one of the exceptions to the Sunshine Act applies. *Id.* §10(d).

[17] Proposed Bulletin, *supra* note 2, at 54029, §3.

[18] *Id.*

the government disseminates, closing the peer review meetings and hiding peer review documents does not serve its purpose.

Second, FACA requires agencies to ensure that their advisory committees are "fairly balanced in its membership in terms of the points of view represented and the functions to be performed."[19] This safeguard is important because it recognizes that peer review inevitably involves matters of judgment about which reasonable scientists can disagree. This is the situation for two reasons. First, although OMB correctly asks that agencies refer only "scientific and technical matters to agencies, leaving policy determinations for the agency," it is virtually impossible to separate scientific and policy issues.[20] Second, even within the realm of "scientific issues," peer reviews will confront issues for which there are no objective answers, requiring them to use their best judgment.[21] Furthermore, allowing an agency to pick peer reviewers without regard to balance invites an agency to tilt peer review to its preferred outcome. This has long been a problem with peer review,[22] and OMB's failure to require the use of FACA will continue the problem.

OMB seeks to avoid FACA by authorizing agencies to "'direct peer reviewers of regulatory information – individually or in a group – to issue a final report detailing the nature of their review and their findings and conclusions."[23] Although FACA may not apply to convening a number of people to obtain the advice of each individually (rather than collectively),[24] individual review is a bad idea. The advantage of conducting peer review by committee is that "each committee member has the opportunity to observe the demeanor of the others and to challenge their evaluations."[25] As a result, "bringing all reviewers together to discuss their opinions can be a powerful shield against favoritism and animus."[26] This shield becomes even more important if OMB succeeds in closing peer review meetings to the public by permitting agencies to avoid FACA by hiring contractors to conduct the peer review.

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[19] 41 C.F.R. §102-3.30(c) (2003).

[20] *See* Wendy E. Wagner, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181, 214 (1999) ("Although these advisory panels have proved helpful in ensuring that the agencies use positive scientific knowledge accurately, these panels often find themselves reviewing the agency's policy choices under the auspices of peer review."); Joel Yellin, *Science, Technology, and Administrative Government: Institutional Designs for Environmental Decisionmaking*, 92 YALE L.J. 1300, 1305-06 (1983) ("If it were possible to separate the technical from the political, ethical, and legal, ... environmental decisions could be made in a simple two step process. ... The history of unsuccessful attempts to distinguish fact from law suggests that separation may be an unattainable goal.")

[21] *See* Holly Doremus, Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy, 75 WASH. U.L.Q. 1029, 1064 (1997) (Reliance on science must, by necessity, include reliance on some hunches.)

[22] *See* Bybee, *supra* note 15, at 58-59 (discussing the uses and abuses of advisory committees); THOMAS O. MCGARITY & SIDNEY A. SHAPIRO, WORKERS AT RISK: THE FAILED PROMISE OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION 196 (1993) (discussing the potential of stacking advisory committees to obtain an agency-favored preordained outcome).

[23] Proposed Bulletin, *supra* note 2, at 54027, §3. This interpretation is open to challenge. *See* Steven P. Croley & William F. Funk, *The Federal Advisory Committee Act and Good Government*, 14 YALE J. REG. 451, 472-78 (1997) (questioning the conclusion that FACA does not apply to individual reviewers).

[24] 41 C.F.R. §102-3.40(e) (2003).

[25] Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and* Sciences, 9 HIGH TECHN. L.J. 1, 64 (1994).

[26] *Id.*

Based on *Byrd v. EPA*,[27] OMB also claims that an agency can avoid complying with FACA if it hires a contractor or consultant, who in turn organizes the peer review.[28] In *Byrd*, the Environmental Protection Agency (EPA) hired a private contractor to select and manage a peer review panel and submit a report to the agency.[29] A majority of the panel held that FACA did not apply because, although EPA had reserved authority to control the contractor's choice of peer reviewers, it did not exercise this power. In their words, the decision was based "on what EPA in fact did, rather than on what it could have done."[30]

The *Byrd* case has not been followed by any other circuit. More importantly, it does not help OMB because OMB requires agencies to ensure that peer review of especially significant regulatory information meets a number of requirements, including that peer reviewers "shall be selected primarily on the basis of necessary scientific and technical expertise."[31] In order to meet this requirement, agencies must actively review the choice of peer reviewers by a contractor and veto any peer reviewer that does not meet this condition. Likewise, agencies have a legal duty to ensure that the other conditions that OMB has established for peer review of especially significant information are met. Thus, unlike the situation in *Byrd*, an agency will have to control the peer review process, which EPA did not do in *Byrd*, according to the majority opinion.

Of course, it is not necessary for OMB to require the formal use of FACA, although that would be a good idea, in order to ensure an open peer review process and balanced peer review. OMB could simply require agencies to comply with the fair balance and open government provisions of FACA without formally chartering peer review committees.

Conflicts of Interest Versus Bias

A fundamental flaw in the proposed Bulletin is its failure to distinguish between conflicts of interest that disqualify prospective scientists from serving on peer review panels under existing law and the bias that scientists may exhibit when they have formulated a position on a scientific issue through their work in the same or related areas. A full range of statutory and regulatory requirements, most notably the Ethics in Government Act,[32] bar scientists who have a direct financial interest in the outcome of an administrative decision from serving on government peer review panels established to review scientific studies that affect such deliberations. Agencies may waive these requirements, but must go through a formal process to do so. The proposed Bulletin uses the phrase "real or perceived conflicts of interest" but does not otherwise recognize

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[27] 174 F3d 239 (D.C. Cir. 1999).
[28] Proposed Bulletin, *supra* note 2, at 54028, §4a.
[29] 174 F.3d at 241.
[30] *Id.* at 247. In his dissent, Judge Williams held that FACA applied because the panel was "so closely" controlled "in membership and purpose." *Id.* at 249. For Judge Williams, the key was EPA's "veto power," and the fact that "it was not used" did not matter because EPA might "exercise it in future applications" and "the contractor was and is quite likely to take the fact of the veto into account in its selection decisions." *Id.*
[31] Proposed Bulletin, *supra* note 2, at 54027. Further, the proposed guidelines require an agency to "provide to peer reviewers an explicit written charge statement describing the purpose and scope of the review." *Id.* at 54028. In addition, the "agency shall provide an opportunity [for public comment]," and it "shall direct peer reviewers ... to issue a final report," and OMB specifies the specific nature of the report. *Id.*
[32] 5 U.S.C. §§ 201 et. seq.

that this term has a legal meaning under existing law.[33] It should be revised to make explicit OMB's recognition that existing legal requirements regarding conflicts of interest remain in force with respect to any peer review panels established under the Bulletin.

Even if scientists possess indirect financial interests (e.g., continued employment with a broadly-based industry trade association) that are not covered by federal conflict of interest rules, such interests may lead to an appearance that they are biased with respect to the outcome of a peer review. Despite its apparently exhaustive review of prominent literature on peer review, including reports by the General Accounting Office (GAO) and the EPA Inspector General, OMB conspicuously omits a recent GAO report documenting EPA's persistent tendency to ignore such financial interests in assembling peer review panels, with the result that scientists who were paid by manufacturers of chemicals under consideration by the EPA Science Advisory Board were actually permitted to serve on such panels.[34] To remedy its apparent insensitivity to this important problem, OMB should consider describing these interests without reference to the legal term of art "conflict of interest," while simultaneously strengthening its exhortations to agencies to avoid choosing such compromised candidates.

OMB advises agencies to consider disqualifying scientists who have or may do research supported by the government,[35] but it does not recommend a parallel rule to disqualify a scientist who has received, or is attempting to receive, research funding from regulated industries.[36] OMB, however, has the situation exactly backwards. If anything, agencies should exhibit more care in their selection of scientists whose research is funded by industry.

OMB is concerned that scientists funded by agencies, or who would seek such funding, could feel pressured to bend their advice to an agency in order to secure present or future funding. Public financing of science, however, occurs under procedures that protect and promote the independence of the scientists doing the research. By comparison, private research occurs under conditions that make it more likely that scientists will lose their funding if they do not produce results that are satisfactory to the industrial source of funding.[37]

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[33] Proposed Bulletin, *supra* note 2, at 54027, § 2.

[34] GENERAL ACCOUNTING OFFICE, EPA'S SCIENCE ADVISORY BOARD: IMPROVED PROCEDURES NEEDED TO ENSURE INDEPENDENCE AND BALANCE 18 (2001) (Report No. GAO-01-536) (describing the impropriety of EPA's appointment of industry-dominated panels) [GAO EPA Report].

[35] *Id.*

[36] OMB apparently does not think that latter situation is a problem unless a scientist has an actual financial interest in the outcome of the study. Proposed Bulletin, *supra* note 2, at 54024. Perhaps OMB anticipates that scientists who undertake research funded by industry will also have a financial stake in the outcome of the research. While this is a growing problem, not all industry-funded scientists are in this situation. OMB's position on this issue, however, is not entirely clear. In its proposed rules, OMB lists as possibly disqualifying the receipt of "substantial funding" from an agency or the application for such funding from an agency. *Id.* at 54027. There is no similar proposed disqualification for scientists who receive, or are seeking to receive, funding from industry, although OMB does propose that agencies consider as potentially disqualifying that a person has "financial interests in the matter at issue." *Id.* OMB's preamble informally defines "financial interest in the subject matter" as "(e.g., ties to a regulated business)." *Id.* at 54024. This seems to suggest an implicit acknowledgment by OMB that ties to a regulated business should be a negative factor in the selection process.

[37] Professor Sheldon Krimsky explains:

> When government funds basic science, it does not have a vested interest in a particular outcome. Given the transparency of the funding and the peer-review process, government agencies have to be very careful

Finally, OMB proposes that an agency can appoint a "biased" reviewer if necessary to gain needed expertise if it appoints someone who has a contrary bias.[38] This proposal reflects OMB's assumption that agencies can generally create a neutral peer review process, which is not actually possible in light of the factors discussed earlier. Moreover, it is unlikely that an agency can match up offsetting biases in the manner that OMB anticipates. What type of person, for example, has a "contrary bias" to a person who has an unrelated contract with the agency? The general prophylactic of requiring a "broadly representative" and "fairly balanced" review group is a more effective protection against biased peer review outcomes and is more manageable.

DISCLOSURE OF AFFILIATIONS

OMB requires that a peer review report shall "disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the agency or issue under peer review consideration."[39] Once again OMB draws a distinction between agency and industry affiliation that is unwarranted. Whereas a peer review report must disclose the involvement of peer reviewers with an agency, there is no similar disclosure requirement for scientists who are involved with the regulated industry. Further, although OMB suggests that an agency may wish to require peer reviewers to disclose "sources of personal or institutional funding,"[40] it is not clear whether OMB is referring to industry funding of research.

OMB should require that a peer review report disclose the historical affiliations of peer reviewers (both agency and industry related) and the sources of funding that a scientist has received. As the General Accounting Office (GAO) has observed, this approach gives the public information that can be used to evaluate the legitimacy of the advice being received because it indicates the degree of balance that the agency has obtained in its appointment of peer reviewers.[41] Moreover, this approach permits an agency to hear from a diverse group of scientists and not disqualify certain scientists because of their previous sources of funding, while assuring the public of the legitimacy of the peer evaluation process.[42] Finally, an agency should gather this information at

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> of not appearing to tease out or share scientific results that meet a political perspective, even in areas of applied research....
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> Private funded science is not transparent. There are unstated agendas. Many scientists who are funded by private companies understand what results would please the company and what results would benefit the company's bottom line. If a scientist is tethered to a company's research program, then the company is likely pleased with the outcome of the research and therefore would benefit by continuing to fund it. It is not unusual for investigators to internalize the interests of the company....

SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? 143-44 (2003).

[38] Proposed Bulletin, *supra* note 2, at 54027, §3.

[39] *Id.* at 54028, §3.

[40] *Id.*

[41] GAO Report, *supra* note 34, at 18.

[42] Disclosures might implicate some protections under the Privacy Act, but the Act permits individuals to waive any privacy protections that they might have. *See* 5 U.S.C. § 552a(b) (permitting written waivers). It is reasonable for an agency to require such waivers as a condition of serving as a peer reviewer.

the beginning of the peer review process when the agency can use it to ensure that peer review is a balanced process.[43]

CENTRALIZED APPOINTMENT OF REVIEWERS

In its proposed guidelines, OMB declines to propose the centralized appointment of reviewers because it "could be unduly inefficient and raise other concerns."[44] OMB understates the difficulties with centralized appointment of reviewers.

First, OMB does not suggest what entity might serve this function, but it is clear that the selection of OMB for this function is unlikely to "lend the appearance of greater integrity to the peer review process." There has been significant concern over the years concerning the accountability of presidential supervision of rulemaking,[45] and OMB's control over peer review would raise the same legitimate concerns.

Second, putting an entity in charge of peer review which has no responsibility for the implementation of a statutory scheme invites the appointing agency to pursue its own political and substantive agenda, regardless of whether it is appropriate for the implementation of the statutory scheme.[46] The risk that a centralized agency would pursue its own agenda is particularly acute to the extent that it is not publicly accountable for its actions. Yet, as indicated above, there is no assurance that the agency that appoints the peer reviewers, whether it is OMB or some other entity, will do so in an accountable way. The lack of accountability invites capture by vested interests. This is particularly a problem because OMB fails to require that peer review be a balanced process.

Finally, peer review is less likely to inform and improve regulatory decision-making when agency employees regard it as a bureaucratic burden imposed on an agency rather than a tool for improving the quality of decision-making.[47] Agency personal are more likely to regard peer review as a bureaucratic requirement, as opposed to an integral part of the agency's decision-making process, when it is imposed on the agency by OMB and implemented by an another entity, be it OMB or some other agency.

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[43] *See* GAO Report, *supra* note 34, at 20 (recommending that EPA collect background information about potential peer reviewers before their appointment to a peer review committee).

[44] *Id.*

[45] *See, e.g.*, GLEN ROBINSON, AMERICAN BUREAUCRACY; PUBLIC CHOICE & PUBLIC LAW 102 (1991), Sidney A. Shapiro, *Presidential Oversight and the Deterioration of Regulatory Policy*, 46 AD. L. REV. 1, 21-23 (1994) (discussing the debate of White House accountability in rulemaking oversight).

[46] This is what happened when Congress located the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Health (NIOSH) in two different cabinet departments. Although Congress created NIOSH to serve as the scientific arm of OSHA, NIOSH at times has pursued this mission according to its agenda and has not always pursued projects helpful or appropriate to OSHA. Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. ON REG. 1, 57-59 (1989).

[47] According to the National Academy report, peer review "must become accepted as part of the agency's culture, not merely a bureaucratic requirement." National Academy of Sciences, Strengthening Science as the US Environmental Protection Agency: Research Management and Peer Review Practices 115 (2000). Professor Lars Noah makes a similar point when he observes that peer review works best when it is peer reviewers interact with agency scientists in an ongoing dialogue. Lars Noah, *Scientific "Republicanism": Expert Peer Review and the Question for Regulatory Deliberation*," 49 EMORY L.J. 1033, 1059-60 (2000)

UNEQUAL TREATMENT OF INDUSTRY INFORMATION

The proposed Bulletin seeks to assure the objectivity of information disseminated by the government by subjecting it to peer review, but the Bulletin exempts an important category of information generated by industry from this procedure. According to the proposal, "agencies need not have peer review conducted on significant regulatory information that ... is disseminated in the course of an individual agency adjudication or proceeding on a permit application."[48] The lack of any apparent justification for these exceptions leads to the conclusion that OMB is protecting industry information from peer review.

OMB presumably exempted information disseminated in adjudications because its Information Quality Guidelines exempted adjudication from the Act altogether,[49] but it is not clear why information disseminated in adjudication is not subject to the Act. Maybe OMB believed that the adjudicatory process is sufficient to vet the accuracy of the information involved, but there are two difficulties with this position. First, the procedures in an adjudication vary widely depending on whether the adjudication is formal or not, and if not, what procedures are required by the statutory mandate under which the agency is operating.[50] Many informal adjudications are conducted with no procedures whatsoever. Second, if this is OMB's position, it is difficult to understand why OMB does not also exempt information disseminated in a rulemaking because the procedures are adequate to vet the information that is disseminated.

OMB also offers no reason why it exempts information disseminated in a proceeding on a permit application. Since these proceedings involve adjudication, OMB's exemption might have been based on the prior reason. Or OMB may have concluded that permit applications were not important enough to deserve peer review. But OMB subjects other types of significant regulatory information to peer review, and there is no indication by OMB why information disseminated in a permit proceeding, if it is significant regulatory information, should not be subject to peer review.

OMB's exemption for permit proceedings may be an attempt to protect propriety or trade secret industry information, but this is an invalid reason for not subjecting this information to peer review. An agency can follow the practice of FDA, which regularly protects such information and still subjects it to peer review.[51]

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[48] Proposed Bulletin, *supra* note 2, at 54027, §2.

[49] In the Guidelines, OMB defines "dissemination" as not including "distribution ... limited to adjudicative processes. Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated By Federal Agencies, 67 Fed. Reg. 8452, 8460 (2002).

[50] See RICHARD J. PIERCE, SIDNEY A. SHAPIRO & PAUL R. VERKUIL, ADMINISTRATIVE LAW & PROCEDURE §§ 6.4.3, 6.4.10 (3d ed. 1999) (explaining the variability of procedures used in adjudication).

[51] FDA advisory committees are composed of scientists who are hired as special government employees, which makes it possible for FDA to reveal the information to them and which imposes on the scientists a legal obligation to keep the information confidential. *See* 21 C.F.R. §14.80 (members of FDA advisory committees serve as special government employees).

The lack of any apparent justification for these exceptions leads one to the suspicion that OMB's exemption is based on the fact that the information disseminated in adjudications and permit proceedings is largely information that is submitted by regulated industries. But there is no apparent reason why industry information should be exempted from peer review, except when the nature of the information does not warrant the cost and delay created by peer review. As noted earlier, peer review should be reserved for the dissemination of information that sets a new precedent or is reasonably controvertible. If industry information meets this test, it is not possible to distinguish it from information that arises in other contexts.

OMB's solicitude for industry information is particularly puzzling because such information is usually not subjected to the same level of scrutiny as information that is the result of public funding.[52] Moreover, since industry often regards information submitted to agencies to obtain permits or licenses as propriety or trade secret, it is far more likely to have received little or no independent scrutiny that information produced by scientists as the result of public funding.

OMB AND CORRECTION REQUESTS

OMB's proposed Bulletin ends with a proposal that agencies provide to it within seven days a copy of each non-frivolous request for information quality correction unless the agency posts the complaint on its web site, and that an agency consult with OMB before it responds to the complaint.[53] In light of the public interest in the outcome of complaints concerning "especially significant regulatory information," it is important that OMB be accountable for its participation in the resolution of information quality complaints, but OMB has proposed nothing in the way of accountability procedures.

OMB should take two steps to promote accountability concerning complaints about "especially significant regulatory information." It should issue a concise written explanation for public disclosure indicating that it recommended that an agency modify existing information in light of a complaint, and it should reveal for public disclosure any written communications, and a summary of any oral communications, pertaining to the substance of an information quality complaint from members of Congress or their staffs or from persons outside of the government.[54]

Sincerely yours,

Sidney A. Shapiro
Board Member and Treasurer

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[52] For example, regarding privately funded research in the life sciences, empirical studies have found a "greater secrecy among colleagues, a significant failure of scientific exchange in the community, and a pattern of delayed publication." KRIMSKY, *supra* note 37, at 84.

[53] §7, Proposed Bulletin, *supra* note 2, at 54029.

[54] These recommendations reflect a formal policy adopted by the American Bar Association concerning the accountability of White House oversight in the context of rulemaking. *See* Recommendation on Presidential Oversight (Feb. 1993), available at http://www.abanet.org/adminlaw/policy.html). The ABA has recommended that government entities designated by the President to engage in a continuing process of oversight of the rulemaking process should issue a written explanation of changes it has requested agencies to make in proposed and final rules. The ABA has also recommended that the entity reveal conduit communications that it has received concerning the matter it is reviewing from members of Congress, their staffs, or from persons outside of the government concerning such proposed or final rules. The former Administrative Conference of the United States (ACUS) has made a similar recommendation of. Presidential Review of Agency Rulemaking (Recommendation 88-9), 1 C.F.R. §305.88-9 (1992)

BIOGRAPHY FOR RENA STEINZOR

Rena Steinzor is a Professor at the University of Maryland School of Law, where she teaches courses in administrative law, risk assessment, critical issues in law and science, contracts and legal method, and a survey of environmental law. She has a secondary appointment at the University of Maryland Medical School.

During the course of her academic career, Professor Steinzor has written extensively on efforts to reinvent environmental regulation in the United States, the use and misuse of science in environmental policy-making, and the devolution of legal

and administrative authority to the states. She edited *A New Progressive Agenda for Public Health and the Environment* (Carolina Academic Press, 2005) with Professor Christopher Schroeder of the Duke Law School. The book proposes an alternative set of values and principles that should guide efforts to reform environmental law.

Steinzor worked with Professor Wendy Wagner of the University of Texas School of Law, to edit a book of essays by prominent academics entitled *Rescuing Science from Politics* (Cambridge University Press, 2005) writing an introduction and conclusion summarizing the issues and recommendations suggested by the book. Professor Steinzor has completed work on a book entitled *Mother Earth and Uncle Sam: How Pollution and Hollow Government Hurt Our Kids,* which was published by the University of Texas Press in December 2007.

Professor Steinzor is the President of the Center for Progressive Reform (CPR) (*www.progressivereform.org*), a virtual think tank comprised of some 45 member scholars from universities across the United States. 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. One component of CPR's mission is to circulate academic papers, studies, and other analyses that promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. CPR seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. CPR rejects the idea that government's only function is to increase the economic efficiency of private markets.

Before joining the law school faculty, Professor Steinzor was the partner in charge of the environmental practice at Spiegel & McDiarmid, a Washington D.C. law firm specializing in the representation of State and local government entities in the energy and environmental areas. Prior to joining the firm, Professor Steinzor was counsel to the Subcommittee on Commerce, Transportation & Tourism of the House Energy & Commerce Committee, which was then chaired by James J. Florio (D–NJ). She advised the Subcommittee during its consideration of the *Superfund Amendments and Reauthorization Act of 1986* and the *Asbestos Hazard Emergency Response Act of 1986.* She also served as an attorney advisor to Commissioner Patricia P. Bailey of the Federal Trade Commission and worked as a consumer protection attorney at the FTC in various staff positions.

Professor Steinzor is a 1976 graduate of Columbia Law School and a 1971 graduate of the University of Wisconsin.

DISCUSSION

Chair MILLER. Thank you, Ms. Steinzor.

We will now have rounds of questioning and I will begin by recognizing myself. With respect to the use of science in rule-making, and actually Dr. Coglianese's statement today was very similar to what I said at our first hearing on this topic two years ago. I don't think scientists at agencies should be platonic guardians, wiser than the rest of us, not motivated by unsavory political considerations or economic considerations, but somehow pure and noble and wise but that we needed to make sure that we had sound science, honest science that informed our decisions. After we got sound science, we still—there was still plenty of room for discussion and decisions about alternatives. It is the difference between risk assessment and risk management. Given that—I don't remember the exact number. I think that there was only one or two or maybe three scientists, people who by academic background or by their professional lives would be considered a scientist at OMB and they were getting scientific assessments, scientific information from specialists in obscure areas from all over government.

APPROPRIATE ROLES FOR OIRA

What should be the role of OIRA in reviewing scientific assessments that come as part of the rule-making from the various agencies of the Federal Government? We can go down the line. Dr. Melberth?

Dr. MELBERTH. Well, I think a more appropriate role for OIRA in that situation might be to ask questions about the process by which that science was generated and to ensure that agencies have adhered to the best practices as they put them in place. They may very well articulate questions about the science that might be raised from other agencies and somehow coordinate that discussion among agencies. But I would agree with you, OIRA does not have that expertise to be questioning an agency about the science that is being proposed. There is a distinction between science and policy, and OIRA can be in a situation to ensure that the process by which the information that goes into policy is sound, but they are not the ones that should be in a situation of being able to assess whether or not that science is sound. That is not their job, it is not their qualification.

Chair MILLER. Anyone else wish to be heard?

Ms. SMITH DEWAAL. I just want to make the point that science is not stagnant and we need to progress regulations much more quickly than they are today. The role of OIRA in reviewing risk assessment should be limited to none: in terms of making sure the risk assessment is there to support the regulation, but beyond that they should have very little role.

Chair MILLER. Mr. Warren.

Mr. WARREN. Well, I think that the key is that there are different ways in which the White House could be involved in some kind of review of an agency submission. What is key is, first of all, they should not be putting any criteria forward for the decision other than what is in the underlying statute. So some notion of a risk assessment requirement that is not in the statute is really not in their domain. They should also not substitute substantive judgments for the substantive expertise of the agencies. They need to defer to the agencies which really have the talent pool as well as the responsibility to sort out conflicting scientific evidence. Their role should be limited to whether they have properly observed the requirements of the underlying statute in terms of using the generally accepted scientific practices. And in some ways it is better for them to rely on the Office of Science and Technology Policy to defer to them even in respect to that particular judgment because that office really is more the repository of scientific expertise within the White House.

Chair MILLER. Dr. Coglianese.

Dr. COGLIANESE. So science is all about open inquiry and taking—asking questions, taking a skeptical approach to things. I don't think you need to be a science expert to ask questions. The expertise comes in answering them. But OIRA, which may not have the same level of expertise, the head of an agency who may not be a scientist, Members of Congress who may not be scientists, it seems to me perfectly consistent with the scientific ethos as well as sound public policy-making to have non-scientists who are in

critical decision-making or advisory roles to be asking questions of those who are the experts.

Chair MILLER. At the conclusion of those questions, can OIRA, if they find themselves unpersuaded, substitute their scientific judgment, again not about what the policy should be but what the facts are for those scientists at agencies?

Dr. COGLIANESE. Well, I think as has been noted, OIRA doesn't have, as a relative matter, the staff to actually evaluate agency science assessments thoroughly. One response to that could be to somehow ban OIRA from engaging with scientific issues. Another response could be, maybe there should be more scientists at OIRA to give them that kind of capacity. Clearly, the law that Congress passes delegates decision-making authority to the agencies. They are the ultimate decision-makers. Their decisions will be based upon a variety of inputs, scientific, policy considerations, economic considerations, political considerations, conversations with the White House, conversations with Congress, conversations with affected parties.

Chair MILLER. I hope Dr. Broun and Ms. Dahlkemper would note that the reason we have gone over five minutes is not my question but the answers.

Ms. Steinzor.

Mr. BROUN. Take all the time you want, Mr. Chair.

Ms. STEINZOR. I will try and be really quick, Mr. Chair. I think your question is a really interesting one and I would only point out that what troubles some of us is not that OIRA has intruded itself in science policy but that OIRA often ignores science, and I think the best example of that would be the mercury rule-making where OIRA had a report that had been assembled at considerable effort by the National Research Council, the gold standard for scientific agencies in our country, that ratified what the agency scientists had said, and I never see anyone who opposes regulation ever mention that that report exists including OIRA economists. So when OIRA asks questions, too often what that sort of morphs into is the economists pushing scientists and everybody else away from the table and making the decision on very narrow economic grounds that as Wesley Warren said doesn't—is not consistent with the statutes and their delegation. So I would only—the problem is not that they ask questions, the problem is that they ignore science when it is inconvenient. It goes back to a phrase coined by one of my colleagues, Tom McGarrity: Your science is bad science and my science is good science. That is unfortunately the posture too often.

Chair MILLER. My time has expired but I will be similarly indulgent to the other Members of the Committee. Dr. Broun.

SEPARATING POLICY FROM SCIENCE

Mr. BROUN. Thank you, Mr. Chair. I want to say to begin with, I am a physician, I am a scientist. There are some Members of this whole committee that are research scientists that would argue with that statement, but I am an applied scientist and I started my political activism by coming to Washington to lobby about conservation and as a scientist I believe that science should be a very integral part of the decision-making process, but I also see problems. Two of you mentioned peanut butter. We had an unfortunate inci-

dent, a very unfortunate incident in America, a very sad incident in America where a peanut butter plant in Blakely, Georgia—where I used to live and practice medicine—provided peanut butter to the world that was tainted with bacteria, though the regulatory process was already in place to prevent that from happening. I also see another very big danger in that we see within Members of this Administration, high-up Members, all the way to the Secretary level, that have embraced a scientific theory of human-induced global warming and there are thousands of scientists that refute that and say that there are minimal, if any, human effects on global warming. I am an adherent actually after looking at data that that is probably true, but I am also as a scientist very open-minded. When I graduated from medical school, the things that I was taught as being absolute, scientifically proven medical facts. Within five years, we were teaching absolutely the opposite. That is the reason continuing medical education is so important.

And herein lies a problem. You have scientists disagreeing on an issue such as human-induced global warming, and what kind of regulatory policy and actually legislative policy we are going to put in place when on one hand you have people who are very ardent supporters of one scientific theory when it is not proven scientifically and then on the other hand we have things which were universally almost adhered to where scientists said the world was flat. Now, we still have those same problems today, so how should OIRA, how should the government, how should we as legislators look at this to put in place policy that takes all stakeholders' issues, thoughts, concerns to bear in developing regulatory authority as well as legislative authority or legislative bills and how we pass laws? So I am very eager to hear how we weigh all those things and not just veil it in the idea that science should be the answer to all of how we set these regulations, because it cannot be. Science absolutely cannot be. So if you all could help us as a committee to see how are we going to make policy where OIRA looks at all those factors. Dr. Coglianese, could you help me out?

Dr. COGLIANESE. Sure. Well, sometimes when you recognize that science is separate from policy-making, even though it is integral to it, you can begin to recognize that sometimes the best and the most justified policy choices are ones that require action even in the face of a tremendous amount of scientific uncertainty, so even though we may not have full answers to all the relevant questions that science could answer about climate change, it may be that policy is justified. It is also the case that sometimes we may have a great deal of certainty about certain kinds of effects in the world that we deem problematic, but the only way to address those would be to create perhaps more problematic effects at some limit, and this is the aspiration of approaching policy through cost-benefit analysis, to try to take into account both the positive effects of addressing a problem and the negative effects that would come from addressing that problem, and to try to achieve the policy that maximizes, as much as possible, the positive effects. Science is integral to figuring out what those effects are, but at the end of the day, won't tell us exactly what the answer to the question of what we should do must be.

Mr. BROUN. Thank you, Doctor.

If I may, Mr. Chair, have one more witness?

Chair MILLER. You are less over your time limit than I was over mine.

Mr. BROUN. Ms. Smith DeWaal.

Ms. SMITH DEWAAL. Thank you very much. I think that one of the things we have to recognize is that the agencies right now are actually hesitant to bring forward regulatory solutions. We have observed this. You made the point about the peanut butter plant in Georgia and that was a tragic event for many, many people including many of the people who worked there. But the regulatory process was not in place in that plant. The overall policy that we have been operating under in the food safety arena is one developed for the astronauts really that does require companies themselves to identify hazards in their products, really to apply science to their process, and to find ways to resolve it. That system was not mandated for that peanut butter facility or any other. It is required only for a few types of food products in the United States, even though it is generally understood by the industry that this is the appropriate tool to use to manage food safety. So I just would urge you that hesitation in even beginning the regulatory process is something that we have observed with the food safety and the two agencies that are principally involved in food safety, and secondly, that the standards that they try to use, what we call performance standards, aren't being modernized, aren't being updated, and that is where the science really comes in. So I think one approach that is being considered is whether the policy and the science should somehow be decoupled so that the science can be updated much more rapidly. Regulations today are taking about five years to get through the process at OMB. It is really too long if you are trying to protect public health.

Mr. BROUN. Thank you, Ms. Smith DeWaal. I want to disagree with you, though, because the problem with the peanut butter plant was that the regulations and the oversight to those regulations just weren't applied by our own state government and it was tragic and unfortunately our Department of Agriculture just didn't do a good job on that. Thank you, Mr. Chair.

Chair MILLER. Ms. Dahlkemper.

Ms. DAHLKEMPER. Thank you, Mr. Chair.

Chair MILLER. For a generous five minutes.

POTENTIAL FIXES FOR OIRA

Ms. DAHLKEMPER. Thank you. I want to thank the panel for coming today and speaking on this very important topic. Several of you have expressed the opinion that the regulatory agencies whose work is public health, public safety and the environment are starved for resources and weakened in many other ways, so I am asking what is the fix, how do we fix the situation, and as we look at OIRA, how we can make them more a partner to make sure that these very important goals are achieved? I am going to ask the entire panel to kind of address this.

Dr. MELBERTH. The authors of our report indicated that was one of the most critical issues that need to be addressed. I think the most—the recommendation on which there was very little disagreement, there was very little discussion, it was just a given from the

very beginning was that agencies are underfunded and understaffed. There has been a great drain of science—of experts, of inspectors. The resource base for agencies needs to be restored, and in order to do that, the authors urge that there be some kind of assessment performed and OIRA may be the agency to be able to do this regarding agencies' statutory responsibility and the new challenges that they are facing so they can get some idea of what is necessary for the agencies to actually meet their missions, and then OIRA should be in place, should take the responsibility for trying to help agencies get that funding and work with the agencies to get that funding. It should not be an office that works to hinder agencies but to help agencies.

Ms. DAHLKEMPER. Ms. Smith DeWaal.

Ms. SMITH DEWAAL. Thank you very much. I think that we need to empower the agencies to start regulating. We have seen the costs of under-regulation in the financial sector. Those are very plain. Let me tell you in food sector, the spinach industry has still not recovered the market share it had prior to the 2006 outbreak. We have seen every time one of these major food-borne illness outbreaks occurs, it is hundreds of millions of dollars in lost profits, lost revenue to those industries involved. So not only are there costs to the consumers who get sick; the costs of hospitalization for E. coli 015787 can run into the hundreds of thousands of dollars, but it is a cost to industry as well. OIRA should be empowered to look at where there is a lack of regulation. We know in the food area, we have seen it is repeatedly with FDA, that they just don't have the tools. It is resources, it is staff but it is also a framework for regulation that would help to prevent these illnesses. Thank you.

Ms. DAHLKEMPER. Thank you.

Mr. Warren.

Mr. WARREN. Well, I want to endorse the comments from the previous two panelists. I want to make a broad point and a specific suggestion in response to your question. I think the broad point goes back to Dr. Broun's question which I think is a fundamental question—How do you take action in the face of uncertainty? And the fact of the matter is, we have great science in this country, but I have never met a scientist who didn't think that they could learn some more by doing some more research in their particular area, especially if they got a government grant. We are always learning more, and that is a good thing, but we can't wait then until we know everything to act, because not acting has costs for society just like overreacting does. So I think in this particular case, although my background is in economics, I have a legal analogy, which is government needs to act more like a civil trial, where the weight of the evidence is used as opposed to a criminal trial with a much higher standard because it is wanting to not have too little regulation as well as not too much regulation. So my specific suggestion where OIRA is concerned is, any time they put a requirement on the agencies to do more analysis, they have to make the budgetary resources available in order to do that, and remember, there is another part of OMB, which is the part that I worked in, which is the budget part, and they should really be united in terms of making sure the resources are there to do the regulatory processes and

the assessments that are required as well as overseeing the requirements.

Ms. DAHLKEMPER. Thank you.

Dr. Coglianese.

Dr. COGLIANESE. Thank you very much. The kind of assessments that Mr. Warren just mentioned and Dr. Melberth mentioned, I mean, there are assessments that are required in the *Government Performance and Results Act* and OMB on the budget side has put in place a review process called PART that has been in place to assess how agencies are doing. There are those processes in place. I am not sure OIRA, given its staff size and its role on the management, the M part of OMB being separate from the budget, is really positioned well to address the resource demands that agencies have.

As to your question about whether OIRA can be more of a partner rather than, I gather, an opponent to regulatory agencies, I think it is actually pretty hard to create that kind of partnership relationship by just changing words in an executive order. So who heads that agency, and the administration in which that agency serves, is going to be very important. I will say lastly on this question of being a partner, being an obstruction, there are at least—there are four major social science studies to date that I am aware of that have examined the extent to which OIRA contributes to delay in the regulatory process, and the results across those studies consistently have failed to find any systematic general pattern of delay that is caused by OIRA. Some of these studies actually indicate that rules that go up to OIRA are completed in a faster manner than rules that don't.

Ms. STEINZOR. I really appreciate your question and I have a very specific recommendation. The Performance Assessment and Rating Tool, the PART tool, is actually located in the management section of OMB, not at OIRA. But it is not in the budget section, it is in the management section. I think that the shortfalls in funding are so severe that they cripple any effort to perform on statutory mandates and that it would be extremely useful if this PART tool would be used to work with the agencies to line up all the things they are required to do by statute and the amount of resources they have and would compare what they would need to complete all those mandates. This is the only way I think we will ever be able to give you the tools—you, Congress—the tools to either give them more money so they are not sued constantly for missing deadlines and not putting rules out on time or repeal the mandates, in which case I suspect we would have quite a lively debate on some of the health and safety mandates.

One other thing I wanted to say is that my testimony cites studies, empirical studies that have been done that show that OIRA's overwhelming influence is to weaken regulatory protections. That are several academics that have written studies that show that, and I would urge the Committee to take a look at that. The rulemaking process takes a long time for a lot of reasons but the overwhelming trend when OIRA gets its hands on something at least in the past many years except perhaps during the Clinton Administration has been to weaken the regulations.

Ms. DAHLKEMPER. Thank you. I thank the panel for specific suggestions. I appreciate that.

Thank you, Mr. Chair.

CREATING REACTIVE AND STREAMLINED REVIEW PROCESS

Chair MILLER. Thank you, Ms. Dahlkemper. I now recognize myself for a second round of questions. There is a Woody Allen movie, I think the name is "Sleeper." It is set several centuries into the future and there is a scene in the movie where a character is distraught and the Woody Allen character, the character played by Woody Allen, hands the other character, the distraught character, a cigarette and says here, smoke this cigarette, scientific research has proven that tobacco is one of the best things for you. I think we all recognize that science can change, does change. People in politics, we have now made flip-flopping the cardinal political sin and it is frequently said of politicians that they are frequently wrong but never in doubt. Scientists are sometimes wrong but always in doubt. And we want to have a rule-making procedure that recognizes the possibility that science is evolving but we need to make decisions based upon the science that exists now.

The hearings that this committee held on the Executive Order was not the only time that the role of OIRA came to our attention. There is a statutory requirement to create in EPA what is called the Integrated Risk Information System. It is simply supposed to be a registry of chemicals that may have some health consequences. It is not risk management. It is risk assessment, what do we think these chemicals do to you, and it—there has been a great deal of procedure involved in those determinations and it is now down to two assessments a year when 600 new chemicals are coming on to the market every year, coming into current—into widespread commercial use every year, and chemicals like TCE and formaldehyde have been tied up for 20 years in the assessment process. Mr. Whittaker has a slide. This was one of my favorite moments in the last two years in the last Congress. This is the procedure. These are actually diagrams prepared for EPA. This was the procedure in effect from 2004 until April of 2008, and the last head of OIRA, Susan Dudley, testified that one of the reasons for the slow rate at which new chemicals made it into the IRIS list was that this was too complicated so she developed a streamlined procedure, which Mr. Whittaker can now show the streamlined procedure. This was post April 10, 2008. Okay. Can we show again quickly the complicated procedure, Mr. Whittaker? That was complicated. Now show simplified. Yes, that was simplified. I cited Woody Allen. There was also a Groucho Marx line, who are you going to believe, me or your lying eyes?

One of President Obama's directives to OMB in developing a new Executive Order is come up with something more streamlined, that doesn't take as long. What can we do to make sure that—that takes into account the right considerations but how can we structure OIRA's participation that makes the review process timely, that makes it happen when it needs to happen? Dr. Melberth.

Dr. MELBERTH. Well, I think the IRIS example is an excellent one to use. One of the—this is an illustration of one of the ways or one of the reasons why OIRA should not be involved in scientific

information. You are absolutely right. The IRIS process is an assessment. It is risk assessment. It is not at all management. This is collecting critical information. It is removed from a policy decision about what do you do when you have this information, what steps should we take now once we know how damaging a certain chemical might be. This process, the quote—unquote, simplified process that OIRA put in place with EPA's help in 2008 changes that process, so not only is it more complicated, but our understanding of it is, it actually gives certain agencies affected by the potential policy outcome of a profile of a chemical the right to veto whether or not that assessment gets finished, whether or not the IRIS office and EPA actually does their work. So that is OIRA interference in the generation of information, the generation of science, not in the policy. That is not a policy-related decision. That has nothing to do with Presidential priorities or consistent—achieving consistency with Presidential policies. It is merely scientific information. That is not an appropriate role for OIRA. That is the kind of thing I think that an Executive Order could very clearly—be worded clearly to separate OIRA from that kind of process, place those kinds of responsibilities for reviewing those processes in some other agency, but certainly not in OIRA.

Chair MILLER. We have been called for votes, 15 minutes. It doesn't take us that long to get there and they always hold it open well beyond that. But could each of you give like a two-sentence answer, anyone who wishes to be heard? You don't have to be heard on every question.

Ms. SMITH DEWAAL. I just want to point out that OIRA's role really should be shifted to prospective before the rules and really considering how rules, how risk assessments can be standardized across the government. At that point their review of the actual regulation should be limited to only very large rules.

Chair MILLER. Very quickly, Mr. Warren.

Mr. WARREN. Well, I think it is two issues. One is, OIRA's role should be limited to its domain and then whatever its domain for reviews are. It should have performance requirements that are very clear, very explicit so that you don't have vague conversations and endless asking of questions and never coming to a conclusion. All agencies have performance requirements under the *Government Performance Review Act.* OIRA should have very specific ones in this area.

Chair MILLER. Dr. Coglianese.

Dr. COGLIANESE. I would just caution about making too much about the number of steps in any procedural map. It is not just the number of steps but how long it takes to get through them and that can often be a function of the will or the motivation of the regulator or the decision-maker.

Chair MILLER. The simplified system has not proven to be a quick system.

Ms. Steinzor.

Dr. COGLIANESE. And my——

Chair MILLER. I understand your point but the experience under these two reviews is consistent with how they appear, the optics of them.

Ms. Steinzor.

Ms. STEINZOR. OIRA should stop reviewing individual rules and OIRA should stop serving as a representative of aggrieved industries and agencies like the Department of Defense in obstructing IRIS numbers from coming out.

Chair MILLER. Marvelously succinct.

Dr. Broun. I think if we finish this round of questioning from Dr. Broun, that may be enough for the day, given that we are being called to votes.

Mr. BROUN. Thank you, Mr. Chair.

A CENTRALIZED REVIEW OF RECORDS

Very quickly, Justice Breyer has noted that civil servants in some regulatory agencies may tend to have "tunnel vision" and fail to consider the broader impacts of regulatory proposals. I would like to ask the panel very quickly yes or no, and if you want to expound on that slightly, do you think centralized review of records is ever appropriate? Dr. Melberth.

Dr. MELBERTH. I am sorry. I can't give a yes or no answer to that because it depends on what you mean by that review. If it is a review as I had outlined in my comments where it is much more of a prospective review and on planning issues, that may be appropriate. The individual review of rules is, in our opinion, inappropriate.

Mr. BROUN. Okay. Ms. Smith DeWaal.

Ms. SMITH DEWAAL. Thank you. Any review that is delaying the implementation, the development of health and safety regulations needs to be modified so it stops delaying those needed rules.

Mr. BROUN. Mr. Warren.

Mr. WARREN. Yes, there can be cases in which this makes sense. Other agencies have expertise and statutory authorities that may need to he harmonized. But any such interaction needs to be made part of the public record and transparently documented so that people can see what is going on.

Mr. BROUN. Dr. Coglianese.

Dr. COGLIANESE. Yes, certainly review of individual rules is appropriate, whether by the President or whether by the Members of a Congressional committee.

Mr. BROUN. Thank you.

Ms. Steinzor.

Ms. STEINZOR. The President has review capacity and that is the political appointees who serve at all the agencies. That is how he controls those agencies. And it really is not necessary or warranted to have OIRA economists second-guessing those appointees.

ON RETAINING FEATURES OF EXECUTIVE ORDER 13422

Mr. BROUN. Okay. That brings up a whole other question but we are very close on the vote. We have less than 10 minutes now. One quick question too is, President Bush largely adopted President Clinton's Executive Order. Are there any parts of President Bush's Executive Order 13422 that should be kept by the Obama Administration? Let us start on the other end, Ms. Steinzor.

Ms. STEINZOR. No.

Mr. BROUN. Completely throw them all away and not have any of——

Ms. STEINZOR. 13422, which is the one, yes, I agree with the Obama Administration. I strongly support their effort to drop that Executive Order.

Mr. BROUN. Well, that is normal that that is rewritten every Administration.

Dr. Coglianese.

Dr. COGLIANESE. Well, I think the Bush amendments to the Executive Order were largely symbolic through and through. I don't think that rescinding it has changed much. I don't think actually having approved it changed much. Perhaps the biggest change that it made was providing some information to OIRA about guidance documents that agencies are contemplating and that is certainly worth investigating further.

Mr. BROUN. Mr. Warren.

Mr. WARREN. No, I wouldn't keep any of the elements. I would start with the Clinton Administration Executive Order and revise from there.

Ms. SMITH DEWAAL. I would agree with Mr. Warren.

Dr. MELBERTH. And I would agree with that as well.

Mr. BROUN. Just for the sake of time, Mr. Chair, I will just submit the rest of the questions as written questions.

Chair MILLER. I have a great many questions as well. We do have time for Ms. Dahlkemper to ask some. We have seven minutes left on the vote.

PUBLIC ACCESS TO OIRA COMMUNICATIONS

Ms. DAHLKEMPER. I will ask a quick question and ask for just a quick answer from each of you. To what extent should OIRA's internal communications and its communications with agencies be made public?

Dr. MELBERTH. We argue that they should all be made public. All those communications should become part of the rule-making docket.

Ms. SMITH DEWAAL. We agree with that, and in addition they should have transcripts of meetings with regulated industry on any rule before them.

Mr. WARREN. We need much greater transparency in this area, both interactions with outside parties and any exchanges between OMB, other agencies and the agency in question that submitted the proposal.

Dr. COGLIANESE. The trend has been toward greater transparency over time. How much more, whether there should be transcripts, whether we should have hidden cameras is not a question I have research background or a basis for opining.

Ms. STEINZOR. I agree with the first three panelists.

Ms. DAHLKEMPER. Thank you very much. I yield back.

Chair MILLER. Thank you, Ms. Dahlkemper.

CLOSING

We will return to this issue. This is an issue on which we will continue to exercise our oversight responsibilities, particularly I

think other committees will as well. The first hearing—the Executive Order I think provoked hearings both in this subcommittee and in the Administrative Law Subcommittee of the Judiciary Committee. So we will return and continue to pay particular attention to how scientific information is used in rule-making but I think for today I want to thank all the witnesses. I know that Dr. Coglianese mentioned a study, not in his prepared testimony but in answer to a question, in response to a question. If any of you have referred to a study, if you could provide those to the Committee and we can include in the record, that would be helpful. Dr. Broun.

Mr. BROUN. Mr. Chair, if you would yield just a second, I appreciate us coming back and reviewing this, and I particularly want to see once the Obama Executive Order comes out for us to look at the principles that he puts forth in his Executive Order and I think we need to look at it very closely.

Chair MILLER. I agree.

The witnesses are now excused and the hearing is adjourned. Thank you very much for being here.

[Whereupon, at 11:23 a.m., the Subcommittee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Rick Melberth, Director of Regulatory Policy, OMB Watch

Question submitted by Representative Paul C. Broun

Q1. In your testimony (p. 3) you state that it is necessary "to make clear that OIRA's role is limited and does not usurp the role of political leaders who lead agencies with direct statutory responsibility for regulatory decisions."

- *Should agency-head's decisions be elevated above that of the President (who is actually elected and accountable)?*

A1. The quote from page 3 of my testimony is itself a quote from a memorandum the authors of *Advancing the Public Interest through Regulatory Reform* submitted to President Obama's transition team on December 24, 2008. There is nothing in the authors' report or in the memoranda from the authors (submitted with the testimony) to either the transition team or to President Obama's new OIRA team that states, suggests, implies, or should be read as a belief by the authors that an agency head's decisions should be elevated above that of the President.

In the December 24th memo, the authors who met with the transition team were responding to a specific question asked by the transition team about the authors' vision of a new relationship between OIRA and the agencies.

The memo makes clear, as does the report, that, in the view of the authors, OIRA should not be reviewing individual rules promulgated by agencies, but should be focusing on "government-wide management issues" as the memo states later in the same paragraph. It is the agency heads who receive statutory delegations from Congress to promulgate rules, not OIRA.

Logically, if OIRA is not reviewing individual rules developed by agencies, there would not be an opportunity for OIRA to usurp the regulatory decisions of those appointed by the President and confirmed by the Senate. Under this revised relationship between OIRA and the agencies, OIRA desk officers, career civil servants who are not elected or accountable, would no longer be in the position of making "Yes/No" decisions on agency rules, as the memo states in the next paragraph (also quoted in my testimony).

Under Executive Order 12866 and its predecessors, OIRA has sometimes usurped the statutorily-delegated authority to agency heads. The report and subsequent memoranda consistently promote the principle that the statutory authority given to agency heads, combined with agencies' expertise in these complicated rule-makings, should be given deference by OIRA even if that office continues to review individual rules.

As noted in my testimony before the Committee (p. 2), the authors wrote in *Advancing the Public Interest* report: "[T]here needs to be a fundamental restructuring of the interaction between OIRA and the agencies, placing greater priority on agency expertise and statutory authority for decision-making." (p. 16 of the report)

Again, I wish to thank the Subcommittee for the opportunity to respond to Members' questions, and for the opportunity to testify.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Caroline Smith DeWaal, Director, Food Safety Program, Center for Science in the Public Interest

Questions submitted by Representative Paul C. Broun

Q1. In your testimony (p. 3) you state that "agencies are beginning to shy away from using regulations at all."

- *Do these new non-regulatory processes limit transparency?*

A1. Extra-regulatory processes may be less transparent than notice and comment rule-making. This was not the case in the *Salmonella* program described on page 8 of my testimony. There, the Food Safety Inspection Service (FSIS) followed a transparent process of publishing and taking comments on its plan to change how it uses the results from the *Salmonella* verification sampling program. I am not aware of a requirement that this always be the case.

The issue is whether it is good policy to make normal rule-making channels so burdensome that agencies are induced to innovate extra-regulatory processes.

Q2. In your testimony (p. 7) you state that "regulators must be able to bring new science to bear in preventing food-borne illness outbreaks."

Q2a. Is this a recommendation unique to food safety regulations, or would you advocate this for all regulations?

A2a. My expertise is in food safety, so my remarks are confined to that field. However, I believe that it would extend to many other agencies tasked with issuing science-based regulation. Such flexibility is essential.

Q2b. What impact would this have if industry was also afforded the ability to always bring "new science to bear?"

A2b. The question carries an implication that new science may be used not only to improve processes, but also to challenge anew past regulatory actions. As a matter of good practice, industry should constantly bring new science to bear in improving processes and product quality.

Where new science is used to challenge existing regulations, a petition process is available. Petitioning is an appropriate and transparent approach. Here, again, reforming OMB would help expedite regulatory action.

Q3. In your testimony (p. 9) you mention that performance standards for food safety were effectively reduced by 50 percent through the use of an innovative approach you dub "name and shame" without ever going through the regulatory process or OIRA.

Q3a. Do you see this as a successful attempt at protecting the public without regulating, or a failure to regulate? In other words, was this good, or bad?

A3a. This is innovation in the face of concerted efforts to thwart regulation through normal channels. As discussed in response to question 1, the use of these extra-regulatory means indicates a systemic failure in the regulatory process. Although the FSIS action resulted in a benefit to the public, there is no reason to expect that will always be the case.

Q3b. Is this what Cass Sunstein would refer to as a "nudge?"

A3b. Richard Thaler and Cass Sunstein define a "nudge" as structuring choices in a way that "alters behavior in a predictable way without forbidding any options or significantly changing . . . economic incentives." From the perspective of the affected plants, the FSIS action is nudge-like, but not a nudge, because processors who are named may suffer economic and inspectional burdens. Nor would a "nudge" be the appropriate means of achieving safety, since the option to operate in an unsafe manner must be forbidden if the goal is to protect public health (as opposed to public choices). From the perspective of downstream processors, retailers and consumers, the FSIS action may fit the definition since it provides information at little cost that allows the public to make better choices. However, I would not advocate for use of a "nudge" in matters of protecting public health. This is because the public does not always have actual access to information, and can make unrealistic assessments of the risk or the ability to mitigate the risk. It could also result in unsafe food being more readily available at a lower cost, creating an incentive to purchase less safe product. In the case of food-borne illness, using a nudge instead of specific

enforceable standards will result in segments of the public suffering preventable, severe health consequences.

Q4. In your testimony (p. 14) you state that "these problems did not originate in the Bush Administration, nor will they necessarily disappear just by having different people in charge."

- *Why do you think this was such a partisan issue two years ago?*

A4. The Bush Administration pushed the process to extremes. That drove the perception of partisanship because the Administration appointed officials who would enforce the President's anti-regulatory political philosophy. However, issues like inappropriate and overly burdensome reliance on cost-benefit analysis is not a strictly partisan issue. The Clinton Administration preserved an over-emphasis on cost-benefit in rule-making to protect the public health.

Congress is the appropriate body for resolving political questions.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Cary Coglianese, Associate Dean for Academic Affairs, Edward B. Shils Professor of Law, Professor of Political Science; Director, Penn Program on Regulation, University of Pennsylvania

Questions submitted by Representative Paul C. Broun

Q1. Can you briefly walk us through the history of regulatory reform?

- *Has it been a partisan endeavor, or a nonpartisan tool employed by various administrations?*

A1. In light of the issues addressed at the April 30, 2009 the hearing, I will focus my answer on "regulatory reform" efforts that systematically require federal agencies to conduct analyses of the benefits and costs of regulations.

Such requirements date back at least to the Nixon Administration, which in 1971 established a "Quality of Life Review" process in the Office of Management and Budget (OMB) that, among other things, estimated the costs of significant new rules. After assuming office, President Gerald Ford adopted Executive Order 11821 which required agencies to follow OMB requirements for "inflation impact statements" on significant regulatory proposals.

President Jimmy Carter adopted Executive Order 12044 which required agencies to conduct analyses of the costs and benefits of proposed rules expected to have an annual economic impact of $100 million or more. OMB was charged with ensuring implementation of E.O. 12044, but President Carter also created a Regulatory Analysis Review Group within the White House to review agencies regulatory analyses.

President Ronald Reagan issued Executive Order 12291 which consolidated responsibility for the White House's oversight of regulations in the Office of Information and Regulatory Affairs (OIRA), an office created in 1980 by the *Paperwork Reduction Act*. E.O. 12291 called for agencies to conduct a "regulatory impact analysis" describing the benefits and costs of proposed "major" regulations, i.e., those expected to have an annual impact on the economy of $100 million or more. E.O. 12291 also required agencies, "to the extent permitted by law," to refrain from issuing new rules "unless the potential benefits to society for the regulation outweigh the potential costs to society." President George H.W. Bush retained E.O. 12291.

President William Clinton adopted Executive Order 12866 that, generally speaking, retained the basic structure of regulatory analysis and review established under E.O. 12291. For example, agencies issuing rules with expected annual economic effects of $100 million were still expected to conduct an assessment of benefits and costs, and the White House's review of these assessment remained within OIRA. However, there were some differences in the language of E.O. 12866, as well as new obligations it placed on OIRA, such as time limits on its reviews and the public disclosure of information about meetings with individuals from outside government. E.O. 12866 instructed agencies that, to the extent permitted by law, they should "propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."

President Clinton also signed the *Unfunded Mandates Reform Act* that imposes a statutory obligation on agencies to conduct analyses of the benefits and costs of proposed rules expected to have an impact on states, local governments, or the private sector of $100 million or more in any single year (2 U.S.C. § 1532).

President George W. Bush retained E.O. 12866. During his second-to-last year in office, he issued Executive Order 13422 that made several minor modifications to E.O. 12866, but nevertheless retained the core requirements for assessing the benefits and costs of significant rules.

President Barack Obama revoked E.O. 13422 but has thus far retained E.O. 12866. He has, however, called for OMB to develop recommendations for a new executive order on regulatory review.

As this brief historical account suggests, systematic efforts to require regulatory agencies to assess the benefits and costs of proposed regulations have been pursued by both Democratic and Republican Administrations. In addition, the statutory requirement for regulatory assessment found in Section 1532 of Title 2 of the U.S. Code was adopted following a vote of wide margins and broad bipartisan support in both houses (394–28 in the House, and 91–9 in the Senate).

Q2. Do you think regulatory policies have more or less affect on initiatives than Presidential involvement?

A2. Regulatory policies reflected in statutes have significant effects on the rules adopted by agencies. Agencies depend on legislation for their authority to issue reg-

ulations, and their regulations must be consistent with statutory requirements. Executive orders calling for agencies to conduct regulatory assessments have consistently acknowledged that agencies must adhere first and foremost to statutory obligations, even over the executive orders' requirements.

Whether statutes have more effect on agency regulations than Presidents will likely depend on several factors, including the level of Presidential interest in different rules and the amount of discretion that different statutes afford the agency. A statute that provides only a general grant of rule-making authority to an agency (e.g., "regulate in the public interest") will presumably have less of an effect on the rules an agency adopts than will a statute that imposes specific standards, criteria, procedures, and deadlines that agencies must follow when issuing new rules.

Q3. Could you please clarify what you mean by "science's role is to provide necessary but not sufficient input into policy decisions?"

A3. Making good policy decisions requires factual knowledge, so science is in that sense "necessary." To solve a problem, policy-makers need to know the extent of that problem, its causes, and the likely effects of different potential solutions. These fact-oriented facets of policy decision-making are and should be informed by science. However, policy decisions call for more than just scientific or factual knowledge. They also require making value judgments too. For example, exactly how safe is safe enough when setting environmental standards? How should a homeland security regulation balance between protection from terrorism risks and protection of individual privacy? At what level should automobile fuel economy standards be set if higher standards would lead to reductions in crash resistance and lower standards would contribute to emissions of greenhouse gases? None of these questions—or any of the myriad others like them that are inherent in making policy decisions in any context—can be answered by science. These are policy questions about what agencies "should" do—not questions about what "is." That is why science, though necessary, is not sufficient by itself for making policy decisions.

Q4. In section 109 of the Clean Air Act, *legislators actual used the word "judgment" when describing how the Administrator is to determine the level of ambient air quality standards by an adequate margin of safety in order to protect public health.*

- *How did this language get interpreted to mean that costs cannot be considered?*
- *If we are to avoid similar interpretations in the future, how would the language have to read?*

A4. In its 1980 decision in *Lead Industries Assn., Inc. v. Environmental Protection Agency,* 647 F.2d 1130, the D.C. Circuit Court of Appeals first held that EPA could not take costs into consideration in setting ambient air quality standards. In reaching this interpretation, the court relied on the absence of specific language in Section 109 authorizing cost considerations to be included in the administrator's "judgment." The court noted that Section 109 only included mention of public health factors, and observed that other provisions of the *Clean Air Act* (such as Section 111) did specifically mention that costs could be included. The court also found statements in the legislative history supporting the position that the *Clean Air Act*'s air quality standards were to be "technology forcing" and not constrained by feasibility or other economic considerations.

In 2001, the U.S. Supreme Court reached the same conclusion about cost considerations in *Whitman v. American Trucking Assns.,* 531 U.S. 457. Like the opinion in *Lead Industries,* the majority opinion in *Whitman* stressed that Section 109 only mentioned public health factors and that other provisions of the *Clean Air Act* (such as Sections 111 and 202) specifically authorized EPA to take costs into account. The majority reasoned that if Congress had intended to have the EPA consider costs, it knew how to direct the agency to do so. Since costs were not mentioned, the majority concluded that "[t]he text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the [standard]-setting process."

To avoid similar interpretations by the courts in the future, Congress would need to mention, explicitly, costs as an authorized factor for agencies to consider when making regulatory decisions. Members of Congress should also be aware that simply by mentioning costs as a permissible consideration in one section of a statute, courts may construe other sections as thereby prohibiting the consideration of costs.

Q5. Does the use of science as the sole justification for setting regulatory standards—like the particulate matter standards you referenced in your testimony—end up contributing to greater number of lawsuits challenging such rules?

- *Do you think if the EPA was able to air its true justification to the public for choosing one level or another that would alter the perception of their integrity?*

A5. Given how the courts have construed Section 109, EPA's continued invocation of science as a basis for its air quality standards has actually spared EPA from judicial reversal on statutory grounds. Assuming Congress changed Section 109, I have no basis for predicting that levels of litigation over EPA standards would change if the agency no longer justified its standards solely on the basis of science. I have empirically studied the litigation decisions made by industry and environmental groups, and these decisions are usually affected by the economic or environmental consequences of standards, which presumably would remain significant no matter how EPA attempted to justify them.

Public perceptions and support for EPA rules are presumably based on a number of factors, including whether public attitudes generally favor greater environmental regulatory protection. Perceptions of EPA's integrity are also likely based on a variety of factors. As much as one might hope that EPA would enhance its credibility and reputation by being forthright about what role science can really play in justifying its policy decisions, it is possible that EPA actually strengthens perceptions of its integrity and support for its policy decisions by cloaking them in rhetoric about science, however untenable that may be as a conceptual and analytic matter.

Q6. Your testimony calls for agencies to be up-front with the policy choices behind their regulations.

- *Other than restoring honesty and integrity into the regulatory process, what other benefits would be realized by such a policy?*

A6. "Restoring honesty and integrity into the regulatory process" is certainly not an unimportant objective in its own right. Of course, getting better decisions by regulatory agencies is also an important goal. For years, administrative law has tried to promote sound policy reasoning by agencies as a way of disciplining and improving their policy decision-making. Agency decisions that are well-reasoned will certainly be less prone to errors of rash decision-making, such as expediency, bias, or tunnel vision. Encouraging agencies to provide sound justifications for their decisions can also assist courts, Congress, and the public in overseeing agency policies.

If agencies fail explicitly to grapple with policy factors that are nevertheless implicitly affecting their decisions, they can miss opportunities for making their decisions better. To use an example from the EPA's air quality standards, I would refer the Subcommittee to the following passage from a published article of mine:

> If EPA considers costs implicitly to temper the outcomes of its standards, something which it almost certainly has done, the question arises whether society would be better off if the Agency considered cost estimates explicitly rather than treating the issue of cost only implicitly. Express consideration of cost data may provide important information that can be used to set standards that are more cost-effective even without sacrificing health protection. This is because costs and benefits from air quality standards, like other regulatory standards, may exhibit discontinuities and non-linearities, which can only be discerned through careful analysis of cost functions. For example, EPA's draft Regulatory Impact Analysis for ozone, published at the time of the Agency's proposed rule, indicated that an eight-hour ozone standard set at 0.08 ppm based on the fifth rather than fourth highest annual concentration would provide roughly equivalent health protection but at approximately 20 percent lower cost. This analysis suggests that there is a discontinuity in the cost-effectiveness in tightening the standard from the fifth to the fourth highest annual concentration. Had EPA explicitly taken this information into account, it could have based the standard on the fifth highest annual concentration and saved the Nation over $1 billion per year without sacrificing health protection.

Cary Coglianese & Gary Marchant, "Shifting Sands: The Limits of Science in Setting Risk Standards," 152 *University of Pennsylvania Law Review* 1255–1360 (2004) (footnotes omitted).

Q7. Has cost-benefit analysis ever been used to justify a regulation rather than simply prevent one?

A7. Yes. For example, the EPA regulation that called for the elimination of lead in gasoline, which is one of the most beneficial public health measures ever taken, was spurred into promulgation because of cost-benefit analysis. See Albert L. Nichols, "Lead in Gasoline," in *Economic Analyses at EPA: Assessing Regulatory Impact* (Richard D. Morgenstern, ed., 1997). More recent examples can be found in the account by former OIRA Administrator John Graham about how cost-benefit analysis

of regulations helped secure support for new regulations during the George W. Bush Administration. Of the EPA's decision to reduce emissions from diesel engines, Graham writes that:

> OIRA helped the EPA persuade other federal agencies and the White House that another multi-billion-dollar regulation of the refining industry was worthwhile. The rule was issued without any court order, with no statutory deadline in the *Clean Air Act,* and with no commitment made by the President during the 2000 campaign. In the absence of the favorable information on benefits and costs and the support from OIRA, I doubt whether the EPA would have issued this rule promptly, if at all.

John D. Graham, "Saving Lives Through Administrative Law and Economics," 157 *University of Pennsylvania Law Review* 395, 468–469 (2008).

Q8. Did President Clinton's E.O. 12866 require agencies to conduct Cost-Benefit Analyses for proposed regulations?

- *If so, what harm would come from simply requiring them to report the aggregate of the analyses they already conducted?*
- *Is this really such a big step?*
- *What specific harm would come from this requirement?*

A8. Yes, Executive Order 12866 requires agencies to conduct analyses of the costs and benefits of significant proposed rules. Agencies are also required to make these analyses available to the public.

To be able to address the other questions, I would need to know more about what a requirement to "report the aggregate" would entail. I would note that even high quality benefit-cost analyses do not always yield a single net-benefit number, something that at least implicitly a proposal for aggregation would seem to demand. E.O. 12866 does not require agencies to quantify all impacts (only when doing so would be feasible), let alone convert those impacts to dollar terms. One study has found that less than 30 percent of benefit-cost analyses produced by federal agencies provide quantified net benefits. Robert W. Hahn & Patrick M. Dudley, "How Well Does the U.S. Government Do Benefit-Cost Analysis," 1 *Review of Environmental Economics and Policy* 192–211 (2007).

I would also note that benefit-cost analyses reflect ex ante predictions of the effects of regulation. Either instead of or in addition to requiring the aggregation of benefit-cost analyses, Congress should consider requiring and funding more ex post evaluation research that would yield a better understanding of what the actual benefits and costs of regulation have been. See Cary Coglianese & Lori Snyder Bennear, "Program Evaluation of Environmental Policies: Toward Evidence-Based Decision Making," in *National Research Council, Social and Behavioral Science Research Priorities for Environmental Decision Making* 246–273 (National Academies Press, 2005).

Q9. One of the criticisms of reporting the aggregate of an agencies cost-benefit analysis is that it would create a "regulatory budget" that would be prime for cuts.

- *Do you believe this is a valid critique when data is already available individually?*

A9. As noted in my response to question 8, I do not believe the data are currently available from individual benefit-cost analyses that would support aggregating single, point estimates of net-benefits across all analyses. Moreover, since benefit-cost analyses are supposed to inform decision-making, an attempt to force agencies to provide such a single number would often be ill-advised, as often the available knowledge simply does not permit an analyst to present a point estimate. Owing to uncertainty, usually quantified benefits and costs can only be best represented as ranges rather than point estimates. Owing to data availability or methodological limitations, some benefits and costs may simply be impossible to quantify at all, but could still be relevant for decision-makers to consider.

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Available online at *ssrn.com/abstract=1371588* as of June 1, 2009.

Appendix 2:

Additional Material for the Record

ADVANCING THE PUBLIC INTEREST THROUGH REGULATORY REFORM

Recommendations for President-Elect Obama and the 111th Congress




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Michael Bird
Caroline Smith DeWaal
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November 2008

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FOREWORD AND ACKNOWLEDGEMENTS

In my 25 years of running OMB Watch, I have never seen a project quite like *Advancing the Public Interest Through Regulatory Reform*, the project that has generated the recommendations herein. What began as an OMB Watch project guided by a Steering Committee transformed into an exciting, organic process with a product no longer owned solely by OMB Watch. Instead, these recommendations are a product of 17 diverse regulatory experts.

OMB Watch selected the members of the Steering Committee with three factors in mind. First, they needed to bring expertise either about specific aspects of the rulemaking system or about specific regulatory policy areas. Second, they had to agree that the current regulatory system needed major reform. Finally, they could not be anti-regulatory ideologues. These criteria left much room for various perspectives. In fact, what was striking about the Steering Committee was that the 17 people were not like-minded in their ideas for regulatory reform.

Such a process has its weaknesses and strengths. This product is clearly not the type of report that would be drafted by any one of the signatories; it reflects a consensus and acknowledges where we could not reach agreement. Of course, that may be its greatest strength: It represents a unified voice from diverse regulatory experts who are committed to finding solutions to fix a dysfunctional federal regulatory system.

This report is a testament to the commitment of each of the participants and a recognition of the seriousness of the problems we were addressing. There were many thorny issues; any one of them could have resulted in intransigence and stalemate. But the members were willing to look at problems in new ways and offer solutions to improve the regulatory process rather than solely advancing their past ideas. As chair of this process, I want to thank each member of the Steering Committee for their steady work on this project.

Yet none of this would have been possible without the outstanding staff work of Rick Melberth, who directs OMB Watch's regulatory program, and Matthew Madia, who is an OMB Watch regulatory policy analyst. The two of them managed this entire project. More importantly, they served as "honest brokers," listening to diverse opinions and finding compromise. It is particularly commendable because they worked to represent the will of the Steering Committee. Their ability to reflect the diverse views of the committee is a tribute to their pledge to make this process work.

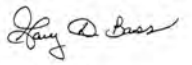
I also want to thank the many people who provided input and support along the way. One part of this project involved creating four task forces to advise us on the development of recommendations. The participants of those task forces are listed in Appendix 4. However, I would like to personally thank the chairs for their work: Cary Coglianese of the University of Pennsylvania, Steven Croley of the University of Michigan, Francesca Grifo of the Union of

Concerned Scientists, and Ruth Ruttenberg of the National Labor College. Many of the ideas presented here had their seeds in the work of these task forces.

This work would not be possible without the philanthropic support of the William and Flora Hewlett Foundation, the HKH Foundation, and the Open Society Institute, along with general support to OMB Watch provided by the Bauman Foundation and several anonymous donors.

I would also like to thank other OMB Watch staff that helped with this project, including Brian Gumm, Paula Shoecraft, Barbara Western, and Sam Kim. Brian provided editorial and planning assistance, while Paula led the efforts to generate the foundation support for the project. Barb and Sam provided logistical support during this long project.

As one of the authors of these recommendations noted at the end of the process, "We've come a long way..." It is my hope that we have reduced the distance that the new president will need to travel to significantly improve the federal regulatory system.



Gary D. Bass
Chair, *Advancing the Public Interest Through Regulatory Reform*
Executive Director, OMB Watch

November 2008

EXECUTIVE SUMMARY

ADVANCING THE PUBLIC INTEREST THROUGH REGULATORY REFORM

Federal regulations are critical elements to implementing public policy. They provide the protections we need to ensure that our food is healthy, our children's toys are safe, our air and water are clean, dangers in our workplaces are reduced or eliminated, and our economy functions efficiently and effectively. Despite the importance of these essential governmental functions, for at least a generation, many politicians and social commentators have taken aim at these protections, flinging inflammatory rhetoric at governmental regulation.

In light of the negative image of government regulations, Congress and the executive branch have imposed a number of requirements on federal agencies that direct them how and when to regulate. Some hurdles were proposed by those intent on stifling regulatory government, while others came from those hoping to create a process that results in "smarter" regulation. Regardless of the reason, with the addition of each requirement, agencies have had to spend more time and resources to justify and complete rulemakings. For some agencies, it now takes more than a decade to implement a major rule.

The current regulatory process no longer adequately protects the public. Examples of regulatory problems make national news almost daily: the crises in the housing and financial sectors; mine and crane collapses; contaminants in consumer products like toothpaste and pet food; contamination of spinach, jalapeños, meat, and other foods; dangerous chemicals used in popular medicines; and the exploitation of our public lands and natural resources. The process is not only fraught with procedural hurdles, but is one that has been dominated by special interests. Americans not only expect their government to protect them from financial harm, but also from other dangers by providing common-sense protections and better enforcement. Most observers concur that the regulatory process is in need of serious repair.

The new president and Congress must address this problem with urgency and precision in order to restore trust in government and protect the public good. Government needs to change the quality of our rules; simplify the process by which they are made, reviewed, implemented, and enforced; make the process more transparent; and provide the resources necessary to make and implement wise decisions that serve the public good.

The Steering Committee for the *Advancing the Public Interest Through Regulatory Reform* project is comprised of 17 experts on the regulatory process, representing contrasting views about solutions to the problems. We began meeting 15 months ago and quickly agreed that this is a time when contrasting views are mitigated by the desire to fix a broken system. We have put forth a set of 49 recommendations for the president and Congress premised on six principles that we believe should be embraced by government:

1. **Regulatory decisions should be timely and responsive to public need.** Timely action is a benefit to the public and all stakeholders. Government must actively assess public needs, identify where regulatory gaps exist, and act to address such gaps. Regulatory decisions should be based on the best available information, balanced with the need to act in a timely manner.
2. **The regulatory process must be transparent and improve public participation.** Openness, from pre-rulemaking to the publication of final rules, is essential to meaningful accountability in the process. The Internet age affords new ways of fostering meaningful public participation.
3. **Regulatory decisions should be based on well informed, flexible decision making.** There needs to be a premium placed on authority within regulatory agencies to decide what information is critical to effective regulations and to ensure those decisions reside with agency scientists and experts.
4. **Authority to make decisions about regulations should reflect the statutory delegation granted by Congress.** Federal agencies are given the responsibility to implement legislation and have the substantive expertise necessary to develop effective standards. That expertise should be recognized and provide the foundation for sound regulatory decisions.
5. **Agencies must have the resources to meet their statutory obligations and organizational missions.** Resources are needed for addressing regulatory gaps, providing accountability and transparency mechanisms, and meeting regulatory compliance and enforcement functions.
6. **Government must do a better job of encouraging compliance with existing regulations and fairly enforce them.** In order to strengthen public protections and provide regulated communities with fair and predictable compliance approaches, agencies must be enabled to meet more effectively both current and new demands and work to improve or create regulatory compliance programs.

ORGANIZATION OF THE REPORT

The Introduction to the report, Chapter I, further explains some of the problems with the current regulatory process and our perspective on why it is so important to reform that process. Chapter II contains our recommendations to both the president and Congress for actions to take in the first 100 days of the new administration. Chapter III is divided into five sections that contain recommendations for how to: 1) improve regulations; 2) restore integrity and accountability to the generation, collection, and use of information; 3) improve the implementation and enforcement of regulations; 4) increase the transparency of the process; and 5) improve mechanisms to allow greater public participation in the regulatory process.

The following section highlights the recommendations we consider to be of highest priority, the ones most critical to making the regulatory process better serve the public interest.

HIGH-PRIORITY RECOMMENDATIONS

We urge the next president to give significant attention to fixing the regulatory process and to make this agenda an early priority. We recommend that on the first day in office, the new president impose a moratorium on finalizing any new regulations and review those rules finalized but not yet in effect, except those required by court order, statute, or necessary to meet regulatory emergencies. The moratorium should be in effect for 60 days pending agency review and reconsideration of these rules. This moratorium has become the pattern for new presidents. To set a new tone, however, we think the president should also instruct agencies on his views of the importance of using regulatory tools to protect the public and that the regulatory process should serve the public, not special interests.

He should also announce his intent to establish a blue ribbon commission of regulatory experts to recommend ways to speed up the regulatory process by reducing unnecessary analytical and procedural requirements imposed by statute or executive authority. The goal of this commission is to make fundamental changes to the regulatory process so that rules are more effective, efficient, and timely.

Analytical and procedural requirements are only part of the problem. Of critical importance is the need to address the relationship between the Office of Information and Regulatory Affairs, the White House office with the current responsibility for reviewing agency regulations, and the federal agencies charged under law with the responsibility for issuing regulations. As a first step, Executive Order 13422, which deals with regulatory review, should be rescinded. It places significant regulatory authority with Regulatory Policy Officers, displacing agency heads and adding inappropriate power to White House rulemaking judgments.

More directly, we believe that the White House has been too involved in the substantive review of agency rulemakings, at times disagreeing with agency experts and changing the science presented by the agencies. This needs to stop. It is essential that any White House requirements on agencies' actions give agencies flexibility to apply regulatory assessment tools in a manner that makes the most sense for agencies' missions and to ensure agency regulatory actions are consistent with statutory requirements.

We are in agreement that Executive Order 12866, *Regulatory Planning and Review*, is outdated and is no longer appropriate for today. This 1993 order outlines the process for agency and executive branch regulatory actions. We are not in agreement on whether E.O. 12866 should be replaced, but if it is, it should adhere to the principles above and benefit from the recommendations presented by the blue ribbon commission.

Cost-benefit analysis has been required by E.O. 12866, and OIRA has provided a prescriptive directive, Circular A-4,, Regulatory Analysis, on how agencies are to conduct such analysis. We have differing views on the utility of cost-benefit analysis, but we do agree that prescriptive directives such as Circular A-4 should be curtailed. If there is White House guidance on cost-benefit analysis, it should provide agency flexibility on how to do such analyses, including the option to decide if such analyses are to be done at all.

We also have strong agreement on the principles that should steer any cost-benefit guidance:

a. Cost-benefit analysis should only be used in ways consistent with the values expressed in statutory or judicial provisions;

b. Cost-benefit analysis is an analytical tool and should not be determinative in regulatory decision making unless specifically required by statute (i.e., it should be a source of information, not a decisional standard);

c. Information and assumptions used in cost-benefit analysis should be transparent and allow for the analysis to be replicated. The analysis should include statements of uncertainty about the assumptions;

d. Cost-benefit analysis should disclose both quantitative and qualitative aspects – and utilize both when interpreting results;

e. Cost-benefit analysis should include an explicit statement about who benefits and who bears the costs; and

f. While it may be appropriate to have methodological questions about cost-benefit analyses conducted by federal agencies, the White House or other regulatory review agencies should never manipulate or alter results.

Overall, we recommend reducing the emphasis on quantification in regulatory decision making, reestablishing the importance of statutes in guiding agency actions, and changing the use of cost-benefit analysis as a determining factor in decision making except when it is specifically mandated in statute.

Research and analysis are essential ingredients to effective rulemaking. Unfortunately, the integrity of the regulatory process has been seriously compromised by placing politics ahead of science and agency expertise. To fix this problem, the president should send a clear message early in the new administration that federal agencies will adhere to the highest principles of scientific integrity and independence. Regulatory development needs the best information that can be garnered from the scientific community, both within and outside of government. Agencies should be encouraged to restore needed collection and monitoring programs and address new information needs. It is equally important that this information is used in an objective and transparent fashion as the foundation for decisions affecting the public interest.

As indicated in the principles outlined above, transparency is a theme throughout this report. Transparency in the rulemaking process leads to a greater sense of government legitimacy, provides an important tool with which to hold government officials accountable, and can enhance public participation. To improve transparency in the regulatory process, the federal government should adopt a strategy that moves toward a presumption of openness through all stages of the process, including those stages where information and communications are not currently disclosed.

The Internet age allows agencies to make information publicly available more easily than in the past, and interactive technologies allow users to more easily access information. Agency rulemaking dockets should be expanded to include a wide range of information related to the rulemaking and available in an easily searchable online format. All research, public or private, used in the rulemaking should be included in the rulemaking docket, along with substantive communications regarding a rulemaking. Agency meetings, including those held to provide policy advice, should be as open as possible. Disclosure should begin upon creation of the rulemaking dockets and should occur as soon as possible after documents, communications, or other types of information are available.

Lack of resources is a critical problem in regulatory agencies. From research to enforcement, resources – both human and financial – have been cut. Agencies are experiencing an exodus of experts as budgets are cut or level-funded, often in the face of increasing regulatory responsibilities. We understand that the recommendations in this report to make the regulatory process work more effectively again will not happen without additional funding. There is public, private, and congressional support for beginning to restore the ability of federal agencies to respond to regulatory issues, even in a time of scarce federal resources. Without sufficient financial and human resources and clear enforcement goals, these issues cannot effectively be solved.

During the transition process, the president should ask agencies to review their regulatory budgetary needs for the current and next fiscal year to begin a process of restoring the personnel and research needed to once

again effectively provide public protections, especially the work to design, implement, and enforce rules. Based on this information, the president should propose needed agency increases, and Congress should appropriate the requested funds.

Also during the transition process, the president should assess last-minute regulations from the previous administration. Outgoing administrations are noted for a rush of late regulatory activity, often called "midnight regulations." We recommend the president and the new Congress review regulations promulgated in the last months of the previous administration to identify ways to stop ill-advised rules from going forward. This review should include an assessment of whether the Congressional Review Act's procedures for resolutions of disapproval are needed.

The vision and the general thrust of the recommendations expressed in this report are supported by each of us, although not all of us agree on every recommendation or characterization. With a new presidential administration and a new Congress taking office in 2009, we believe there is a great opportunity to reform a regulatory system urgently in need of repair. We hope these recommendations contribute to that important work.

CHAPTER 1:

INTRODUCTION

ADVANCING THE PUBLIC INTEREST THROUGH REGULATORY REFORM

Federal regulations are critical elements to implementing public policies. Together these regulations provide the protections we need to ensure that our food is healthy, our children's toys are safe, our air and water are clean, dangers in our workplaces are reduced or eliminated, and our economy functions efficiently and effectively. Despite the importance of these essential governmental functions, neither the process for creating these protections nor the protections themselves receive much public attention until we discover they do not work or are not there at all.

With the growth of regulatory government, many politicians and social commentators have taken aim at these protections, flinging inflammatory rhetoric at governmental regulation: red tape, burdensome paperwork, bureaucrats run amok, and big government are just some of the invectives used. For 28 years, a philosophy of de-regulation and weak oversight has prevailed in Washington. The recent financial crisis affecting nearly every aspect of American life demonstrates the importance of having common sense protections and meaningful oversight. When it comes to Wall Street, few today would say "less regulation is better regulation."

Americans expect their government to protect them not only from financial harm but also from other dangers by providing common-sense protections and better enforcement. Virtually every day, there is news of food-borne illnesses, unnecessary workplace injuries, health problems emanating from environmental hazards, and other dangers. The majority of the public expects our government to ensure that the food we eat, the water we drink, the air we breathe, the items we buy, and the places we work are safe.[1]

This national election was largely about the need for change, including the way government approaches these public protections. Thus, the new administration has an opportunity to demonstrate that government will once again provide sensible protections to safeguard them and ultimately change the way we think about "government regulation."[2] But it must act now.

Government needs to change not only the substance of our rules but also the process by which they are made, reviewed, implemented, and enforced. Government needs to streamline the regulatory process, open it up and make it more transparent, link it more effectively to the expert community and the public that it serves, and give it the resources it needs to make and implement wise decisions that serve the public good.

This report is the work of the *Advancing the Public Interest Through Regulatory Reform* project – a group of 17 regulatory experts with varying perspectives on the regulatory process. We begin with a set of basic principles that should guide the thinking about regulatory reform. We then lay out a plan

for regulatory reform for the president and the Congress to take up in the first 100 days. Finally, we recommend a series of ongoing reforms aimed at creating a regulatory process that is open, inclusive, and efficient.

Ultimately, we envision governance that elevates the importance of sensible regulation and protects the public from harm. This vision relies on six principles that the next president should embrace:

1. **Regulatory decisions should be timely and responsive to public need.** It takes far too long to complete most rules. Timely action is a benefit to public and business interests. Government must actively assess public needs, identify where regulatory gaps exist, and act to address such gaps. Regulatory decisions should be based on the best available information, balanced with the need to act in a timely manner.
2. **The regulatory process must be transparent and improve public participation.** Too many important regulatory decisions are made behind closed doors. Openness, from pre-rulemaking to publication, is essential to meaningful accountability. The Internet age affords new ways of fostering meaningful public participation.
3. **Regulatory decisions should be based on well informed, flexible decision making.** The current regulatory process consists of unprecedented levels of suppressing, altering, and discrediting the information used to support regulatory decisions. There needs to be a premium on placing authority within regulatory agencies to decide what information is critical to effective regulations.
4. **Authority to make decisions about regulations should reflect the statutory delegation granted by Congress.** Federal agencies are given the responsibility to implement legislation and have the substantive expertise necessary to develop effective standards. That expertise should be recognized and provide the foundation for sound regulatory decisions.
5. **Agencies must have the resources to meet their statutory obligations and organizational missions.** For decades agency resources – human, financial, and organizational – have been cut or have not matched the growing responsibilities agencies have for implementing their statutory mandates. Resources are needed for addressing regulatory gaps, providing accountability mechanisms, and meeting regulatory compliance and enforcement functions.
6. **Government must do a better job of encouraging compliance with existing regulations and fairly enforcing them.** Agencies have too often been discouraged or prevented from using their compliance and enforcement tools to achieve effective compliance. In order to strengthen public protections and provide regulated communities with fair and predictable compliance approaches, agencies must be enabled to more effectively meet both current and new demands and work to improve regulatory compliance.

OUR PERSPECTIVE

The *Advancing the Public Interest Through Regulatory Reform* project was conceived during a time when regulatory problems were making national news. Mine and crane collapses killed workers; contaminants in toothpaste, pet food, and other products shipped from overseas made people and animals sick; contamination of spinach, jalapeños, meat, and other foods caused death and illness; dangerous chemicals were used in popular medicines; over-the-counter cough syrups were withdrawn because of hazards to toddlers; public lands and natural resources were exploited; endangered species and the climate went unprotected; and the housing and financial sectors began to collapse. In some instances, business interests are calling for better and stronger regulations to help reassure the public that their products are safe. Public interest advocates argue that these examples, and others, are a result of putting politics above the public interest.

It is our view that the new president and Congress must take decisive action to fix a regulatory system that, after a generation of attacks, has become dysfunctional. Quick action is needed to restore trust in government and better serve the public.

A key part of the "Reagan Revolution" was reducing regulation in the name of cutting government red tape. Operating on the principles of limited government and marketplace supremacy, the Reagan administration put forward a centralized regulatory review process controlled by the Office of Management and Budget (OMB) that imposed on agencies a central role for cost-benefit analysis in assessing the utility of a regulatory proposal. From the early 1980s to today, through legislation and various executive actions, there have been a number of requirements imposed on agencies to perform detailed analyses, focused on costs in particular, before moving forward with new regulation.[3] With the addition of each requirement, more and more time and resources are needed by agencies to complete rulemakings. Thus, a key part of the problem today is that it takes too long to get rules completed.

Seldom, if ever, has there been an effort to reduce the complexity of requirements imposed on agencies – the internal red tape. As a result, a number of students of the regulatory system criticized the process as "ossified."[4] Recognizing the growing list of requirements agencies must go through in order to finalize a rule, one study identified a comprehensive list of these requirements.[5] The list identified 110 requirements under 20 different laws, executive orders, and other policy pronouncements that agencies must follow. Since this study was published in 2000, there have been additional requirements imposed. For some agencies, it now takes more than a decade to implement a major rule.

Because the current regulatory system is so severely weighed down with procedural and analytical delays, we have tried to propose recommendations that do not impose additional burdens on regulatory agencies. The one

exception to this general rule is in the area of transparency. As we note above in the second principle, openness is critical to meaningful government accountability and much easier to accomplish with current information technology. The need to know what our government is doing and to participate fully as informed citizens requires the availability of information. As a result, government transparency and disclosure, and the public's right to know, are themes that run through this entire report.

The vision and the general thrust of the recommendations in this report are supported by each of us, although not all of us agree on every recommendation or characterization. With a new presidential administration and a new Congress taking office in 2009, we believe there is a great opportunity to reform a regulatory system urgently in need of repair. We hope these recommendations contribute to that important work.

ENDNOTES

1. See, for example, a nationwide Harris poll of adults taken October 16-23, 2007 found 53 percent believed there was too little government regulation around environmental protection; only 21 percent thought there was too much regulation. In another Harris poll of adults, from October 9-15, 2007, a majority of Americans believed oil, drug, and health insurance companies should be more regulated. At least 41 percent wanted more regulation of HMOs, gas and electric utilities, and tobacco.
2. Federal regulations, or rules, are "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency", according to the Administrative Procedure Act (APA) 5 USC §551(4), the principle federal law governing how agencies make rules to implement legislative mandates from Congress. In this report, the terms "regulations," "rules," and "protections" include regulations (the products of the rulemaking process), orders (the products of adjudicatory proceedings including permits and licenses), and deregulatory actions.
3. One outcome of these requirements is that the burden imposed on the regulated community has come to dominate considerations of regulations, except when explicitly stated otherwise in law.
4. Thomas McGarity has been making these arguments for more than 15 years. He argues that there is an "increasingly rigid and burdensome" federal regulatory process. See Thomas O. McGarity, "Some Thoughts on "Deossifying" the Rulemaking Process," Duke Law Journal, vol. 41 (1992), pp. 1385, 1385-86. Four years later, during debate over the Contract with America, McGarity makes the "paralysis by analysis" argument in Thomas O. McGarity, "The Expanded Debate Over the Future of the Regulatory State," University of Chicago Law Review, vol. 63 (1996), pp. 1463, 1523.
5. Mark Seidenfeld, "A Table of Requirements for Federal Administrative Rulemaking," Florida State University Law Review, vol. 27 (2000), pp. 533, 533-545.

CHAPTER 2:

THE FIRST 100 DAYS

This chapter identifies recommendations that President-Elect Obama should implement within the first 100 days of his administration. Those recommendations are followed by legislative action that should begin in the first 100 days of the 111th Congress.

RECOMMENDATIONS FOR PRESIDENT-ELECT OBAMA

1. **Place a moratorium on finalizing any new regulations, and review those rules finalized but not yet in effect,** except those required by statutory deadlines, court order, or necessary to meet regulatory emergencies, for 60 days pending agency review and reconsideration.

   Most recent presidential administrations have developed regulations in the closing days and months of their administrations that reflect that outgoing president's policy priorities. These "midnight regulations" may be hurriedly developed without full vetting or careful consideration.

   Some midnight regulations may still be winding their way toward completion as a new president takes office. The new president should issue a 60-day moratorium on all rules not yet finalized, giving his appointees time to adequately review them. The moratorium should be announced in a memorandum to agency heads on the first day in office in January 2009. Moratoria have become standard operating procedure for incoming administrations to stop any regulations that are in the pipeline that may be inconsistent with the new president's policies and priorities.

   For those midnight regulations the previous president finalized and published, the new administration should review any final rules not yet in effect. If new rules that have not been implemented need reconsideration, the administration should determine the approaches that can be employed to change or rescind a rule on a case-by-case basis.

2. **To set a new tone for the new administration, the president should pursue the timely appointment of qualified individuals to regulatory agencies critical to protecting the public.** In the past, presidents have too often appointed people to head agencies who were either unqualified or were too closely tied to interests they are asked to regulate as agency

leaders. These appointments often have had severe consequences for the interests public protections are intended to serve. If a president appoints officials who formerly worked for the industries they will now oversee, the president and Congress need to ensure that the appointee will work in the public's interest.

The new president should draw attention to the importance and uniqueness of regulatory agencies by quickly appointing qualified people with the knowledge, technical expertise, and management skills to restore these agencies to the mission of protecting the public.

3. **Increase agency funding for regulatory implementation and enforcement.** Regulatory agencies urgently need more resources to meet their statutory obligations and organizational missions, as well as for regulatory compliance and enforcement. (See Recommendation C.1.) The new president will immediately need to begin preparing his budget proposal for FY 2010. The president-elect should ask agencies to review their budgets to identify data gaps, restore needed collection programs, and address new areas of information needs as they are confronted with new regulatory problems, and for developing and enforcing regulations. Once the new president takes office, any changes to agency budget requests should be submitted to OMB to help the president in preparing budget revisions for Fiscal Years 2009 and 2010.

4. **The president should form a blue ribbon commission to analyze the regulatory process with the goals of examining existing requirements and reducing unnecessary delay.** The president should establish a blue ribbon commission of experts on federal regulation, including those who may work in government, to: (a) identify existing regulatory requirements imposed by statute, by executive branch policies, and by organizational barriers; (b) make recommendations for changes in regulatory executive orders, directives, and memoranda in order to reduce delays in the rulemaking process; and (c) make recommendations for changes in statutory and procedural requirements in order to reduce delays. The commission should be created within the first 100 days of the administration and the results sent to the president within six months. The president should use this report as a basis for making changes to executive orders and other regulatory policy pronouncements as identified below.

We arrived at the decision to recommend a blue ribbon panel from our discussions about the many requirements – assessments, directives, legislative requirements, etc. – that create burdens on agencies as they try to promulgate regulations in a timely and flexible manner. Some of us felt that the Small Business Regulatory Enforcement Fairness Act (SBREFA), along with risk assessment, peer review, and other requirements, have caused unnecessary delay. Others focused on different analytical requirements or institutional barriers. Although many people have different opinions

about which of these requirements are burdens and which are necessities, we agreed that serious reform should start by considering the removal of all such requirements from the process and then the addition of requirements deemed essential to efficient, effective, and timely rulemaking. A balanced blue ribbon panel of regulatory experts may be the most thoughtful way of achieving this broad evaluation of the process.

The commission should assess the costs involved in rulemaking. There is not reliable information about how much it costs agencies to develop rules or the costs of the procedural burdens imposed on agencies by various directives and assessments.

The president should use the results from the commission to consolidate needed analytical requirements and procedures so that agencies, Congress, and the public are clear about steps the president is imposing beyond those required by statute. Additionally, the president should ask Congress to remove or modify statutory requirements that are unnecessary or reduce agency flexibility in addressing regulatory needs. The president should use the report as the basis for suggesting to Congress a thorough reexamination, consolidation, and simplification of all statutes concerning rulemaking.

Congress should use the commission's work to address changes in the structure of the regulatory process, including 1) legislative reforms to the role of agencies, and 2) legislative reforms that address the role of the executive branch in the regulatory process (such as changes to the Paperwork Reduction Act, the Regulatory Flexibility Act, etc.)

Examining Procedural Requirements

The extensive number of analytical requirements and procedural hurdles are key factors in causing agency delay in promulgating rules.[1] The commission should review statutes, executive orders, legislative provisions, and other procedural requirements currently imposed on agencies in developing and promulgating regulations. This broad review should include requirements that may not only affect a few agencies (such as panels created under the Small Business Regulatory Enforcement Fairness Act) but also government-wide requirements (such as assessments on private property rights and the impacts on children). The commission should then recommend executive and legislative branch actions to reduce delay from unnecessary burdens and lead to better protections and potential costs savings.

Executive Order 12866, Regulatory Planning and Review

The commission should also examine the appropriate relationship among agencies and between agencies and White House offices such as the Office of Information and Regulatory Affairs (OIRA). This review should occur with a focus on reducing procedural delays in the regulatory process. One important aspect of the review should be an examination of Executive Order 12866, *Regulatory Planning and Review*. The order establishes the president's

policies regarding White House review of agency regulatory activities and establishes the relationship between the White House and the regulatory agencies.

Many strongly oppose centralized White House review, and there are equally strong proponents. The Steering Committee does not have a recommendation about whether there should be White House review of regulation, but the Committee does believe that if such review continues, it must be done in a manner far different than the past 28 years. The White House, including OMB, cannot continue to micromanage agency regulations.

This has significant implications for E.O. 12866, as this order (and its predecessor, E.O. 12291) has served as the vehicle for defining White House review of regulations and requirements imposed on agencies. Accordingly, we believe:

1. That E.O. 12866 is outdated and should no longer continue to be used;
2. That there needs to be a fundamental restructuring of the interaction between OIRA and the agencies, placing greater priority on agency expertise and statutory authority for decision-making; and
3. That the era of imposing simplistic one-size-fits-all approaches to rulemaking in agencies by White House offices must end.

We are divided about whether any executive order is needed to replace E.O. 12866. If the president chooses to replace the order, we do agree that the restructuring or replacement of the order should be a product of the blue ribbon commission's careful review. We strongly urge the president to ensure that any new order streamlines or eliminates requirements that unnecessarily cause delay, encourages agency flexibility in addressing regulatory issues, and respects both the statutory authority and the expertise that regulatory agencies have in the rulemaking process. The locus of decision making authority should reside in the federal agencies given the legal mandate to promulgate regulations.

5. **The president should appoint a qualified administrator for the Office of Information and Regulatory Affairs within the Office of Management and Budget who can lead the office in fulfillment of its statutory obligations and transform the role of OIRA.** There has been great controversy over the role of OIRA in regulatory affairs because of its control over regulatory information and decisions. In this role, it has strayed from its responsibilities under the Paperwork Reduction Act and created procedural hurdles in the regulatory process. Too often, OIRA has usurped agency authority by forcing agencies to use certain standards, to rely solely on specific research that bolsters OIRA's point of view, and to change results in agency analyses in order to achieve outcomes the office wants.

The new administrator must change the role of OIRA, altering its substantive engagement in individual rules. We recognize that the president has a right to pursue consistency between agency decisions and his priorities. Also, the president exercises some control over regulatory decisions through the appointment and removal of agency heads. When conflicts arise over substance – whether between an agency developing a rule and the president or between two or more agency heads – the president (or more likely his designee, currently the OIRA administrator) should consult with agency heads, recognizing the legal responsibility of those appointed by the president to implement congressional delegations of authority, including regulatory responsibilities.

The new OIRA administrator should be well versed in issues pertaining to information resources management, including those dealing with dissemination of information, particularly since information management is the statutory responsibility of the office. The administrator should be charged with coordinating the recommendations from the blue ribbon commission (see Recommendation 4 above) that the president approves and assisting agency heads in implementing them. The president should appoint a person who is committed to and qualified to lead OIRA in this revised role.

6. **The president should rescind E.O. 13422 immediately.** The executive order, issued in January 2007, places significant rulemaking authority in Regulatory Policy Officers, displacing agency head authority and adding more power to White House rulemaking judgments. The E.O. requires that Regulatory Policy Officers approve the initiation of any rulemaking. Concerns have been raised about the constitutionality of delegating this authority and about placing the authority for initiating a rulemaking, especially in very large agencies, in one person's hands. In addition, the order is overly broad in its definition of what constitutes guidance from agencies, allowing OIRA to control the substance and timing of disclosure for information clearly not intended to impact rules. The elimination of E.O. 13422 should be announced at the same time as the 60-day moratorium on publishing new rules. (See Recommendation 1 above.)

7. **The president should improve executive branch transparency by replacing the Ashcroft memorandum with another memorandum directing agencies to make more information publicly available.** On October 12, 2001, then-Attorney General John Ashcroft issued a memorandum urging federal agencies to exercise greater caution in disclosing information requested under the Freedom of Information Act (FOIA). The Ashcroft memo prompted agencies to unnecessarily withhold government information from the public and, by pushing agencies to resist the public over FOIA requests, worsened the FOIA backlog. Ashcroft's memo superseded a 1993 memorandum from then-Attorney General Janet Reno that promoted disclosure of government information under FOIA unless it was "reasonably

foreseeable that disclosure would be harmful." The Reno memo created an agency climate in which officials were more likely to share information with the public when responding to FOIA requests.[2] The president should instruct the new Attorney General to embrace the policy direction of the Reno memo and to reverse the Ashcroft memo. He should do so as soon as possible to send a message that the new administration favors a presumption of greater transparency. (See Recommendation D.3.a.)

ENDNOTES

1. We recognize that analytical and procedural requirements are not the sole reason for agency delay and inaction. In fact, when an administration wants to move quickly on a regulation, it has found a way to do so notwithstanding the many requirements that must be hurdled. Nonetheless, we agree that the existing requirements have been layered one on top of the other, creating hoops that are no longer meaningful and indeed add to the ossification.
2. Because this report addresses the rulemaking process, the focus here is on the benefits of disclosing information on domestic policy issues, not foreign policy or national security matters. However, to the best of our knowledge, the push for greater disclosure under the Reno memo never led to the release of government information that risked our national security or public well-being.

RECOMMENDATIONS FOR THE 111TH CONGRESS

1. **Use the Congressional Review Act (CRA) to stop ill-advised "midnight regulations" from the previous administration.** The CRA allows Congress to enact a resolution of disapproval within 60 session days in the Senate and 60 legislative days in the House of a rule being promulgated. The resolution follows an expedited process that cannot be amended or filibustered, but, if passed by a majority in the Senate and House, it is sent to the president. For final regulations submitted to Congress with less than 60 session days in the Senate or 60 legislative days in the House before Congress adjourns *sine die*, the rule is carried over to the next session of Congress. The new Congress has 15 legislative days (House) or session days (Senate) before the 60-day clock is restarted. Depending on when the 110th Congress adjourns, final regulations published in early June 2008 could still be subject to the CRA in the 111th Congress.

   Within 15 legislative days (House) and session days (Senate), the 111th Congress should review regulations published in 2008 that fall within the CRA time limits and determine whether it should proceed with a resolution of disapproval.

2. **As the new Congress organizes itself, it should clarify committee jurisdiction and reassert its responsibilities for review and oversight of cross-cutting regulatory issues.** Each congressional committee oversees agency actions, including regulatory actions. For government-wide regulatory process issues, oversight can be in various committees, including those dealing with government operations, administrative law, and science. In the past, Congress has been lax in overseeing regulatory issues, creating an imbalance between the executive and legislative branches in their respective responsibilities to see that agencies are meeting their organizational missions.

Two things need to happen early in the 111th Congress. First, leaders in the House and Senate need to clarify committee jurisdiction for government-wide regulatory matters. Where overlapping jurisdiction exists, clarifying committee jurisdiction would help. Second, the appropriate committee chairs need to commit to meaningful oversight, which includes using the resources of the Government Accountability Office, the Congressional Research Service, and the Congressional Budget Office, and responding with legislative changes where needed.

3. **Increase agency funding for regulatory implementation and enforcement.** Agencies need more resources immediately to meet their statutory obligations and organizational missions, as well as for regulatory compliance and enforcement. (See Recommendation C.1.) For FY 2009, as Congress addresses the expiring continuing resolution to provide funding for government agencies in March, it should begin to provide the resources for agencies to identify data gaps, restore needed collection programs, and address new areas of information needs as they are confronted with new regulatory problems, and for developing and enforcing regulations.

4. **Strengthen federal protections for whistleblowers by passing pending legislation in both chambers.** Federal government and private sector whistleblowers serve as important checks on government misconduct in the regulatory process. Congress began addressing whistleblower protections in the 110th Congress in proposed and completed legislation that may form the basis for further strengthening accountability. (See Recommendation B.2.)

CHAPTER 3:

DETAILED RECOMMENDATIONS

PART A.

IMPROVING THE QUALITY OF REGULATIONS

THE PROBLEM

There are two related problems that affect the quality of regulations and the timeliness with which they are promulgated. First, the number of analytic requirements imposed on agencies has grown in number and complexity. These requirements are now so vast that their sum significantly delays most rulemakings without necessarily improving the quality of the regulations. These requirements need to be rationalized, simplified, and in many cases deleted.

Second, the application of some of these analytic requirements has tilted regulatory outcomes decidedly in favor of regulated interests. Regulatory outcomes are often determined by the application of analytical techniques that are mostly used to narrow the criteria by which regulatory standards are set or to justify not regulating at all. Agencies are increasingly forced into regulation-by-numbers. Some quantitative analyses can be helpful in the regulatory process, but they should not be determinative (i.e., not a decisional standard) or unnecessarily imposed on top of statutory mandates. Many of these tools hide assumptions that exist in conducting quantitative analyses; these assumptions can significantly affect the outcome of the analyses. These analyses may also ignore or diminish that which cannot or should not be quantified.

Presidents since Ronald Reagan have required agencies to send a cost-benefit analysis to the White House Office of Information and Regulatory Affairs (OIRA) for major or significant rules. OIRA has frequently used its power as a regulatory clearinghouse to delay or reject agency draft rules, not only on the merits of policy proposals, but because it finds fault with the accompanying analyses. The cost-benefit analysis has been elevated to a key factor in OIRA's decision making, at times conflicting with the agency's statutory mandate.

The complexity of risk assessment and cost-benefit calculations can also delay regulation. Because agencies are required to complete certain analyses before proceeding with a rulemaking, difficulties in researching or composing analyses or disagreements over how to quantify factors can delay completion of an analysis, and therefore slow the movement of actual policy.

As currently employed, cost-benefit analysis results not just in the quantification of costs and benefits, but also in an even narrower quantification – the monetization of cost and benefits to arrive at a "net benefit" calculation, a single dollar number. Cost-benefit analysis hides the uncertainty involved in measuring the costs to society of regulating hazards in certain ways. For example, estimating the monetized benefits from preventing future incidence of cancer generally involves the application of controversial methods and assumptions. Furthermore, cost-benefit analysis ignores altogether both costs and benefits that can't be quantified. Even as presidential executive orders encourage the use of non-quantifiable elements in the cost-benefit analysis equation, the use of "net benefits" ultimately means that non-quantifiable factors are removed in favor of subtracting dollar costs from dollar benefits.

Moreover, calculations of costs and benefits rarely acknowledge market transformations that may occur when businesses adapt to new rules. For example, compliance costs may drop as new technologies are employed. These market changes are excluded from agency analyses.

The one-size-fits-all approach to cost-benefit analysis calculations in regulatory analysis is expensive and time-consuming and often provides an incomplete and inaccurate assessment of the costs and benefits of various policy alternatives. Cost-benefit analysis systematically overstates the costs of potential rules and systematically underestimates the benefits of potential rules because of its focus on quantification.

Congress has passed many public health, worker safety, and environmental quality statutes designed to improve the quality of life in America: for example, the Clean Air Act; the Clean Water Act; the Occupational Safety and Health Act; the Mine Safety and Health Act, the Transportation and Motor Vehicle Safety Act; the Consumer Product Safety Act; the Comprehensive Environmental Response, Compensation, and Liability Act; the Toxic Substances Control Act; and the Resource Conservation and Recovery Act. In passing these statutes, Congress made a conscious choice to make public health and safety the highest priority, not the costs of achieving it.

SUMMARY OF RECOMMENDATIONS

The recommendations below aim to counter the increasing trend toward quantification in regulatory decision making. Data and information can be critically important to quality regulation, identifying unmet needs, and executing smart policymaking. Nonetheless, the problems regulatory statutes address are complex, and solutions defy a simple numeric answer.

Most importantly, these recommendations call for scaling back the use of cost-benefit analysis as a determining factor in regulatory decisions, for reestablishing the primacy of statutory provisions to guide the promulgation of rules, and eliminating White House directives that instruct agencies on how and when to use cost-benefit analysis.

DETAILED RECOMMENDATIONS

A.1. Regulatory solutions and the analysis of regulatory alternatives should be consistent with statutory provisions. If a statute directs agencies to promulgate regulations according to standards of best available technology or with an adequate margin of public health protections, for example, the regulatory options should follow that statutory mandate. This fundamental principle must be followed if the president decides he wishes OIRA to continue transactional reviews of individual significant regulations.

A.2. To the extent that cost-benefit analyses are done, they should be guided by a set of core principles. We have differing perspectives on the utility of cost-benefit analysis as a tool for regulatory decision-making, and therefore have no recommendations on methods for conducting such analyses. We unanimously agree, however, that OMB's prescriptions for a one-size-fits-all approach to all agency cost-benefit analysis, such as Circular A-4, "Regulatory Analysis," are not the right approach. If the White House or OMB chooses to issue guidance regarding cost-benefit analysis, there must be flexibility for agencies to use this tool in a way that allows agencies to pursue their organizational missions; this principle means that for some agencies, it may be inappropriate to use cost-benefit analysis. To the extent that agencies choose to use cost-benefit analysis, we have unanimity on principles that should guide the use of these analyses within the federal government:

a. Cost-benefit analysis should only be used in ways consistent with the values expressed in statutory or judicial provisions;

b. Cost-benefit analysis is an analytical tool and should not be determinative in regulatory decision making unless specifically required by statute (i.e., it should be a source of information, not a decisional standard);

c. Information and assumptions used in cost-benefit analysis should be transparent and allow for the analysis to be replicated. The analysis should include statements of uncertainty about the assumptions;

d. Cost-benefit analysis should disclose both quantitative and qualitative aspects – and utilize both when interpreting results;

e. Cost-benefit analysis should include an explicit statement about who benefits and who bears the costs; and

f. While it may be appropriate to have methodological questions about cost-benefit analyses conducted by federal agencies, the White House or other regulatory reviewing agencies should never manipulate or alter results.

Underlying these principles is a belief expressed in other parts of this report that agencies should be afforded flexibility in pursuing regulations. In the context of cost-benefit analyses, the diversity of agency missions, mandates, expertise, and processes makes a one-size-fits-all prescription from the White House or OMB counterproductive.

A.3. Scientific uncertainty per se does not provide sufficient justification to avoid promulgating regulations. Federal officials should stop using claims of uncertainty to delay or avoid regulation for at least three reasons.

First, full scientific certainty can never be achieved. Pushing for certainty may result in completely stopping regulation in policy areas that rely on scientific information. Scientific research is based on the premise that some uncertainty and variability will always exist. Thus, the decision to regulate should consider the level of scientific uncertainty and risk, but the level should not be a controlling factor.

Second, federal laws often recognize that the government has a responsibility to protect citizens from harms they cannot control. Some statutes explicitly call for some margin of protection. The notion that officials must pinpoint risk (e.g., using dose-response data to find a precise exposure threshold at which harm occurs) before taking action runs counter to many of these statutory requirements. When pursuing statutory goals that emphasize prevention of harm, agencies should not delay action simply because scientific or technical uncertainties exist.

Finally, regulation is not an irreversible course of policy. In the event of significant uncertainty, federal officials should still choose to extend at least some protection as soon as possible while new information develops. As evidence grows, standards can be made more or less stringent if necessary. In fact, subsequent rulemakings may enhance the trust among federal officials and between government and outside stakeholders.

Despite the pleas of public health advocates, the Environmental Protection Agency and the Food and Drug Administration have refused to regulate diacetyl, a chemical used to add butter flavor to processed foods. Exposure to diacetyl is known to cause *bronchiolitis obliterans*, a rare degenerative lung disease, in workers exposed to it. However, less certainty exists on the effects of diacetyl in consumers. In June 2007, FDA said, "The agency does not have evidence that would cause it to take immediate action with respect to diacetyl," but pledged to continue to "monitor the scientific literature." In September 2007, the public became aware of the first known consumer to be diagnosed with bronchiolitis obliterans as a result of diacetyl exposure. The federal government has yet to take up a rulemaking to protect consumers from diacetyl.[3]

A.4. Agencies should clearly state problems, identify data gaps, restore needed collection and monitoring programs, and address new information needs as they are confronted with new regulatory problems. As agencies' budgets were reduced and regulatory priorities changed, many data collection programs across policy areas were reduced or eliminated. These cuts have affected the ability of agencies to perform their statutory functions. Public safety and adequate evaluation of regulations requires agencies to collect and analyze data.

> In 1997, the U.S. Geological Survey's Water Resources Investigations Division faced budget cuts that affected data collection activities nationwide that were important to evaluate hazards such as floods, landslides, and droughts. In the winters of 1996 and 1997, the data saved an estimated $2.7 billion in flood damage and saved lives during flooding in the Willamette Valley in Oregon.[1]
>
> In December 2006, EPA finalized a rule that raised the threshold for reporting data on toxic chemical releases for most substances from 500 pounds to 5,000 pounds per year, resulting in the loss of data for dozens of chemicals and reduced data on hundreds of others.[26] The reports are used to determine where, how, and in what amounts toxic chemicals are released or managed in communities and who is responsible for emitting them.[2]

In addition, many agencies lack sufficient information technology tools to collect and analyze data to help improve the quality of regulations. Applying new information technology systems can potentially reduce the burden of collecting, reporting, and analyzing data. As part of identifying data gaps and the need for new information, agencies should be given the necessary resources to build this capability.

Not only should the president request adequate resources from Congress each year to do this important work, but Congress should also approve adequate appropriations. Congress also has a responsibility to provide oversight to ensure resources are available and used effectively.

A.5. The Paperwork Reduction Act needs to be amended and reauthorized. The law requires agencies to seek approval of information collection requests from OIRA when attempting to collect information from ten or more people. The OIRA approval process can delay an agency's ability to collect information it needs to fulfill an agency function. OIRA reviews the "burden" the collection will impose and can reject the request if it believes the number of burden hours to be unreasonable or believes the request lacks practical utility. The Paperwork Reduction Act also requires agencies to reduce paperwork burden by five percent each year and set general goals for burden reduction. Even though the law is mostly noted for the OIRA paperwork clearance process, it primarily addresses the management of information resources, including records management, statistical policy, information dissemination, privacy and security, and information technology. Authorization for appropriations under the law expired in 2001, and Congress has not reauthorized the law.

As Congress moves to reauthorize the law, it should first rebalance the statute to address more clearly the management of information resources in the 21st century (including possibly changing the name of the law).

Second, Congress must eliminate mandatory or automatic percentage reductions in paperwork "burdens" and encourage the use of electronic collection and reporting methods. The five percent reduction has sometimes served as a powerful disincentive within agencies for collecting information to evaluate programs and to identify regulatory gaps. This disincentive must be eliminated.

Third, the president and Congress should consider alternative approaches to the paperwork clearance process that would provide agency flexibility for collection of information on emerging or pressing issues in a timely way. For example, OIRA and agencies could work together to set an annual burden-hour budget that would allow the agency flexibility to collect information on issues as it sees fit without OIRA's approval as long as it is within the budget. This burden-hour budget could be limited to new information collections on new or pressing issues, not for routine collections or standard renewals, which might still go through the traditional OIRA review process.

A.6. **Agencies should develop their own standards for the use of risk assessment according to best practices applicable to the issues with which they are confronted.** National Academy of Sciences reports on risk assessment have concluded that agencies should tailor risk assessments to the specific needs for which they are undertaken.[4] Consistent with our principle of deference to agency expertise, we strongly concur with this recommendation.

A.7. **Implied preemption in rulemakings must be curtailed.** The president should instruct agency heads to avoid preemption of state laws when there is no express authority to do so. Too often, agencies have used federal regulation to inappropriately preempt state positive law (proscriptive requirements enacted by legislatures or set by regulatory bodies) and, in some cases, state tort law.

When agencies unilaterally and inappropriately decide to preempt state law through regulation, they remove a proven, valuable method of experimenting with policy solutions, and it removes citizens' recourse if they are harmed by defective products, for example. States have often provided the models for subsequent federal programs and regulatory approaches that advance the public good. The practice of preempting without statutory authority is leading to regulatory standards turned on their heads. Instead of federal regulations traditionally being the floor below which states cannot relax their standards, this approach creates federal standards, without congressional action, as ceilings above which states cannot issue stronger health, safety, and environmental protections.

Unless statutes or the courts expressly give agencies the discretion to preempt state positive law or tort law through regulation, agencies should not include preemption language in rules. If Congress gives agencies authority to preempt state positive law through regulation, agencies should not try to extend their authority to preempt tort law as well.

The next president should ensure his administration leaves decisions about preemption to Congress and abides by those decisions.

ENDNOTES

1. U.S. Water News Online, "ASCE tells Congress that proposed cuts to Geological Survey budget risk public safety and property," April 1997, available at http://uswaternews.com/archives/arcpolicy/7asctel4.html, last accessed September 23, 2008.
2. U.S. Environmental Protection Agency, "Toxics Release Inventory Burden Reduction Final Rule." 71 Federal Register 76932, December 22, 2006.
3. Background information and source documents compiled by the Project on Scientific Knowledge and Public Policy, available at http://defendingscience.org/case_studies/A-Case-of-Regulatory-Failure-Popcorn-Workers-Lung.cfm
4. See, for example, National Research Council, Risk Assessment in the Federal Government: Managing the Process, Washington, DC: National Academies Press, 1983. This publication establishes the parameters for using risk assessment.

PART B.

INTEGRITY AND ACCOUNTABILITY

THE PROBLEM

A democratic, accountable, and effective government, and an engaged and participatory citizenry, rely on an open and informed exchange of ideas. Information of all types – economic, scientific, technical, and social – is critical to a well functioning democracy. Government policymakers at all levels of the U.S. federal system, and those affected by the decisions made, rely on information collected, analyzed, and disseminated by federal agencies. Whether providing information for private financial markets or determining the safety of foods at the local market, all segments of society need reliable, accurate information.

In the regulatory arena, accurate and timely information is critical to setting standards protective of health and safety. It is critical to helping the regulated community understand how to formulate voluntary standards for regulatory compliance. Equally important are the processes for determining what information should be included in regulatory decision making. The processes for determining whether a new bridge design will meet adequate weight support limits, or whether an adequate margin of safety exists to protect the public from exposure to chemical toxins in drinking water, should be sufficiently open and transparent to provide the public and those tasked with implementing government policies with confidence that the public will be protected.

Beginning 28 years ago with the advent of centralized review of agencies' proposed regulations, presidents have exerted some control over the substance of regulations. Sometimes that meant trying to control the information – usually scientific information – that went into promulgating the regulations. The current regulatory process, however, consists of unprecedented levels of restrictions, manipulation, and suppression of scientific information

essential to regulatory decision making. Some major industries and their representatives have made a concentrated effort at the federal level to create a perception that there is too much scientific uncertainty, thus weakening the case for regulations.

Additionally, agency expertise is too often ignored by political appointees. While ultimately, regulatory decisions are made by political appointees, an accountable system ensures that agency decisions are formulated based on the best available information from experts within the agency, as well as others. Such a model would preclude manipulation of science, suppression of data, or silencing the voice of agency scientists. Two examples illustrate the problem:

- Former Consumer Product Safety Commission statistician Robin Ingle collected statistics on injuries and fatalities from all-terrain vehicle (ATV) accidents. The results indicated that in 2004, deaths and injuries were at a 20-year high. The general counsel at the agency tried to insert language into the executive summary of Ingle's report indicating the risk of riding these vehicles was decreasing. The general counsel at the time had been a lawyer for the ATV industry.[1]
- The Department of Interior's Inspector General (IG) investigated former deputy assistant secretary for fish, wildlife and parks Julie A. MacDonald and found she had intimidated staff and changed the scientific information agency scientists developed for decisions about listing or delisting threatened or endangered species. The IG's report was released to Congress the week of March 26, 2007, and showed MacDonald's involvement in "editing, commenting on, and reshaping the Endangered Species Program's scientific reports from the field."[2]

SUMMARY OF RECOMMENDATIONS

An accountable and responsive regulatory process must generate independent and credible information to be used in regulatory policy decisions. Agencies should have the most reliable scientific and technical information available from the scientific community and adhere to the highest principles of scientific integrity. Both the process and the information derived therefrom must be free from political interference. Government-sponsored research must be insulated from political interference. Agency experts, federal advisory committees, peer reviewers, and other experts involved in the design, conduct, and analysis of government research and regulations should be free from interference from political appointees within the agency and within White House offices. They should be free from political harassment and censorship and free to disclose information considered relevant to the recommendations they forward to policymakers. Agency experts must have access to and be able to generate independent scientific, technical, economic, and social information.

The recommendations below mostly address the need to restore scientific integrity to the process. They focus on: 1) ways the public can hold government officials accountable for the actions they take on behalf of the citizens that rely on them; and 2) the need to ensure that information critical to policy decisions is independently developed and constitutes the best thinking that can be brought to solving policy problems. In conjunction with transparency recommendations that stress the importance of disclosing the range of meetings and materials relevant to agencies' regulatory decisions in agency dockets, these recommendations can begin to restore integrity and accountability in the regulatory process. As with other sections in this report, the definition of "regulation" includes permitting, licensing, and other activities that provide controlling actions.

DETAILED RECOMMENDATIONS

B.1. The president should instruct his agency heads that scientific integrity must be a core component of regulatory actions. The president should send a clear message early in the new administration that federal agencies will adhere to the highest principles of scientific integrity and independence. Although this message can be sent in several ways, such as appointing a high-level science advisor and expanding the network of executive branch advisory panels, the message must be that the government will apply the highest standards of scientific integrity and that this is a critical aspect of an improved regulatory system. The government must be committed to having the most reliable scientific and technical information available, both from expertise within agencies and from the larger scientific community, and using that information in an objective and transparent fashion as the foundation for decisions affecting the public interest.

B.2. Federal protections for public and private sector whistleblowers need to be strengthened to serve as a check on misconduct. Whistleblower protections are the backstop for accountability in government. Time and again, dedicated civil servants have stepped up to talk about misconduct in government science, regulation, and general decision making that can cost lives and money. Necessary improvements include:

- Strengthening the Office of Special Counsel's processes for reporting misconduct and corruption, reviewing whistleblowers' claims, and protecting from retaliation those who report abuses in good faith;
- Allowing whistleblowers to disclose to any member of Congress information regarding government misconduct or corruption;
- Strengthening the independence of agencies' inspectors general, along with creating and streamlining the mechanisms to permit agency employees to report misconduct anonymously; and
- Evaluating the effectiveness of the implementation of whistleblower reforms within agencies.

Both houses of the 110th Congress passed legislation to address loopholes in the Whistleblower Protection Act of 1989, which has been weakened by subsequent court rulings.[3] The stronger protections in the House bill include due process protections for federal whistleblowers experiencing retaliation from co-workers and employers. The president should encourage the new Congress to pass legislation quickly in each house, reconcile their differences, and send him legislation early in 2009.

On August 14, President Bush signed the Consumer Product Safety Improvement Act of 2008, which provides whistleblower protections to nearly 20 million private sector workers in the manufacturing, distribution, and sale of consumer products such as children's products and household goods. The new law provides protections, enforceable by jury trials, for workers who disclose product safety violations or refuse to engage in illegal behavior.

Congress should extend the model established under the Consumer Product Safety Improvement Act of 2008 to other industries regulated by the federal government.

The president should make clear early in the administration that he stands for strong government accountability and the independence of public information. The president should highlight the importance of whistleblower protections for federal employees.

B.3. Strengthen the Federal Advisory Committee Act (FACA). Science advisory committees are a vital means through which agencies obtain valuable advice and information. Agencies use scientific committees and stakeholder or policy committees for different purposes. Scientific committees are used to provide agencies with expert advice and analysis of the complex scientific information critical to informing final decisions about public health or environmental quality standards, for example. Stakeholder or policy committees may be used to actively solicit the opinions of stakeholders who have expertise and are likely to be the parties impacted by regulatory actions. For example, the Department of Interior may wish to solicit the advice of western ranchers who may be affected by changes to policies about grazing practices on federal lands. Candidates for service on a federal advisory committee may be named either as "representatives," those who voice the views of specific interested parties, or "special government employees" (SGEs), those chosen to provide objective analysis and advice. It is important to note these differences when considering new ways of strengthening the use of these committees.

In some cases, agencies have stacked science advisory committees with representatives of special interests, thereby endangering the independence of the advice the FACA committees dispense.[4] The president should emphasize to agencies the importance of implementing the intent and spirit of FACA.

Congress should consider strengthening FACA in several ways:

- Require agencies to appoint to scientific advisory committees individuals from the disciplines relevant to solving the charge of the advisory committee. Such appointments should be made without consideration of political affiliation or activity.
- End the practice of hiring private contractors to develop advisory committees to avoid FACA requirements. This practice has been used by some agencies to claim under a legal loophole that they do not have strict management over the committees. Congress should close this loophole.
- Extend FACA requirements to all subgroups of covered advisory committees.
- Make the processes by which committees operate and their members are selected fully transparent. For example:
  - Agencies should announce publicly any plans to form a new FACA committee, disclose the expected charge to the committee, and solicit nominations from the public for committee membership.
  - Agencies should disclose committee nominations and appointments on their websites so that the information is easily accessible; the names of appointees (and perhaps, the names of nominees similar, to the approaches used by the National Academy of Sciences (NAS) and the Environmental Protection Agency (EPA) for specific science advisory boards[5]) and any conflicts of interest or potential biases, as well as any waivers of conflicts should be included. Agencies should also provide a limited time for public comment on the appointments of committee members.
  - Agencies should disclose on their websites the records of all committee and subgroup meetings, the members of all committees and subgroups, and the transcripts or electronic records of any meeting.

B.4. Improve conflicts of interest laws. Special Government Employees (SGEs) are currently subject to the conflict of interest provisions of FACA, provisions that are enforced by the Office of Government Ethics. We believe there is a need for specific FACA conflict of interest guidelines.

As noted above in B.3, FACA committees may be used for different purposes. For scientific committees, the goal should be to establish a government-wide policy that strives for an absence of real and apparent conflicts of interest for committee membership. One model for accomplishing this policy is the approach taken by the World Health Organization's International Agency for Research on Cancer (IARC). Membership in IARC Working Groups is based on "(a) knowledge and experience and (b) absence of real or apparent

conflicts of interests. Consideration is also given to demographic diversity and balance of scientific findings and views."[6] The model recognizes that there may be instances in which special expertise is needed and may have to come from those who have real or apparent conflicts. In these instances, the "invited specialists" are limited in the ways in which they can participate in a working group.

B.5. Disclose the scientific, technical, economic, and social analyses used in the formation and promulgation of regulatory documents. The information that forms the foundation of regulatory decisions is too often unavailable or hidden from public view. The labeling of information as classified business information (CBI) is overused, agency rulemaking dockets are not easily available, and studies are often used selectively to justify a predetermined policy outcome.

As recommended in D.1.a, all research results considered in the promulgation of regulations should be made part of the agency's rulemaking docket, which should be made available in an online searchable format. The docket should include all supporting materials – regardless of their source – unless classified or otherwise exempted by FOIA.

More specifically:

- The burden of justifying confidential business information (CBI) should be shifted to those making such claims on information critical to a substantive regulatory decision. The justification warranting the protection should be provided prior to receiving the protection and certified by a senior executive of the business requesting the protection. This approach has worked successfully in several programs, including the Toxics Release Inventory operated by the EPA. The president has substantial authority to make this shift in certain areas.
- Increasingly, information that may be important to a rulemaking is being categorized as critical infrastructure information or sensitive but unclassified. These control markings have been interpreted in an uneven manner throughout the government, oftentimes resulting in less disclosure of the information. On May 9, 2008, President George W. Bush issued a memo to agency heads that created a tiered system of designations to standardize the proliferation of these control markings under the name "Controlled Unclassified Information."[7] The president should refine this CUI policy by reining in the use of CUI designations and making very clear that a CUI control marking has no bearing on whether the information should be disclosed under FOIA; and
- Congress should consider legislation to require the disclosure of privately sponsored research used in the regulatory process in the same way that public research should be disclosed. Agencies must often rely on private research to develop regulations. Disclosure of privately sponsored research that identifies the extent to which the sponsor controlled the

research design, analysis, and reporting of the results is necessary so the public and the agencies can judge the soundness of the research. This change would bring privately funded research under similar disclosure requirements that now exist for publicly funded research under the Shelby Amendment.[8] (See Recommendation D.1.a.)

- The president should establish a new standard of disclosure regarding non-governmental challenges to research and data used by agencies. Currently, agencies can face challenges of government-sponsored science used in rulemakings without the challenger submitting evidence of factual errors or flawed science. These challenges may call for other science to be considered instead of, or in addition to, the studies used by agencies. The president should establish a new standard that requires the challenger to submit evidence of errors in the agencies' use of science and ensure that the underlying data used for the challenge is available for public inspection for challenges to be considered valid.

B.6. Resurrect the Office of Technology Assessment (OTA). As previously constituted, OTA provided Congress and the scientific and technical communities with objective analyses of a wide range of scientific, technical, and comparative policy knowledge. Reconstituting OTA would provide Congress with its own scientific and technical research arm that could complement and/or check executive agencies. Congress should resurrect the OTA with sufficient funds to operate effectively and appoint a well respected scientist to head the office.

Unlike the National Academy of Sciences, which focuses on long-term analysis of scientific information, OTA was able to respond to short-term congressional needs for specialized knowledge that Congress's other two research arms, the Government Accountability Office and Congressional Research Service, cannot provide.

B.7. For key areas of international health and safety regulation affecting Americans and U.S. businesses, Congress and the president should call for greater transparency in order to make the process more democratic. Consumers are living in a global economy, and it is vital that consumer, labor, and environmental standards be upheld as the U.S. meets its obligations under various trade agreements. Some standard-setting bodies, like the Codex Alimentarius, which establishes food standards for international trade, are operating in the absence of full transparency. Consumer organizations can only participate if they are part of an international coalition approved by the World Health Organization. All interests should have the same opportunity to influence and preview the positions taken in international fora.

The president should allow full access to documents and ensure that the rights of U.S. organizations and citizens to comment are fully preserved. The president, along with Congress, should advocate for full disclosure and

open meetings for international bodies that set standards with international implications. If international standards are affecting American consumers or businesses, we believe Americans should have a place to go to find out what is required of them, and there should be an opportunity for them to make their voices heard.

B.8. The president should encourage agency heads to adopt (or modify) guidelines to allow scientists to communicate freely. Federal scientists in some agencies are prevented from speaking with the media, the public, and even their professional colleagues. Instead, questions about the scientific studies are directed to public affairs officers, not scientists who conducted or know about the research in question. The president should encourage agencies to adopt media polices that respect two basic rights of scientific communications: 1) like any other federal employee, scientists have a right to express their personal views, with the express disclaimer that they are speaking as private citizens and not representing official agency policy; and 2) scientists have the right to review, approve, and comment publicly on publications or documents that rely significantly on their research or identify them as an author or contributor to ensure the accuracy of the information has been maintained during internal agency review processes.

B.9. Agencies should abstain from inappropriate interference in the work of other agencies and end secretive interagency reviews of scientific and technical information. Congress delegates responsibilities to federal agencies based on its determination of which agency is most suited to fulfill certain duties. Congress may consider which agency possesses the requisite expertise to competently address a task and will consider whether that agency's mission is consistent with statutory goals.

However, agencies may also have an interest in the work of other agencies with delegated authority from Congress, and, in some cases, one agency's decision may directly impact the operation of another. For example, under the Resource Conservation and Recovery Act, EPA can order the clean up of dangerously polluted land on both private and government property. But the Department of Defense (DOD) has refused to abide by official EPA clean-up orders for three military bases. The Department of Defense has even asked the White House to intervene on its behalf.[9]

The president should ensure that when these kinds of disputes arise, agencies defer to the agency given responsibility under federal law. Agencies subject to another agency's regulations must not be allowed to delay decisions or usurp power. The primary function of regulatory agencies is to carry out federal law. Other agencies have the right to comment and make known their interest in the issues and regulations that affect them, but they should not undermine the work of the agencies given the statutory responsibility for rulemakings.

The president should also terminate inappropriate interagency review and control of scientific and technical information that serves as the basis of

rulemaking. For example, the interagency review process of toxicology profiles performed under EPA's Integrated Risk Information System allows other agencies potentially impacted by the assessments to direct EPA's scientific investigations and limits the dissemination of scientific information to the public. The review affords agencies that use toxic substances, such as DOD or NASA, multiple opportunities to delay, dispute, or alter EPA's scientific research and conclusions. Such reviews can interfere with and ultimately affect the outcome of a rulemaking.

In 2004, the Environmental Protection Agency (EPA) submitted to the White House Office of Management and Budget (OMB) a draft toxicity assessment for naphthalene, a chemical found in jet fuel, moth balls, and a variety of other products. OMB, consulting with the Department of Defense, objected to EPA's findings and suspended the assessment, citing the need for additional research. OMB then persuaded EPA to form an ad hoc scientific panel to research the issues related to OMB and DOD's objections. After continued delays, the initial studies upon which EPA had formed its opinion had become outdated, and the agency restarted the assessment process.[1]

There is a clear distinction between assessing the impacts of risks to the public and the policies for managing those risks. Scientific integrity is at greatest risk in situations where considerations other than science determine the assessments. Other considerations, including political considerations, are properly included in decisions about risk management and communication. Those considerations should not be a part of the assessment process. (See Recommendation A.6.)

The president should clarify which agencies have primary authority in various areas of expertise and limit the review of scientific or technical information by other agencies to advice and comment. When review does take place, the process should be completely transparent, and the comments of other agencies should be disclosed online.

ENDNOTES

1. Robin Ingle, "Which Toys Are Okay? Don't Ask the Safety Police," The Washington Post, December 23, 2007, available at http://www.washingtonpost.com/wp-dyn/content/article/2007/12/21/AR2007122101555.html, last accessed October 6, 2008.
2. U.S. Department of the Interior, Office of Inspector General, Investigative Report On Allegations Against Julie MacDonald, Deputy Assistant Secretary, Fish, Wildlife and Parks, available at http://www.doioig.gov/upload/Macdonald.pdf, last accessed October 6, 2008.
3. See H.R. 985, the Whistleblower Protection Enhancement Act of 2007, and S. 274, Federal Employee Protection of Disclosures Act.

4. U.S. Government Accountability Office, Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance, April 2004, available at http://www.gao.gov/new.items/d04328.pdf, last accessed September 24, 2008.

5. See, for example, EPA's Clean Air Scientific Advisory Committee (SAB) approach to forming an SAB Asbestos Panel in 2006-2007. EPA published in the Federal Register a notice request for nominations to the panel, sought comments on the short list of nominees, and then published another request for additional expertise for the panel. Documents are available at http://www.epa.gov/sab/panels/asbestos_expert_panel.htm, last accessed September 26, 2008.

6. World Health Organization, International Agency for Research on Cancer, "Preamble to the IARC Monographs, A. General Principles and Procedures," January 23, 2006, available at http://monographs.iarc.fr/ENG/Preamble/currenta5participants0706.php, last accessed September 26, 2008.

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8. The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999. Public Law No. 105-277, also called the Data Access Act, available at http://thomas.loc.gov/cgi-bin/toGPObss/http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=105_cong_public_laws&docid=f:publ277.105.pdf, last accessed October 23, 2008.

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10. John B. Stephenson, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System," United States Government Accountability Office, GAO-08-440, March 2008, 35-37. Available electronically at www.gao.gov/new.items/d08440.pdf

PART C.

IMPLEMENTATION AND ENFORCEMENT

THE PROBLEM

By far the biggest problem facing agencies that implement federal regulations – monitoring, inspecting, and enforcing rules – is the extreme shortfall of both human and financial resources. Many agencies are experiencing an exodus of expertise as scientists, engineers, trained inspectors and safety officials, and lawyers leave as budgets are cut or level-funded, often in the face of increasing regulatory responsibilities. This decades-long trend has left some agencies unable to respond as ably to crises and problems as necessary. Moreover, the problem is likely to compound itself as the federal workforce gets older and people perceive that working in the federal government does not inspire innovation.

In addition, as societal issues arise that require action on the part of the federal government, such as the current financial crisis, disasters like Hurricane Katrina, or the introduction of nanotechnology, agencies may fall even further behind in providing essential public protections.

The inability of federal agencies to respond adequately to some problems may have reached a peak in recent years. The U.S. is facing severe problems in mortgage and other lending practices and a rising tide of imported products (such as toys, tires, toothpaste, and a variety of food products) that made newspaper headlines for the risks they posed to consumers. For example, in 2007, approximately 104 recalls of lead-contaminated children's products were announced. The recalls covered more than 17 million individual products, 95 percent of which were manufactured in China. The number of products recalled in 2007 increased nearly six-fold compared to 2006.

Federal agencies responsible for regulating these financial and consumer products, and for regulating public health risks from environmental hazards,

are plagued by declining resources and authority, making it more difficult to ensure the safety and soundness of consumer products. For example:

- The federal regulator of meat, poultry, and egg products, the Food Safety and Inspection Service (FSIS), faces resource limitations that make it more difficult for the agency to ensure the safety of the food supply. Although the agency's budget has risen since it was created, staffing levels have dropped steadily. From FY 1981 to FY 2007, the number of full-time employees at FSIS fell from 9,932 to 9,184 – a 7.5 percent drop. FSIS's inspection force has an average national vacancy rate of at least ten percent.[2]
- Over the past three decades, the Occupational Safety and Health Administration's (OSHA) budget, staffing levels, and inspection activity have dropped while the American workforce has grown and new hazards have emerged. Since FY 2001, OSHA's budget has been cut every year when adjusted for inflation. In FY 1980, OSHA's staffing level hit its peak of 2,950. For FY 2006, OSHA had a staff of only 2,092, the second-lowest level in 30 years. OSHA's budget for enforcement activity is currently 12 percent lower than it was in FY 1980. OSHA was appropriated $264 million for enforcement activity for FY 2006, compared to $301 million in FY 1980, when adjusted for inflation.[3]

There is public, private, and congressional support for restoring the ability of federal agencies to respond to some of these unmet needs. Many businesses hurt by consumers' refusal to buy unsafe products or by the inability to get short-term credit are supportive of expanded regulatory authority and quality standards while improving their own practices. Americans have become painfully aware of the positive role government can play and the consequences that can occur when regulatory protections break down. Public support is crucial to reestablishing agency funding as a priority amidst the competition for scarce federal dollars.

The public expects that if a regulation is on the books, it should be enforced. By the same measure, businesses, particularly small businesses, which intend to comply with federal regulations, may at times not know about the requirements. Strengthening compliance assistance would be extremely useful.

Evaluating the effectiveness of agency regulations is especially problematic. Agencies are starved for resources, under legislative and/or court-ordered mandates to issue regulations, and burdened with a wide array of procedural requirements. These factors make it increasingly difficult for agencies to plan rulemaking agendas, track regulatory effectiveness, or estimate the costs of rulemaking activities. In addition, the rulemaking process may require years to reach a final outcome, while the appropriations process is annual, thus leaving agencies to struggle with allocating resources each year for multi-year rulemaking efforts.[3] Part of an evaluation initiative should include some method of evaluating individual rules for their effectiveness.[4]

SUMMARY OF RECOMMENDATIONS

Effective implementation of many financial, public health, worker and consumer safety, and environmental quality regulations require a complex mix of federal, state, and local government actions, as well as third party involvement. This mix relies substantially on the leadership of federal agencies: setting priorities, providing technical and financial assistance, and ultimately enforcing compliance with regulations. Without sufficient financial and human resources, clear enforcement goals, and sound evaluation tools, the problems identified and addressed in law cannot effectively be solved.

DETAILED RECOMMENDATIONS

C.1. Funding for enforcement of regulations must be increased. Agencies need more resources immediately to meet their statutory obligations and organizational missions. Agencies must be enabled to more effectively meet both current and new demands. The president should ensure adequate resources in his budget requests to Congress. And Congress, even in the context of tight budgets, must provide resources to support enforcement of regulations.

C.2. Develop a comprehensive regulatory compliance initiative. Working with small businesses, state and local governments, and other stakeholders, agencies should work to create or improve programs for strengthening compliance with regulations. Programs adopted by agencies should include compliance assistance, enforcement, and sanctions components, and these should be reflected in annual budget requests, to which Congress should give close scrutiny. Improving and strengthening enforcement programs can lead to a more efficient use of scarce federal dollars in an intergovernmental enforcement framework. In the competition for resources, however, the first priority should be for enforcement of regulations.

C.3. Modernize enforcement tools across government to assure credible deterrence. Increasing the resources available to agencies to enforce regulations is not the only way to improve enforcement. Alternative tools such as citizen suits with fee-shifting can be a useful enforcement tool that deputizes the public to act as private attorneys general instead of depending entirely on a federal enforcement staff. Additionally, there can be technological tools, such as pollution monitoring systems and electronic on-board recorders for trucking hours, that could improve compliance monitoring without requiring a vast expansion of the federal inspectorate. While these new tools can be helpful, so is ensuring that there are strong deterrents, such as meaningful civil and criminal penalties, for failure to comply with regulations. In that context, the president and congressional committees should review traditional enforcement tools to address weaknesses.

C.4. Fund an historical assessment of regulatory agency budgets and resource needs. Congress should direct the GAO or the Congressional Research Service to assess the historical trends in regulatory agency budgets in order to begin restoring agencies to their traditional role of meeting statutory obligations and organizational missions. For example, agency budgets should be evaluated for changes over time in personnel, overall and programmatic funding, numbers of inspectors and inspections, numbers of inspectors and inspections compared to the growth of the regulated sector (or other baselines), enforcement personnel and actions, data collection, monitoring and management, and research requirements and priorities. These changes then need to be placed in the historical context of the statutory mandates placed on agencies.

Once data is collected, analyzed, and made available to Congress, there should be continued updating and analysis of resource capabilities and needs. The data collection effort should become an important part of essential congressional oversight. As the public and congressional oversight committees learn more about current resources for regulatory activity in the context of past expenditures, they may achieve greater understanding of the need for resources. This assessment may help Congress more efficiently allocate resources, especially in the short term as it faces difficult budgetary decisions. In addition, such data may better insulate agency regulatory needs from political interference and control by administrative fiat.

ENDNOTES

1. OMB Watch, "Federal Meat Inspectors Spread Thin as Recalls Rise," March 4, 2008, available at http://www.ombwatch.org/article/articleview/4183/1/527, last accessed September 23, 2008.
2. OMB Watch, "Workers Threatened by Decline in OSHA Budget, Enforcement Activity," January 23, 2008, available at http://www.ombwatch.org/article/articleview/4143/1/219, last accessed September 23, 2008.
3. There is some evidence that the number of proposed and final rules issued is decreasing. One recent report urges Congress to adopt an initiative to study systematically the development of regulations in federal agencies including best practices and methodologies. See Jeffrey S. Lubbers, "The Transformation of the U.S. Rulemaking Process—For Better or Worse," Ohio Northern University Law Review, vol. 34 (2008), pp. 469, 472-73.

4. U.S. Government Accountability Office, Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews, GAO-07-791, July 16, 2007, available at http://www.gao.gov/new.items/d07791.pdf, last accessed Sept. 24, 2008. This GAO report on retrospective reviews of agencies' regulations, noted that although there are some mandatory requirements for reviews, agencies generally used their discretion in determining whether and what to review. The report concludes: "Multiple factors helped or impeded the conduct and usefulness of retrospective reviews. Agencies identified time and resources as the most critical barriers, but also cited factors such as data limitations and overlapping or duplicative review requirements. Nonfederal parties said that the lack of transparency was a barrier; they were rarely aware of the agencies' reviews. Both agencies and nonfederal parties identified limited public participation as a barrier." See also Jeffrey S. Lubbers, A Guide to Federal Agency Rulemaking, Fourth Edition, p. 395 et seq. Chicago: American Bar Association, 2006.

PART D.

TRANSPARENCY

THE PROBLEM

The process by which a rule is developed can be hidden from public view by institutional mechanisms, a lack of disclosure requirements, and government officials who would prefer not to disclose certain documents or communications. The opacities in the process are most acute during the pre-rule stage – the developmental phase of a rulemaking (before the publication of the Notice of Proposed Rulemaking (NPRM)) where federal officials make critical decisions on the direction of national policy.

White House review adds another hidden dimension to the regulatory process. During the Clinton administration, the Office of Management and Budget (OMB) began posting to its website a list of all rules under review and updates on OMB's decisions. During the George W. Bush administration, OMB began posting to the White House website a list of people from outside of government participating in meetings with OMB's Office of Information and Regulatory Affairs (OIRA) regarding rules under review. Although openness has improved, the website does not meet modern standards for transparency (e.g., it is not searchable). Additionally, the content of what is provided could be improved. For example, substantive reviews of regulations conducted by OMB, mostly done through oral, not written, communications with agencies, are not part of the public record. Increasingly, OMB input on a rule occurs prior to the formal regulatory review process described in Executive Order 12866 and is excluded from any form of transparency. This pre-rulemaking input can shape the regulatory outcome in undocumented ways.

Transparency in the rulemaking process is important for three main reasons. First, transparency leads to a greater sense of legitimacy from those outside government, improving both public support and compliance. Citizens are

more likely to trust that a rule is in their best interest if they can follow and participate in the process. The regulated community is more likely to understand how to comply with a rule it has been able to follow in development. Second, where government is perceived to have erred, a transparent decision making process will provide citizens, stakeholders, Congress, and the courts an important tool with which to hold the proper official(s) accountable. Third, transparency is critical to public participation (discussed in the next section) because an open and well documented process will lead to better informed commenters and, presumably, more helpful comments.

SUMMARY OF RECOMMENDATIONS

To improve transparency in the rulemaking process, the federal government should broadly adopt a strategy that moves toward a presumption of openness. This strategy is particularly important in the pre-rule, or rule development, stage where the bulk of policy formation occurs and can be shaped through undocumented interactions with OMB. Once an agency decides that an issue is a priority, that the agency has sufficient resources, has legal authority, and decides (or is directed) to regulate, the agency should create the rulemaking docket. The creation of this docket should signal the beginning of the period when all subsequent and significant actions, communications, and information should be disclosed, including those that may occur with OMB or the White House prior to any formal review process.

The Internet age has also redefined the concept of government transparency: Information should be available online in a timely fashion and in searchable formats to be considered truly transparent in modern society. New interactive technologies can make it easier to find and use information. For example, the government should use open programming interfaces (e.g., application programming interfaces, or APIs) to make sharing of information more possible.

Transparency also means the content of what is being disclosed must be complete. Rulemaking dockets must include all information relevant to the development of a rule, as well as information relevant to permitting and licensing. A tracking system should be established so the public can examine the progress of a rule from its beginning (e.g., at the creation of the rulemaking record or announcement in the *Unified Agenda*) to its implementation, as well as any paperwork requirements that may be associated with the rule.

In general, the recommendations in this report avoid imposing additional procedural requirements on agencies – there are far too many as it is. Achieving government accountability through a transparent and open regulatory process is the exception to this general rule. Information technology today makes it far easier to have transparent processes consistent with democratic principles.[2]

DETAILED RECOMMENDATIONS

D.1. Agency rulemaking dockets should be expanded, complete, and available online. Finding information related to a specific rulemaking can be difficult. Often, the only information an agency provides to the public at the time a rule is proposed or finalized is the text of the rule itself. Regulatory impact assessments, which identify, in monetary terms, the potential costs and benefits a rule may have to society, sometimes accompany a rule's release.

The public should have access to a broader range of information used in a rulemaking. The public also should have access to draft proposed rules and draft final rules sent to OMB for review. Agencies should include these drafts in the rulemaking docket in a timely manner so that the materials are available to the public as part of the notice-and-comment period. Disclosing a broader range of rulemaking materials would likely avoid the need for some information requests under FOIA and may help reduce the resources needed for FOIA actions. (See Recommendation D.3.)

In July 2008, without prior notice, the Department of Labor sent to OMB a draft rule restructuring the Department's internal policies for the conduct of risk assessments. An entry on the OMB website revealed only the title of the rule; unlike other rules, the entry did not provide an abstract or proposed timeline. (Eventually, a draft of the rule was leaked to *The Washington Post*.) The Department did not consult experts inside the Occupational Safety and Health Administration or Mine Safety and Health Administration – the agencies the rule will affect. Instead, according to news reports, the Department based the rule on the report of a consultant who received a $350,000 contract to analyze the Department's current risk assessment regime. The Department refuses to release the consultant's report.

Online rulemaking dockets should be among the primary vehicles for disclosure. Regulations.gov – the federal government's central location for online access to rulemaking dockets and public commenting – is in need of improvement, as will be discussed in the next section. If dockets are complete and material is posted in a timely fashion, Regulations.gov, and the federal government's online rulemaking docket system as a whole, will improve rulemaking transparency.

We believe it is essential for at least the following classes of information (identified in the subsections of this recommendation) to be included in rulemaking dockets. Disclosure should begin upon creation of the rulemaking dockets. Disclosure should occur as soon as possible after documents, communications, or other types of information described below surface.

D.1.a. Agencies should disclose online all studies in their possession related to a rulemaking, regardless of whether the study was used to inform the policy option the agency chose. Currently, agencies sometimes include in the rulemaking docket only the information that is directly cited in a rule. Other information to which the agency had access, but which it chose not to draw on or chose to ignore, is not included. The public may never find out about such information.

Studies, research results, and other inputs that *could* inform agency decision makers should be disclosed online, even if the information did not persuade or affect the chosen outcome. The public needs to have available in the administrative record all the information the agency had at its disposal during the decision making process so that interested parties can draw their own conclusions about the issue. Furthermore, existing law sets the foundation for disclosure of information during development of a rule.

D.1.b. Agencies should disclose online all written communications among federal officials from different agencies, including the White House, regarding rules under development or under review. Currently, the rulemaking process contains no requirements for disclosing communications made among federal offices. Agencies often have an interest in the rules other agencies are considering and the requirements those rules may impose.

OIRA purports to use the review period to mediate between an agency developing a rule and other agencies. Two problems exist. First, instead of serving as a mediator, OIRA often uses the period to challenge or alter the substance of a rule. Unlike agencies, however, OIRA often does not possess the requisite expertise to make substantive contributions. Second, other agencies with an interest in the rule may intervene in the rulemaking outside of the E.O. 12866 review period where communication and negotiation is even murkier. Transparency can serve as a check on these problems.

Officials outside of the agency developing the rule, including those in the White House, can have an enormous impact on the rule's substance. To avoid improper influence, whether real or perceived, the public should have greater access to the communications between and among officials. Therefore, written communications between and among federal agencies and White House offices should be disclosed to the public once the rulemaking docket is created.

The issuing agency should make available promptly in its online rulemaking docket any written communications between or among federal agencies and OIRA or other White House offices. This disclosure requirement should apply to communications made at any point during the rulemaking process, including the pre-rule stage (once the docket is created).

To improve transparency during the review period, agencies should look to Section 307 of the Clean Air Act as a model. The act states:

> The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

As mentioned above, we recommend this type of disclosure be extended throughout the rulemaking process, even before the agency submits a draft rule for review.

When OIRA chooses to reject an agency proposal, improved transparency among federal officials may also provide the public with a better understanding as to why the rule was insufficient in OIRA's view. OIRA provides in writing its reasons for returning a regulation under review for agency reconsideration. However, the written document most often does not convey the multiple interactions between OIRA and the agency. The final letter sometimes appears sanitized so as not to reveal the true reasons for the rejection.

D.1.c. Agencies should disclose online all substantive communications, written or oral, between any White House office and any nongovernmental entity regarding rules under development or under review. Currently, OIRA shares with regulatory agencies written communications it receives from nongovernmental entities regarding a regulation under review. It also invites agencies to any meetings that OIRA has with nongovernmental entities regarding a regulation under review. Finally, any meetings with nongovernmental entities are logged on OMB's website, which provides the general topic, the date of the meeting, and a list of participants.

There are two problems with this system. First, it only applies to a regulation under review. Any substantive communication with nongovernmental entities regarding the development of a rule, such as those made during the pre-rulemaking stage, is not required to be provided to the agencies. Second, the content of oral communications, such as meetings, are not recorded or summarized.

Since OIRA can have significant influence in the outcome of a rulemaking, its actions should be documented in the rulemaking record, just as the regulatory agencies' actions are documented. The public should have a right to know about OIRA's communications with these entities.

To improve transparency between White House offices and nongovernmental entities, the president should require any White House office to document any substantive communications, written or oral, with nongovernmental entities regarding a regulation being considered. For oral communications, the date of the communication, who participated, and a summary of the communication should be written and made part of agencies' online rulemaking dockets.

Promptly after the meeting, if the agency was not already involved, the White House office should notify the agency of the meeting and provide the agency with any documents or meeting summaries. The agency should then post this information in its online rulemaking docket.

In June 2007, the Environmental Protection Agency proposed changes to the national public health standard for exposure to ozone. EPA proposed a range from which it would choose its final standard. The proposed range was weaker than the recommendation of EPA's scientific advisors and staff. The public never learned why EPA ignored the advice of its experts or who made the decision to do so. However, many fear the White House, acting on behalf of industry, played a role. OIRA held three closed-door meetings prior to publication of the proposal – two with industry and one with public health experts. Neither OIRA nor EPA disclosed what was discussed during the meetings. Before publication of the final rule, which adopted the weakest end of the proposed range, OIRA held two more closed-door meetings with industry lobbyists. The nature of these meetings was not disclosed.

D.1.d. Agencies should disclose online all substantive communications between the agency and nongovernmental entities regarding regulations. The primary mechanism for nongovernmental entities to communicate with federal agencies about a rule is through the comment period following publication of an NPRM. These communications are currently disclosed in the rulemaking docket. However, nongovernmental entities also communicate with agencies outside of the public comment period. Currently, rules do not exist to govern disclosure of these communications.

Interest groups, especially those in Washington, with the resources and contacts to access agency decision makers are much more likely to engage in communications outside of the public comment period and off the public record, thus creating an imbalance. Small interest groups, groups outside of Washington, and individual citizens generally use the public comment period to comment on a rule, and the agency includes their comments in the public record.

Agencies should begin disclosing both written and oral communications made with any nongovernmental entity related to a rulemaking once the docket has been created. For oral communications, the date of the communication, who participated, and a summary of the communication should be written and made part of agencies' online rulemaking dockets. Written communications

and the logs of meetings between nongovernmental entities and the agency should also be made part of the online rulemaking docket.

D.2. Create a system that allows the public to track the status of a rule and its associated paperwork requirements. The rulemaking process as currently devised provides few mechanisms for the public to learn about a rule's status. Twice a year, federal agencies are required to announce the rules they have in the pipeline, their stage of development (i.e., early stages of development, proposed rule, or final rule), and an approximate timeline. The information is published in the *Unified Agenda* and is notoriously inaccurate.

Rules are given a Regulatory Identification Number early in the regulatory formulation process, but that identification does not necessarily always follow the regulation through its lifecycle. If the regulation is substantially revised, it may be given a new number, but there is no systematic way to trace its origins and connections to previous proposals. Moreover, there is no way to track paperwork that is associated with a particular rule.

OMB, in concert with the agency overseeing the e-rulemaking initiative (see Recommendation E.1), should develop a regulatory tracking system. Creating a tracking system may require federal agencies to establish online, searchable holdings of regulatory actions under development. The system should be updated regularly, giving the public a better indication as to the rule's progress and when significant rulemaking decisions have been made. It may take years to perfect the system, but the work should begin as part of the broader e-rulemaking project.

The creation of such a system would benefit both the public and the agency. The public would be better informed, earlier in the process (that is, before publication of the NPRM). If the public is better informed, an agency can better gauge public reaction and incorporate the public's views into a proposal during its formation, rather than after it has been fully developed and internally vetted. (The democratic benefits of public participation earlier in the process will be discussed in the next section.)

A tracking system would be a helpful tool for small business. For example, businesses could look up a final rule and find out what paperwork is associated with the rule. That way, a company could know more easily what is expected of it.

D.3. To the extent permitted by law, agencies should make government information publicly available. Improvements to the FOIA process could aid in rulemaking transparency. Although FOIA's reach extends beyond rulemaking and into other areas of government information, improved access to a broad class of records can contribute to a better public understanding of how government works, including rulemaking.

Section (a)(2) of FOIA embodies the disclosure principles federal agencies should embrace. Under Section (a)(2), agencies are required to make publicly

available certain categories of government documents, the contents of FOIA requests the agency has fulfilled if they "have become or are likely to become the subject of subsequent requests," and an index of those documents.

Currently, federal agencies are not fully embracing the spirit of Section (a)(2), in particular the clause in Section (a)(2) that requires them to make publicly available information they believe the public will request repeatedly, nor do most agencies keep an index of those documents. As with rulemaking information, it is important for government openness and accountability that agencies make such information available online.

Making greater use of Section (a)(2) of FOIA to make government information available online would greatly enhance transparency and public participation. Embracing Section (a)(2) would also benefit the agency because officials would not have to spend as much time processing duplicative, repeat FOIA requests. (See Recommendation D.1.)

By enacting the following recommendations, agencies can make strides in embracing FOIA's idea that government information be made available to the public in a timely way.

D.3.a. **The president should instruct the attorney general to issue a memo calling on agencies to make government information publicly available under FOIA whenever possible.** (See Recommendation 7 in "The First 100 Days: Recommendations for President-Elect Obama" section.) On October 12, 2001, then-Attorney General John Ashcroft issued a memorandum urging federal agencies to exercise greater caution in disclosing information requested under FOIA. The Ashcroft memo has prompted agencies to unnecessarily withhold government information from the public and, by encouraging agencies to battle the public over FOIA requests, worsened the FOIA backlog.

Ashcroft's memo superseded a 1993 memorandum from then-Attorney General Janet Reno that promoted disclosure of government information under FOIA unless it was "reasonably foreseeable that disclosure would be harmful." The Reno memo created an agency climate in which officials were more likely to share information with the public upon request.

Because this report relates to the rulemaking process, we have focused on the benefits of disclosing information related to rulemaking issues, not foreign policy or national security matters. However, to the best of our knowledge, the push for greater disclosure under the Reno memo never led to the release of government information that risked our national security or public well-being.

The president should direct the new attorney general to instruct agencies that the Justice Department will embrace the policy direction of the Reno memo to provide a defensible argument for aggressively disclosing information when possible. The president should act as soon as possible to send a message that the new administration stands for greater transparency.

D.3.b. Agencies should work to reduce the FOIA backlog. The FOIA backlog – the number of FOIA requests in the federal government's queue waiting to be addressed – continues to be a problem. In 2007, the FOIA backlog improved, but it still stands at 33 percent of the total number of requests processed.[2] From 2006 to 2007, eleven agencies did not make progress in reducing their FOIA backlog or presided over a worsening FOIA backlog.[3] Severe FOIA backlogs are an impediment to transparency and public access.

Agencies should actively work to reduce FOIA backlogs. A new administration-wide directive on FOIA (see Recommendation D.3.a above) will help, as will making more information publicly available in rulemaking dockets, but agencies should take other steps as well. Agencies should devote more time and resources to fulfilling FOIA requests.

D.3.c. The president should request, Congress should appropriate, and agencies should use more funds to fulfill FOIA requests. As a general trend, the number of FOIA requests the government receives increases each year. The cost to the federal government of handling FOIA requests was more than $350 million for 2007.[4]

Because the FOIA backlog is so significant, and because FOIA requests are likely to increase each year, agencies will eventually require more funds if they are to make progress in reducing the FOIA backlog and to promptly handle new FOIA requests.

D.3.d. Agencies should develop plans for digitizing non-digital information. As mentioned above, the rise of the Internet has redefined the expectations for government transparency. For government information to be truly transparent, it should be available online.

Untold numbers of government documents predate the Internet age, and some new documents are in a non-digital format. Scanning these documents and uploading them to agency websites will be costly and time consuming.

Agencies should develop long-term plans for digitizing non-digital information. Agencies should plan to transition existing non-digital documents into digital, full-text searchable formats. Agencies should also plan to minimize the amount of new information that is created in non-digital and/or non-full-text searchable formats.

D.3.e. Agencies should not use the Confidential Business Information (CBI) claims under FOIA during public health emergencies. One of the nine FOIA exemptions allows agencies to deny FOIA requests if the information in question is "privileged or confidential" business information.[5] Agencies can and do claim the CBI exemption during public health emergencies. For example, during meat recalls, the federal meat inspection agency has refused to disclose the names of retail outlets where contaminated beef has been shipped if the list of retailers is considered confidential. The agency may be legally protected

in doing so, but not releasing the information unnecessarily puts the public at risk. During public health crises such as these, agencies should be disclosing CBI to the extent necessary to address the emergency. Where agency statutes do not provide authority to disclose CBI during public health emergencies, the Congress should provide necessary authority to do so.

D.3.f. Agencies should disclose online the calendars of senior agency officials. The calendars of government officials often provide valuable evidence of how officials and/or their staffs spend their time. Officials' calendars are often the subject of FOIA requests. In the spirit of FOIA Section (a)(2), agencies should disclose online the calendars of political appointees and senior career officials.

D.3.g. The president should ensure the FOIA ombudsman is housed at the National Archives and Records Administration, not the Department of Justice. The OPEN Government Act of 2007 created a new Office of Government Information Services at the National Archives and Records Administration (NARA) to serve as a FOIA ombudsman. It is to oversee the federal FOIA process and settle disputes within agencies. Although the Department of Justice holds the primary responsibility for enforcing FOIA, Congress saw fit to house the ombudsman at NARA in order to insulate it from political influence. In his FY 2008 budget request, President Bush attempted to move the ombudsman's office to the Justice Department.

The president should ensure that NARA has adequate resources to implement the new Office of Government Information Services.

ENDNOTES

1. See, for example, the American Bar Association's 2008 study on the status and future of e-rulemaking, entitled Achieving the Potential: The Future of Federal E-rulemaking, for a thorough evaluation of electronic rulemaking and recommendations for the future.
2. OpenTheGovernment.org, "Secrecy Report Card 2008: Indicators of Secrecy in the Federal Government," p. 11, available at http://www.openthegovernment.org/otg/SecrecyReportCard08.pdf, last accessed October 6, 2008.
3. Ibid.
4. Ibid., p. 10.
5. Use of Exemption 4, which covers CBI issues, has increased dramatically since 2003 in the aftermath of instructions from then-Attorney General John Ashcroft and White House Chief of Staff Andrew Card instructing agencies to make greater use of FOIA Exemptions 2 (internal agency rules), 4 (proprietary information and trade secrets), and 5 (inter-agency memoranda) in handling "sensitive" information. Use of Exemption 4 increased 46% in the five years since the instructions (2003 to 2007) compared to the five year prior to the instructions (1998 to 2002). In 2007, there were 10,136 uses of Exemption 4 by federal agencies. Source: OMB Watch analysis of data in Coalition of Journalists for Open Government, "An Opportunity Lost: An In-depth Analysis of FOIA Performance from 1998 to 2007," July 3, 2008,available at http://cjog.net/documents/Part_1_2007_FOIA_Report.pdf, last accessed November 3, 2008.

PART E.

PUBLIC PARTICIPATION

THE PROBLEM

The primary vehicle for public participation is the comment period directly following publication of a notice of proposed rulemaking (NPRM). What the public does not fully appreciate, however, is that notice of a proposed rulemaking comes quite late in the rule development process. Agencies often decide the general framework for regulatory actions during the pre-rule stage (before the publication of the NPRM). Therefore, participation during the standard comment period provides post hoc reactions to largely predetermined policy choices, and those earlier policy choices have not been made in an open, inclusive, or transparent process.

The participation that occurs either in the pre-rule stage or during the comment period is one in which interested parties give feedback to government officials but where there is no clear process for regular interaction between agency officials and the public. As a result, the participation that actually impacts agency decision making is limited to those with the knowledge, resources, and access that enables them to contact decision makers informally at key points in the process.

Public participation in the rulemaking process is important for both the public and for federal agencies developing rules. The public has a right to participate in the rulemaking process, and doing so enhances both civic engagement and understanding. The rulemaking process does not, and should not, operate as plebiscite or referendum. However, the ability of citizens to have a voice in the policymaking process is a central tenet of our representative democracy, even if that voice is not determinative. Agencies benefit, too. Meaningful public participation can provide decision makers with valuable insight into how a policy proposal will actually be implemented, what its real world impacts may be, or simply how it will be received in the court of public opinion.

The "public" can include experts and people who are not directly interested in the rule and might not otherwise participate, but who bring vast knowledge and experience, directly or indirectly, with the issues raised by the rulemaking. In the past, it was difficult or impossible to include these people because they were geographically dispersed. In addition, there are laws that allow certain stakeholders (for example, state and local governments, small business representatives) affected by rules to have access to the rulemaking process prior to the time when the experts and other knowledgeable segments of the public have access. Online commenting opens new possibilities for reaching out to these people, bringing them into the regulatory process, thus leveling the playing field and drawing on their knowledge and insight to craft a better rule. If federal officials incorporate such insights into their thinking as they craft the proposed and final rules, the result will be rules of greatly improved quality that better serve the public.

Another problem with the process as currently structured is that the comment period does not easily allow for a dialogue among commenters. Commenters often file on the last day of a period partly because they have used the entire comment period to prepare and polish their submissions, and partly so as not to reveal their arguments to those holding opposing views. Interested stakeholders can and do use their comments to refute what they *anticipate* will be the arguments of their opponents, but this approach is not as helpful as replies to actual comments through dialogue or debate. The absence of a debate underscores the need for a comment process that can generate an actual dialogue about a proposed rule.

Ultimately, the objective should be to bring to the process a broad range of relevant expertise, interests, and perspectives, and then improve the quality of the dialogue between the public and the agency so that regulatory outcomes are of the highest quality possible and are perceived as fair, open, and legitimate. Given the technical nature of rulemakings, numerous challenges present themselves. First, even experts may have limited understanding of the rulemaking process and may not be aware that a rule of potential interest is being developed. Second, the public may not understand complex rules, but may still be able to provide helpful input on the substantive issues in proposed regulations. Third, when the public has value to add, it may not possess the means or time to do so. Fourth, there is a tendency for the regulatory process to become captive to narrow audiences that may not adequately reflect the broader public perspective.

These problems have always been with us and will afflict any regulatory process. The rise of electronic communication offers new possibilities for reforming the rulemaking process to include a wider range of experts and stakeholders in a process that, for the first time, is truly open, interactive, and well informed. It is too soon to prescribe specific methods and procedures for how electronic rulemaking should work, but agencies have begun to experiment with new procedures. The president should strongly encourage agencies in such experiments – both by directive and by funding such pilots in agency budgets.

SUMMARY OF RECOMMENDATIONS

Public participation in the rulemaking process should involve more constructive communication between federal officials, the public at large, and outside stakeholders. Federal agencies should experiment with new techniques that allow for an exchange of ideas between interested parties and the government and among interested parties with diverse views. New techniques should create opportunities for participation in the pre-rule stage while policies are still under development.

DETAILED RECOMMENDATIONS

E.1. **The federal e-rulemaking initiative needs to be reformed and accelerated to strengthen public engagement in the rulemaking process.** Regulations.gov is a government-run website, the primary purpose of which is to provide the public and other agencies with a central location to find, view, and comment on proposed rules. Regulations.gov displays the text of proposed policies and the text of comments. It can also allow users to search for and read supporting material that serves as the basis for rulemakings.

Regulations.gov has made pioneering strides in making the rulemaking process more accessible in the Internet age, but it has not lived up to expectations nor to its full potential. The site is difficult to use, and finding regulatory proposals or other information can be tedious. For example, the site does not allow users to easily search for dockets – the collection of documents related to a specific rulemaking.

Changes to Regulations.gov should allow the website to better serve the public's need for access to rulemaking dockets. (See Recommendation D.1.) A top priority should be to improve the website to make it easier for the public to find regulations of interest and to comment on them.

To engage the public earlier in the process, agencies should open dockets as soon as they make the decision to undertake a rulemaking and regularly post information on developments occurring before publication of the NRPM. For example, contact information for agency officials, updates on regulatory planning included in the semiannual *Unified Agenda*, and the posting of key studies could all be included in the online docket before the NPRM is finished and posted.

Regulations.gov should also be a mechanism for allowing both user and agency experimentation in order to improve the regulatory process. It could provide the platform for assessing and supporting greater information technology capabilities and resources within agencies and among stakeholders. It could allow, for example, the public and regulated communities to have the option of using either the central website or agency sites to get needed information. Having multiple pathways to regulatory information in today's world of distributive databases would mean that the same core data are available to the

public no matter which approach is used to find information. Visiting agency websites, however, the user might find other value-added information; if visiting Regulations.gov, the user might find more comparative information across government.

The Office of Management and Budget (OMB) should make improvements to e-rulemaking a high priority, working closely with the appropriate agencies, to formulate and implement a plan of action. Here are two ways OMB can be helpful. First, it should request resources from Congress to adequately fund the e-rulemaking initiative. Currently, federal agencies are required to divert resources from other programs to fund the initiative. This requirement may be a disincentive to encourage participation. Second, OMB should seek resources to strengthen agency information technology capacity so that they further expand the objectives of the e-rulemaking initiative.[1]

E.2. Agencies should be encouraged to experiment with interactive technology to solicit stakeholder input. Agencies should be encouraged to try new ways of stimulating public participation, such as using pilot programs to experiment with interactive technology. For example, agencies could experiment with making field hearings open to broader audiences than ever before by using online and teleconference tools. Just the same, technological innovations cannot completely preclude real-world practical concerns: a recent Mine Safety and Health Administration hearing on drug and alcohol testing for miners was set up as a teleconference, but MSHA did not provide for large-enough spaces for the public to attend and participate in the teleconference. These experiments should be evaluated and the tension between expediting the rulemaking process and improving participation should be balanced before full-scale approaches are adopted.

E.3. Agencies should experiment with new ways to encourage participation by the public and stakeholders even prior to proposed rulemaking in order to level the playing field. Either by statutory requirement or executive prerogative, agencies seek input even before the rule enters the formal notice-and-comment stage. Unfortunately, this involvement in the pre-rulemaking stage is selective to certain stakeholders, building unfairness into the rulemaking process.

The Small Business Regulatory Enforcement Flexibility Act requires the Environmental Protection Agency and the Occupational Safety and Health Administration to consult with a panel of small business men and women before proposing or finalizing rules that might impact the small business community. However, this consultation occurs before the public is privy to information about the rule and can affect rules in ways that tilt the outcome toward regulated interests. In 2006, OSHA finalized a health standard for workers exposed to hexavalent chromium, a dangerous carcinogen. The standard announced in the final rule was significantly weaker than what OSHA had proposed two years earlier. In the final rule, OSHA indicated it changed the standard partly as a result of the SBREFA panel's input.

We need to find new ways to engage the public. To facilitate improved participation in the pre-rule stage, agencies should notify the public of its plans to undertake a rulemaking and then provide regular updates. For example, improved tracking capabilities would allow the public to follow the rule as it develops and comment at any critical juncture that may set the course of the new policy. Allowing the public to voice concerns in a timely way permits the agency to respond to concerns in conjunction with making a decision instead of long after. See Recommendation D.2. for how to improve rule tracking.

Examples of other mechanisms with which agencies might experiment to solicit diverse views about a rulemaking could include:

- Creating an interactive website similar to the European Union's Your Voice in Europe site (see http://ec.europa.eu/yourvoice/index_en.htm);
- Employing public health/environmental analysts to help explain technical issues to the public;
- Creating an ombudsman/public interest advocate similar to one that exists for small business;
- Funding outside groups on a rule-by-rule basis similar to the community advocate funding provided under Superfund legislation; and/or
- Hosting online meetings/communications using interactive technologies.

E.4. Agencies should make better use of advisory committees to serve as vehicles for hearing the views of stakeholder groups and the public at large, especially in the pre-rule stage. Federal agencies should use federal advisory committees (FACs) more frequently to elicit public, scientific, and stakeholder views, including during the pre-rule stage. Agencies may form standing FACs to address scientific issues that are likely to remain of national concern, such as climate change or import safety. Agencies may also wish to form ad hoc FACs when they decide to undertake a specific rulemaking. These FACs can run a parallel course to the agency's efforts to develop rules; panel members could weigh in on questions, determinations, or evidence in the pre-rule stage as they arise. In any case, the committees should be used to solicit information important to forming effective options and alternatives before policy decisions are made.

The Federal Advisory Committee Act (FACA) requires, with limited exception, that advisory meetings be open to the public. The act also requires FACs to be "fairly balanced in terms of the points of view represented." Taking those two points into consideration, FACs can be a vehicle to hear the views of stakeholder groups and the public at large on pressing issues – especially in the pre-rule stage before an agency narrows policy into one or more regulatory options.

To realize the promise of advisory committees as participation vehicles, provisions requiring both openness and balance must be met. Currently, FACA meetings are not as open as Congress likely envisioned. In 2007, only 30 percent of FACA meetings were fully open to the public.[2] Agencies must open more meetings to the public and provide time for comments or questions, especially for meetings related to a rulemaking. Agencies must also make concerted efforts to inform the public of upcoming meetings. Specific recommendations about strengthening the workings of federal advisory committees are in Recommendation B.3 and B.4.

ENDNOTES

1. American Bar Association, Achieving the Potential: The Future of Federal E-rulemaking.
2. According to the General Service Administration's FACA database, 6,940 meetings were held in FY2007. Of those, 2,109 were open, 4,541 were closed, and 290 were partially closed. Available at http://www.fido.gov/facadatabase/public.asp, last accessed October 6, 2008.

APPENDICES

APPENDIX 1.

LISTS OF RECOMMENDATIONS

ORGANIZED BY TOPIC

Below is the list of recommendations as they appear in the report, without explanatory text.

The First 100 Days: Recommendations for President-Elect Obama

1. Place a moratorium on finalizing any new regulations, and review those rules finalized but not yet in effect.
2. To set a new tone for the new administration, the president should pursue the timely appointment of qualified individuals to regulatory agencies critical to protecting the public.
3. Increase agency funding for regulatory implementation and enforcement.
4. The president should form a blue ribbon commission to analyze the regulatory process with the goals of examining existing requirements and reducing unnecessary delay.
5. The president should appoint a qualified administrator for the Office of Information and Regulatory Affairs within the Office of Management and Budget who can lead the office in fulfillment of its statutory obligations and transform the role of OIRA.
6. The president should rescind E.O. 13422 immediately.
7. The president should improve executive branch transparency by replacing the Ashcroft memorandum with another memorandum directing agencies to make more information publicly available.

The First 100 Days: Recommendations for the 111th Congress

1. Use the Congressional Review Act (CRA) to stop ill-advised "midnight regulations" from the previous administration.

2. As the new Congress organizes itself, it should clarify committee jurisdiction and reassert its responsibilities for review and oversight of cross-cutting regulatory issues.

3. Increase agency funding for regulatory implementation and enforcement.

4. Strengthen federal protections for whistleblowers by passing pending legislation in both chambers.

A. Improving the Quality of Regulations

A.1. Regulatory solutions and the analysis of regulatory alternatives should be consistent with statutory provisions.

A.2. To the extent that cost-benefit analyses are done, they should be guided by a set of core principles.

A.3. Scientific uncertainty per se does not provide sufficient justification to avoid promulgating regulations.

A.4. Agencies should be encouraged to clearly state problems, identify data gaps, restore needed collection and monitoring programs, and address new information needs as they are confronted with new regulatory problems.

A.5. The Paperwork Reduction Act needs to be amended and reauthorized.

A.6. Agencies should develop their own standards for the use of risk assessment according to best practices applicable to the issues with which they are confronted.

A.7. Implied preemption in rulemakings must be curtailed.

B. Integrity and Accountability

B.1. The president should instruct his agency heads that scientific integrity must be a core component of regulatory actions.

B.2. Federal protections for public and private sector whistleblowers need to be strengthened to serve as a check on misconduct.

B.3. Strengthen the Federal Advisory Committee Act (FACA).

B.4. Improve conflicts of interest laws.

B.5. Disclose the scientific, technical, economic and social analyses used in the formation and promulgation of regulatory documents.

B.6. Resurrect the Office of Technology Assessment (OTA).

B.7. For key areas of international health and safety regulation affecting Americans and U.S. businesses, Congress and the president should call for greater transparency in order to make the process more democratic.

B.8. The president should encourage agency heads to adopt (or modify) guidelines to allow scientists to communicate directly with interested parties.

B.9. Agencies should abstain from inappropriate interference in the work of other agencies and end secretive interagency reviews of scientific and technical information.

C. Implementation and Enforcement of Regulations

C.1. Funding for enforcement of regulations must be increased.

C.2. Develop a comprehensive regulatory compliance initiative.

C.3. Modernize enforcement requirements across government to assure credible deterrence.

C.4. Fund an historical assessment of regulatory agency budgets and resource needs.

D. Transparency in the Rulemaking Process

D.1. Agency rulemaking dockets should be expanded, complete, and available online.

D.1.a. Agencies should disclose online all studies in their possession related to a rulemaking, regardless of whether the study was used to inform the policy option the agency chose.

D.1.b. Agencies should disclose online all written communications among federal officials from different agencies, including the White House, regarding rules under development or under review.

D.1.c. Agencies should disclose online all communications, written or oral, between any White House office and any nongovernmental entity regarding rules under development or under review.

D.1.d. Agencies should disclose online all substantive communications between the agency and nongovernmental entities regarding regulations.

D.2. Create a system that allows the public to track the status of a rule and its associated paperwork requirements.

D.3. To the extent permitted by law, agencies should make government information publicly available.

D.3.a. The president should instruct the attorney general to issue a memo calling on agencies to make government information publicly available under FOIA whenever possible.

D.3.b. Agencies should work to reduce the FOIA backlog.

D.3.c. The president should request, Congress should appropriate, and agencies should use more funds to fulfill FOIA requests.

D.3.d. Agencies should develop plans for digitizing non-digital information.

D.3.e. Agencies should not use the Confidential Business Information (CBI) claim under FOIA during public health emergencies.

D.3.f. Agencies should disclose online the calendars of senior agency officials.

D.3.g. The president should ensure the FOIA ombudsman is housed at the National Archives and Records Administration, not the Department of Justice.

E. Public Participation in the Rulemaking Process

E.1. The federal e-rulemaking initiative needs to be reformed and accelerated to strengthen public engagement in the rulemaking process.

E.2. Agencies should be encouraged to experiment with interactive technology during comment periods.

E.3. Agencies should experiment with new ways to encourage participation by the public and stakeholders even prior to proposed rulemaking in order to level the playing field.

E.4. Agencies should make better use of advisory committees to serve as vehicles for hearing the views of stakeholder groups and the public at-large, especially in the pre-rule stage.

ORGANIZED BY DECISION MAKER

In each recommendation in the report, the Steering Committee has identified one or more decision making bodies responsible for carrying out the recommendation. This list categorizes recommendations by decision making body – either Executive Branch (the President, the Executive Office of the President, or federal agencies) or Congress. Where a recommendation is the responsibility of both branches, it is included in both categories and marked with an asterisk (*).

Executive Branch

Next Administration 1. Place a moratorium on finalizing any new regulations, and review those rules finalized but not yet in effect.

Next Administration 2. To set a new tone for the new administration, the president should pursue the timely appointment of qualified individuals to regulatory agencies critical to protecting the public.

Next Administration 3. Increase agency funding for regulatory implementation and enforcement.

Next Administration 4. The president should form a blue ribbon commission to analyze the regulatory process with the goals of examining existing requirements and reducing unnecessary delay.

Next Administration 5. The president should appoint a qualified administrator for the Office of Information and Regulatory Affairs within the Office of Management and Budget who can lead the office in fulfillment of its statutory obligations and transform the role of OIRA.

Next Administration 6. The president should rescind E.O. 13422 immediately.

Next Administration 7. The president should improve executive branch transparency by replacing the Ashcroft memorandum with another memorandum directing agencies to make more information publicly available.

A.1. Regulatory solutions and the analysis of regulatory alternatives should be consistent with statutory provisions.

A.2. To the extent that cost-benefit analyses are done, they should be guided by a set of core principles.

A.3. Scientific uncertainty per se does not provide sufficient justification to avoid promulgating regulations.

A.4. Agencies should be encouraged to clearly state problems, identify data gaps, restore needed collection and monitoring programs, and address new information needs as they are confronted with new regulatory problems.

A.6. Agencies should develop their own standards for the use of risk assessment according to best practices applicable to the issues with which they are confronted.

A.7. Implied preemption in rulemakings must be curtailed.

B.1. The president should instruct his agency heads that scientific integrity must be a core component of regulatory actions.

B.2. Federal protections for public and private sector whistleblowers need to be strengthened to serve as a check on misconduct.*

B.3. Strengthen the Federal Advisory Committee Act (FACA).*

B.4. Improve conflicts of interest laws.*

B.5. Disclose the scientific, technical, economic and social analyses used in the formation and promulgation of regulatory documents.*

B.7. For key areas of international health and safety regulation affecting Americans and U.S. businesses, Congress and the president should call for greater transparency in order to make the process more democratic.*

B.8. The president should encourage agency heads to adopt (or modify) guidelines to allow scientists to communicate directly with interested parties.

B.9. Agencies should abstain from inappropriate interference in the work of other agencies and end secretive interagency reviews of scientific and technical information.

C.1. Funding for enforcement of regulations must be increased.*

C.2. Develop a comprehensive regulatory compliance initiative.

C.3. Modernize enforcement requirements across government to assure credible deterrence.

D.1. Agency rulemaking dockets should be expanded, complete, and available online.

D.1.a. Agencies should disclose online all studies in their possession related to a rulemaking, regardless of whether the study was used to inform the policy option the agency chose.

D.1.b. Agencies should disclose online all written communications among federal officials from different agencies, including the White House, regarding rules under development or under review.

D.1.c. Agencies should disclose online all communications, written or oral, between any White House office and any nongovernmental entity regarding rules under development or under review.

D.1.d. Agencies should disclose online all substantive communications between the agency and nongovernmental entities regarding regulations.

D.2. Create a system that allows the public to track the status of a rule and its associated paperwork requirements.

D.3. To the extent permitted by law, agencies should make government information publicly available.

D.3.a. The president should instruct the attorney general to issue a memo calling on agencies to make government information publicly available under FOIA whenever possible.

D.3.b. Agencies should work to reduce the FOIA backlog.

D.3.c. The president should request, Congress should appropriate, and agencies should use more funds to fulfill FOIA requests.*

D.3.d. Agencies should develop plans for digitizing non-digital information.

D.3.e. Agencies should not use the Confidential Business Information (CBI) claim under FOIA during public health emergencies.

D.3.f. Agencies should disclose online the calendars of senior agency officials.

D.3.g. The president should ensure the FOIA ombudsman is housed at the National Archives and Records Administration, not the Department of Justice.

E.1. The federal e-rulemaking initiative needs to be reformed and accelerated to strengthen public engagement in the rulemaking process.

E.2. Agencies should be encouraged to experiment with interactive technology during comment periods.

E.3. Agencies should experiment with new ways to encourage participation by the public and stakeholders even prior to proposed rulemaking in order to level the playing field.

E.4. Agencies should make better use of advisory committees to serve as vehicles for hearing the views of stakeholder groups and the public at-large, especially in the pre-rule stage.

Congress

Next Congress 1. Use the Congressional Review Act (CRA) to stop ill-advised "midnight regulations" from the previous administration.

Next Congress 2. As the new Congress organizes itself, it should clarify committee jurisdiction and reassert its responsibilities for review and oversight of cross-cutting regulatory issues.

Next Congress 3. Increase agency funding for regulatory implementation and enforcement.

Next Congress 4. Strengthen federal protections for whistleblowers by passing pending legislation in both chambers.

A.5. The Paperwork Reduction Act needs to be amended and reauthorized.

B.2. Federal protections for public and private sector whistleblowers need to be strengthened to serve as a check on misconduct.*

B.3. Strengthen the Federal Advisory Committee Act (FACA).*

B.4. Improve conflicts of interest laws.*

B.5. Disclose the scientific, technical, economic and social analyses used in the formation and promulgation of regulatory documents.*

B.6. Resurrect the Office of Technology Assessment (OTA).

B.7. For key areas of international health and safety regulation affecting Americans and U.S. businesses, Congress and the president should call for greater transparency in order to make the process more democratic.*

C.1. Funding for enforcement of regulations must be increased.*

C.4. Fund an historical assessment of regulatory agency budgets and resource needs.

D.3.c. The president should request, Congress should appropriate, and agencies should use more funds to fulfill FOIA requests.*

APPENDIX 2.

PROJECT DESCRIPTION

OMB Watch initiated this regulatory reform project, *Advancing the Public Interest Through Regulatory Reform,* in Spring 2007 to develop recommendations to improve the US regulatory system. Comprehensive reform of the entire regulatory system in all its complex details is well beyond the scope of this project; to achieve a fully restructured regulatory system will require the public, private enterprise, the president, Congress, and federal agencies to be thoughtfully engaged. We hope our efforts to address the most pressing issues and identify principles of reform can be a catalyst for that broader reform effort.

Nineteen people agreed to serve on the Steering Committee to oversee the project.[1] The criteria for service on the Steering Committee were 1) a knowledge of the regulatory system, 2) belief that the system is in need of substantial reform, and 3) a belief that the federal government has an important regulatory role to play in providing essential public protections. Membership in the Steering Committee changed only slightly over the course of the project.

The initial goals of the project were to produce:

- A report with specific recommendations the next president can implement to improve the regulatory process, as well as longer-range ideas for changing the regulatory process;
- Public opinion research to frame regulatory discussions; and
- A web-based regulatory resource center.

Recommendations to the next president and other recommendations for changing the regulatory process are included in this report. The public opinion research was used to inform much of the report. For example, it lends credence to the call for reforming the regulatory process generally and

for the transparency reforms in particular. The Regulatory Resource Center is part of OMB Watch's website (available at http://www.ombwatch.org/regresources). Each of these project segments are described below.

In leading the project, the Steering Committee 1) identified topics that should be covered by this project, 2) provided the structure and topics for the work of four task forces to help develop recommendations, 3) assisted with approaches to frame regulatory matters, including advice and background materials for the public opinion research, 4) provided advice during the development of the regulatory resource center, 5) developed recommendations that the next president can immediately implement to strengthen the regulatory process, 6) developed a longer-range framework for a more efficient and responsive regulatory structure in government, and 7) developed the strategy and products to disseminate the results of the project.

The Steering Committee met four times between July 2007 and September 2008 either in person or by teleconference. In addition, there were two ad hoc subcommittees formed, one to assist with framing the public opinion research issues and one to assist in the development of the outline of the final report and the products to help disseminate the recommendations. OMB Watch provided staff support to the project. The following sections describe the processes the Steering Committee used to achieve each of the project goals.

DEVELOPING REGULATORY RECOMMENDATIONS

The project was initiated and potential Steering Committee members contacted in early 2007. OMB Watch initiated the project well in advance of the change in presidential administration in order to more comprehensively address the problems in the regulatory process. Steering Committee members brought unique knowledge of and experience with the regulatory system. The members brought the perspectives of business, scientific, public health, and government accountability public interest organizations, unions, academia, and law practitioners. (See Appendix 3 for a list of members and their affiliations.)

At the first committee meeting in July 2007, members established the guidelines for the project, such as the project's objectives and Steering Committee and staff responsibilities. More importantly, the Committee: 1) set out the principles government should try to advance through its regulatory process; and 2) reached agreement on the subjects of four task forces that would be vehicles for helping the Committee develop its list of recommendations.

The Steering Committee created the task forces organized around four topics deemed critical to addressing the range of regulatory issues the Committee identified. The task force topics were: 1) transparency and public participation; 2) scientific integrity; 3) regulatory tools; and 4) government

management. In subsequent communications, the Steering Committee established the basic mandates for each task force, insisting each operate independently from the Committee and from each other.

Each task force consisted of a chair and a variety of members selected by the chair in coordination with the project staff. The task forces were formed and began their work early in 2008. Each addressed its individual mandate from the Committee in different ways as described below. (See Appendix 4 for lists of task force members.)

The task force members did not participate in any way in developing this overall project report. Involvement by task force members implies no endorsement of the Steering Committee's analysis or recommendations.

Transparency and Public Participation Task Force

This task force addressed several questions focused on improving both transparency and public participation in the rulemaking process specifically. The task force also addressed ways to strengthen both technical aspects as well as government-wide issues of transparency and participation. For example, it addressed steps that can be taken to improve the way the public can track individual agency regulations and their associated records, and better participate in the notice-and-comment period when regulations are being developed; it also addressed steps to strengthen transparency of the rulemaking process across government agencies.

Professor Cary Coglianese of the University of Pennsylvania chaired the task force. The task force consisted of fifteen members from academia, public interest groups, consultants, lawyers, and academic librarians. The members were brought together to discuss problems and issues and reviewed materials prepared by the chair and two University of Pennsylvania law students acting as reporters. Individual members were asked to contribute language regarding specific issues the task force addressed, and the preparation of the task force report was completed by Professor Coglianese and the reporters and reviewed by task force members. The task force did not set a goal of consensus on recommendations; thus, the recommendations presented in the final task force report represent a synthesis of the discussions. The report of the Transparency and Public Participation Task Force is available online at www.ombwatch.org/regs/PDFs/TPPreport.pdf.

Scientific Integrity Task force

The Steering Committee asked this task force to address issues around ways to safeguard scientific information in the rulemaking process: the independence of the information and the mechanisms used to generate it, and the independence of scientists and the climate within the agencies in which they work. For example, the task force addressed the appropriate role for federal advisory committees within agencies and how agencies might better deal with the selection of committee membership and with conflict of interest issues.

Dr. Francesca Grifo of the Union of Concerned Scientists chaired the task force. In an approach similar to the transparency task force, Dr. Grifo and her staff drafted materials and circulated them to the members of the task force and to colleagues in the scientific community familiar with the way agencies conduct their regulatory work. The reviewers made suggestions and comments about realistic improvements to the draft materials. The report was again circulated to members of the task force for subsequent review. The report of the Scientific Integrity Task Force is available online at www.ombwatch.org/regs/PDFs/SIreport.pdf.

Government Management Task Force

This task force had the broadest mandate from the Steering Committee. The task force addressed the philosophical and legal frameworks for a new vision of the regulatory process. In addition to these important elements, the Steering Committee asked the task force to address ways to make agencies more responsive and effective in everything from their planning, review, and enforcement responsibilities to their responsiveness in emergency situations. Finally, the task force recommended steps the next president should take immediately upon entering office to change the regulatory system.

Professor Steven Croley of the University of Michigan was the task force chair. The task force consisted of nine total members representing government officials, academia, and the public interest community. Due to the breadth of the mandate to this task force, Professor Croley asked the members to volunteer to write papers on each of the questions asked of the task force. Singularly and in pairs, members drafted papers for review by the chair and subsequently by the entire task force. The chair then combined the papers into a final Government Management Task Force report, which is available online at www.ombwatch.org/regs/PDFs/GOVMGMTreport.pdf.

Regulatory Tools Task Force

The Steering Committee asked this task force to address issues surrounding the range of tools agencies use in their analyses of regulatory options and to explore and recommend alternative methods if available. Among the many tools used are risk assessments, cost-benefit analysis, various data collection techniques, environmental impact statements, and peer review procedures. The application of these many tools is critical to setting the levels of protective standards such as air pollution limits or toxic chemical exposure levels.

Dr. Ruth Ruttenberg of the National Labor College chaired the task force which consisted of nine total members representing public health professionals, unions, academia, law, and the public interest community. The task force members had a wide range of opinions, based on their diverse experiences, about the range of tools that the task force should address. As a result, the members provided information about the regulatory process in a series of conference calls and by drafting statements describing the way various tools are and should be used in their areas of expertise. This approach provided the project staff with information about the range of tools and their applications. The task force issued draft reports but did not issue a final report.

The task forces were used as important, but not the only, sources of information to inform project staff as staff developed recommendations for the Committee's consideration. The task forces completed their work in July and August. The staff drafted an initial version of recommendations drawing on the task force work, outside materials from a wide range of sources (academic studies, regulatory reports and analyses, legal sources, etc.), conversations with regulatory experts from different fields, their own regulatory expertise, and interviews with Steering Committee members.

The Steering Committee met for two days in September 2008 to review the recommendations and to decide which recommendations for reforming the regulatory process they would advance. Staff revised the draft report, circulated it again to the Steering Committee for revisions, and then drafted the final report issued by the Steering Committee after a final review by the Committee. At the September meeting, Steering Committee members agreed that the report should not be issued as an OMB Watch report, but as a product produced by the 17 participants since it reflected a combined effort. Project staff prepared a separate summary of the recommendations to use with the transition team and congressional visits.

PUBLIC OPINION RESEARCH

As part of OMB Watch's project, *Advancing the Public Interest Through Regulatory Reform*, Lake Research Partners (LRP) conducted a series of focus groups. In early 2008, LRP held four focus groups with likely voters of no strong partisan affiliation. Two were held in Philadelphia on Feb. 6, 2008. One group was mixed race, white collar (those with college or graduate-level education), and female. The other was mixed race, blue collar (those who were high school graduates who may have attended trade schools but did not graduate from college), and male. The other two focus groups were held in Atlanta on Feb. 12, 2008. One group was mixed race, blue collar, and female. The other was all white, white collar, and male. All four groups had 10 participants.

LRP also conducted two focus groups of small business owners (businesses with no more than fifty employees) of no party affiliation or no strong party affiliation. Both were held in Chicago on April 17, 2008. One group was male, the other was female, and both groups were mixed race. Both groups had six participants.

A subcommittee of the Steering Committee provided valuable assistance in framing the issues addressed in the focus group research. In two meetings with LRP staff, one about the likely voter group and one about the small business group, the subcommittee helped develop the guides used by the moderators of the focus groups. The subcommittee raised issues and provided examples to test in the groups.

The research was done to gauge public sentiment about the role of government today and the public's views on the pros and cons of regulation. The research was also designed to begin framing regulatory issues for policymakers, advocates, and other interested parties. LRP completed its final report in June 2008 and their findings are reflected throughout the Steering Committee's report.

REGULATORY RESOURCE CENTER

An additional component of the regulatory project was the creation of a web-based resource center for advocates and the public to learn about the regulatory process and how to participate in it. The Regulatory Resource Center is housed on OMB Watch's website (http://www.ombwatch.org/regresources). The center consists of an advocacy center and a policy library. It is designed to educate citizens on how they can become involved in the regulatory process (Advocacy Center) and to inform the public about the workings of the regulatory process (Policy Library).

The Steering Committee reviewed the center as it was being developed by OMB Watch staff and tested early components. Staff conducted beta testing with the Steering Committee and OMB Watch employees. OMB Watch then publicized the website in a developmental stage and users were encouraged to submit suggestions on the design, content, and usability. After making modifications to the website, the center was officially launched in March 2008. It is one of the few web-based sites for information about the regulatory process and is being continually updated.

ENDNOTES

1. Three people had to resign from the Steering Committee during the project, and one person joined mid-way, resulting in 17 people on the Steering Committee at the end of the project.

APPENDIX 3.

STEERING COMMITTEE MEMBERSHIP

Below are the Steering Committee members for the *Advancing the Public Interest Through Regulatory Reform* project as of November 2008.* Affiliations are for identification purposes only and do not indicate involvement or an endorsement of the project recommendations by the organizations.

Gary D. Bass
Executive Director
OMB Watch

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Caroline Smith DeWaal
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Center for Science in the Public Interest

N. Bruce Duthu
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Dartmouth College

David J. Goldston
former Chief of Staff
U.S. House Committee on Science

Mark Greenwood
Partner
Ropes & Gray

Francesca Grifo
Senior Scientist and Director of Scientific Integrity Program
Union of Concerned Scientists

John Irons
Research and Policy Director
Economic Policy Institute

Edwin S. Jayne
Associate Director of Legislation
American Federation of State, County, and Municipal Employees

Sylvia Johnson
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United Automobile Aerospace and Agricultural Implement Workers of America (UAW)

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Peter L. Strauss
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Columbia Law School

Wesley Warren
Director of Programs
Natural Resources Defense Council

* We also benefited greatly from the contributions of John Arensmeyer of the Small Business Majority, Rena Steinzor of the University of Maryland School of Law, and Mike Wright of the United Steelworkers, who left the Steering Committee before the report was finalized. Ed Jayne joined the project in mid-2008.

APPENDIX 4.

TASK FORCE MEMBERSHIP

Below are the members of the four task forces that helped develop background information for the *Advancing the Public Interest Through Regulatory Reform* project. The task forces operated independently of the Steering Committee and have neither considered nor endorsed the specific recommendations presented in this report. As such, the listing of task force members here does not indicate any involvement in or an endorsement of the project recommendations. Affiliations are for identification purposes only.

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Jeffrey Lubbers
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Cary Coglianese, ***Task Force Chair***
Associate Dean for Academic Affairs and the Edward B. Shils Professor of Law and Professor of Political Science
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Beth Noveck
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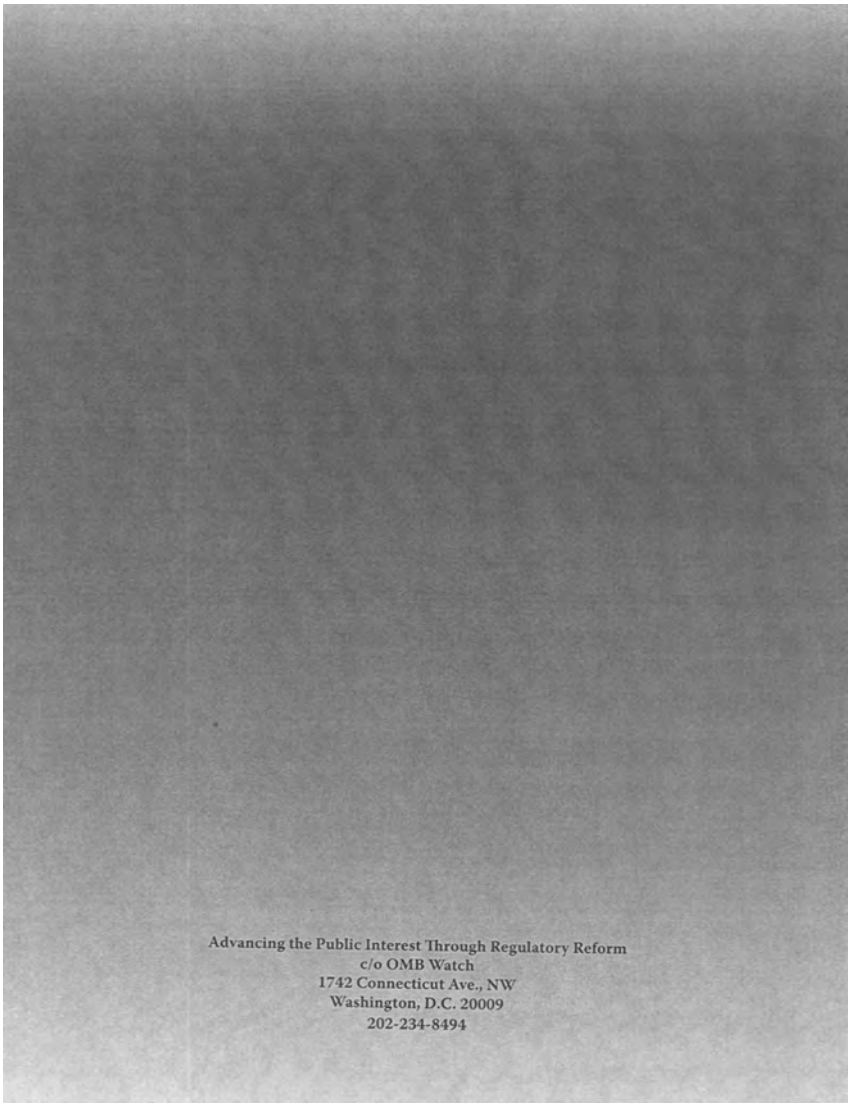
The New York Law School

Stuart Shapiro
Assistant Professor
Edward J. Bloustein School of Planning and Public Policy
Rutgers University

Dan Turner
Founder and President
Turner Consulting Group, Inc.



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The Rhetoric and Reality of Regulatory Reform

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The Rhetoric and Reality of Regulatory Reform

Cary Coglianese

Abstract

In January 2007, President George W. Bush stirred up widespread controversy by issuing amendments to an executive order on regulatory review adopted initially by President Clinton. The Bush amendments variously require agencies to issue written regulatory problem statements, assign gate-keeping responsibilities to Regulatory Policy Officers within each agency, and undertake analytic reviews before adopting certain kinds of guidance documents. Both legal scholars and policy advocates charge that the Bush amendments place significant new burdens on administrative agencies and will delay the issuance of important new regulatory policies. This paper challenges the rhetorical claims of obstructionism that have emerged in response to the Bush amendments. It begins by comparing criticisms of the Bush amendments with criticisms of previous regulatory reforms, showing that concerns about delay date all the way back to the creation of the Administrative Procedure Act of 1946. Notwithstanding the perennial nature of charges of delay and obstruction, the U.S. regulatory state has grown dramatically in both size and impact over the last six decades. In addition, the extant social science literature has failed to find any systematic delays associated with the specific procedure affected by the Bush amendments, namely regulatory review by the Office of Management and Budget. Overall, the burdens associated with regulatory reforms appear to be far smaller, or more manageable, than critics usually suppose. This paper concludes with several explanations for persistent reality of regulatory growth in the face of the persistent rhetoric of obstruction. These alternative accounts not only help explain the rhetoric-reality divide over regulatory reform in general, but they also provide reason to expect the Bush amendments will have, at most, only a trivial impact on the overall regulatory process.

The Rhetoric and Reality of Regulatory Reform

Cary Coglianese[†]

Executive Order 13,422[1] leaves in place most of the existing review process established earlier under Presidents Reagan through Clinton.[2] But it makes several controversial changes to Clinton's Executive Order, such as requiring that agencies specify in writing the regulatory problems they seek to solve, giving presidential appointees certain gatekeeping functions as regulatory policy officers, and imposing new review requirements on certain guidance documents.[3] Although these amendments add to or modify only a very small amount of the text in the pre-existing Executive Order on regulatory review, the changes have provoked a firestorm. Critics charge that the new Order solidifies presidential control over rulemaking and will hamper agencies' ability to issue timely regulations in the service of social welfare.

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† Edward B. Shils Professor of Law and Professor of Political Science, University of Pennsylvania Law School; Director, Penn Program on Regulation. The author is grateful for research support provided by Jocelyn D'Ambrosio and Tim Von Dulm and comments on an earlier draft from Matthew Adler, Jocelyn D'Ambrosio, Stuart Shapiro, Natalya Shnitser, and Christopher Yoo. A version of this paper is forthcoming in the *Yale Journal on Regulation*.

1 Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007) (hereinafter referred to in the text as "the Order" or "13,422").

2 Exec. Order No. 12,291, 3 C.F.R. 127 (1982), 46 Fed. Reg. 13,193 (Feb. 17, 1981); Exec. Order No. 12,866, 3 C.F.R. 638 (1994), 58 Fed. Reg. 51,735 (Sept. 30, 1993), *reprinted in* 5 U.S.C. § 601 (2000).

3 In addition to these changes, 13,422 also includes provisions about reporting cumulative regulatory benefits and costs as well as about the use of formal rulemaking procedures.

In this essay, I focus specifically on the concern that the Order will burden and delay the regulatory process. I compare the criticisms of 13,422 with criticisms of past procedural changes to the regulatory process, and I juxtapose the perennial concern about administrative burdens and delay with the growth in federal regulation over the past half-century. If procedural controls, such as those in 13,422, really do impose on regulatory agencies a "paralysis by analysis," then why is the federal government still producing so many high-impact regulations? This essay raises possible explanations for the disjunction between the rhetoric and reality surrounding regulatory reform, including the possibility that the ultimate impact of the Bush amendments will be largely symbolic.

I. Rhetoric Reacting to Executive Order 13,422

For a short presidential decree on administrative rulemaking, Executive Order 13,422 has received a remarkable degree of public attention, including a front-page story in *The New York Times*,[4] a broadcast on MSNBC,[5] and two congressional hearings[6]—not to

4 Robert Pear, *Bush Directive Increases Sway on Regulation*, N.Y. TIMES, Jan. 30, 2007, at A1 (reporting that "[c]onsumer, labor, and environmental groups denounced the executive order" and feared that it "would hinder agencies' efforts to protect the public").

5 *Countdown with Keith Olbermann: Executive Order 13,422* (MSNBC television broadcast Jan. 30, 2007), *available at* http://olbermannnation.com/index.php/2007/01/30/executive_order_13,422

and http://www.youtube.com/watch?v=Sz6NEoKZRMY (conversation between host Keith Olbermann and guest John Dean highlighting potentially "outrageous" consequences of 13,422, including its "hurdles" for new regulatory actions).

6 There have been at least two congressional hearings *so far*. The House Science and Technology Committee's Subcommittee on Investigations and Oversight held hearings on February 13, 2007 and April 26, 2007. *See Amending Executive Order 12,866: Good Governance or Regulatory Usurpation? Parts I and*

mention the passage of a House appropriations bill blocking its implementation.[7] In the course of the highly visible debate over 13,422, critics have advanced two rhetorical arguments. The first emphasizes the balance of power between Congress and the President, tapping into broader critiques of the Bush Administration's positions on executive authority in domestic and foreign affairs.[8] The second, and the one on which I focus here, is a variation on what economist Albert Hirschman calls the "rhetoric of jeopardy."[9]

Executive Order 13,422, the argument goes, "deals a body blow to the ability of our agencies to do their jobs."[10] Its requirement that agencies state the problem they seek to solve imposes "another hurdle for agencies to clear" before they can adopt good public

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II: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology, 110th Cong. (2007), *available at* http://democrats.science.house.gov/publications/hearings_markups_details.aspx?NewsID=1269 *and* *http://democrats.science.house.gov/publications/hearings_markups_details.aspx?NewsID=1777*.

7 Financial Services and General Government Appropriations Act 2008, H.R. 2829, 110th Cong. § 901 (2007). The Senate did not pass similar legislation.

8 *See, e.g.*, Peter L. Strauss, *Overseer or "The Decider"? The President in Administrative Law*, 75 GEO. WASH. L. REV. 696, 732-38 (2007).

9 ALBERT O. HIRSCHMAN, THE RHETORIC OF REACTION: PERVERSITY, FUTILITY, JEOPARDY 84 (1991). Although Hirschman focuses most of his attention on the rhetoric of conservatives, he readily acknowledges that progressives make parallel rhetorical moves. *Id.* at 149-54 (labeling the progressives' parallel to the jeopardy argument the "imminent danger thesis"). Conservatives' rhetoric of jeopardy emphasizes the dangers of *action*, while progressives' parallel rhetoric of imminent danger focuses on the dangers of *inaction*. *Id.* at 153.

10 *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation?: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. (2007) (Statement of David C. Vladeck, Associate Professor, Georgetown University Law Center), *available at* http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/13feb/vladeck_testimony.pdf.

policies "protecting public health and safety."[11] Its provisions on guidance documents give the Office of Management and Budget (OMB) the ability "to keep the agencies in an endless loop of analysis and [will] lead to endless regulatory delays."[12] The Order's relatively obscure, if somewhat puzzling, provision on formal rulemaking procedures causes at least one prominent administrative law scholar to wonder if its purpose is "[j]ust to help one's friends slow things down—throw a good dose of sand into the gears of rulemaking."[13]

According to critics, 13,422 generates "gridlock"[14] or "a new bureaucratic bottleneck."[15] It "codifies regulatory delay"[16]—and hence "lead[s] to the further

11 Pear, *supra* note 4, at A19 (quoting Gary D. Bass, Executive Director of OMB Watch).

12 OMB WATCH, A FAILURE TO GOVERN: BUSH'S ATTACK ON THE REGULATORY PROCESS 22 (2007), *available at* http://www.ombwatch.org/regs/PDFs/FailuretoGovern.pdf. Even an otherwise supportive treatment of 13,422 expresses concern that the revised "process could slow or stop the issuance of some guidance that serves a useful social purpose." *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation? Part II: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. 4 (2007) (statement of Robert W. Hahn, President, AEI-Brookings Joint Center for Regulatory Studies), *available at* http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/26apr/hahn_testimony.pdf.

13 *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation? Part II: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. 12 (2007) (Statement of Peter L. Strauss, Professor, Columbia University School of Law) *available at* http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/26apr/strauss_testimony.pdf.

14 Union of Concerned Scientists, Presidential Mandate Centralizes Regulatory Power, Endangers Citizens, http://www.ucsusa.org/scientific_integrity/interference/executive-order.html (last visited Nov. 18, 2007).

15 Public Citizen, Latest White House Power Grab Puts Public at Risk; Problems of the Jan. 2007 Executive Order and Bulletin on Guidance (Jan. 2007), http://www.citizen.org/documents/new-eo-and-guidance-overview.pdf.

ossification of an already overburdened administrative process."[17] One member of Congress claims 13,422 provides "another avenue for special interests to slow down and prevent agencies from protecting the public."[18] Still another declares that it "make[s] it harder for agencies to take virtually any action."[19] A former OMB regulatory policy administrator predicts that due to 13,422, along with recent OMB bulletins and standards, "fewer regulations can be issued."[20]

II. Rhetoric and Reaction in Administrative Law

The kinds of criticisms that have been leveled against 13,422 are hardly new. Burdens and delays have figured prominently in the rhetoric against a variety of administrative law reforms. When President Reagan first established formal White House review of

16 OMB WATCH, UNDERMINING PUBLIC PROTECTIONS: PRELIMINARY ANALYSIS OF THE AMENDMENTS TO EXECUTIVE ORDER 12,866 ON REGULATORY PLANNING AND REVIEW 3 (2007), *available at* http://www.ombwatch.org/regs/EO12866_amendments_analysis.pdf.

17 Vladeck, *supra* note 10, at 19.

18 Press Release, Subcomm. on Investigation and Oversight, H. Comm. on Science and Technology, Miller Leads Subcommittee Hearing into White House Exec. Order that Gives More Political Control Over Public Health, Safety Regulations (Feb. 13, 2007), *available at* http://democrats.science.house.gov/press/PRArticle.aspx? NewsID=1328 (quoting Hon. Brad Miller).

19 153 CONG. REC. E 1438 (June 28, 2007) (statement of Rep. Waxman).

20 *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation?: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. 9 (2007) (Statement of Sally Katzen, Adjunct Professor, University of Michigan Law School), *available at* http://democrats.science.house.gov/Media//File/Commdocs/hearings/2007/oversight/13feb/katzen_testimony.pdf.

rulemaking under Executive Order 12,291,[21] critics raised separation of powers questions[22]—but they also complained that OMB review would impede agencies' ability to make new regulations.[23] A widely cited article published in the *Harvard Law Review* during the Reagan years declared that "OMB control imposes costly delays that are paid for through the decreased health and safety of the American public."[24] Even after President Clinton changed the Reagan Order to reserve OMB review for a more limited set of

21 Exec. Order No. 12,291, 3 C.F.R. 127 (1982).

22 *See, e.g.*, Morton Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 MICH. L. REV. 193 (1981).

23 Felicity Barringer, *If Rules Are Made To Be Broken, So Are Rulemakers*, WASH. POST, June 25, 1981, at A21 (describing the Reagan Order as "requiring further delays and studies of all pending rules"); Philip Shabecoff, *Reagan Order on Cost-Benefit Analysis Stirs Economic and Political Debate*, N.Y. TIMES, Nov. 7, 1981, at 28 (noting that the Reagan Administration had issued only about thirty new major regulations compared with "100 to 200 such major regulations" in previous years, and quoting observers who suggested that OMB review was "stemming regulation" and serving as a means to "obstruct regulations"). *See also* Christopher C. DeMuth & Douglas H. Ginsburg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075, 1087-88 (1986) ("[M]ost criticism has focused . . . on the delay that OMB review entails."); OMB Watch, OMB Control of Rulemaking: The End of Public Access 13 (Aug. 1985) (on file with author) ("The required cost/benefit analyses impose[ ] often heavy burdens on the regulatory agencies"). Even earlier efforts of presidential oversight were said to obstruct rulemaking. *See* OMB Watch, *supra* at 3 (stating that Nixon's "[h]ighly controversial" review process stood "accused of delaying the already lengthy environmental regulatory process").

24 Alan B. Morrison, *OMB Interference with Agency Rulemaking: The Wrong Way To Write a Regulation*, 99 HARV. L. REV. 1059, 1064 (1986). Publishing in the same issue of the *Harvard Law Review*, Christopher DeMuth and Douglas Ginsburg lauded OMB review because it "encourages policy coordination, greater political accountability, and more balanced regulatory decisions." DeMuth & Ginsburg, *supra* note 23, at 1081. DeMuth and Ginsburg both served as Administrators of the Office of Information and Regulatory Affairs within OMB. DeMuth & Ginsburg, *supra* at 1075. Their claims, and those of other supporters of OMB review, can and should be scrutinized along with the claims of critics—especially since empirical studies generally "have failed to show that economic analysis and OMB review have significant effects on the cost-effectiveness of government regulations." Cary Coglianese, *Empirical Analysis and Administrative Law*, 2002 U. ILL. L. REV. 1111, 1123 (2002). *See also id.* at 1123 nn.54-57 (citing studies of the impact of economic analysis on regulatory decisions).

significant rules and to place time limits on the review process,[25] scholars continue to claim that OMB review slows down the regulatory process, and even grinds it to a halt in certain instances.[26]

OMB review is not the only procedure to stand accused of obstruction. What critics say about OMB generally, and 13,422 specifically, mirrors the charges leveled against many other administrative procedures. For example, environmental impact statements required by the National Environmental Policy Act purportedly postpone many federal actions.[27] The Freedom of Information Act allegedly imposes high costs on federal agencies.[28] Critics of recent proposals for peer review and other checks on information

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25 The Reagan Executive Order required agencies to submit *all* rules to OMB for review. Exec. Order No. 12,291, §§ 3(c)(3), 3(e)(2)(C), 3(f)(2). In contrast, the Clinton Executive Order only required agencies to submit *significant* rules to OMB. Exec. Order No. 12,866 §§ 6(a)(3)(A), 6(a)(3)(B), 6(b)(1). Furthermore, unlike the Reagan Order, the Clinton Order stated that when reviewing proposed and final rules "OIRA shall . . . notify the agency in writing of the results of its review . . . within 90 calendar days." Exec. Order No. 12,866 § 6(b)(2), 3 C.F.R. 638, 642 (1993), *reprinted in* 5 U.S.C. § 601.

26 *See, e.g.*, Richard B. Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. REV. 437, 447 (2003) ("OMB regulatory analysis and other forms of regulatory impact review have also contributed to 'paralysis by analysis.' Agencies increasingly turn to less formal, less accountable, and more opaque methods of making regulatory policy."). It has even been said that "OMB's review of agency rulemaking has proved far more intrusive during the 1980s and early 1990s than either judicial or congressional review." Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1429 (1992).

27 *See, e.g.*, Sharon Buccino, *NEPA Under Assault: Congressional and Administrative Proposals Would Weaken Environmental Review and Public Participation*, 12 N.Y.U. ENVTL. L.J. 50, 52 (2003) ("Some critics blame the NEPA process for delay and inefficiency."); Bradley C. Karkkainen, *Toward a Smarter NEPA: Monitoring and Managing Government's Environmental Performance*, 102 COLUM. L. REV. 903, 906-7 (2002) (NEPA "demands the impossible" and "places extreme demands on agency resources"); James T.B. Tripp & Nathan G. Alley, *Streamlining NEPA's Environmental Review Process: Suggestions for Agency Reform*, 12 N.Y.U. ENVTL. L.J. 74, 75 (2003) ("[C]ommentators and the agencies bound by [NEPA's] requirements have often decried the Act as a time- and resource-consuming annoyance.").

28 *See, e.g.*, Antonin Scalia, *The Freedom of Information Act Has No Clothes*, REGULATION, Mar./Apr. 1982, at 15, 16 (FOIA requests "have greatly burdened investigative agencies"). Scalia's argument

quality claim that they will unduly delay regulatory policy-making.[29] It has become widely accepted that judicial review under the arbitrary and capricious standard has "burdened, dislocated, and ultimately paralyzed" certain agencies' rulemaking.[30]

"Paralysis by analysis" has become a cliché in regulatory circles today.[31] This appealing rhyme, though, is itself far from new, dating at least to the first half of the twentieth century when it appeared in religious sermons and writings.[32] The underlying

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against FOIA, along with criticisms of delays caused by NEPA, suggest how arguments about the burden of administrative procedures can cut across ideological lines.

29 *See, e.g.*, Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 KAN. L. REV. 897, 935 (2004) (arguing that "the result [of the Information Quality Act] can only be added expense and delay in the decisionmaking process"); J.B. Ruhl & James Salzman, *In Defense of Regulatory Peer Review*, 84 WASH. U. L. REV. 1, 6 (2006) (quoting a critic of peer review who predicted that regulatory peer review will "introduce potentially massive costs and delay, thus injecting paralysis by analysis into the regulatory process").

30 Jerry L. Mashaw & David Harfst, *Inside the National Highway Traffic Safety Administration: Legal Determinants of Bureaucratic Organization and Performance*, 57 U. CHI. L. REV. 443, 443 (1990). *See also* Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885, 932 (2003) ("[Judicial] review has contributed to the 'ossification' of notice-and-comment rulemaking, which now takes years, in part as a result of the effort to fend off judicial challenges. In light of the risk of invalidation, many agencies have turned away from notice-and-comment rulemaking altogether.").

31 *See, e.g.*, Daniel A. Farber, *Rethinking Regulatory Reform After* American Trucking, 23 PACE L. REV. 43, 51 (2002) ("Environmentalists respond that cost-benefit analysis is a recipe for 'paralysis by analysis.'"); Thomas O. McGarity, *The APA at Fifty: The Expanded Debate over the Future of the Regulatory State*, 63 U. CHI. L. REV. 1463, 1523 (1996) (noting the "fear that many of the cognitive regulatory reforms . . . will lead to 'paralysis by analysis'"); Chris Mooney, *Paralysis by Analysis*, WASH. MONTHLY, May 2004, at 23, *available at* http://www.washingtonmonthly.com/features/2004/0405.mooney.html.

32 *See, e.g.*, ELI STANLEY JONES, THE CHRIST OF EVERY ROAD: A STUDY IN PENTECOST 40 (1930). Although the phrase appears to have been employed most commonly by Christian writers and preachers during the early part of the twentieth century, it came into more general usage after Martin Luther King, Jr. made it part of his call for racial justice. *See* MARTIN LUTHER KING, JR., STRENGTH TO LOVE 17 (1963). The rhyme appeared within the pages of the *Federal Register* as early as in 1952, used by a Republican appointee to the Federal Communications Commission. *See* Dissenting Opinion of Comm'r Robert F. Jones, 17 Fed. Reg. 4093, 4094 (1952) ("The Commission has had the paralysis of analysis for 1 year, not consumed in

concern the rhyme conveys about administrative process also dates back to the early part of the last century. In an article published in the *Harvard Law Review* in 1938, an administrative law scholar asked whether New Deal changes in rulemaking procedures would lead at least to "a partial paralysis . . . by reason of excessive formality and litigation."[33]

At the time of the New Deal, proposals for government-wide procedural reform triggered the "fear of unduly hampering" agencies."[34] Of course, today the informal rulemaking provisions of the Administrative Procedure Act (APA) of 1946 are held up as a model of administrative simplicity and efficiency,[35] only to have been spoiled by developments in judicial and regulatory oversight in the last several decades.[36] It is little known that the APA was itself once viewed as a major source of ossification. Scholars in the 1940s feared that its uniform procedures would "severely cramp the style of

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drafting the general rules and standards [for television service], but consumed in a search for a city-to-city allocation plan which it can freeze on the country by rule-making proceedings.").

33 Ralph F. Fuchs, *Procedure in Administrative Rule-Making*, 52 HARV. L. REV. 259, 280 (1938).

34 *Administrative Law—Developments 1940-45*, 44 MICH. L. REV. 797, 803 (1946).

35 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE 283 (1970) (describing informal rulemaking under the APA as being among the "greatest inventions of modern government"). This phrase of Davis's continues to be quoted today.

36 McGarity, *supra* note 26, at 1385 ("Professor Kenneth Culp Davis captured the prevailing sentiment . . . when he called informal rulemaking 'one of the greatest inventions of modern government.' Twenty years later, the bloom is off the rose. . . .[The] rulemaking process has become increasingly rigid and burdensome [due to an] assortment of analytical requirements . . . and evolving judicial doctrines . . . .") (citation omitted).

government regulation."[37] The right to file a rulemaking petition under § 553(e) was of "doubtful value," especially since agencies could be "swamped by frivolous requests having delay as their sole objective."[38] It is hard to imagine now, but at the time of the APA's adoption some academic observers forecasted "disastrous" effects from the law, characterizing the Act as nothing short of a "sabotage of the administrative process."[39]

III. The Reality of Regulatory Growth

So we have heard complaints about procedural burdens many times before. What, then, should we make of the rhetorical similarities between criticisms of 13,422 and of administrative procedures more generally? The perennial nature of the refrain about delay and obstruction might well make anyone suspicious that the criticisms of 13,422 are nothing more than the rhetorical ploy trotted out by the opponents of any reform. But as Hirschman reminds us, the mere fact that a rhetorical argument is repeated or even overused does not necessarily make it wrong.[40] The impact of OMB review, with or

37 Fritz Morstein Marx, *Some Aspects of Legal Work in Administrative Agencies*, 96 U. PA. L. REV. 354, 354 n.2 (1948).

38 Foster H. Sherwood, *The Federal Administrative Procedure Act*, 41 AM. POL. SCI. REV. 271, 279 (1947).

39 Frederick F. Blachly & Miriam E. Oatman, *Sabotage of the Administrative Process*, 6 PUB. ADMIN. REV. 213, 213 (1946).

40 HIRSCHMAN, *supra* note 9, at 166.

without 13,422, is ultimately an empirical question that requires looking at what agencies have actually done in terms of rulemaking.[41]

Yet here is where suspicions about the rhetoric of paralysis grow strongest, because the regulatory state has increased considerably in size and impact since the establishment of the APA and subsequent reforms, including OMB review. The sheer volume of rules, as measured by pages in the Code of Federal Regulations (CFR), has increased about five times since 1946 and has continued to grow since the advent of OMB review. For the past couple of decades, the federal government has issued an average of about 4,000 new rules each year in the *Federal Register*. The 2006 CFR contains about 33% more pages than did the 1980 volume of the CFR.[42]

Pages of rules are only one way to measure regulatory activity. When estimated monetarily, the impact of federal regulation has also increased. Not only do new rules deliver substantial benefits to society, they also impose substantial costs. According to the estimates collected by OMB during its review process, government regulations issued since 1981 have imposed $127 billion in annual costs on the economy.[43] According to a

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41 *See generally* Coglianese, *supra* note 24.

42 The values reported in this paragraph draw on data on file with the author that were collected by and obtained from the Office of the Federal Register. A recent study by Anne Joseph O'Connell similarly "calls into question much of the existing debate on regulatory 'ossification'" and reports data on rulemaking frequency that "strongly suggest that the administrative state is not ossified." Anne Joseph O'Connell, *Political Cycles of Rulemaking: An Empirical Portrait of the Modern Administrative State*, 94 VA. L. REV. (forthcoming June 2008).

43 OFFICE OF MGMT. & BUDGET, DRAFT 2007 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS 34 (2007), *available at* http://www.whitehouse.gov/omb/inforeg/2007_cb/

retrospective study conducted by the National Highway Traffic Safety Administration, the annual costs attributable to mandatory federal auto safety standards have increased from $255 per car during the 1968-78 period to $760 per car in the 1991-2001 period, even controlling for inflation.[44] An independent study has reported that the annual costs associated with environmental regulations more than quadrupled between 1972 and 1992, roughly a decade before and a decade after the establishment of OMB review.[45]

Given the overall increase in pages of regulation and their costs, government regulators have clearly not been paralyzed. Have they nevertheless been hobbled? Is it possible that regulatory growth would have been greater still in the absence of OMB review? Several empirical studies have tried to determine whether OMB review slows down the rulemaking process, thus making it harder for agencies to issue as many rules as they otherwise would. Although it might seem intuitive that OMB review would increase the time and expense of issuing new rules, researchers have not found systematic evidence that OMB review imposes any significant delay on the regulatory process, notwithstanding careful analysis of both large-sample datasets and matched case studies. For example,

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2007_draft_cb_report.pdf. The same report indicates that annual average regulatory costs have tended to be lower during the second Bush Administration than during previous administrations, although of course these data precede the issuance of Executive Order 13,422. *Id.*

44 Marcia J. Tarbet, Cost and Weight Added by the Federal Motor Vehicle Safety Standards for Model Years 1968-2001 in Passenger Cars and Light Trucks, NHTSA Report No. DOT HS 809 834 at 145, Table 5A, *available at* http://www.nhtsa.dot.gov/cars/rules/regrev/Evaluate/809834.html (reporting all data on unit costs in 2002 dollars).

45 Adam B. Jaffe et al., *Environmental Regulation and the Competitiveness of U.S. Manufacturing: What Does the Evidence Tell Us?*, 33 J. ECON. LIT. 132, 140 (1995).

political scientists Cornelius Kerwin and Scott Furlong published a regression analysis of the determinants of EPA rulemaking duration in which they found little by way of any statistically significant effect from OMB review.[46] Stuart Shapiro, another social scientist, analyzed a series of matched *state* agencies and found that even seemingly cumbersome rulemaking procedures, like economic analysis review, did not affect the rate of regulatory change, although the partisan control of the political branches did.[47] More recently, political scientist Steven Balla and his colleagues studied the determinants of the duration of OMB review and found that, contrary to claims that special interests try to capture OMB review to delay rules, reviews were actually shorter when only narrow sets of businesses

46 Cornelius M. Kerwin & Scott R. Furlong, *Time and Rulemaking: An Empirical Test of Theory*, 2 J. PUB. ADMIN. RES. & THEORY 113 (1992). The Kerwin and Furlong study analyzed determinants of the duration of 150 non-routine U.S. Environmental Protection Agency (EPA) rules issued during the period October 1, 1986 through September 30, 1989, drawing on data collected from the EPA's internal regulatory management system. *Id.* at 122. The authors reported results from three separate regression models. In two of these models, the OMB review variable was not significant at all. *Id.* at 130. In the model of duration between proposed and final rules, OMB review was statistically significant, but only had an effect that for every day a rule was under OMB review, the duration of the process was lengthened by two days. *Id.* Even with this one apparent statistical relationship, the variable for OMB review could be serving as at least a partial proxy for the overall complexity or political salience of rules. *Id.* at 132. In other words, at least part of any statistically observed delay may stem from the fact that rules that go to OMB for review are simply more complex and controversial to begin with than the ordinary rule.

47 Stuart Shapiro, *Speed Bumps and Roadblocks: Procedural Controls and Regulatory Change*, 12 J. PUB. RES. & THEORY 29 (2002). Shapiro studied day care regulation in eight states, selecting states in pairs that otherwise were geographically and economically similar. He chose to study day care regulation because it is a domain that has largely escaped federal preemption, thus helping to maximize the possibility of variation across states. Contrary to prior expectations, Shapiro found that regulators in states with purportedly cumbersome regulatory procedures were not deterred from issuing new regulations. Instead, he found that the key determinant of the level of regulatory activity was the political environment within the states. When the political alignment in the legislature and executive branch favored regulatory change, change generally occurred, even in states with higher procedural hurdles. *Id.*

were in contact with OMB.[48] To be sure, no broad-based empirical study can rule out that OMB review might have the effect of slowing the issuance of an individual rule now and then. The existing work does fail, though, to find clear evidence of any *general* effects consistent with the *general* rhetorical claims made about OMB review.[49]

IV. Explaining the Rhetoric-Reality Divergence

How, then, can the bold rhetoric about 13,422 and OMB review be reconciled with the stark reality of continued and substantial outflows of regulation from the federal government? Perhaps additional research is needed to uncover the real, but more subtle effects that procedures like these have on regulatory behavior. Or perhaps OMB review truly has failed to delay rulemaking so far, but the implementation of 13,422 will take the administrative process past a tipping point to where rulemaking does finally begin to slow

48 Steven J. Balla et al., Outside Communication and OMB Review of Agency Regulations, presented at the 2006 annual Midwest Political Science Association meeting, Chicago, Illinois. The authors examined nearly 2,000 OMB reviews undertaken from 2002 through 2004 to determine whether contacts between OMB and outside parties over specific rules tended to correspond with the duration of OMB review of those rules. *Id.* at 6. Based on OMB logs of staff contact with outside parties, the authors reported that contacts took place in only about 7% of the rules. *Id.* Although reviews where contacts occurred did take longer on average than reviews without any contacts, once other variables were controlled for, contacts with business groups were not associated with a lengthening of the OMB review process. As Balla et al. state, "contrary to widely held expectations. . . . outside communications do not operate in a way that particularly advantages business firms and trade associations seeking to derail prospective agency regulations." *Id.* at 15.

49 *See* MATTHEW D. ADLER & ERIC A. POSNER, NEW FOUNDATIONS OF COST-BENEFIT ANALYSIS 87 (2006) (noting that "existing evidence and the political economy of rulemaking call into question the claim that [cost-benefit analysis] produces substantial incremental delay"). In one recent paper, two political scientists report results suggesting that OMB review can "actually speed up agency rulemaking—a finding directly contrary to what ossification theory predicts." Jason Webb Yackee & Susan Webb Yackee, Is Federal Agency Rulemaking "Ossified"? The Effects of Procedural Constraints on Agency Policymaking, paper presented at the 2007 meeting of the Midwest Political Science Association, at 24 (on file with the author).

down, if not grind to a standstill. Or perhaps ultimately the rhetoric surrounding 13,422 and OMB review is just that, rhetoric.[50]

These are all certainly possibilities. But I find more interesting three other possible explanations that might offer theoretical insights about the relationship between administrative procedures and regulatory decision-making. The first possibility might be that administrative procedures like 13,422 are epiphenomenal, or at least so highly malleable to make them merely symbolic. That is, rulemaking procedures may look like they impose burdens on agencies, but the real burdens depend entirely on whether or how they are implemented—not on the existence of procedure *qua* procedure. As a result, an administration that wants to regulate a lot will regulate a lot, and an administration that wants to slow down regulation will slow down regulation—regardless of what procedures are on the books.[51]

A second possible account is that the behavioral effect of a law or procedure is real, rather than illusory, but just simply trivial (at least for certain effects of interest). For

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50 *See* CURTIS W. COPELAND, CHANGES TO THE OMB REGULATORY REVIEW PROCESS BY EXECUTIVE ORDER 13,422, at 5 (Congressional Research Service No. RL33862, Feb. 5, 2007) (noting that "concerns about the usurpation of congressional standards for rulemaking and unnecessary delay may be exaggerated"). *See also* Stuart Shapiro, *The Role of Procedural Controls in OSHA's Ergonomics Rulemaking*, 67 PUB. ADMIN. REV. 688, 697 (2007) (describing the limited, even symbolic, role of various procedural steps in the development of OSHA's ergonomics rule in the 1990s).

51 Stuart Shapiro has suggested as much, concluding that "the new regulatory procedures [put in place during the Bush-II administration] may either be irrelevant to regulatory outcomes or may be used by future pro-regulatory presidents to achieve their own regulatory goals." Stuart Shapiro, *Presidents and Process: A Comparison of the Regulatory Process under the Clinton and Bush (43) Administrations* 22, (AEI-Brookings Joint Center for Regulatory Studies, Working Paper No. 06-30), *available at* http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/RP06-30_topost.pdf.

example, even if state laws requiring consumers to pay a five-cent deposit for soda bottles and cans reduce roadside litter and increase recycling, it is hard to see that these so-called bottle bills place any meaningful barrier in the way of the purchase of soda, and hence it seems unlikely they would lead to any discernible decline in soda sales in states after these laws are adopted.[52] In a similar vein, some administrative procedures probably have only trivial effects on rulemaking because agencies can satisfy them by publishing boilerplate language in their *Federal Register* notices. If agencies come to satisfy 13,422's new written problem statement requirement using boilerplate language or by creating check-boxes on a form, the requirement's impact will surely be inconsequential in terms of the pace and cost of rulemaking.

A third possibility is that procedures do have both real and consequential effects, but these effects are drowned out by other behavioral factors moving in the same direction. For instance, on the assumption that Reagan's regulatory review order was truly more burdensome than Clinton's Order,[53] the additional burden may not have had much of an effect on agency behavior in an administration where appointees were already less inclined to regulate. If it turned out that agencies issued fewer or less costly rules during the Reagan Administration than the Clinton Administration, these results may well have stemmed not

52 In other words, while a price increase can have real effects on purchasing behavior, it would be hard to imagine the demand for soda is so highly elastic that a five-cent deposit has anything but the most trivial effect on overall sales.

so much from procedure than from the ideology of the political appointees heading the agencies.

For much the same reason, if other legal rules, professional norms, or political exigencies already are pushing agencies to take benefit-cost analysis seriously—something Cass Sunstein has suggested[54]—then any additional, incremental stringency of a regulatory review order may yield at best only a small and diminishing behavioral return. In other words, if agencies are already, for other reasons, engaging in exactly the kind of analysis called for by the new Executive Order, the Order will impose no (or negligible) additional costs and delays. To predict the extent of any delay from 13,422's provisions on guidance documents, for example, we need to know more about what analysis of these non-binding documents agencies conduct anyway. It would not be surprising to discover that many agencies already conduct analysis of their most significant guidance documents, precisely the ones covered by the new Executive Order. If this is true, the additional time and effort needed to satisfy OMB review under 13,422 will most certainly turn out to be much smaller than has been widely imagined.[55]

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53 *See supra* note 25. For a further discussion of some of the differences between the Reagan and Clinton Orders, see Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 827-29, 849-50 (2003).

54 CASS R. SUNSTEIN, THE COST-BENEFIT STATE (2002).

55 Moreover, OMB's review of significant guidance documents may turn out to be much more limited than critics apparently assume it will be. *See* OMB Regulatory Policy Chief Anticipates New Draft of Risk Assessment Guidance, BNA Daily Report for Executives, May 10, 2007, at A-24 (quoting OMB regulatory director, Susan Dudley, as anticipating review of guidance documents will be "a quick turnaround thing. . .not the same as [reviewing] a regulation."). If so, it seems still more conceivable that agencies' pre-

Conclusion

For these reasons, scholars and policy decision makers should exercise caution before concluding that Executive Order 13,422 will have anything more than the most minor effects on actual agency operations. The Order's requirement for a written problem statement and its provisions calling for OMB review of guidance documents, for example, may well be easily met or add only superfluously to what agencies already do. Such an outcome would be consistent with the longstanding disjunction between the rhetoric and reality of regulatory reform. Alarms of delay and paralysis have sounded in response to nearly every major regulatory reform since the establishment of the Administrative Procedure Act of 1946—and yet the regulatory state has nevertheless marched rather dramatically onward over the last six decades.

As it applies to the operation of government bureaucracies, administrative law is embedded within a complex web of politics, institutions, and organizational behavior. Within this web, law is but one factor influencing behavior in government agencies among a variety of institutional, professional, social, financial, and political factors that interact with each other, and even adapt and change over time. Social scientists who have devoted their careers to the empirical study of bureaucracy have yet to create a parsimonious theory

existing level of analysis behind guidance documents will often satisfy OMB, thus rendering 13,422's new requirement largely superfluous.

of bureaucratic behavior.[56] Their failure to do so, combined with the obvious expansion of regulation in the face of repeated warnings to the contrary, should make both institutional designers and their critics more circumspect about their predictions—and their rhetoric—concerning the impact of regulatory reform.

56 JAMES Q. WILSON, BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT xi (1989) ("After all these decades of wrestling with the subject, I have come to have grave doubts that anything worth calling 'organization theory' will ever exist.").

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ARTICLES

SHIFTING SANDS: THE LIMITS OF SCIENCE IN SETTING RISK STANDARDS

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INTRODUCTION

Administrative law aspires to bring reason to agency policymaking.[1] The Administrative Procedure Act[2] requires agencies to specify the basis for the rules they promulgate,[3] and in exercising their review

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[1] *See, e.g.*, CASS R. SUNSTEIN, ONE CASE AT A TIME: JUDICIAL MINIMALISM ON THE SUPREME COURT 31 (1999) ("Much of administrative law consists of an effort to ensure reason-giving by regulatory agencies . . . . The agency . . . must generate a convincing explanation . . . ."); Lisa Schultz Bressman, *Disciplining Delegation After* Whitman v. American Trucking Ass'ns, 87 CORNELL L. REV. 452, 485 (2002) ("[Administrative law principles] require agencies in general to articulate a basis for their policy determinations and, in particular, to articulate the standards for those determinations."); Jerry L. Mashaw, *Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State*, 70 FORDHAM L. REV. 17, 20 (2001) (arguing that the demand for reason is stronger in administrative law than even in judicial decision making).

[2] 5 U.S.C. §§ 551–559, 701–706 (2000).

[3] *Id.* § 553(c).

of agency action under the arbitrary and capricious standard,[4] courts have repeatedly demanded that agencies justify their decisions with careful reasoning.[5] In striving to meet administrative law's demands and aspirations, agencies have applied their expertise to gather facts and to invest in sustained scientific research. For regulatory decision makers, science provides a systematic basis for understanding policy problems and the potential consequences of different policy options, and therefore, scientific evidence must play a key role in agency decision making.[6] But even though science is valuable for what it can tell administrators about policy problems and their possible solutions, science alone cannot provide a complete rationale for a policy decision

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[4] *Id.* § 706(2)(a).

[5] *See, e.g.*, Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 48 (1983) (referring to the "strict and demanding" requirement that "an agency must cogently explain why it has exercised its discretion in a given manner"); *see also* AT&T Corp. v. FCC, 236 F.3d 729, 736 (D.C. Cir. 2001) (invalidating an FCC rule because the agency "ha[d] considered this question on several occasions, each time applying a test different from that applied here"); Pearson v. Shalala, 164 F.3d 650, 660-61 (D.C. Cir. 1999) (holding that an agency cannot "refuse to define the criteria it is applying," and that "it must be possible for the regulated class to perceive the principles which are guiding agency action"); Am. Lung Ass'n v. EPA, 134 F.3d 388, 392-93 (D.C. Cir. 1998) ("[U]nless [the Administrator] describes the standard under which she has arrived at this conclusion, . . . we have no basis for exercising our responsibility to determine whether her decision is 'arbitrary [or] capricious . . . .'" (citation omitted)); Hall v. McLaughlin, 864 F.2d 868, 872 (D.C. Cir. 1989) ("Reasoned decisionmaking requires treating like cases alike; an agency may not casually ignore its own past decisions. Divergence from agency precedent demands an explanation." (footnote omitted)); Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 525 (D.C. Cir. 1983) ("By EPA's logic, adverse health effects would permit it to justify any lead standard at all, without explaining why it chose the level it did. We cannot accept such incomplete reasoning."); Greater Boston Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir. 1970) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute." (footnotes omitted)).

[6] *See, e.g.*, COMM. ON RESEARCH AND PEER REVIEW IN EPA, NAT'L RESEARCH COUNCIL, STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY: RESEARCH-MANAGEMENT AND PEER-REVIEW PRACTICES 24 (2000) ("In the absence of sound scientific information, high-risk problems might not be adequately addressed, while high-profile but lower-risk problems might be targeted wastefully."), *available at* http://www.nap.edu/openbook/0309071275/html/24.html; CHRISTOPHER F. EDLEY, JR., ADMINISTRATIVE LAW: RETHINKING JUDICIAL CONTROL OF BUREAUCRACY 13-14 (1990) (highlighting science as one of the three central aspects of administrative decision making); Alon Rosenthal et al., *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269, 270 (1992) ("Scientific information about the human health risks of exposure to toxic chemicals is critical to making sound regulatory decisions.").

because it does not address the normative aspects of administrative policymaking.[7] To fulfill administrative law's aspiration of reason, agencies need to explain their decisions by reference not only to scientific evidence but also to policy principles that speak to the value choices inherent in their decision making.

In this Article, we examine the role and limitations of science in the important policy domain of environmental risk management. In particular, we offer a detailed account of the use—and misuse—of science by the Environmental Protection Agency (EPA) in its efforts to justify recent changes to its national ambient air quality standards (NAAQS) for ozone[8] and particulate matter (PM).[9] Environmental risk management is an area of public policy where science plays a vital role in revealing the health effects associated with human exposure to different substances.[10] It is also an area, however, where agencies have often exaggerated the role of science and thus have escaped their responsibility to give careful reasons for the value judgments implicit in their decision making.[11]

EPA's recent revisions to its air quality standards hold profound implications for both public health and the economy.[12] Not surprisingly, these revisions generated substantial political controversy[13] and led to several rounds of litigation.[14] In the first case to come before the D.C. Circuit, the majority rejected EPA's revised standards,

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[7] *See infra* notes 34-36 and accompanying text (showing how EPA's exclusive reliance on science in its ozone and particulate matter rulemakings was fundamentally mistaken).

[8] National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856 (July 18, 1997) (codified as amended at 40 C.F.R. §§ 50.9–.10) [hereinafter EPA, Ozone Final Rule].

[9] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652 (July 18, 1997) (codified as amended at 40 C.F.R. §§ 50.6–.7) [hereinafter EPA, PM Final Rule].

[10] *See infra* notes 34, 413 and accompanying text (noting the role of scientific analysis in EPA decision making).

[11] *See* Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1617 (1995) ("[A]gencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions.").

[12] *See infra* notes 369-70 and accompanying text (detailing estimated costs of the revisions).

[13] *See, e.g., infra* note 70 and accompanying text (describing the congressional hearings on the standards).

[14] The standards were the subject of multiple decisions in the D.C. Circuit in addition to a major decision in the U.S. Supreme Court. For a discussion of the litigation, see *infra* notes 15-20, 408-12 and accompanying text.

holding that the Agency's application of the Clean Air Act violated the constitutional nondelegation doctrine.[15] Congress delegated authority to EPA to set air quality standards that "'protect the public health' with an 'adequate margin of safety,'"[16] language that the majority held could pass constitutional muster only if EPA applied an "intelligible principle" to cabin its discretion in setting air quality standards.[17] The D.C. Circuit's novel constitutional ruling generated considerable attention and seemed potentially to cast other regulatory statutes into some doubt.[18] On appeal, in the much-heralded case of *Whitman v. American Trucking Ass'ns*,[19] the Supreme Court rejected the D.C. Circuit's constitutional analysis, holding that the Clean Air Act did not violate the nondelegation doctrine.[20]

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[15] Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1038-40 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

[16] *Id.* at 1034 (quoting 42 U.S.C. § 7409(b)(1) (2000)).

[17] *Id.* at 1038-40.

[18] The constitutional issues presented in *American Trucking* received extensive academic and legal analysis. For examples of such analysis, see Cary Coglianese, *The Constitution and the Costs of Clean Air*, 42 ENV'T 32 (2000); Ernest Gellhorn, *The Proper Role of the Nondelegation Doctrine*, 31 Envtl. L. Rep. (Envtl. L. Inst.) 10,232 (Feb. 2001); C. Boyden Gray, *The Search for an Intelligible Principle: Cost-Benefit Analysis and the Nondelegation Doctrine*, 5 TEX. REV. L. & POL. 1 (2000); Lisa Heinzerling, *The Clean Air Act and the Constitution*, 20 ST. LOUIS U. PUB. L. REV. 121 (2001); Thomas O. McGarity, *The Clean Air Act at a Crossroads: Statutory Interpretation and Longstanding Administrative Practice in the Shadow of the Delegation Doctrine*, 9 N.Y.U. ENVTL. L.J. 1 (2000); Craig N. Oren, *Run Over by* American Trucking *Part I: Can EPA Revive Its Air Quality Standards?*, 29 Envtl. L. Rep. (Envtl. L. Inst.) 10,653 (Nov. 1999); 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); Cass R. Sunstein, *Is the Clean Air Act Unconstitutional?*, 98 MICH. L. REV. 303 (1999).

[19] 531 U.S. 457 (2001).

[20] *Id.* at 475-76; *see also* Cass R. Sunstein, *Regulating Risks After* ATA, 2001 SUP. CT. REV. 1, 3 ("[*Whitman*] reestablish[es] long-settled law allowing Congress to delegate broad discretionary authority to regulatory agencies."). *But cf.* Bressman, *supra* note 1, at 469-70 ("[*Whitman*] denie[s] agencies the power to cure deficiencies in delegating statutes."). The Supreme Court also rejected industry's statutory argument that EPA can consider costs in setting air quality standards, affirming a string of D.C. Circuit decisions holding likewise. *Whitman*, 531 U.S. at 464-71 (citing Am. Lung Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998); Natural Res. Def. Council v. Adm'r., EPA, 902 F.2d 962, 973 (D.C. Cir. 1990); Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1185 (D.C. Cir. 1981); Lead Indus. v. EPA, 647 F.2d 1130, 1148 (D.C. Cir. 1980)). The Supreme Court did leave open the possibility for separate consideration of EPA's decision under the arbitrary and capricious standard on remand to the D.C. Circuit. *Id.* at 476. Given the Supreme Court's affirmation of the adequacy of EPA's decision making on constitutional grounds, it came as little surprise that the D.C. Circuit subsequently (although not necessarily correctly) found EPA's decision making to withstand the arbitrary and capricious test. Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 358 (D.C. Cir. 2002).

The Supreme Court's decision to uphold the Act—and by implication EPA's revised standards—against constitutional challenge resolved what had become one of the most significant and controversial issues in environmental, health, and safety regulation to emerge in recent years. Nevertheless, although the constitutional issues raised by the case have been settled, the revised ozone and particulate standards remain one of EPA's most significant environmental policy decisions. Not only will the standards have important impacts on public health, but these two standards alone are expected to impose more costs on the economy than all other air pollution regulations combined.[21] The policy significance of these standards makes all the more salient another vital issue raised by this case, one that was not explicitly addressed by the Supreme Court and that has also escaped much scrutiny in the academic commentary on the case.[22] The unaddressed issue is the question of the appropriate role of science in setting risk standards.

Agencies like EPA must rely on science to make well-informed and effective policy decisions, such as where air quality standards should be set, but they cannot rely on science exclusively to justify these decisions.[23] This Article explains how EPA's invocation of science in defense of its new air quality standards contributed to, or at least deflected attention from, a remarkable series of inconsistencies in EPA's positions. Given the way EPA and the courts have interpreted the Clean Air Act, the Agency has been able to, if not been forced to, cloak its policy judgments under the guise of scientific objectivity, with the consequence that the Agency has evaded accountability for a shifting set of policy positions having major implications for public health and the economy.[24] In short, EPA's use of a science-based rhetoric enabled it to avoid responsibility for providing any clear, consistent reasons for its policy choices in setting air quality standards.[25] The Agency's shifting and incoherent approach to its NAAQS decisions

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[21] *See infra* note 370 and accompanying text (detailing the amount of money spent on compliance with the Clean Air Act).

[22] The academic literature has focused predominantly on the constitutional issues raised in *Whitman*. *See* sources cited *supra* notes 18, 20.

[23] *See infra* Part I.B (defining the appropriate role of science in decision making while pointing out common uses of it).

[24] *See infra* Part II (discussing EPA's invocation of science instead of reliance on reasoned policy judgments).

[25] *Infra* Part II.

ultimately failed to live up to the aspiration for reasoned decision making that undergirds contemporary administrative law.[26]

In Part I of this Article, we show how EPA invoked science to justify its NAAQS revisions, and we explain why such an approach misconceived the role of science in regulatory decision making. Drawing on the conventional distinction between risk assessment and risk management, we show how EPA's retreat behind the cloak of science mistook the normative nature of risk management decisions, such as those involved in setting air quality standards. We also show how policy choices enter into standard setting even more starkly for nonthreshold pollutants (such as ozone and particulate matter), where it appears there is no level of exposure that is free from all health effects.

In Part II, we demonstrate that EPA's positions on various aspects of its NAAQS decision making have shifted over time, even during the course of its most recent rulemakings on ozone and particulate matter. When agencies like EPA rely on science as a justification for how they set risk standards, they neglect to offer a principled justification for their policy decisions.[27] In fact, EPA has quite explicitly argued that it should be able to approach each NAAQS rulemaking in an ad hoc manner.[28] With such an ad hoc approach to risk management, inconsistencies are to be expected as an inevitable result, as we show in the incoherent positions EPA adopted in its recent revisions to its air quality standards.

Finally, in Part III we review several alternative principles for justifying risk standards, showing what direction EPA and other regulatory agencies need to take in order to develop more principled approaches to risk management. We conclude that in order to bring greater clarity and coherence to air quality standard setting, Congress will need to step in and direct EPA to use clear policy principles in justifying its decisions. This will almost certainly require a repudiation of the fundamental fiction, endorsed by both EPA and the Supreme Court in *Whitman*, that risk standards can be set without consideration for the

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[26] On administrative law's aspirations for reason, see *supra* notes 1, 5 and *infra* notes 398-402.

[27] By "principled justification," we simply mean an explicit reason or explanation for why, given what is known about the world, a standard should be set at a particular level, such that in situations with similar conditions a similar result should follow.

[28] *See infra* notes 188-89 and accompanying text (presenting the Agency's claim that it cannot be constrained by any "generalized paradigm").

costs or feasibility of complying with them.[29] By amending the underlying statute, Congress can enable and encourage the Agency to live up to the aspirations for reason embedded within contemporary administrative law.

I. SCIENCE AND SETTING RISK STANDARDS

Throughout its recent ozone and particulate matter rulemakings, EPA attempted to justify its selection of its air quality standards based on scientific evidence, namely evidence of the health effects of such pollution.[30] In the early stages of the rulemaking, EPA's emphasis on science was more restrained, and Agency documents sometimes noted obliquely that there was some room for policy inputs in risk management.[31] As the Agency's rulemaking proceedings progressed, however, and as the amount of controversy surrounding them increased, EPA's reliance on science to justify and defend its standards became more pronounced.

EPA initially emphasized its scientific evidence partly in response to a campaign by opponents who questioned the soundness of the science underlying EPA's standards.[32] EPA understandably responded to these attacks by attempting to defend the validity of its scientific findings. Yet, in addition to defending the Agency's scientific research on its own merits, EPA soon came to inflate the role of science,

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[29] *See supra* Part III.B (arguing that the Agency did, in fact, take cost into consideration).

[30] Throughout this Article, we use the terms "science" or "scientific evidence" to refer to the natural sciences, though our discussion would in theory apply to positive social science as well. In addition, while we refer to the "EPA" repeatedly in this Article in its capacity as a legal entity, we recognize that government organizations are not unitary actors, but instead are comprised of many individuals with views that may or may not be in agreement with an agency's official rulemaking documents and court briefs.

[31] *See infra* note 164 and accompanying text (citing the Agency's brief acknowledgment of a policy choice in its *Federal Register* notice).

[32] *See, e.g.*, *Air Quality Standards: Science-Driven Ozone, PM Proposals Will Be Finished by July 19, EPA Says*, 27 Env't Rep. (BNA) 2068 (Feb. 14, 1997) ("Industry officials . . . continued to hammer EPA proposals as lacking a sound scientific basis . . . ."); Allan Freedman, *Latest Fight on Clean Air Rules Centers on Scientific Data*, CONG. Q., Mar. 1, 1997, at 530 (pointing out the tendency of opponents to say that the regulations were based on flimsy science); Joby Warrick, *Panel Seeks Cease-Fire on Air Quality but Gets a War*, WASH. POST, Feb. 6, 1997, at A21 (describing opponents of EPA air quality standards carrying placards reading "EPA—Show me the science").

using science in an attempt to justify its standards in order to provide greater support for its position in the political arena and the courts.[33]

In this Part, we show how EPA appealed to a science-based rhetoric in its ozone and particulate matter rulemakings, and we explain why such an exclusive reliance on science is fundamentally mistaken. Science does properly play a vital role in environmental regulatory decisions, and regulatory agencies do need to develop credible and relevant scientific analysis of environmental risks.[34] Yet regulatory agencies have too often invoked science in order to answer questions that science is not designed to answer.[35] By purporting to rely on science to justify normative policy decisions, agencies succumb to a category mistake, since science speaks to what *is*, rather than to what *should be*.[36] Relying exclusively on science, as EPA has done in its

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[33] A telling anecdote of this shift in EPA's emphasis can be found in Professor Craig Oren's contrasting of two statements by EPA Administrator Carol Browner. Oren, *supra* note 18, at 10,653. In November 1996, at the time the ozone and fine PM standards were first proposed, the EPA Administrator was quoted as stating that "[t]he question is not one of science, the real question is one of judgment." *Air Pollution; Agency Announces Proposals to Toughen Regulations for Ozone, Particulate Matter*, 27 Env't Rep. (BNA) 1571 (Nov. 29, 1996). Four months later, at the height of heated public, congressional, and regulatory debate on the standards, Administrator Browner made a 180-degree reversal, stating that "I think it is not a question of judgment, I think it is a question of science." *Air Quality Standards: Science-Driven Ozone, PM Proposals Will Be Finished by July 19, EPA Says*, *supra* note 32, at 2068. As we outline below in Part I.A, EPA never emerged from its retreat behind the cloak of science and indeed only hid itself further behind its apparent shield. Of course, this is not the first time that EPA has made an about-face on the role of science and policy in its decision making. *See* Sheila Jasanoff, *The Problem of Rationality in American Health and Safety Regulation*, *in* EXPERT EVIDENCE: INTERPRETING SCIENCE IN THE LAW 151, 168-69 (Roger Smith & Brian Wynne eds., 1989) (describing EPA's contradictory characterization of its cancer principles in the context of proceedings involving the pesticides heptachlor and chlordane in the 1970s).

[34] *See* EXPERT PANEL ON THE ROLE OF SCI. AT EPA, EPA, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS 2 (1992) ("Scientific knowledge has assumed an increasingly critical role as the environmental issues faced by the nation and the world grow in complexity and cut across all environmental media."); *see also id.* at 15 ("Strong science provides the foundation for credible environmental decision-making."); MARK R. POWELL, SCIENCE AT EPA: INFORMATION IN THE REGULATORY PROCESS 8 (1999) (noting that science plays "an important part in environmental regulatory decisionmaking"); Administrator Christine Todd Whitman, Remarks at the EPA Science Forum (May 1, 2002) ("Sound science is the foundation of EPA's work."), *available at* http://yosemite.epa.gov/administrator/speeches.nsf.

[35] Wagner, *supra* note 11, at 1617 (arguing that agencies have often used science to "camouflag[e] controversial policy decisions").

[36] This is not to say, of course, that normative judgments cannot affect the way that questions of scientific research are framed or how scientific research is interpreted. On the contrary, especially with policy-relevant research, the ways in which normative judgments enter into the research process can themselves be "disguised in the cloak of

ozone and particulate rulemakings, is as misguided as it would be to disregard relevant scientific information altogether.[37]

A. *"Listen to the Science:" EPA's Use of Science as a Policy Rationale*

Science has considerable rhetorical appeal when it comes to defending regulatory decisions, as it is often described and perceived as being "objective."[38] Because of its perceived objectivity, as well as the extensive advancements in science and technology that have emerged over the past century, science is viewed by the public as highly credible if not even infallible.[39] Politicians and advocates regularly call for government to use "sound science" in making regulatory decisions.[40] For

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objectivity." Peter Brown, *Ethics and Policy Research*, 2 POL'Y ANALYSIS 325, 340 (1976); *see also infra* notes 107-08 and accompanying text (discussing the difficulties in completely separating science and policy when making decisions).

[37] For an argument that agencies sometimes disregard scientific evidence, see James W. Conrad, Jr., *The Reverse Science Charade*, 33 Envtl. L. Rep. (Envtl. L. Inst.) 10,306 (Apr. 2003).

[38] Whether the "objectivity" of science even makes sense as a philosophical or sociological matter is certainly subject to debate. *See* SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 207 (1995) ("There is no way for the law to access a domain of facts untouched by values or social interests."); *see also* SCIENCE WARS (Andrew Ross ed., 1996) (collecting essays critical of the notion of a value-free science); AFTER THE SCIENCE WARS (Keith M. Ashman & Philip S. Baringer eds., 2001) (exploring the debate over the extent to which science is objective versus socially constructed). Regardless of where one stands on this issue, the fact that science is perceived by many people to be "objective" does lend persuasive strength to scientific claims when they are made in political and legal fora. *See, e.g.*, Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1059 (D.C. Cir. 1999) (asserting that because members of EPA's Clean Air Science Advisory Committee (CASAC) bring "scientific methods to their evaluation of the Agency's Criteria Document and Staff Paper, CASAC provides an objective justification for the pollution standards the Agency selects.") (Tatel, J., dissenting); James D. Wilson & J.W. Anderson, *What the Science Says: How We Use It and Abuse It to Make Health and Environmental Policy*, RESOURCES, Summer 1997, at 5, 6 ("To many laymen, certainty and precision is [sic] the essence of science: as they understand it, a scientific question can have only one right answer.").

[39] *See, e.g.*, NAT'L SCI. BD., NAT'L SCI. FOUND., SCIENCE AND ENGINEERING: INDICATORS 2000, at 8-1, 8-13 (2001) (describing public trust in scientists and medical researchers), *available at* http://www.nsf.gov/sbe/srs/seind00/; Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 569-75 (1992) (discussing the "allure of science" in environmental decision making); Samuel J. McNaughton, *What Is Good Science?*, NAT. RESOURCES & ENV'T, Spring 1999, at 513, 519 ("[S]cience in our society has come to have a quality of infallibility attached to it.").

[40] *See, e.g.*, *The Regulatory Flexibility Act: Are Federal Agencies Using "Good Science" in Their Rule Making?: Joint Hearing Before the Subcomm. on Gov't Programs and Oversight and the Subcomm. on Regulation Reform and Paperwork Reduction of the House Comm. on Small Bus.*, 105th Cong. 115 (1997) (prepared statement of James M. Harless, Techna Corp.)

regulators, invoking science to defend a regulatory decision can be an effective and expedient political strategy.[41] Given the political appeal of science, regulatory decision makers have an incentive to exaggerate the determinacy of science in an effort to mask contested policy choices and escape scrutiny.[42] Professor Wendy Wagner has dubbed this practice the "science charade."[43]

("A common refrain today among all stakeholders in the regulatory process is 'use good science.'"), *available at* 1997 WL 10569570.

[41] *See* KAREN T. LITFIN, OZONE DISCOURSES: SCIENCE AND POLITICS IN GLOBAL ENVIRONMENTAL COOPERATION 4 (1994) (observing that science is a "key source of legitimation"); POWELL, *supra* note 34, at 6 (remarking that science "is a favorite weapon in political battles over environmental policy"); Elizabeth Fisher, *Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration*, 20 OXFORD J. LEGAL STUD. 109, 130 (2000) (noting the tendency for increased reliance on science in standard setting because of its perceived objectivity and legitimacy). Not only can policymakers use science to defend decisions to issue new regulatory standards, as EPA did in the case of its revised NAAQS, but they can also use science to defend decisions to defer issuing new standards. For an argument that science has been used as a political defense for regulatory inaction over food safety, see MARION NESTLE, SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM 46 (2003) (noting "the invocation of 'science' as an obstructive measure" thwarting the development of regulations on the use of antibiotics in animal feed).

[42] *See, e.g.*, RICHARD N.L. ANDREWS, MANAGING THE ENVIRONMENT, MANAGING OURSELVES: A HISTORY OF AMERICAN ENVIRONMENTAL POLICY 269 (1999) (asserting that EPA risk-based decisions "in effect used scientific language to mask fundamentally political decisions, and to allow policy to be controlled by an EPA subgovernment rather than by a broader political process"); JASANOFF, *supra* note 38, at 207 (noting "the law's desire to cloak morally difficult judgments with the 'objective' authority of experts and instruments"); LITFIN, *supra* note 41, at 4 ("[T]he cultural role of science as a key source of legitimation means that political debates are framed in scientific terms; questions of value become reframed as questions of fact, with each confrontation leading to the search for further scientific justification."); NAT'L ENVTL. POLICY INST., ENHANCING SCIENCE IN THE REGULATORY PROCESS 5 (1999) (observing that policymakers can blame science "instead of acknowledging social, political, or economic bases for policy decisions and taking responsibility for including those factors in their decisions"); David L. Bazelon, *Risk and Responsibility*, 205 SCIENCE 277, 278 (1979) ("[S]cientists are tempted to disguise controversial value decisions in the cloak of scientific objectivity, obscuring those decisions from political accountability."); Giandomenico Majone, *Science and Trans-Science in Standard Setting*, 9 SCI., TECH., & HUM. VALUES, Winter 1984, at 15, 15 ("Traditionally, government regulators have sought legitimacy for their decisions by wrapping them in a cloak of scientific respectability."); Mark E. Rushefsky, *The Misuse of Science in Governmental Decisionmaking*, 9 SCI., TECH., & HUM. VALUES, Summer 1984, at 47, 47 ("Some policymakers have attempted also to legitimize decisions by clothing them with the 'respectable neutrality' of science."); Andrew D. Siegel, *The Aftermath of* Baltimore Gas & Electric Co. v. NRDC*: A Broader Notion of Judicial Deference to Agency Expertise*, 11 HARV. ENVTL. L. REV. 331, 377 (1987) ("One possible result of the deference [to scientific findings] rule is that agencies will strain to characterize their policy decisions, especially if they are controversial, as resting on technical or scientific judgments."); Eugene B. Skolnikoff, *The Role of Science in Policy*, ENV'T, June 1999, at 17, 19 ("[I]f the level of uncertainty is high enough, science

Perhaps no agency has so mistakenly and prominently advanced science as a justification for its policy decisions as did EPA in defending its recent revisions to air quality standards for ozone and particulate matter. In its rulemaking documents, in the courts, in Congress, and before the general public, EPA invoked science as its exclusive justification for revising its air quality standards.[44] The EPA Administrator repeatedly argued that she simply "listened to the science" in establishing new air quality standards.[45] The Agency generally avoided describing its decisions as policy judgments that required the articulation of a principled explanation for why the standards should be lowered to the chosen level. Instead, EPA defended its decisions as determined exclusively by scientific evidence.[46]

The Clean Air Act specifies the steps EPA must take in setting or revising its air quality standards.[47] The Act provides, in section 108,

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may become the principal lever that all sides use to justify positions reached primarily on other grounds.").

[43] Wagner, *supra* note 11, at 1617.

[44] EPA and other regulatory agencies have had a long history of invoking science as a policy rationale under both Democratic and Republican Administrations. *See generally* Wagner, *supra* note 11 (discussing the exaggeration of science in agency decision making). For example, former Administrator William Reilly, working in the first Bush Administration, called generally for more "science-based regulation," arguing that "EPA must and will continue to rely on a rational, science-based process for determining when to take risk management actions." William Reilly, *Taking Aim Toward 2000: Rethinking the Nation's Environmental Agenda*, 21 ENVTL. L. 1359, 1364 (1991). Since EPA's decisions to revise the ozone and particulate standards were some of the most costly and controversial risk management decisions in the Agency's history, the extent to which EPA used science as a shield was particularly problematic in this instance.

[45] *See infra* notes 71-87 and accompanying text (detailing Administrator Browner's statements that she based the new standards on science).

[46] The science-based rationale deployed by EPA was not merely an example of political rhetoric, as serious legal scholars have also argued for a similar normative justification for environmental standard setting. For example, Dan Tarlock has suggested, with few qualifications, that "environmental law and management should derive their primary political power and legitimacy from science, not ethics." A. Dan Tarlock, *Environmental Law: Ethics or Science?*, 7 DUKE ENVTL. L. & POL'Y F. 193, 194 (1996); *see also* Susan Buck, *Science as a Substitute for Moral Principle*, *in* THE MORAL AUSTERITY OF ENVIRONMENTAL DECISION MAKING 25, 27-30 (John Martin Gillroy & Joe Bowersox eds., 2002) (arguing that most decisions made by environmental regulators are properly based on "scientific and technical information" rather than on "moral principle"). For additional examples, see *infra* notes 117-18 and accompanying text.

[47] 42 U.S.C. §§ 7401-7601 (2000). The Act directs EPA to issue both primary and secondary standards. *Id.* § 7409(a). Primary standards aim at protecting human health, while secondary standards address nonhuman biological and physical effects. *Id.* § 7409(b). Although this Article focuses on EPA's decisions to revise its primary standards for ozone and particulate matter, our discussion of the limits of science also applies to secondary standards.

that the first step in promulgating a new or revised NAAQS is for the Agency to prepare a "criteria document" for the relevant pollutant.[48] The criteria document is required to report "the latest scientific knowledge" on "all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air."[49] Section 109 of the Act then directs the EPA Administrator to use her "judgment" to select a primary NAAQS that is "requisite to protect the public health" based on the criteria document and allowing for "an adequate margin of safety."[50]

In July 1997, EPA promulgated revised primary NAAQS for ozone and particular matter. The Agency revised the previous one-hour, 0.12 ppm, average primary ozone standard to an eight-hour, 0.08 ppm, average standard.[51] It also added two new fine particulate matter standards—a 15 $\mu g/m^3$ annual standard and a 65 $\mu g/m^3$ daily standard for $PM_{2.5}$[52]—while retaining the existing PM_{10} standard with only minor technical changes.[53] In explaining its decision, EPA stressed

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[48] *Id.* § 7408(a).

[49] *Id.* § 7408(a)(2). The criteria documents for the most recent revisions of the ozone and particulate matter standards were voluminous, spanning over 1500 and 2400 pages respectively. Although the stage of preparing these criteria documents can be thought of as akin to the stage of risk assessment discussed below in Part I.B, it is interesting to note that, on its face, the language of the Clean Air Act seems to acknowledge that certain policy considerations need to enter into the Administrator's decision making, even in the process of listing criteria pollutants and developing the criteria documents. Section 7408(a) directs the Administrator (a) to add to the criteria list those air pollutants "which, *in his judgment*, cause or contribute to air pollution which may *reasonably* be anticipated to *endanger* public health or welfare;" (b) to ensure that the criteria documents "*reflect*" the useful and current scientific knowledge (though arguably not necessarily be based solely on such knowledge); and (c) to include in these documents information about the impact of atmospheric patterns, interactions with other pollutants, and any possible impacts on welfare—but only "to the extent *practicable*." *Id.* § 7408(a) (emphases added).

[50] *Id.* § 7409(b)(1).

[51] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857. Compliance with this averaging standard is measured in several steps. First, the mean ozone concentration over every period of eight consecutive hours is continuously measured at a given site. Second, the fourth highest eight-hour average ozone concentration over the entire year is determined. Finally, the three-year average of the annual fourth-highest daily maximum eight-hour ozone concentrations is calculated. If the three-year average is at or below 0.08 ppm, the site is in attainment with the new ozone standard. If it is above 0.08 ppm., it is in nonattainment.

[52] $PM_{2.5}$, or fine particulate matter, refers to particles that are equal to or smaller than 2.5 micrometers in diameter. The term "$\mu g/m^3$" means "micrograms per cubic meter."

[53] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,652. PM_{10} refers to particles that are equal to or smaller than 10 micrometers in diameter.

the sources of information on which it based its decision, principally the risk assessments conducted by the Agency's staff and the advice given by the Agency's Clean Air Science Advisory Committee (CASAC), a panel dedicated to providing EPA with scientific input on air pollution issues.[54] Yet a statement of information sources is not a statement of principles, and nothing in any of these information sources explicated a policy justification for the revised standards.[55]

After EPA promulgated its revised ozone and particulate matter standards, industry groups and three States filed petitions seeking judicial review of the standards in the United States Court of Appeals for the District of Columbia Circuit. In the initial round of this litigation, EPA argued that the Agency's "scientific review" led it "to the inescapable conclusion" that the existing NAAQS were not protecting the public health with an adequate margin of safety.[56] After a panel of the Court of Appeals rejected EPA's decisions on nondelegation grounds, finding that the Agency failed to articulate an intelligible principle to guide its NAAQS selection, EPA appealed to the United States Supreme Court. The Agency argued before the Supreme Court that its decision under the Clean Air Act did not offend the nondelegation doctrine because the Agency had been constrained by three types of factors that together effectively constituted an "intelligible principle."[57] The three factors were the Agency's criteria documents reflecting "the latest scientific knowledge," the advice from CASAC, and the rulemaking requirements of section 307(d) of the Clean Air Act.[58] The first two factors—the criteria documents and CASAC advice—emphasized scientific inputs exclusively.[59] Since the last of these factors was merely a procedural limitation, EPA in effect argued that

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[54] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859; EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,655-56.

[55] For a further discussion of the Agency's science-based argument in the rulemaking process, see *infra* Part II.A.

[56] Brief for Respondent at 3-4, Am. Trucking Ass'ns v. EPA, 195 F.3d 4 (D.C. Cir. 1999) (No. 97-1440) [hereinafter EPA, D.C. Cir. PM Brief].

[57] Brief for Petitioners at 22-24, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257) [hereinafter EPA, Supreme Court Petitioners' Brief].

[58] *Id.* at 23-24.

[59] *Supra* notes 49, 54 and accompanying text. Section 109(d)(2)(C)(iv) required CASAC to provide advice on other issues that go beyond scientific matters, but EPA took the position that "neither CASAC's recommendations nor EPA's decisions on NAAQS revisions may be influenced by § 109(d)(2)(C)(iv) factors." Brief of Respondent at 53, Am. Trucking Ass'ns v. EPA, 195 F.3d 4 (D.C. Cir. 1999) (No. 97-1441) [hereinafter EPA, D.C. Cir. Ozone Brief]. Thus, under EPA's interpretation of the statute, CASAC's advice in NAAQS proceedings was limited to scientific matters.

science alone provided the Agency with its substantive principle for how it selected its NAAQS standards.

EPA offered other statements in its briefs to the Supreme Court that claimed or suggested that its revised standards could be justified on the basis of science alone. For example, it argued that "Congress has unambiguously indicated its intent that NAAQS should be based on scientific evidence regarding the health and welfare effects of ambient pollution."[60] In addition, the Agency argued "that Congress made a policy choice to cabin EPA's discretion by requiring the Agency to set NAAQS on the basis of a specific body of information: the latest scientific knowledge on the public health and welfare effects caused by the presence of criteria pollutants in the ambient air."[61] In its opening brief to the Supreme Court, EPA repeatedly referred to scientific evidence as the basis for its NAAQS standards:

- "EPA revised the PM standards based on new scientific studies that had emerged since EPA's last PM review . . . ."[62]
- "To select the levels requisite to protect public health, with an adequate margin of safety, the Administrator relied chiefly on epidemiological studies that employed direct measures of fine particles . . . ."[63]
- "The scientific evidence convinced the Administrator that she should revise both the averaging time and the concentration level of the 1979 one-hour ozone standard."[64]
- "EPA must consider the factors that the [Clean Air] Act prescribes and provide a reasoned explanation, based on scientific evidence, for its decision."[65]

EPA even suggested that the Supreme Court should be highly deferential to the Agency under the Court's *Baltimore Gas*[66] decision precisely because the selection of NAAQS standards was, it argued, a "scientific determination."[67]

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[60] Brief for the Federal Respondents at 18, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1426) [hereinafter EPA, Supreme Court Respondents Brief].

[61] Reply Brief for Petitioners at 9, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257) [hereinafter EPA, Supreme Court Reply Brief].

[62] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 9.

[63] *Id.* at 10.

[64] *Id.* at 12.

[65] *Id.* at 30.

[66] Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, 462 U.S. 87 (1983).

[67] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 27 ("'When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing

After the Supreme Court upheld EPA's decision on constitutional and statutory grounds, the litigation returned to the D.C. Circuit Court of Appeals for consideration of challenges to the rule under the arbitrary and capricious standard. Again, EPA stressed the scientific basis for the standards. The Agency argued that it had "revised the PM standards based primarily on scientific studies that had emerged since the EPA's last review, including an extensive body of epidemiological studies on exposure to PM pollution."[68] Similarly, in defending its ozone decision, EPA repeatedly invoked scientific factors for its decision, emphasizing in particular that "[s]ignificant new clinical studies provided 'conclusive evidence'" in support of the Agency's action.[69]

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court must generally be at its most deferential.'" (quoting *Baltimore Gas*, 462 U.S. at 103)). The type of "scientific determination" that the Supreme Court referred to in *Baltimore Gas* appears to have been much closer to a science-based prediction than to a more obviously policy-based judgment such as selecting an air quality standard. In that case, the Nuclear Regulatory Commission estimated that the long-term environmental impact of nuclear waste disposal was zero, an action that the Supreme Court characterized as "making predictions, within its area of special expertise, at the frontiers of science." *Baltimore Gas*, 462 U.S. at 103. In its reply brief filed with the Supreme Court, EPA responded to various amici briefs, including one we wrote on behalf of twenty law professors and scientists that argued that EPA had mistakenly claimed that science, by itself, could justify its standard-setting decisions. Brief of Amici Curiae Gary E. Marchant et al., Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257). EPA asserted that "[t]hose amici simply ignore the rulemaking record," but, tellingly, the government cited no policy justification for its decision in the *Federal Register* or elsewhere to support its assertion that the Agency had indeed recognized a need to make a policy rather than a scientific determination. EPA, Supreme Court Reply Brief, *supra* note 61, at 6 n.10. Instead, the Agency only cited two supporting EPA staff papers, neither of which provided any policy justification for the Agency's decisions. *Id.* at 6-7 n.10 ("For example, EPA prepared a detailed 'Policy Assessment of Scientific and Technical Information' in each rulemaking 'to evaluate the policy implications of the key studies and scientific information contained in [the Criteria Document].'" (citation omitted)). It speaks volumes that EPA cited only these supplementary documents, which simply identify a range of possible standards potentially consistent with the scientific evidence and statutory requirements, without identifying any factors or rationales that the Administrator would subsequently rely on to select a particular standard from within this range. Moreover, these documents are neither part of the Administrator's actual decision published in the *Federal Register* nor defended in the Agency's extensive briefs filed with the D.C. Circuit and Supreme Court.

[68] Brief for Respondent at 4, Am. Trucking Ass'ns v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (No. 97-1440) [hereinafter EPA, 2001 D.C. Cir. PM Brief]; *see also id.* at 2 ("In developing the $PM_{2.5}$ standards, EPA relied primarily on studies . . . ."); *id.* at 5 ("To select the levels requisite to protect public health, with an adequate margin of safety, the Administrator relied chiefly on epidemiological studies . . . .").

[69] Brief for Respondent at 8, Am. Trucking Ass'ns, Inc. v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (No. 97-1441) [hereinafter EPA, 2001 D.C. Cir. Ozone Brief]; *see also id.* at 2 (asserting that EPA relied on scientific criteria as the basis for its decision); *id.* at 6 (characterizing the Administrator's decision as "[b]ased on the extensive new science").

EPA also took its science-based rhetoric into the halls of Congress, where the Agency faced intense opposition to its proposed revisions to the ozone and particulate matter standards.[70] At a legislative hearing in February 1997, Administrator Browner testified that "[c]learly, the science calls for action."[71] "In a most compelling way," she continued, "the science leads us to the new, stronger standards that EPA has proposed for smog and soot."[72] She argued that "[s]cience now tell[s] us that our air pollution standards are not adequate to protect the public's health. Let us listen to science."[73]

At another hearing held a few months later, following completion of the public comment period but before announcement of the final standards, Administrator Browner testified to Congress that, "[a]s you can see from the description of the process I went through to choose proposed levels on ozone and particulate matter, the focus has been entirely on health, risk, exposure and damage to the environment."[74] On questioning at the same hearing, the Administrator claimed that "[t]he proposal that we take comment on is based on 250 peer-reviewed, published scientific studies" and that "the best available current science . . . forms the proposal we have made to the American people."[75] When urged by one member of Congress to keep an open mind on the multiple alternatives that might meet the statutory requirements, the Administrator replied succinctly: "We will go where the science takes us."[76]

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[70] Steven P. Croley, *Public Interested Regulation*, 28 FLA. ST. U. L. REV. 7, 63-65 (2000) (describing the intense congressional hearings as "no picnic, for Browner especially"); Wilson & Anderson, *supra* note 38, at 6 ("In congressional hearing after hearing, EPA's Administrator, Carol Browner, defended her proposed standards as merely reflecting 'the science.'"). Again, this strategy may have also helped defend against critics who attacked the credibility of EPA's scientific analysis. *See supra* notes 38, 41 and accompanying text (noting the reliance on science based on its supposed objectivity).

[71] *Clean Air Act: Ozone and Particulate Matter Standards: Hearing Before the Subcomm. on Clean Air, Wetlands, Private Property and Nuclear Safety of the Senate Comm. on Env't and Pub. Works*, 105th Cong. (1997) (testimony of Carol M. Browner, Administrator, EPA).

[72] *Id.*

[73] *Id.*

[74] *EPA's Particulate Matter and Ozone Rulemaking: Is EPA Above the Law?: Hearings Before the Subcomm. on Nat'l Econ. Growth, Nat. Res., and Regulatory Affairs of the House Comm. on Gov't Reform and Oversight*, 105th Cong. 360, 380 (1997) (statement of Carol M. Browner, Administrator, EPA) [hereinafter April 23, 1997 Hearing].

[75] *Id.* at 396-97.

[76] *Id.* at 409; *see also Joint Hearing Before Subcomms. on Health & Env't and Oversight & Investigations of the House Commerce Comm.*, 105th Cong. 265 (1997) (testimony of Carol A. Browner, Administrator, EPA) [hereinafter Browner, May 15, 1997 Hearing] (stating that "we should go where the science takes us").

Shortly after finalizing the ozone and PM standards, Administrator Browner appeared before Congress to explain her decision. But in that setting, she identified only scientific factors in her decision making:

> Clearly, the best available science shows that the previous standards were not adequately protecting Americans from the hazards of breathing polluted air.
>
> . . . .
>
> These updated standards are based on more than 250 of the latest, best scientific studies on ozone and PM—all of them published, peer-reviewed, fully-debated and thoroughly analyzed by the independent scientific committee, CASAC. We're talking literally peer review of peer review of peer review.
>
> It is good science. It is solid science.[77]

At other legislative hearings, Administrator Browner stated that the science "determined" or "warranted" the new standards.[78]

EPA continued to invoke science in public speeches, media interviews, and press releases.[79] For example, when EPA proposed the revised ozone and PM standards, its press release claimed that Congress required the proposed standards to be "based solely upon the best current scientific opinion on public health effects"[80] and that accordingly the Agency "will use the very best science to do what is necessary to protect public health in common-sense, cost-effective ways."[81] The

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[77] *Clean Air Act Implementation: Joint Hearing Before Subcomms. on Health & Env't and Oversight & Investigations of the House Commerce Comm.*, 105th Cong. (1997) (testimony of Carol A. Browner, Administrator, EPA).

[78] *E.g.*, Browner, May 15, 1997 Hearing, *supra* note 76, at 263 (arguing that EPA's regulatory process is designed "to achieve the goals set forth in the Clean Air Act that every American breathe clean, healthy air as determined by the latest and best scientific information."); *id.* ("[I]f the science warrants a revision to the standards, the law sets forth a reasonable and rational procedure for implementation . . . ."); *Hearing Before the Subcomm. on Energy & Env't of the House Comm. on Sci.*, 105th Cong. (May 21, 1997) (testimony of Carol A. Browner, Administrator, EPA) (repeating that the law prescribes the implementation process "if the science warrants a revision in the standards").

[79] The Administrator was not the only EPA official to invoke science as the Agency's justification for its NAAQS revisions. In an interview, EPA's General Counsel was likewise quoted as saying: "'Even without the consideration of cost, there are sound scientific reasons for setting the standards at a particular level.'" David Rubenstein, *Legions of Business Groups Take on the Clean Air Act*, CORP. LEGAL TIMES, Oct. 2000, at 96 (quoting EPA General Counsel Gary S. Guzy).

[80] Press Release, EPA, EPA Proposes Air Standards for Particulate Matter & Ozone (Nov. 27, 1996), http://yosemite.epa.gov/opa/admpress.nsf.

[81] *Id.* (quoting EPA Administrator Carol M. Browner).

Agency's press release also quoted Administrator Browner as stating that "'EPA has based its proposal on a thorough review of the best available science.'"[82]

In defending her selection of the proposed standards to the public, the Administrator told reporters at an Agency briefing that "I think it is not a question of judgment, I think it is a question of science."[83] In Philadelphia, she told the local Chamber of Commerce that "[t]he Clean Air Act clearly requires levels of smog and soot to be based solely on health, risk, exposure and damage to the environment, as determined by the best available science."[84] The Administrator continued by stating that "[t]he current best science must prevail in determining the level of protection the public will be guaranteed. Nothing else can take precedence."[85] In a speech to the American Enterprise Institute on the proposed air quality standards, Administrator Browner stated that "[t]he science is clear and compelling . . . . We have to go where the best available science leads us."[86] Claiming that science determined the adequacy of the Agency's revised standards, Administrator Browner typically ended her speeches on the ozone and PM NAAQS with the admonition: "Let us listen to the science."[87]

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[82] *Id.*

[83] *Science-Driven Ozone, PM Proposals Will Be Finished by July 19, EPA Says*, 27 Env't Rep. (BNA) 2068 (Feb. 14, 1997).

[84] Administrator Carol M. Browner, Remarks Before the Greater Philadelphia Chamber of Commerce (May 12, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf.

[85] *Id.* The Administrator repeated this statement in other speeches. For an example of such a speech, see Administrator Carol M. Browner, Remarks Before the Society of Environmental Journalists (May 17, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf.

[86] Administrator Carol M. Browner, Remarks at the American Enterprise Institute Conference: Clearing the Air: An Examination of EPA's Proposed Regulations for Particulate Matter and Ozone (Feb. 10, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf. In a speech to the City Club of Cleveland, the Administrator stated that EPA was being "truthful" to the American people by telling them that science dictated the new standards. Administrator Carol M. Browner, Remarks Before the City Club of Cleveland (Mar. 25, 1997), *available at* http://yosemite.epa.gov/administrator/speeches.nsf [hereinafter Browner, Cleveland Speech] (claiming that "[s]cience now tells us that our air pollution standards are not adequate to protect the public's health" and arguing that EPA needed to "tighten those standards in order to ensure that we are being truthful with the American people about the quality of the air they are breathing and what it is doing to them").

[87] Browner, Cleveland Speech, *supra* note 86; *see also* Browner, *supra* note 84; Browner, *supra* note 85; John H. Cushman, Jr., *On Clean Air, Environmental Chief Fought Doggedly, and Won*, N.Y. TIMES, July 5, 1997, at A8 (quoting Administrator Browner as stating that "[w]hat we have done is follow the science").

B. *Standard Setting, Science, and the Management of Risk*

Although EPA invoked science as its core defense for its NAAQS revisions, doing so mistook the ability of science to serve as a principle for setting environmental policy standards. Science describes; it does not prescribe. Scientific claims are empirical rather than normative. Science seeks to supply verifiable descriptions of—and explanations and inferences about—what *is*, rather than imposing judgments about what *should be*.[88] While science provides valuable information needed for regulatory decisions, science cannot *on its own* dictate the appropriate decision about where to set environmental standards.[89]

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[88] *See, e.g.*, Lee Epstein & Gary King, *The Rules of Inference*, 69 U. CHI. L. REV. 1, 19-20 (2002) ("[A]ll empirical research seeks to accomplish one of three ends, or more typically some combination thereof: *amassing data* for use by the researcher or others; *summarizing data* so they are easier to comprehend; and *making descriptive or causal inferences* . . . ."); Marcia R. Gelpe & A. Dan Tarlock, *The Uses of Scientific Information in Environmental Decisionmaking*, 48 S. CAL. L. REV. 371, 385 (1974) ("Science is concerned with describing physical relationships and thus with drawing inferences from observed to unobserved behavior."); Lee Loevinger, *The Distinctive Functions of Science and Law*, 24 INTERDISC. SCI. REV. 87, 87 (1999) ("The function of science is to enlarge our knowledge and understanding of both the natural and cultural environments in which we live . . . . Thus, the role of science is to learn, to report, and to teach—but only facts."); Peter H. Schuck, *Multi-Culturalism Redux: Science, Law, and Politics*, 11 YALE L. & POL'Y REV. 1, 4 (1993) ("Science appeals to the capacity of technical rationality and specialized expertise to generate and test empirically falsifiable propositions."); *see also* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590 (1993) (noting that science is "'a *process* for proposing and refining theoretical explanations about the world'" (quoting Brief for the American Association for the Advancement of Science et al. as Amici Curiae at 7-8, *Daubert* (No. 92-102))).

[89] *See, e.g.*, JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 218 (1988) (observing that "science cannot answer the ultimate regulatory questions"); NAT'L ACAD. OF PUB. ADMIN., SETTING PRIORITIES, GETTING RESULTS: A NEW DIRECTION FOR EPA 61 (1995) ("Technical information can inform EPA's decisions, but the decisions remain policy judgments with political and ethical components."); John S. Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decision-Making*, 63 U. CIN. L. REV. 1643, 1645 (1995) ("Risk is appropriately the starting point of much standard setting and priority setting for health-based environmental regulation, but other factors must have equal weight . . . . [I]t is the business of public policy, not of science, to decide how these problems should be handled."); Paul Fischbeck et al., *The Challenge of Improving Regulation*, *in* IMPROVING REGULATION: CASES IN ENVIRONMENT, HEALTH, AND SAFETY 1, 4 (Paul Fischbeck & R. Scott Farrow eds., 2001) ("Even in the best of worlds, good science is rarely sufficient for informed regulatory decisionmaking."). To say that science alone is insufficient is not to say that science is not helpful, or even essential, for setting regulatory policy. Setting regulatory standards requires both ethical or policy analysis as well as scientific information. *See* ROBERT A. DAHL, DEMOCRACY AND ITS CRITICS 69 (1989) (acknowledging that, although "both moral understanding and instrumental knowledge are always necessary for policy judgments, neither alone can ever be sufficient").

To clarify the role of science in setting environmental policy, we distinguish in this Section between two aspects of the standard-setting process: "risk assessment" and "risk management." The National Research Council of the National Academy of Sciences (NAS/NRC) recognized this distinction between risk assessment and risk management in its influential 1983 report known as the *Red Book*,[90] which established a framework for risk-based decision making that regulatory agencies continue to follow today. The *Red Book* defined risk assessment as "the characterization of the potential adverse health effects of human exposures to environmental hazards."[91] Risk assessment is based extensively on scientific information, supplemented with what have been termed "risk assessment policy" judgments to bridge gaps and uncertainties in the scientific evidence.[92] Risk assessment is therefore considered to be predominantly—though not exclusively[93]—based on scientific evidence and analysis.[94]

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[90] NAT'L RESEARCH COUNCIL, NAT'L ACAD. OF SCI., RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter NAS/NRC RED BOOK]; *see also* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 9 (1993) (recognizing that risk regulation "has two basic parts, a technical part, called 'risk assessment,' designed to measure the risk associated with the substance, and a more policy-oriented part, called 'risk management'").

[91] NAS/NRC RED BOOK, *supra* note 90, at 18; *see also* 2 THE PRESIDENTIAL/CONGRESSIONAL COMM'N ON RISK ASSESSMENT AND RISK MGMT., FINAL REPORT: RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION-MAKING 2 (1997) [hereinafter RISK COMM'N] ("Risk assessment is the systematic, scientific characterization of potential adverse effects of human or ecological exposures to hazardous agents or activities."), *available at* http://www.epa.gov/ncea/pdfs/riskcom/riskcom2.pdf.

[92] NAS/NRC RED BOOK, *supra* note 90, at 37. Such risk assessment policy judgments include factors such as which health effects to consider and group together, the type of models and assumptions to use in the risk assessment, how to extrapolate data from one small segment of a population to the entire population, and how to compute, present, and account for uncertainties. *Id.* at 29-33; *see also* REGULATORY IMPACT ANALYSIS PROJECT, INC., CHOICES IN RISK ASSESSMENT: THE ROLE OF SCIENCE POLICY IN THE ENVIRONMENTAL RISK MANAGEMENT PROCESS, at xi (1994) (acknowledging that there are "gaps and uncertainties in scientific knowledge, data, and methodology that arise in the assessment of risks to human health and the environment associated with exposure to substances, conditions, activities, and sites"), *available at* http://www.library.ucsf.edu/tobacco/batco/html/600/687/otherpages/7.html; Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 732-47 (1979) (discussing a range of science policy issues that arise in risk regulation including the sufficiency of data and varying scientific interpretations of data).

[93] *See* DANIEL M. BYRD III & C. RICHARD COTHERN, INTRODUCTION TO RISK ANALYSIS: A SYSTEMATIC APPROACH TO SCIENCE-BASED DECISION MAKING 6-8, 330-34 (2000) (noting that risk assessment inherently and inevitably involves some judgment); Sheila Jasanoff, *Contested Boundaries in Policy-Relevant Science*, 17 SOC. STUD. SCI. 195, 211 (1987) (observing that analysts have "agreed that very little in a typical risk

Risk management, on the other hand, is "an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard."[95] It "necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control."[96] As a subsequent National Research Council report reiterated, "science alone can never be an adequate basis for a risk decision" because "[r]isk decisions are, ultimately, public policy choices."[97] The U.S. Supreme Court has likewise recognized that the risk management decision of selecting the level at which to set health and

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assessment could be labeled as pure science"); Mark E. Rushefsky, *Assuming the Conclusions: Risk Assessment in the Development of Cancer Policy*, 4 POL. & LIFE SCI. 31, 31 (1985) (arguing that "[i]n reality facts and values in policy making are hopelessly mixed"). Even the NRC, in its "1983 report and accompanying working papers[,] acknowledged that risk assessment unavoidably combined elements of both science and policy." Sheila Jasanoff, *Science, Politics, and the Renegotiation of Expertise at EPA*, 7 OSIRIS 194, 209 (1992) [hereinafter Jasanoff, *Science, Politics, and the Renegotiation of Expertise*]; *see also infra* note 108 and accompanying text (recognizing the roles that both science and policy play in risk assessments).

[94] *See* GAIL CHARNLEY, DEMOCRATIC SCIENCE: ENHANCING THE ROLE OF SCIENCE IN STAKEHOLDER-BASED RISK MANAGEMENT DECISION-MAKING (2000) ("[R]isk assessment generally constitutes the vehicle for including science in risk management decision-making . . . . [R]isk assessment is based on science to the extent possible and on judgment when necessary."), *available at* http://www.epa.gov/sab/pdf/eccm01006appne.pdf; Frank Cross, *The Public Role in Risk Control*, 24 ENVTL. L. 887, 889-90, 90 n.5 (1994) ("[Even though] purely scientific judgments contain underlying values[,] [i]n the case of risk assessment . . . the overriding value is accuracy [in determining] . . . the objective probability of an event's occurrence. Value judgments are largely irrelevant to the probabilistic determination of scientific risk." (footnote omitted)).

[95] NAS/NRC RED BOOK, *supra* note 90, at 18-19; *see also* NAT'L ACAD. OF PUB. ADMIN., *supra* note 89, at 37 ("[Risk management] includes a wide array of actions such as writing and enforcing regulations, providing information and technical assistance, and establishing market incentives for risk reduction."); RISK COMM'N, *supra* note 91, at 2 (finding that "risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems" for the purpose of adopting "scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations").

[96] NAS/NRC RED BOOK, *supra* note 90, at 19; *see also* Oren, *supra* note 18, at 10,660 ("[T]he decision of who should be protected, and what effects they should be protected against, is an ethical decision, not a scientific one.").

[97] NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 26 (1996).

environmental standards is primarily a policy, rather than a scientific, undertaking.[98]

While risk assessment is thus conventionally understood to be predominantly (but not exclusively) a scientific undertaking, risk management decisions, including the selection of regulatory standards, require making value judgments that extend beyond the scope of science.[99] The *Red Book* recommended that regulatory agencies "maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies."[100]

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[98] In the Court's 1980 review of the Occupational Safety and Health Act's (OSHA) benzene occupational exposure standard, Justice Marshall's dissenting opinion stated:

> [W]hen the question involves determination of the acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of the facts.

Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 706 (1980) (Marshall, J., dissenting). The plurality opinion responded directly to Justice Marshall's policy argument: "We agree. Thus, while the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." *Id.* at 656 n.62 (plurality opinion); *see also* EDLEY, *supra* note 6, at 75 (noting that in setting new OSHA standards "[s]cience alone . . . cannot determine what to do with [the] uncertainties" and that "[t]he science is inseparable from the value choices which are the familiar grist of political decision making").

[99] *See* WILLIAM W. LOWRANCE, OF ACCEPTABLE RISK 75-76 (1976) ("Determining safety, then, involves two extremely different kinds of activities . . . . Measuring risk—measuring the probability and severity of harm—is an empirical, scientific activity; Judging safety—judging the acceptability of risks—is a normative, political activity."); Fisher, *supra* note 41, at 130 ("[Risk] standards are normative prescriptions which require the balancing of different social and political factors and the consideration of scientific and other specialist information in the context of scientific uncertainty."); *see also* Jocelyn Kaiser, *Showdown over Clean Air Science*, 277 SCIENCE 466, 469 (1997) ("Deciding whether to set a stringent standard . . . 'becomes a value judgment. It's not a scientific question.'" (quoting environmental health scientist Arthur Upton)).

[100] NAS/NRC RED BOOK, *supra* note 90, at 7. Even though the authors of the *Red Book* argued for conceptual clarity in distinguishing between risk assessment and risk management, this does not mean that they did not acknowledge that policy considerations entered into the risk assessment process. *See id.* (noting "the scientific findings and policy judgments embodied in risk assessments"); *see also* Jasanoff, *supra* note 33, at 171 (arguing that the *Red Book* "definitively established that most of the determinations made in the process of carcinogenic risk assessment involve a mixture of science and policy").

In other contexts, EPA has endorsed and relied on the NAS/NRC's distinction between risk assessment and risk management.[101] For example, in a recent EPA guidance document on conducting risk analysis, EPA directed Agency staff to separate risk assessment from risk management, with risk assessment involving the selection, evaluation, and presentation of "scientific information," but not "decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks."[102] In contrast, EPA noted that risk management decisions should be based on, to the extent

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[101] EPA describes the "risk assessment/risk management paradigm" as an "important Agency organizing principle." Office of Research and Development, EPA, *Risk Assessment*, *at* http://www.epa.gov/ord/htm/risk.htm (last visited Feb. 10, 2004); *accord* William D. Ruckelshaus, *Risk, Science, and Democracy*, ISSUES SCI. & TECH., Spring 1985, at 19, 28 (representing a former two-time EPA Administrator's view that there should be a "strict distinction" between risk assessment and risk management "in all statutes seeking to deal with risk"); *see also* Announcement of Preliminary Determinations for Priority Contaminants on the Drinking Water Contaminant List, 67 Fed. Reg. 38,222, 38,225 (June 3, 2002) (noting that EPA's overall approach to research on drinking water contaminants "is closely aligned with the 1983 National Research Council (NRC) risk assessment/risk management paradigm").

> Risk assessment . . . defines the potential adverse health consequences of exposure to a toxic agent. The other component, risk management, combines risk assessment with . . . socioeconomic, technical, political, and other considerations, in order to decide whether to control future exposure to the suspected toxic agent and, if so, the nature and level of control.

Guidelines for Neurotoxicity Risk Assessment, 63 Fed. Reg. 26,926, 26,928 (May 14, 1998).

> [R]isk assessment and risk management are two distinct activities. The former involves the evaluation of the likelihood of adverse effects, while the latter involves the selection of a course of action in response to an identified risk that is based on many factors (e.g., social, legal, political, or economic) in addition to the risk assessment results.

Guidelines for Ecological Risk Assessment, 63 Fed. Reg. 26,846, 26,852 (May 14, 1998); *see also* Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,960 (Apr. 23, 1996) (citing NAS/NRC report as recommending risk assessment guidelines "to ensure that the risk assessment process was maintained as a scientific effort separate from risk management"); Guidelines for Developmental Toxicity Risk Assessment, 56 Fed. Reg. 63,798, 63,800 (Dec. 5, 1991) ("Risk assessment . . . defines the potential adverse health consequences of exposure to a toxic agent," while risk management "combines risk assessment with . . . socioeconomic, technical, political, and other considerations."); Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,992-93 (Sept. 24, 1986) (stipulating that risk assessment should "use the most scientifically appropriate interpretation" and "be carried out independently from considerations of the consequences of regulatory action"); Sci. Pol'y Council, EPA, *Guidance for Risk Characterization*, *at* http://www.epa.gov/OSP/spc/rcguide.htm (Feb. 1995) ("In 1984, EPA endorsed these [NAS/NRC] distinctions between risk assessment and risk management for Agency use, and later relied on them in developing risk assessment guidelines." (endnotes omitted)).

[102] Sci. Pol'y Council, *supra* note 101.

permissible, a consideration of "technical feasibility (e.g., treatability and detection limits), economic, social, political, and legal factors," in addition to the output of the risk assessment process.[103] According to the EPA guidance document, "risk assessors and managers should understand that the regulatory decision is usually not determined solely by the outcome of the risk assessment."[104] In order to make risk assessments "transparent," EPA has further stated that it is important "that the conclusions drawn from the science are identified separately from policy judgments."[105] Risk management, the Agency has acknowledged, "goes beyond scientific considerations alone."[106]

Of course, in practice the distinction between risk assessment and risk management is surely not as clear cut as the distinction made in the *Red Book* might suggest.[107] This is because policy considerations almost invariably underlie, and may even dominate, many of the choices made in conducting a risk assessment, just as they inherently must pervade risk management determinations.[108] For this reason, a

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[103] *Id.*; *see also* EPA, SCIENCE POLICY COUNCIL HANDBOOK: RISK CHARACTERIZATION 51 (2000) ("The scientific risk assessment and its peer review provide the sound scientific underpinnings for a decision. However, it is only one of the many factors that a decision maker considers in arriving at a final environmental decision.").

[104] Sci. Pol'y Council, *supra* note 101.

[105] Draft Water Quality Criteria Methodology Revisions: Human Health, 63 Fed. Reg. 43,756, 43,769 (Aug. 14, 1998).

[106] Guidelines for Neurotoxicity Risk Assessment, *supra* note 101, 63 Fed. Reg. at 26,928.

[107] *See* Jasanoff, *Science, Politics, and the Renegotiation of Expertise*, *supra* note 93, at 209 (noting the "impracticability of cleanly separating science from policy").

[108] *See* CARNEGIE COMM'N ON SCI., TECH., & GOV'T, RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING 69 (1993) ("The lines between science, science policy, and policy are fuzzy and wavering."); MARC K. LANDY ET AL., ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS 186 (2d ed. 1994) ("[T]here is no way to make a simple separation between the 'scientific' and the 'policy' aspects of labeling a compound 'carcinogenic.'"); Mary R. English, *Can Risk Assessment and Risk Prioritization Be Extricated from Risk Management?*, *in* RISK ASSESSMENT IN SETTING NATIONAL PRIORITIES 495, 496 (James J. Bonin & Donald E. Stevenson eds., 1989) (arguing that many risk assessments require policy considerations); Sheila Jasanoff, *Bridging the Two Cultures of Risk Analysis*, 13 RISK ANALYSIS 123, 129 (1993) ("[T]he principles by which we organize the 'facts' of risk have to derive, at least in part, from underlying concerns of public policy . . . ."); Sheila Jasanoff, *Relating Risk Assessment and Risk Management: Complete Separation of the Two Processes is a Misconception*, 19 EPA J. 35, 35 ("Risk assessment . . . requires the exercise of subjective judgment . . . [which] must remain sensitive to the policy context."); Howard Kunreuther & Paul Slovic, *Science, Values, and Risk*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 116, 119 (1996) (discussing "the subjective and value-laden nature of risk assessment"); Paul Slovic, *Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield*, 1997 U. CHI. LEGAL F. 59, 95 (1997) ("Risk assessment is inherently subjective

subsequent National Research Council report has cautioned against making a strict separation in practice between the conceptually distinct aspects of risk assessment and risk management because nonscientific considerations, including policy concerns and deliberation, are relevant to risk assessment.[109] That said, agencies and commentators continue to maintain that, notwithstanding the unavoidable intrusion of certain policy considerations, the process of risk assessment remains primarily a scientific undertaking that should be treated as largely distinct from the policy-dominated domain of risk management.[110]

For the purposes of this Article, the debate over how sharply to distinguish risk assessment from risk management is not crucial because it is a debate that focuses on how to characterize the risk assessment enterprise.[111] Those who reject a strict dichotomy between risk assessment and risk management do so because they conclude

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and represents a blending of science and judgment with important psychological, social, cultural, and political factors.").

[109] NAT'L RESEARCH COUNCIL, *supra* note 97, at 34.

[110] *See, e.g.*, International Standard-Setting Activities, 67 Fed. Reg. 37,760, 37,770-71 (May 30, 2002) (defining risk assessment as a "scientifically based process" and risk management as a "process, distinct from risk assessment, of weighing policy alternatives . . . and, if needed, selecting appropriate prevention and control options"); Guidelines for Neurotoxicity Risk Assessment, *supra* note 101, 63 Fed. Reg. at 26,950 (distinguishing risk characterization (assessment) from risk management and noting that "[t]he risk manager uses the results of the risk characterization along with other technological, social, and economic considerations in reaching a regulatory decision"); Bernard D. Goldstein, *If Risk Management Is Broke, Why Fix Risk Assessment?*, 19 EPA J. 37, 37 ("[R]isk management is contextual, with the best decision being related to time and place, while risk assessment inherently embraces the concept that there is a single right assessment for all time."); Howard Raiffa, *Science and Policy: Their Separation and Integration in Risk Analysis*, *in* THE RISK ANALYSIS CONTROVERSY: AN INSTITUTIONAL PERSPECTIVE 27, 28 (Howard C. Kunreuther & Eryl V. Ley eds., 1982) (distinguishing between risk "assessment" and risk "evaluation"); Ruckelshaus, *supra* note 101, at 28 ("It is impossible to evaluate the merits of these positions without first drawing a distinction between the assessment of risk and the process of deciding what to do about it, which is 'risk management.'"); *see also* GRAHAM ET AL., *supra* note 89, at 218 (calling for a "neoseparationist" approach which would entail "a good-faith attempt by regulatory institutions to address separately and explicitly the extent of risks from chemical exposures and the acceptability of such risks").

[111] *See, e.g.*, CARNEGIE COMM'N ON SCI., TECH., & GOV'T, *supra* note 108, at 78 (acknowledging that risk assessment can be "assumption- and value-laden"); LANDY ET AL., *supra* note 108, at 200 ("Risk assessment is an enterprise that is neither wholly scientific nor wholly independent of science."); Terry Davies, *Risk Assessment in Environmental Policy*, EARTH MATTERS 8 (Mar. 1999) (noting that "the practice of risk assessment has, from the beginning, been a hybrid mixture of science and non-science"), *available at* http://www.earthinstitute.columbia.edu/library/earthmatters/march99/Pages/page8.html.

that social values inevitably enter into (or should enter into) risk assessment judgments, not because they believe risk management decisions can be based solely on science.[112] In the debate over the separation of risk assessment and risk management, neither side disputes that risk management decisions are normative.[113]

We have highlighted the distinction between risk assessment and risk management here because a decision about where to set an air quality standard falls squarely in the domain of risk management.[114]

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[112] *See, e.g.*, Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 90 (1988) (challenging the conventional separation between risk assessment and risk management by arguing that "social policy considerations must play as prominent a role in the choice of risk estimates [i.e., risk assessment] as in the ultimate determination of which predicted risks should be deemed unacceptable [i.e., risk management]"). In part, this criticism emerges because the conventional separation between risk assessment and risk management serves to draw a boundary that may make it appear as if risk assessment is a purely scientific enterprise. *See, e.g.*, BYRD & COTHERN, *supra* note 93, at 335 (noting that risk assessors at times "attempt to disguise . . . values and ethics in some decisions with scientific or technical labels"). Of course, demarcating where science ends and policy begins, sometimes referred to as "boundary work," is seldom easy or uncontestable. *See generally* THOMAS F. GIERYN, CULTURAL BOUNDARIES OF SCIENCE: CREDIBILITY ON THE LINE 66 (1999) ("Boundary work gets especially interesting when it happens in places of power, for the demarcation games played out there often have large consequences for the symbolic and material conditions of scientific work."); Thomas F. Gieryn, *Boundaries of Science*, *in* HANDBOOK OF SCIENCE & TECHNOLOGY STUDIES 393, 393 (Sheila Jasanoff et al. eds., rev. ed. 1995) (focusing on "the "boundary problem" in science and technology studies: Where does science leave off, and society—or technology—begin? Where is the border between science and non-science?").

[113] *See generally* Ralph L. Keeney, *The Role of Values in Risk Management*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 126, 134 (concluding that "values are crucial to risk management").

[114] The development of a regulatory standard is the quintessential risk management decision. *See* NAT'L ACAD. OF PUB. ADMIN, *supra* note 89, at 37 (noting that risk management includes "writing and enforcing regulations"); RISK COMM'N, *supra* note 91, at 2 (describing the "traditional definition" as referring "to the process of evaluating alternative regulatory actions and selecting among them," though arguing for a still broader conception of risk management to include voluntary, private sector initiatives), *available at* http://www.epa.gov/ncea/pdfs/riskcom/riskcom1.pdf; Fisher, *supra* note 41, at 113 (arguing that "risk regulation standards are *regulative* and thus *normative* prescriptions"). EPA has frequently characterized air quality standard setting as a risk management process. *See, e.g.*, National Emission Standards for Hazardous Air Pollutants: Pesticide Active Ingredient Production, 64 Fed. Reg. 33,550, 33,553 (to be codified at 40 C.F.R. pts. 9, 63) (June 23, 1999) (noting that "[t]he EPA's risk management strategy could include the development of risk based emission standards under the [Clean Air Act]"); National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,668 (to be codified at 40 C.F.R. pt. 50) (July 18, 1997) (referring to the risk management for a "short-term . . . standard"); National Ambient Air Quality Standards for Ozone and Particulate Matter, 61 Fed. Reg. 29,719, 29,723 (to be codified at 40 C.F.R. pt. 50) (June 12, 1996) (describing EPA's decision as one

EPA's national ambient air quality standards represent the core risk management objectives for the nation, with significant regulatory ramifications depending on the levels at which these standards are set. Areas of the country that do not attain a level of air quality meeting NAAQS are subject to more stringent regulatory controls, such as standards for reformulated gasoline, automobile inspection and maintenance programs, and tighter federal standards for the development of new sources of pollution.[115] In setting NAAQS, or any other regulatory standard, EPA officials need to draw upon the available scientific evidence on the health effects of different pollutants, but ultimately they must make a decision based on factors other than just the science. Standing alone, scientific data on ozone and particulate matter do not, and cannot, provide a principled justification for the level at which the respective air quality standards are set.[116]

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of "selecting a suite of standards that would focus risk management approaches"); Proposed Requirements for Designation of Reference and Equivalent Methods for $PM_{2.5}$ and Ambient Air Quality Surveillance for Particulate Matter, 61 Fed. Reg. 65,780, 65,793 (Dec. 13, 1996) (to be codified at 40 C.F.R. pts. 53, 58) (referring to "the risk management approach of the proposed new $PM_{2.5}$ NAAQS"); Revised Requirements for Designation of Reference and Equivalent Methods for $PM_{2.5}$ and Ambient Air Quality Surveillance for Particulate Matter, 62 Fed. Reg. 38,764, 38,780 (to be codified at 40 C.F.R. pts. 53, 58) (July 18, 1997) (noting EPA's "risk management approach" in setting NAAQS); NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors, 64 Fed. Reg. 52,828, 52,841 (to be codified at 40 C.F.R. pts. 60, 63, 260, 261, 264, 265, 266, 270, 271) (Sept. 30, 1999) (characterizing decisions about "the protectiveness of the MACT standards" as "national risk management decisions"); National Emission Standards For Hazardous Air Pollutants: Standards for Inorganic Arsenic, 51 Fed. Reg. 27,956, 27,957 (to be codified at 40 C.F.R. pt. 61) (Aug. 4, 1986) (describing EPA's "Risk Management Approach" to selecting standards); National Emission Standards For Hazardous Air Pollutants: Regulation of Radionuclides, 49 Fed. Reg. 43,906, 43,909 (Oct. 31, 1984) (to be codified at 40 C.F.R. pt. 61) ("[T]he individual facts, calculational operations, scientific judgments, and estimates of uncertainty [are] documented and integrated in a clear and logical manner to provide a risk assessment that can be used as a scientific basis for risk management purposes, i.e., standard-setting.").

[115] *See* 42 U.S.C. § 7503(a), (c) (2000) (permit requirements); *id.* § 7507 (new motor vehicle emissions standards); *id.* § 7511a (state submission requirements); *id.* § 7512(a) (classification and attainment dates for nonattainment areas); *id.* § 7513 (additional classification and attainment dates); *id.* § 7545 (fuel regulation).

[116] *See* Lead Indus. v. EPA, 647 F.2d 1130, 1146 (D.C. Cir. 1980) (recognizing that the selection of a NAAQS "presents complex questions of science, law, and social policy under the Act"); *Reauthorization of the Clean Air Act Reauthorization: Hearing Before the Senate Subcomm. on Clean Air, Wetlands, Private Property and Nuclear Safety of the Comm. on Env't & Pub. Works*, 106th Cong. (1999) (statement of John D. Graham, former Director of the Harvard Center for Risk Analysis) [hereinafter Graham Testimony] ("[S]cientific information (alone) does not typically provide an intelligible basis for the setting of safe (yet non-zero) amounts of air pollution."); Morton Lippmann, *Role of Science Advisory Groups in Establishing Standards for Ambient Air Pollutants*, 6 AEROSOL

C. *The Clean Air Act and the Problem of Non-Threshold Pollutants*

Given the way the Clean Air Act has been written and interpreted, scholars have sometimes suggested that EPA not only can, but legally must, base its NAAQS decisions solely on science. For example, Professor Lisa Heinzerling has argued that EPA properly revised its standards "based on mounting scientific evidence of the harmfulness of these pollutants at levels allowed by the existing standards."[117] Similarly, Professor Robert Percival has argued that the "EPA's determination of what levels of air pollution harm health has consistently been understood to require a judgment based on science, not economics."[118] It is true that the Clean Air Act specifies the steps EPA must take in setting or revising its air quality standards,[119] and that these steps have been interpreted to preclude the consideration of costs.[120] But even though the statute may constrain EPA in certain ways, it remains inherently necessary to make risk management policy judgments when setting air quality standards.

As noted earlier, the Clean Air Act provides that in promulgating a new or revised NAAQS, EPA must draw upon a "criteria document"

SCI. & TECH. 93, 114 (1987) (suggesting that with respect to setting NAAQS standards, "[s]cience and scientists cannot solve all of the EPA's problems"); Oren, *supra* note 18, at 10,660 (arguing that "the decision of who should be protected, and what effects they should be protected against, is an ethical decision, not a scientific one"). For a discussion of policy principles applicable to setting air quality standards, see *infra* Part III.A.

[117] Lisa Heinzerling, *The Clean Air Act and the Constitution*, 20 ST. LOUIS U. PUB. L. REV. 121, 122 (2001). Heinzerling also has claimed that EPA's "standards [were] promulgated based on this body of scientific evidence." *Id.*; *see also* David M. Driesen, *Sustainable Development and Air Quality: The Need to Replace Basic Technologies with Cleaner Alternatives*, 32 Envtl. L. Rep. (Envtl. L. Inst.) 10,277, 10,282 (Mar. 2002) (noting that "[t]he revised standards reflect new health data"); Thomas O. McGarity, *The Clean Air Act at a Crossroads: Statutory Interpretation and Longstanding Administrative Practice in the Shadow of the Delegation Doctrine*, 9 N.Y.U. ENVTL. L.J. 1, 2 (2000) (stating that each time EPA has established or revised a NAAQS "the Agency based its decision on one or more air quality criteria documents that set out in considerable detail the available scientific information on the adverse health effects of the relevant pollutants"). To be sure, science could demonstrate that health effects occurred at levels of exposure below current standards, but this scientific evidence by itself cannot be used to justify a decision about where a standard should be set. *Supra* note 89 and accompanying text.

[118] Robert V. Percival, *Joint Center Amici Brief Misses the Mark* (AEI-Brookings Joint Ctr. for Regulatory Studies, Policy Matters No. 00-11, 1990), *available at* http://www.aei.brookings.org/policy/page.php?id=55.

[119] *Supra* notes 47-50 and accompanying text.

[120] *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 464-70 (2001) (finding that Congress' instructions to EPA to set air quality standards do not allow consideration of "the costs of achieving such a standard"); *Lead Indus.*, 647 F.2d at 1148 (stating that "economic considerations play no part in the promulgation of ambient air quality standards").

that reflects "the latest scientific knowledge" of the health effects of the relevant pollutant.[121] Then, under section 109 of the Act, EPA is to set a standard that is "requisite to protect the public health" with "an adequate margin of safety."[122] The legislative history of the Clean Air Act provides some additional guidance for construing the brief statutory language. In 1970, when the current language of section 109 was enacted, the Senate Report stated that the objective of air quality standards was to ensure "an absence of adverse effects on the health of a statistically related sample of persons in sensitive groups."[123] NAAQS were intended to protect susceptible groups such as "bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment."[124] Based on this language, EPA and the courts have construed section 109 to require air quality standards to "be set at a level at which there is 'an absence of adverse effect' on . . . sensitive individuals."[125]

Moreover, NAAQS must provide a "margin of safety" to ensure that "'a reasonable degree of protection is to be provided against hazards which research has not yet identified.'"[126] Thus, at least as reflected in the 1970 Senate Report, EPA was required to set NAAQS at a level that would ensure no detectable adverse health effects in even susceptible subgroups of the population, and then to add an additional margin of safety to protect against unknown health risks that may be discovered in the future. In short, the NAAQS were apparently intended to provide near-absolute protection against adverse health effects.

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[121] 42 U.S.C. § 7408(a)(2) (2000).

[122] *Id.* § 7409(b)(1).

[123] S. REP. NO. 91-1196, at 10 (1970). The Senate explained that an adequate sample is "the number of persons necessary to test in order to detect a deviation in the health of any person within such sensitive group which is attributable to the condition of the ambient air." *Id.*

[124] *Id.*

[125] *Lead Indus.*, 647 F.2d at 1153; *see also Whitman*, 531 U.S. at 464-65 (agreeing with the approach taken by the D.C. Circuit in *Lead Industries*).

[126] *Lead Indus.*, 647 F.2d at 1150 (quoting S. REP. NO. 91-1196, at 2-3 (1970)); *see also id.* at 1154 (observing that the margin of safety requirement was intended to protect against health effects "which have not yet been uncovered by research"). According to EPA:

> The margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below

The statutory provisions for adopting NAAQS, initially enacted in their present form in 1970, are based on the assumption that pollutants have thresholds for which it is possible to set a "safe" level.[127] Such a "threshold pollutant" causes adverse effects only above a certain exposure level, designated as the threshold level. In contrast, a "non-threshold" pollutant is one that may cause adverse effects at any level above zero exposure.[128]

For threshold pollutants, it would appear as if science alone might be sufficient to determine the level at which an air quality standard should be set. If a pollutant shows a clear threshold, the science would presumably provide the basis for using this threshold as a "safe" point below which the regulator could be assured the complete protection of public health. Yet even with threshold pollutants, some judgments would still be required on the part of the Administrator.[129] Moreover, even when the standard is set below the threshold level, the Administrator must make a clear policy judgment in selecting an

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those at which human health effects can be said to occur with reasonable scientific certainty.

EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857; *see also* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,653 (same).

[127] *See Clean Air Act Amendments of 1977: Hearing Before the Subcomm. on Envtl. Pollution of the Senate Comm. on Env't & Pub. Works*, 95th Cong., 1st Sess., pt. 3, at 8 (1977) (statement of Sen. Edmund Muskie, Member, Senate Subcomm. on Envtl. Pollution) ("The Clean Air Act is based on the assumption, although we knew at the time it was inaccurate, that there is a threshold."); Joseph M. Feller, *Non-Threshold Pollutants and Air Quality Standards*, 24 ENVTL. L. 821, 823 (1994) ("A critical . . . assumption underlies . . . the structure of the Clean Air Act . . . . The assumption is that, for each pollutant of concern, there is a threshold concentration, represented by the NAAQS, above which the pollutant is a threat to health or welfare and below which it is not."); William K. Reilly, *Foreword* to ROBERT D. FRIEDMAN, SENSITIVE POPULATIONS AND ENVIRONMENTAL STANDARDS, at vii, vii (1981) ("The Clean Air Act incorporates the notion of threshold values of pollutants, levels below which there are presumed to be no adverse health effects, and requires that standards be set on the basis of the threshold, with a margin of safety.").

[128] *See* Natural Res. Def. Council v. EPA, 824 F.2d 1146, 1148 (D.C. Cir. 1987) (defining a "non-threshold" pollutant as one that "appears to create a risk to health at all non-zero levels of emission"). A non-threshold pollutant is always defined provisionally, because it is "impossible to scientifically prove the absence of a threshold, as one can never prove a negative." David L. Eaton & Curtis D. Klaassen, *Principles of Toxicology*, *in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 11, 21 (Curtis D. Klaassen ed., 6th ed. 2001).

[129] Judgment would be needed in (1) evaluating the scientific evidence indicating that a threshold exists, (2) determining that the threshold has been adequately specified, and (3) defining what counts as an "adverse effect" covered by the threshold. Judgment would also be needed to determine whether the threshold protected susceptible groups and accounted for interindividual variability in response to the pollutant in question.

"adequate margin of safety" to protect against uncertain or unknown health effects at lower exposure levels.[130]

The need for making a policy judgment is still clearer for non-threshold pollutants. Unlike with threshold pollutants, where a standard can be set at a level below the threshold to provide complete health protection, the only way to protect against the entire continuum of adverse health effects from a non-threshold pollutant would be to set a standard at the level of zero.[131] As a result, when regulators set standards for non-threshold pollutants at levels above zero, they must, at least implicitly, do so based on some criteria other than the science, since the science indicates that health effects likely occur at levels below the standard selected by the regulators.

It turns out that few, if any, criteria pollutants regulated under the Clean Air Act exhibit a clear threshold.[132] The scientific data for ozone and fine PM indicate a continuum of health effects down to background (or natural) concentrations of the pollutants in the air, at which point the health effects associated with the pollutants cannot be distinguished from effects caused by other factors.[133] In other words, there is no identifiable threshold below which a standard for ozone or particulate matter could be set to avoid all health effects.[134]

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[130] 42 U.S.C. § 7409(b)(1) (2000).

[131] *See* Sunstein, *supra* note 18, at 315 (noting that the apparent continuum of biological responses to ozone "means that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an 'adequate margin of safety' is not possible").

[132] According to one report:

> In no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at or above some level of pollution, but no effects at all below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, and with no sharp lower limit.

NAT'L ACAD. OF SCI. & NAT'L ACAD. OF ENG'G, AIR QUALITY AND AUTOMOTIVE EMISSION CONTROL, S. DOC. NO. 93-24, at 17 (1974) [hereinafter NAS/NAE].

[133] *See, e.g.*, EPA, *EPA's Updated Clean Air Standards: A Common Sense Primer*, *at* http://www.epa.gov/oar/primer/science.htm (Sept. 1997) (stating that "[t]he scientific community, EPA, Congress and the courts have long recognized there is no health threshold for ozone and other air pollutants—in other words, no specific-level at which all people can be fully-protected"); Heinzerling, *supra* note 117, at 122 (acknowledging that, at the time of EPA's decision, "the existing evidence seemed to point to the possibility that there is no level at which ozone exerts no effect whatsoever on the human body"); *see also infra* notes 146-50 and accompanying text (describing Congress' acknowledgment of the absence of thresholds).

[134] Lisa Heinzerling has sought to downplay the inherent policy judgment called for in NAAQS decision making by arguing that EPA never definitively determined that

EPA acknowledged this point in its rulemaking. With respect to ozone, EPA stated that ozone "may elicit a continuum of biological responses down to background concentrations" and that "in the absence of any discernable threshold, it is not possible to . . . identify a level at which it can be concluded with confidence that no 'adverse' effects are likely to occur."[135] Moreover, the Agency specifically rejected industry arguments that the health evidence for ozone indicated the existence of a threshold, responding that the available evidence suggested "a linear relationship down to a background level of 0.04 ppm."[136] For fine PM, EPA speculated that a threshold might exist, but acknowledged that "the level or even existence of population thresholds below which no effects occur cannot be reliably determined by an examination of the results from the available studies."[137]

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ozone and particulate matter had adverse health effects down to zero. She has written:

> EPA's observation that particulate matter and ozone may be "nonthreshold" pollutants was nothing more than an admission that the agency had not proven the existence of a level at which these pollutants had no effects on human health. . . . It was also not a claim that the agency would regard all such effects on health, if detected, to be sufficiently "adverse" to warrant a regulatory response. Nor was it a claim that the agency would regard all such effects to be effects on *public* health within the meaning of the Clean Air Act.

Heinzerling, *supra* note 117, at 126 (footnotes omitted). This argument misses the point. Even though the Agency did not definitively demonstrate health effects all the way to zero, its own analyses indicated that there were health effects below the levels at which it chose to set its standards, including in the case of PM, a substantial number of premature deaths every year, which certainly must be considered "adverse." Moreover, EPA most certainly did need to make a policy judgment in deciding that some effects were not "sufficiently 'adverse'" to warrant protection. The Agency knew that there would be many individuals who would suffer health effects at levels of exposure permitted by EPA's standards, and it strongly suspected that there would always be such individuals so long as there was some level of ozone or particulate matter in the air. *Infra* Part II.B–C. Choosing to disregard these effects in setting its regulatory standard may well have been reasonable and even justified, but it was a clear policy choice that EPA failed to acknowledge openly and explain adequately. For further criticism of Heinzerling's argument, see Richard J. Pierce, Jr., *The Appropriate Role of Costs in Environmental Regulation*, 54 ADMIN. L. REV. 1237, 1261-65 (2002).

[135] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863 (citation omitted). EPA further acknowledged that "no standard within the range of levels and forms considered in this review, including the selected standard, is risk free, due to the continuum of risk likely posed by exposures to ambient O_3 [ozone] potentially down to background levels." *Id.* at 38,873.

[136] EPA, RESPONSES TO SIGNIFICANT COMMENTS ON THE 1996 PROPOSED RULE ON THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE 81 (Docket No. A-95-58, 1997) [hereinafter EPA, OZONE RESPONSE TO COMMENTS]; *see also id.* at 84 ("There is clear evidence from hospital admission studies that effects continue down to background.").

[137] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,670; *see also* Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1034 (D.C. Cir. 1999) ("EPA regards ozone definitely,

CASAC, the advisory committee that must review the scientific basis of EPA's criteria document and NAAQS standards,[138] concurred with EPA that "the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations."[139] Rather, "it appears that ozone may elicit a continuum of biological responses down to background concentrations."[140] Likewise, in its review of particulate matter, CASAC concluded that "[a]s with ozone, there appears to be no apparent threshold for biological responses to PM exposures."[141] According to CASAC, the absence of a demonstrated threshold implies "that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an 'adequate margin of safety' is no longer possible."[142] For ozone, CASAC also concluded that "there is no 'bright line' that distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of health" and thus "the selection of a specific level and number of allowable exceedences is a policy judgment."[143] In testimony to Congress, the Chair of CASAC reiterated that "the decisions to select a given level or number of allowable exceedences within [EPA's] proposed ranges cannot be based on science;"[144] rather, the selection of a particular standard was "strictly a policy judgment."[145]

The absence of clear thresholds for these pollutants was a well-known fact to members of Congress during deliberations over the 1977 amendments to the Clean Air Act, if not earlier.[146] Senator

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and PM likely, as non-threshold pollutants, i.e., ones that have some possibility of some adverse health impact (however slight) at any exposure level above zero.").

[138] 42 U.S.C. § 7409(d)(2) (2000).

[139] Letter from Dr. George T. Wolff, Chair, Clean Air Scientific Advisory Committee, to Administrator Carol M. Browner 2 (Nov. 30, 1995), *available at* http://www.epa.gov/sab/pdf/casac02.pdf.

[140] *Id.*

[141] Letter from Dr. George T. Wolff, Chair, Clean Air Scientific Advisory Committee, to Administrator Carol M. Browner 3 (Jan. 5, 1996), *available at* http://www.epa.gov/sab/pdf/casac03.pdf.

[142] Wolff, *supra* note 139, at 2.

[143] *Id.* at 2-3.

[144] *EPA Proposed Clean Air Regulations: Hearing Before the House Subcomm. on Health & Env't and House Subcomm. on Oversight & Investigations*, 105th Cong. 2 (1997) (statement of George T. Wolff, Chair, EPA's Clean Air Scientific Advisory Committee's Panels on Ozone and PM), *available at* 1997 WL 10569483.

[145] *Id.* at 1.

[146] Congress was strongly influenced by a 1974 report prepared for the Senate by the National Academy of Sciences and National Academy of Engineering which

Muskie, the primary Senate sponsor of the amendments, observed that for nearly all criteria pollutants, "[t]here is no threshold health effect which can be used to say that above this threshold there is danger to health and below it there is not."[147] The House likewise acknowledged in 1977 that the "safe threshold" concept underlying section 109 was "at best, a necessary myth"[148] since "no safe thresholds can be established."[149] Accordingly, the House noted that air quality standards set by EPA at the time had failed to satisfy either of "the two main safeguards which have been recognized as necessary in the protection of public health: proof of a safe threshold level of exposure and a fully adequate margin of safety beyond harm levels which have already been proved."[150]

In setting air quality standards at any level above zero, the EPA Administrator is compelled to rely upon some criterion other than the absolute protection against health effects. As Senator Muskie recognized in 1977:

> I wish it were possible for the Administrator to set national primary and secondary standards that fully implement the statutory language . . . . The fact is, as testimony and documents disclose, the standards do not fully protect in accordance with the statutory language which gives the Administrator authority to provide for additional protection. He has had to make a pragmatic judgment in the face of the fact that he found

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concluded that, contrary to the assumption underlying the 1970 Act, there were no thresholds for criteria pollutants. NAS/NAE, *supra* note 132, at 17-18.

[147] STAFF OF SENATE COMM. ON ENV'T & PUB. WORKS, 95TH CONG., LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1977 (Comm. Print 1978), *reprinted in* 3 COMM. ON ENV'T & PUB. WORKS, 95TH CONG., LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1977, at 781 (1978) (remarks of Sen. Edmund Muskie). Senator Muskie likewise stated:

> [T]estimony on the health question over the last 7 years over and over again has made the point that there is no such thing as a threshold for health effects. Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.

123 CONG. REC. 18,460 (1977) (statement of Sen. Edmund Muskie).

[148] H.R. REP. NO. 95-294, at 111 (1977).

[149] *Id.* at 127. The House Report also quoted the National Academy of Sciences in support of this understanding:

> "[I]n no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at and above some level of pollution, but no effects at all below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, with no sharp lower limit."

Id. at 110 (quoting NAS/NAE, *supra* note 132, at 17).

[150] *Id.* at 111-12.

> there is no threshold on health effects, which makes it very difficult then to apply absolute health protection, and he has not been able to do that.[151]

The House recognized that some limits were necessary to prevent the kind of zero-risk standards that would follow from strict application of the Clean Air Act to non-threshold pollutants: "Some have suggested that since the standards are to protect against all known or anticipated effects and since no safe thresholds can be established, the ambient standards should [b]e set at zero or background levels. Obviously, this no-risk philosophy ignores all economic and social consequences and is impractical."[152] Nevertheless, Congress did not amend the statutory language of section 109 to reflect this recognition. Nor did it provide any further guidance to EPA on how to justify a nonzero standard for a non-threshold pollutant in a way that would satisfy the Clean Air Act's requirement to "protect the public health" with an "adequate margin of safety."[153]

The House's recognition that a zero-risk approach would "ignore all economic and social consequences," however, implicitly demonstrated the inevitable need to incorporate factors other than scientific evidence about health effects in justifying where standards are set for non-threshold pollutants. Any nonzero standard for a non-threshold pollutant must inherently take into account economic and social considerations in addition to the scientific evidence of health effects, since a science-only approach that seeks to prevent all "adverse effects" with an "adequate margin of safety" can only be set at zero, which everyone agrees would be nonsensical.

II. THE ABANDONMENT OF REASON IN EPA'S AIR QUALITY STANDARD SETTING

The selection of a NAAQS standard, especially for a non-threshold pollutant, is a quintessential risk-management decision that, while drawing on scientific evidence, ultimately turns on social, political, and economic choices.[154] While science provides relevant information describing the frequency and severity of adverse effects at various

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[151] 123 CONG. REC. 18,463 (1977) (statement of Sen. Edmund Muskie).

[152] H.R. REP. NO. 95-294, at 127 (1977).

[153] 42 U.S.C. § 7409(b)(1) (2000).

[154] Reilly, *supra* note 127, at viii ("In the absence of a scientifically definable threshold, the decision makers responsible for establishing a standard are inescapably forced to make social, not scientific, judgments.") (statement of former Administrator Reilly before he assumed his position as head of EPA).

pollutant levels, this information, by itself, fails to identify the level at which to set the standard. As we have detailed, EPA has attempted to justify its recent NAAQS decisions (as it has earlier ones) based exclusively on science, when the selection of such a standard necessarily requires policy judgments.[155] EPA's most recent revisions to its ozone and fine PM NAAQS not only provide yet another case study of the so-called science charade, but, more importantly, they reveal the consequences of a regulatory regime that permits, and even encourages, agencies to cloak their policy decisions in science. When EPA or any other agency invokes science to justify its regulatory decisions, it fails to provide the public with a transparent and principled justification for its regulatory decisions.[156]

In the recent ozone and particulate matter rulemakings, EPA took a series of inconsistent positions that remained largely hidden behind the Agency's repeated invocation of science as the basis for its decisions. Throughout its rulemakings and subsequent rounds of litigation, EPA's policy positions resembled shifting sands. For example, even though the Agency claimed to justify its standards based on a singular concern for evidence of health risks, it explicitly rejected options that, according to its own analysis, would have provided greater protection to the public from such risks.[157] In this Part, we present some of the most significant inconsistencies that emerged in EPA's rulemaking documents and its arguments in court. EPA's use of science as a rhetorical defense helped to mask the absence of a coherent, principled account for why the Agency revised its ozone and particulate matter standards as it did.[158]

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[155] *See* R. SHEP MELNICK, REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT 261 (1983) ("There is, in short, no simple answer to the question of how the EPA sets air quality standards. Medical evidence cannot offer definitive guidance. . . . The EPA itself has refused to deal with the problem in a forthright manner, hiding its policy choices behind its interpretation of scientific evidence."); Kevin D. Hill, *Smog, Science & the EPA*, 25 N. KY. L. REV. 1, 27 (1997) ("Decisions as costly and important as the ozone standard should not hide behind a charade of science but should be part of the public debate."); Pierce, *supra* note 18, at 73 ("The *ATA* case is laced with symptoms of the science charade."); Wagner, *supra* note 11, at 1640-44 (arguing that EPA's reliance on scientific and medical evidence alone to justify its previous ozone NAAQS is a "vivid illustration" of an "intentional science charade").

[156] *See* Nicholas A. Ashford et al., *A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking*, 7 HARV. ENVTL. L. REV. 297, 311 (1983) (noting that "[s]uch an approach frustrates any effort to measure agency decisions against the reasoned decisionmaking standard.").

[157] *Infra* Part II.B–C.

[158] This is not to say that no consistent set of reasons could have been offered to justify EPA's decisions. An agency's decision making may be reasonable, even if

A. *Science and EPA's Ad Hoc Policymaking*

EPA's reliance on science as a rationale made it easier for the Agency to claim that it could make ad hoc policy judgments without the need to provide a consistent set of principles to guide its NAAQS decision making. In the ozone and particulate matter rulemakings, EPA explicitly asserted that it could rely on scientific inputs and therefore, did not need to provide any consistent set of policy principles to explain its decisions.[159]

EPA's revision of the ozone and PM NAAQS began with the preparation of a Criteria Document and then a Staff Paper for each pollutant. As required by the statute, the Criteria Document provided a review of "the latest scientific knowledge" on "all identifiable effects on public health or welfare" that may result from ambient levels of a pollutant.[160] As EPA and its amici argued to the Supreme Court, the Criteria Document was thus a "descriptive" document that was "limited" to scientific information.[161] Although the Staff Paper was intended to "help bridge the gap between the scientific review contained in the Criteria Document and the judgments required of the Administrator in setting ambient standards," it too emphasized "conclusions and uncertainties in the available scientific literature" to be considered in setting the standards.[162] Neither the Criteria Document

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inadequately reasoned. That said, given the wide disparity in health benefits achieved between the ozone and PM decisions, we have our doubts about whether EPA's decisions across these rulemakings could ever have been adequately justified. *Infra* Part II.D.

[159] *See infra* notes 164, 188-90, 202-03 and accompanying text (elaborating on the Agency's reluctance to establish a framework for its decision making).

[160] 42 U.S.C. § 7408(a)(2) (2000); *see also supra* note 49 and accompanying text (discussing the preparation of criteria documents).

[161] As EPA indicated in its subsequent Supreme Court brief defending its ozone and PM standards, section 108(a)(2) "limits the kind of information to be included in the 'criteria' to 'the latest scientific knowledge.'" EPA, Supreme Court Respondents Brief, *supra* note 60, at 19. Indeed, the criteria documents are intended to be "descriptive." *See* Brief for Respondents Massachusetts and New Jersey at 18-19, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1426) [hereinafter Massachusetts and New Jersey Brief] (citing statements from early criteria documents that such documents are "descriptive" summaries of "scientific knowledge," and noting that Congress ratified this understanding of the purpose and content of the criteria documents in the 1970 Clean Air Act); *see also* S. REP. NO. 90-403, at 26-27 (1967) ("Air quality criteria are an expression of the scientific knowledge of the relationship between various concentrations of pollutants in the air and their adverse effects on man, animals, vegetation, materials, visibility and so on." (citation omitted)).

[162] OFFICE OF AIR QUALITY PLANNING & STANDARDS, EPA, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER: POLICY

nor the Staff Papers purported to recommend or justify any specific regulatory standard, but instead they identified a range of possible standards that the staff believed would protect public health with some margin of safety.[163]

The EPA Administrator is supposed to select specific standards only after considering the information from the Criteria Document and Staff Paper, along with public comments that had been filed during the rulemaking process. In explaining the Administrator's decisions on ozone and particulate matter, EPA began by making two brief and uncontroversial assertions. First, EPA acknowledged briefly in the *Federal Register* that the Administrator's decision was a "policy choice," though one the Agency asserted was "left specifically to the Administrator's judgment."[164] This latter language seemed to imply that the exercise of the Administrator's judgment did not need to be explained with any meaningful policy justification. Second, EPA reaffirmed statements in the 1977 legislative history of the Clean Air Act that the Agency was not required to set a zero-risk standard for a non-threshold pollutant.[165] Of course, no major participant in environmental policymaking has ever seriously argued that a zero-risk standard is required, given that a zero-risk standard for a non-threshold pollutant would result, at a minimum, in the end of the industrialized

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ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION, at I-1 (1996) [hereinafter PM STAFF PAPER], *available at* http://www.epa.gov/ttn/oarpg/t1sp.html.

[163] OFFICE OF RESEARCH AND DEVELOPMENT, EPA, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS (1996) [hereinafter CRITERIA DOCUMENT]; OFFICE OF AIR QUALITY PLANNING & STANDARDS, EPA, REVIEW OF NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE: ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION 213-14 (1996) [hereinafter OZONE STAFF PAPER] (recommending a primary eight-hour ozone standard in the range of 0.07 to 0.09 ppm); PM STAFF PAPER, *supra* note 162, at VII-47 ("Staff recommends that the Administrator consider selecting the level of a new 24-hour $PM_{2.5}$ standard from the range of 20 $\mu g/m^3$ to approximately 65 $\mu g/m^3$, and the level of a new annual $PM_{2.5}$ standard from the range of 12.5 $\mu g/m^3$ to approximately 20 $\mu g/m^3$.").

[164] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857; EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,653.

[165] *E.g.*, EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,857 ("The Act does not require the Administrator to establish a primary NAAQS at a zero-risk level but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety."); *id.* at 38,863 ("[A] zero-risk standard is neither possible nor required by the Act."); *id.* at 38,867 ("Clearly, for pollutants, such as O_3, that have no discernible thresholds for health effects, no standard can be risk-free."). EPA made identical statements in the preamble to the final PM standard. EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,653, 38,656.

economy as we know it.[166] But as we will see, this position has put the Agency in an especially difficult, if not impossible, position when it comes to providing a consistent justification for its standards.[167]

What EPA failed to address in its rulemaking was the critical question of what risk management principle or criterion justified the Administrator's "policy choice" in selecting nonzero standards along the continuum of predicted health risks for ozone and fine PM.[168] Instead, EPA identified only scientific factors to defend its choices, arguing that risk assessments played a "central role in identifying an appropriate level."[169] In the preamble for the final ozone standard, EPA summarized its basis for its decision by identifying the information which it gathered in the rulemaking process: (1) the Criteria Document, (2) the Staff Paper, (3) CASAC's advice, and (4) public comments.[170] Of course, a simple bibliography is not the same as a meaningful explanation, but more importantly these various sources of information do not themselves contain any principled justification for the revised standards. As noted earlier, the Criteria Document is limited to a description of scientific information,[171] and the Staff Paper was intended to "bridge" the scientific evidence and the Agency's policy determination but did not itself recommend or develop a

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[166] *See, e.g.*, Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1038 (D.C. Cir. 1999) ("No party here appears to advocate this [zero-risk policy], and EPA appears to show no inclination to adopt it."); Paul R. Portney, *EPA and the Evolution of Federal Regulation*, *in* PUBLIC POLICIES FOR ENVIRONMENTAL PROTECTION 11, 17 (Paul R. Portney & Robert N. Stavins eds., 2000) ("[I]t is impossible to eliminate all traces of environmental pollution without simultaneously shutting down all economic activity, an outcome which neither Congress nor the public would abide.").

[167] *Infra* notes 364-67 and accompanying text.

[168] CASS R. SUNSTEIN, THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION 112 (2002) ("The basic problem is that the agency did not explain, in concrete terms, why it chose one level of regulation rather than another."). For a discussion of risk management principles, see *infra* Part III.A.

[169] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863 (citation omitted). Later, in a brief defending the PM rule, EPA claimed that the Agency's full risk assessment played only a "limited role," but that the standards "were based primarily on EPA's analysis of the epidemiological studies in the record," also a clearly scientific consideration. EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, at 51.

[170] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859. Although we focus in this part of the text primarily on the justification EPA offered for its revisions to the ozone standard, EPA provided a similar account in its preamble to the final rule revising the particulate matter standards. *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,655 ("These decisions are based on a thorough review, in the Criteria Document, of the latest scientific information on known and potential human health effects associated with exposure to PM at levels typically found in the ambient air.").

[171] *Supra* notes 49, 160 and accompanying text.

justification for specific policy determinations.[172] The Staff Paper expressly acknowledged that setting a NAAQS standard was "a policy choice left specifically to the Administrator's judgment."[173] As with the staff materials, CASAC's input was similarly limited, almost by definition, to scientific advice.[174] Finally, while public comments may raise policy arguments in addition to scientific conclusions, they reflect the opinions of interested individuals and organizations, not the judgment of the Administrator. Even though some of these comments undoubtedly discussed policy issues and not merely scientific evidence of health effects, EPA did not (and could not) rely on these comments to offer the justification that the Agency itself is required to provide in exercising its governmental authority.[175]

Based solely on these sources of information contained in the rulemaking record, EPA claimed to have determined that a revision to its current standards was "appropriate."[176] Once it made this determination, EPA needed to decide the specific level at which the revised standards should be set. In its final rule, EPA stated that a revised ozone primary standard set at 0.08 ppm based on an eight-hour average was likewise "appropriate."[177] It offered as its purported "rationale"

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[172] *Supra* text accompanying note 162.

[173] OZONE STAFF PAPER, *supra* note 163, at 3 (citation omitted); *id.* at 213 ("In making recommendations, staff notes that the decision ultimately made by the Administrator regarding level of the primary O_3 NAAQS will be based on a policy judgment as to the degree of risk reduction that is necessary to protect public health with an adequate margin of safety.").

[174] *Supra* note 59 and accompanying text.

[175] *See, e.g.*, Brief of Amici Curiae Environmental Defense et al. at 21, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1426) ("[T]here is no plausible scenario under which the requirement that the agency consider comments could modify the standards defined in the statute for the setting of the NAAQS."); Massachusetts and New Jersey Brief, *supra* note 161, at 34 (describing as "fantastical" the argument that "the Administrator must consider anything submitted in the public record as relevant to her decision setting the NAAQS" because "[s]uch a process would allow public commenters to determine the scope and content of EPA's obligations in setting the NAAQS"). Indeed, there is no indication in the rulemaking record that EPA adopted any policy criteria for setting NAAQS suggested by a public commentator.

[176] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859. EPA took a similar approach in its final rule on particulate matter:

> Based on the rationale and recommendations contained in the Staff Paper and the advice of CASAC, and taking into account public comments, the Administrator concludes that it is appropriate at this time to revise the current PM standards to increase the public health protection provided against the known and potential effects of PM identified in the air quality criteria.

EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,666.

[177] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,859.

for this decision the Agency's "consideration of" health effects information, human exposure, and risk assessments: "[s]pecific conclusions . . . that, taken together, would be *appropriate* to protect public health with an adequate margin of safety."[178] Of course, it is far from clear what the Agency meant by basing its decision on "consideration of" scientific information or, more significantly, what made its judgment "appropriate." The Agency was simply begging the question.

In the preamble to the final ozone rule, EPA stated that CASAC recognized that "the selection of specific standards requires that the Administrator make public health policy judgments in addition to determinations of a strictly scientific nature."[179] But what did such judgments entail and what was EPA's reasoned basis for making them as it did? EPA claimed that its public health policy judgment was "framed by" the scientific information and its view that the standards should be set at some "appropriate level."[180] It also stated that its public health policy judgment was "informed by" various "key observations and conclusions,"[181] including the results of various health studies, the types of health effects identified in those studies, the levels of human exposure, the results of EPA's risk assessment, and the advice from CASAC.[182] Again, these types of data are relevant scientific inputs for any risk management decision, but even taken together they categorically differ from a policy reason that justifies setting risk standards at one level rather than another.[183] EPA concluded in its preamble that these factors, in particular the fact that no CASAC member endorsed a standard below 0.08 ppm, led the Agency to focus on the alternative

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[178] *Id.* (emphasis added). The Agency also stated that it examined "[a]lternative views of the significance of the effects and factors to be considered in policy judgments about the *appropriate* elements of the standard." *Id.* (emphasis added).

[179] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863.

[180] *Id.*

[181] *Id.*

[182] *Id.* at 38,863-65. The only type of public health "policy judgments" that EPA identified were "the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed." *Id.* at 38,883. These factors are an integral part of characterizing risks, the final step in risk assessment, but they do not provide any policy principles that would justify a risk management decision. NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 27 (1994) (noting that such "science-policy" factors "are distinct from the policy choices associated with ultimate decision-making").

[183] *See, e.g.*, LANDY ET AL., *supra* note 108, at 56 ("[T]erms like sensitive group, health, and adequate margin of safety are not self-defining. The science of the situation could not, by itself, produce a decision." (emphasis omitted)).

levels of 0.08 ppm and 0.09 ppm.[184] The remainder of EPA's explanation for its selected standard consisted of a list of factors that simply supported the obvious descriptive point that an 0.08 ppm standard provides more health protection than does an 0.09 ppm standard.[185]

Other statements that EPA made in the preambles to its final rules likewise reflected a reliance on scientific factors to justify its decisions and failed to specify any risk management criterion. For example, EPA summarized its approach for establishing a "margin of safety" (clearly a policy decision) almost entirely in terms of scientific information. According to the Agency, its task was "to select an approach that best takes into account the health effects and other information assessed in the air quality criteria for the pollutant in question and to apply appropriate and reasoned analysis to ensure that the scientific uncertainties are taken into account in an appropriate manner."[186] However, this itself is not an explanation of why the Agency arrived at its revised standards. No one can deny that the Administrator should make an "appropriate" decision, but the Administrator's underlying rationale for these decisions was never stated, nor was any principle offered that could explain these decisions as well as similar decisions made by any other Administrator in the past or future. The factors invoked by EPA speak to how the risk is characterized, not to how that risk should be managed.[187] After discussing the scientific data and associated uncertainties, EPA basically stopped and pronounced the standards it had selected, explaining its decisions simply by asserting that they were "appropriate."

The lack of any policy justification was all the more striking because the one issue where EPA most clearly should have explained its risk management judgment would have been in setting the margin of safety. Yet, the Agency failed to articulate any clear or consistent policy principles for establishing a margin of safety, instead arguing

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[184] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,864-65.

[185] *Id.* at 38,865, 38,867-68. Of course, this observation is obvious only if ground-level ozone provides no countervailing health benefits. *See infra* notes 312-13 and accompanying text (indicating that there may be potential health benefits of ozone).

[186] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883. EPA's preamble to the revised particulate matter standard contains virtually the same language. *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688-89 ("[T]he task of the Administrator is to select an approach that best takes into account the nature of the health effects . . . and to apply appropriate and reasoned analysis to ensure that scientific uncertainties are taken into account in an appropriate manner.").

[187] For the distinction between risk characterization and risk management, see *supra* notes 91-95 and accompanying text.

against the need to provide a principle at all. The Agency claimed that "no generalized paradigm . . . can substitute for the Administrator's careful and reasoned assessment of all relevant health factors in reaching . . . a judgment."[188] Moreover, because the Agency's determination is "largely judgmental in nature," it "may not be amenable to quantification in terms of what risk is 'acceptable' *or any other metric*."[189] EPA even argued that it can change its approach for setting NAAQS on a case-by-case basis, stating that "the Administrator is not limited to any single approach to determining an adequate margin of safety and, in the exercise of her judgment, may choose an integrative approach, a two-step approach, or perhaps some other approach, depending on the particular circumstances confronting her in a given NAAQS review."[190] In effect, EPA argued that it possessed complete discretion to set standards in any way it desired, without the need to offer any consistent, reasoned explanation for its decision.

It is not surprising, then, that EPA has been inconsistent in how it sets the margin of safety required by the Clean Air Act. In particular, the Agency has shifted its position on whether the margin of safety provision requires the Agency to set primary standards below the lowest probable adverse effects identified by scientific studies. In the recently revised ozone standard, EPA set the primary standard at 0.08 ppm, the level at which it claimed that adverse health effects were directly observed in clinical studies.[191] In past rulemakings, however, EPA has taken the position that the margin of safety requirement

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[188] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883; EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688.

[189] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883 (emphasis added); EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688 (emphasis added).

[190] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,688; *see also* EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883 (providing an almost identical statement).

[191] *See, e.g.*, EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 15 ("[N]ew clinical studies provided 'conclusive evidence' that prolonged ozone exposure decreases lung function and causes respiratory symptoms at ozone concentrations down to 0.08 ppm."); EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863-64 (noting "clear evidence from human clinical studies . . . of the following statistically significant responses at 6- to 8-hour exposures to the lowest concentration evaluated, 0.08 ppm O_3, at moderate exertion: lung function decrements, respiratory symptoms . . . , nonspecific bronchial responsiveness, and biochemical indicators of pulmonary inflammation" and admitting that these effects in some individuals are "sufficiently severe and extended in duration to be considered adverse"); EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 13-14 ("The Agency's decision . . . is that the O_3 primary standard should be set with an 8-hour averaging period and at 0.08 ppm, a level at which numerous controlled-exposure human studies have reported health effects such as lung function decrements, respiratory symptoms, and indicators of inflammation.").

directs the Agency to set the standards below those at which adverse health effects are found or expected in sensitive groups.[192] EPA had earlier argued that "[t]he intent of the margin of safety requirement was to direct the Administrator to set air quality standards at pollution levels below those at which adverse health effects have been found or might be expected to occur in sensitive groups."[193] EPA even acknowledged before the Supreme Court its view that air quality "standards must be 'preventative or precautionary,' reflecting an emphasis on the 'predominant value of protection of public health'"[194] and that EPA should be sure to "err on the side of caution."[195]

Accordingly, EPA previously claimed to have set the primary standard substantially below the lowest level of demonstrated adverse effects in order to ensure an adequate margin of safety. For example, in the previous revision of the ozone standard in 1979, EPA concluded that "the probable level for adverse effects in sensitive persons . . . is in the range of 0.15-0.25 ppm."[196] Nevertheless, EPA set the standard at 0.12 ppm, well below the probable effects level, because, based on its statutory interpretation, it was required to make a "[j]udgment of a standard level *below* the probable effect level that provides an

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[192] *See* National Ambient Air Quality Standards for Ozone-Final Decision, 58 Fed. Reg. 13008, 13,009 (Mar. 9, 1993) [hereinafter EPA, 1993 Ozone Decision] ("[T]he 'margin of safety' requirement by definition only comes into play where no conclusive showing of adverse effects exists."); National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46,246, 46,247 (Oct. 5, 1978) ("It is clear from section 109 that [EPA] should not attempt to place the standard at a level estimated to be at the threshold for adverse health effects but should set the standard at a lower level in order to provide a margin of safety."); *see also supra* notes 50, 122, 127 and accompanying text. *See generally* William F. Pederson, *Costs Matter: Effective Air Quality Regulation in a Risky World*, 20 ST. LOUIS U. PUB. L. REV. 153, 159 (2001) ("A standard that incorporates a 'margin of safety' is one that goes beyond addressing provable harms.").

[193] Revisions to the National Ambient Air Quality Standards for Particulate Matter, 52 Fed. Reg. 24,634, 24,641 (July 1, 1987) [hereinafter EPA, 1987 PM Rule]; *see also* Lead Indus. v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980) (remarking that Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement").

[194] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 24 (citing *Lead Indus.*, 647 F.2d at 1152 (quoting H.R. REP. NO. 294, 95th Cong. 49 (1977))).

[195] *Id.* (citing *Lead Indus.*, 647 F.2d at 1155).

[196] Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202, 8216 (Feb. 8, 1979) [hereinafter EPA, 1979 Ozone Rule]. EPA explained that it "uses the terminology 'probable effects level' to refer to the level that in its best judgment is most likely to be the adverse health effect threshold concentration." *Id.* at 8203.

adequate margin of safety."[197] As EPA subsequently explained its 1979 decision, it set the ozone standard at 0.12 ppm because of "the *possibility* of adverse effects occurring below 0.15 ppm O_3."[198] When EPA next revisited the ozone standard in 1993, it concluded that the controlled human studies failed to show any "adverse effects" below 0.15 ppm and thus retained the existing ozone NAAQS set significantly below that level at 0.12 ppm.[199] Likewise, EPA set the annual PM_{10} standard at 50 $\mu g/m^3$ in 1987 to provide a "reasonable margin of safety" based on evidence showing that long-term degradation in lung function was "likely" at 80-90 $\mu g/m^3$ and possible at concentrations above 60 to 65 $\mu g/m^3$.[200]

Thus, when it came to its recent ozone and PM revisions, EPA abandoned its earlier approach. It even argued in court that it was not "required to follow any particular paradigm of decision making"[201] and that "nothing in the statute requires [the Administrator] to make any specific 'findings' or to structure her decision making in any particular way."[202] EPA's inconsistent application of the margin of safety concept, combined with its assertions that it did not even need to try to be consistent, revealed an agency intentionally or unintentionally dodging its responsibility to give the public a principled justification for its preferred policy outcome.

B. *EPA's Incoherent Disregard of the Health Effects from Particulate Matter*

EPA could not help but struggle to apply its preventative notion of a margin of safety coherently, given that the Agency predicted that adverse health effects would persist at levels below the Agency's new

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[197] *Id.* at 8213 (emphasis added). EPA further stated:

> [A]t levels in the range of 0.15–0.25 ppm, adverse health effects will almost certainly be experienced by significant numbers of sensitive persons. Unless the standard is set somewhat below that level, the Agency would not be exercising the degree of prudence called for by the 'adequate margin of safety' requirement of the Clean Air Act.

Id. at 8217.

[198] National Ambient Air Quality Standards for Ozone; Proposed Decision, 57 Fed. Reg. 35,542, 35,547 (Aug. 10, 1992) (emphasis added) [hereinafter EPA, 1992 Ozone Proposal].

[199] EPA, 1993 Ozone Decision, *supra* note 192, 58 Fed. Reg. at 13,011.

[200] EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,645.

[201] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 29.

[202] *Id.* at 43. After losing in the D.C. Circuit, EPA changed its tune in its argument to the Supreme Court, claiming that the Clean Air Act severely constrained its discretion. EPA, Supreme Court Reply Brief, *supra* note 61, at 8.

standards. Although EPA purported to act to protect the public health and err on the side of safety, the Agency actually disregarded a range of public health effects in both the ozone and particulate matter rulemakings. While the Agency might well have had good cause for treating some level of health risk as tolerable, it never provided any coherent account for why it turned its back on what were, at times, quite substantial health effects.[205]

In its rulemaking on particulate matter, EPA set two standards for fine PM—an annual standard set at 15 $\mu g/m^3$ and a daily (i.e., twenty-four-hour average) standard set at 65 $\mu g/m^3$ (after initially proposing a daily standard of 50 $\mu g/m^3$).[204] The daily standard effectively acts as a constraint on the variation around the average annual level of fine PM in any given area, and in this way provides its own health protection.[205] Assuming the validity of EPA's interpretation of the scientific data on the health effects of fine PM,[206] EPA could have saved hundreds, if not thousands, of additional lives per year by setting a more stringent daily standard than the one it did.[207] Indeed, some public health advocacy groups claimed that EPA's PM standard left tens of millions of Americans at risk for serious health effects.[208]

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[203] As noted in one recent review of the PM standard:

> [O]ne must recognize the arbitrariness of the limits set by U.S. EPA. There is little, genuine, data-based or risk-based justification for the specific values chosen by the Agency: one might as easily have set a $PM_{2.5}$ annual standard set at either 10 or 20 $\mu g/m^3$, rather than the 15 $\mu g/m^3$ chosen.

Laura C. Green et al., *What's Wrong with the National Ambient Air Quality Standard (NAAQS) for Fine Particulate Matter ($PM_{2.5}$)?*, 35 REG. TOXICOLOGY & PHARMACOLOGY 327, 334 (2002).

[204] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,679.

[205] The annual standard could be met by averaging together periods of higher concentrations with periods during which wind or climate patterns, or fluctuations in industrial or transportation activity, significantly reduced the concentration of air pollutants. The daily standard therefore creates an upper bound on those periods of higher concentration.

[206] We assume the validity of EPA's risk assessment only for the purpose of our discussion here. Many commentators disagreed with EPA's conclusion that the available data sufficiently demonstrated mortality health risks from $PM_{2.5}$, leading them to advocate less stringent standards than those ultimately adopted by EPA. In the words of EPA's CASAC Chairman, "[i]f all of the [CASAC] panel members were convinced that the reported $PM_{2.5}$/mortality relationship was causal, I believe we would have come to consensus on PM standards at the low end of the EPA's recommended range." George T. Wolff, *In Response to the PM Debate*, REGULATION, Winter 1997, at 9; *see also* Green et al., *supra* note 203, at 327 (summarizing concerns with EPA's fine PM analysis).

[207] *See infra* notes 212, 214 and accompanying text.

[208] The American Lung Association, for example, advocated a 24-hour standard set at 18 $\mu g/m^3$, claiming that EPA's proposed standard set at 50 $\mu g/m^3$ would fail to protect the health of 89 million people. *See* ALA Calls for Tighter Fine PM Standard,

EPA's risk assessment document reported the Agency's estimates of the consequences of alternative standards for fine PM in two cities: Philadelphia and Los Angeles.[209] In Philadelphia, EPA estimated that the incidence of mortality associated with short-term exposure to fine PM would be reduced by 60 deaths per year, from 370 deaths per year under the existing standards to 310 deaths per year under EPA's new fine PM standard set at 15 $\mu g/m^3$ annually, 65 $\mu g/m^3$ daily.[210] Yet if EPA had reduced the daily standard even further to 25 $\mu g/m^3$, without changing the annual standard, premature mortality from short-term exposure would have been reduced to 110 deaths per year, or a reduction of 200 deaths per year above and beyond the 60 lives predicted to be saved by the standard EPA adopted.[211] For mortality from long term exposure to fine PM in Philadelphia, EPA's new standard would reduce mortality from 920 deaths per year under the existing standards to 660 deaths per year, for a net reduction of 260 deaths per year.[212] Had the Agency's sole focus been on protecting the public health, presumably it should have adopted the more stringent alternative standard it considered, namely a standard set at 15

Says EPA Proposal Leaves Millions at Risk, Env't Rep. (BNA), Jan. 14, 1997, at A-6. A more stringent annual PM standard would also likely result in additional health protection, but EPA did not evaluate a more stringent alternative than the 15 $\mu g/m^3$ standard it ultimately adopted. *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,676 (admitting that "the possibility of effects at lower annual concentrations cannot be excluded").

[209] In the rulemaking, EPA claimed that it relied on the risk assessment "as an aid to the Administrator in judging which alternative PM NAAQS would reduce risks sufficiently to protect public health with an adequate margin of safety . . . ." EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656. While acknowledging uncertainty in the quantitative estimates of health effects in the two-city study, EPA stated that "they do represent reasonable estimates as to the possible extent of risk for these effects given the available information." *Id.* Moreover, the Agency relied on its risk assessment to argue that "the risk remaining after attaining the current PM_{10} standards was on the order of hundreds of premature deaths each year, hundreds to thousands of respiratory-related hospital admissions, and tens of thousands of additional respiratory related symptoms in children." *Id.* Subsequently, in litigation, EPA emphasized that the Agency's risk assessment played only a "limited role" in EPA's decision making. EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, at 51.

[210] PM STAFF PAPER, *supra* note 162, at VI-49.

[211] *Id.*

[212] *Id.* EPA later revised its estimates of the mortality effects from long term exposure "to reflect the actual statistics used in the study upon which they were based," noting that these revisions "cumulatively reduce estimates of mortality associated with long-term exposures by 20 to 35%." EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656. The Agency stated that these revisions had "no effect on risk estimates for mortality associated with short-term exposures or the estimates for any other effects." *Id.*

$\mu g/m^3$ annually and 25 $\mu g/m^3$ daily. This more stringent standard would have reduced mortality in a city of this size to zero, securing an additional reduction of 660 deaths per year.[213]

In total, the standard that EPA adopted was expected to reduce mortality in Philadelphia by 320 deaths per year, while the more stringent alternative rejected by EPA would have resulted in an additional reduction in overall mortality of 860 deaths per year, or over two and a half times the mortality benefits than EPA's chosen standard. Similarly, EPA's risk assessment indicated that in Los Angeles the Agency could have prevented an additional 1080 deaths annually by adopting a more stringent standard. If EPA could claim it needed to revise its PM standard to prevent 1620 premature deaths per year in Los Angeles (as the Agency predicted it would achieve under the less stringent standard), it is hard to understand why the Agency saw no need to lower the standard still further to prevent an additional 1080 premature deaths each year in Los Angeles (or an annual total of 2700 premature deaths avoided under the more stringent alternative).[214]

In both Philadelphia and Los Angeles, the marginal reductions in nonmortality effects (such as respiratory and cardiac health effects) associated with the more stringent alternative were greater than the selected standard for every health endpoint evaluated by EPA.[215] EPA's own analysis showed that the Agency could have achieved substantially greater health benefits by further reducing the twenty-four-hour fine PM standard from the 65 $\mu g/m^3$ standard selected by EPA to the more stringent 25 $\mu g/m^3$ daily alternative.[216] As EPA's PM Staff

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[213] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656. Even if these mortality effects are overstated by twenty to thirty-five percent (as the Agency has subsequently claimed), this would still mean preventing 430 to 530 cases of premature mortality.

[214] PM STAFF PAPER, *supra* note 162, at VI-51. EPA explained that the greater absolute and relative differences between Los Angeles and Philadelphia are based largely on differences in current air quality levels: "As expected, the estimated health risk reductions are larger for Los Angeles County than Philadelphia County due to the higher PM air quality levels associated with meeting the current PM_{10} standards (i.e., baseline air quality in Philadelphia is below the level required to meet the current standards)." *Id.* at VI-54.

[215] *Id.* at VI-49, -51.

[216] As the EPA PM Staff Paper stated:

> Based on the limited risk analyses for two example cities, using base case assumptions, a 24-hour $PM_{2.5}$ standard of 25 $\mu g/m^3$ is estimated to reduce PM-related risks associated with short-term exposures for the effects considered by roughly 70%–85%, relative to risks associated with attaining the current standards. Alternatively, at a 24-hour $PM_{2.5}$ level of 65 $\mu g/m^3$, risks are estimated

Paper concluded, "rough estimates of incidences are *appreciably lower*, but not eliminated in going from a $PM_{2.5}$ standard of 65 to 25 $\mu g/m^3$."[217]

What stopped EPA from further tightening its daily fine PM standard to the more stringent level and thereby saving thousands of additional lives? The answer certainly cannot be based exclusively on a concern for protecting the public from health risks. The record demonstrated that, according to EPA's interpretation of the data, statistically significant increases in premature mortality and significant morbidity effects occurred at levels far below EPA's selected twenty-four-hour standard of 65 $\mu g/m^3$ for fine PM. As EPA's own PM Staff Paper acknowledged, "[e]pidemiological studies reporting statistically significant associations were conducted in areas in which the mean twenty-four-hour $PM_{2.5}$ concentrations ranged from approximately 16 to 30 $\mu g/m^3$ for mortality studies, with hospital admissions and respiratory symptoms studies falling within this range."[218] The Staff Paper continued by noting that "[s]everal epidemiological studies reporting statistically significant effects include ranges of air quality that may approach estimates of background levels in some locations."[219] It also stated that "mortality studies show significant associations even when the observed means of twenty-four-hour $PM_{2.5}$ concentrations in each of the study locations are approximately at or below 20 $\mu g/m^3$."[220] Furthermore, the EPA Staff Paper noted that the results from the Agency's quantitative risk assessment "suggest a pattern of a continuum of decreasing risk with lower levels of alternative $PM_{2.5}$ standards, extending over and likely below the range of 65 to 25 $\mu g/m^3$ $PM_{2.5}$ included in the risk analyses."[221] EPA, in defending its selection of its final daily fine PM standards set at 65 $\mu g/m^3$, observed that short-term exposures appeared to offer the most compelling evidence of a health problem[222] and agreed with the Staff Paper that short-term exposures

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to be reduced by roughly 10% and 40% for the Philadelphia and Los Angeles study areas, respectively.

Id. at VII-28.

[217] *Id.* at VII-29 (emphasis added).

[218] *Id.* at VII-26.

[219] *Id.* at VII-30.

[220] *Id.*

[221] *Id.* at VII-28.

[222] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,676 ("In accordance with EPA staff and CASAC views on the relative strengths of the epidemiological studies, the Administrator has placed greater emphasis on the short-term exposure studies in selecting the level of the annual standard.").

in the range of 16–21 $\mu g/m^3$ resulted in statistically significant health effects.[223]

EPA made an attempt to justify its decision not to set a more stringent twenty-four-hour fine PM standard. The Agency argued that "the risk associated with infrequent peak 24-hour exposures in otherwise clean areas [that is, those meeting the annual standard] is not well enough understood at this time to provide a basis for selecting the more restrictive levels . . . [below] 65 $\mu g/m^3$."[224] This claim, though, is inconsistent with other EPA conclusions. EPA's own analysis indicated that it was not merely occasional "peak" concentrations that presumably should have been of concern under a 24-hour standard, but more frequent days with below-peak concentrations as well. EPA's examination of the available health data concluded that "most of the aggregate risk associated with short-term exposures likely results from the large number of days during which the 24-hour average concentrations are in the low- to-mid-range, below peak 24-hour concentrations."[225] Moreover, if residual levels of fine PM remaining under EPA's new standard would still result in hundreds, if not thousands, of additional premature deaths, it is hard to see how EPA could properly claim that areas meeting the annual standard were "otherwise clean" and that there was no basis for adopting the lower standard.[226]

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[223] *Id.*

[224] *Id.* at 38,677. EPA also argued that an annual standard can "provide the requisite reduction in risk associated with both annual and 24-hour averaging times in most areas of the United States" and that a 24-hour standard "would be intended to provide supplemental protection against extreme peak fine particle levels that may occur in some localized situations or in areas with distinct variations in seasonal fine particle levels." *Id.* at 38,674. Yet, as the textual discussion suggests, EPA's own analysis showed that major reductions in premature mortality would be achieved with a more stringent 24-hour standard than that which was adopted by EPA, even under EPA's selected annual standard.

[225] National Ambient Air Quality Standards for Particulate Matter; Proposed Decision, 61 Fed. Reg. 65,638, 65,652 (Dec. 13, 1996).

[226] Even after a few rounds of litigation, EPA apparently still could not explain why it was acceptable, as a policy matter, to turn its back on the remaining mortalities it predicted under the PM levels allowed under the revised standards. EPA responded to arguments that it should have adopted more stringent PM standards by noting that it revised its risk assessment in a way that "resulted in a substantial reduction in the number of deaths predicted" from exposure to levels permitted under the standard. EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, at 54. Acknowledging that even under the revised risk assessment the "values of estimated risk are not zero" (that is, the Agency still predicted premature deaths under the new standard), the Agency simply dismissed its own risk assessment as "not sufficiently reliable." *Id.* Without saying anything more, EPA then retreated to its science-based rhetoric claiming that it based its new PM standards on the "analysis of the epidemiological studies themselves." *Id.*

Science by itself certainly could not explain why EPA did not adopt a more stringent daily standard for fine PM, nor could a precautionary approach based solely on a concern for avoiding significant health effects. After all, the scientific analysis relied upon by EPA indicated that the Agency could have reduced both mortality and morbidity effects still further than it did. EPA's action was inconsistent with its frequently recited position that it must "err on the side of caution" by setting a margin of safety that will protect against "not just known adverse effects, but those of scientific uncertainty or that 'research has not yet uncovered.'"[227] EPA's own analysis, which the Agency used to defend its decision to tighten the PM standard, predicted that at least hundreds of cases of premature mortality nationwide would result from fine PM exposure even if all regions in the country were to meet EPA's new standards.[228]

Throughout the PM rulemaking, EPA invoked uncertainty as a wild card in an effort to defend its regulatory decisions. The Agency dismissed the sometimes large uncertainties in the estimates it used to support its regulatory actions, but it then cited uncertainty as a barrier to adopting regulations that it was not otherwise inclined to adopt. For example, EPA relied on results from "key" epidemiology studies showing significant mortality risks from fine PM, but did so only for the results at concentrations at and above the standard level EPA selected, dismissing similar results for lower concentrations in the same studies as too uncertain to support the standards.[229] Yet the underlying studies reported no distinctions between the concentration ranges in terms of magnitude of effect, statistical significance, or methodological approach.[230] For EPA, it was as if the same studies could be

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[227] EPA, D.C. Cir. PM Brief, *supra* note 56, at 49 (quoting Lead Indus. v. EPA, 647 F.2d 1130, 1153 (1980)).

[228] *See* Sunstein, *supra* note 18, at 329-30 (asserting that EPA's own figures suggested that more deaths could be prevented by more stringent regulations); *see also* Pierce, *supra* note 18, at 74 ("Even if every area of the country were in compliance with the new primary standards the court struck down in *ATA*, the best scientific evidence available suggests that ozone and particulates would continue to kill several thousand people per year.").

[229] *See* EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,675 ("While placing substantial weight on the results of the key health studies in the higher range of concentrations observed, EPA is persuaded that the inherent scientific uncertainties are too great to support standards based on the lowest concentrations measured in such studies . . . .").

[230] *See, e.g.*, Douglas W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENG. J. MED. 1753, 1753 (1993) (concluding that "these results suggest that fine-particulate air pollution, or a more complex pollution mixture associated with fine particulate matter, contributes to excess mortality in certain U.S.

reliable or unreliable depending simply on what was more expedient for the Agency.[231] The uncertainty inherent in setting air quality standards—and any other risk standards—creates the potential for opportunism by any agency that decides to engage in post hoc rationalization of its decisions. Without a principled basis explaining how it treats uncertainty, EPA's claim that uncertainty prevented it from taking action to lower the PM standard only further served to illustrate the kind of unbounded discretion that the Agency effectively claimed for itself.[232]

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cities"); Joel Schwartz et al., *Acute Effects of Summer Air Pollution on Respiratory Symptom Reporting in Children*, 150 AM. J. RESPIRATORY & CRITICAL CARE MED. 1234, 1240-41 (1994) (discussing study results that did not indicate that concentration ranges affected the results); Joel Schwartz et al., *Is Daily Mortality Associated Specifically with Fine Particles?*, 46 J. AIR & WASTE MGMT. ASS'N 927 (1996). These studies found that each 10 $\mu g/m^3$ elevation in fine PM levels was associated with a significant (six to four percent, depending on the study) increase in all-cause mortality, with no apparent threshold. *See generally* Kenneth A. Colburn & Philip R.S. Johnson, *Air Pollution Concerns Not Changed by S-PLUS Flaw*, 299 SCIENCE 665, 665-66 (2003) (summarizing studies relied on by EPA). Subsequent to EPA's rulemaking, one of the authors upon whom EPA relied published an analysis showing that the mortality effects from fine PM decreased in a linear fashion over the range from 35 to 0 $\mu g/m^3$, supporting the existence of significant mortality at levels permitted by the new standard selected by EPA. Joel Schwartz et al., *The Concentration-Response Relation Between $PM_{2.5}$ and Daily Deaths*, 110 ENVTL. HEALTH PERSP. 1025 (2002).

[231] EPA's treatment of statistical significance has also, on occasion, appeared to be opportunistic. In the PM rulemaking, EPA claimed to have placed "greatest weight on those studies that were clearly statistically significant . . . ." EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,676; *see also* EPA, 2001 D.C. Cir. PM Brief, *supra* note 68, 62 Fed. Reg. at 49 (arguing that "EPA's conclusion [on an annual standard] is supported by the fact that epidemiological studies performed in areas with annual mean concentrations below 15.7 $\mu g/m^3$ did not find a statistically significant relationship between daily fine particle concentration and adverse health effects"). Yet, in 1992, when EPA set the ozone standard at 0.12 ppm, the "key study" on which EPA relied to find an "adverse effect" at 0.15 ppm did not contain statistically significant findings. *See* EPA, 1992 Ozone Proposal, *supra* note 198, 57 Fed. Reg. at 35,546 ("The key study . . . by DeLucia and Adams (1977) . . . reported symptoms of discomfort and small but statistically-nonsignificant lung function decrements . . . at concentrations as low as 0.15 ppm O_3."); EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207 ("EPA acknowledges that Delucia and Adams failed to demonstrate any statistically significant decrements in pulmonary function resulting from exposure to 0.15 ppm for one hour.").

[232] As the D.C. Circuit stated, "the increasing-uncertainty argument is helpful only if some principle reveals how much uncertainty is too much." Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1036 (D.C. Cir. 1999). For a review of systematic ways to account for uncertainty in regulatory decision making, see GRANGER MORGAN & M. HENRION, UNCERTAINTY: A GUIDE TO DEALING WITH UNCERTAINTY IN RISK AND POLICY ANALYSIS (1990); Jonathan P. Caulkins, *Using Models that Incorporate Uncertainty*, 21 J. POL'Y ANALYSIS & MGMT. 486 (2002) (discussing models used in policy analyses and ways of addressing the inherent uncertainty that comes with using them).

C. *EPA's Incoherent Disregard of the Health Effects from Ozone*

EPA's decision making in the ozone rulemaking resulted in still more incoherence. Even though the Agency claimed to set its standards based on a precautionary approach to protecting the public health,[233] EPA nevertheless disregarded a range of adverse health effects and failed to provide an adequate explanation for why one level of risk was acceptable while another level was not. Indeed, over the course of the ozone rulemaking, EPA actually shifted the level of remaining risk it found acceptable.

When EPA proposed its new eight-hour, 0.08 ppm standard in 1996, it did so knowing that the new standard still would leave the public exposed to risk. According to EPA's risk estimates at the time, the proposed standard still would result in 1 million occurrences of moderate decreases in lung function and 74,000 cases of moderate-to-severe cough in outdoor children.[234] Presumably EPA viewed this residual risk as acceptable, as it did not propose the still lower option of 0.07 ppm. As it turned out, by the time EPA issued its final standard in 1997, its risk estimates had changed and the level of risk under the old standard, the one EPA tightened, was actually lower than what it had previously predicted would remain under the proposed 0.08 ppm standard.[235] According to EPA's revised risk assessment, the old standard resulted in only 931,000 cases of moderate decreases in lung function and 58,000 cases of moderate-to-severe cough.[236] If 1 million cases of decreased lung function could be tolerated by EPA in its

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[233] In defending its decision to lower the standard to 0.08 ppm, EPA argued in court that "EPA must 'err on the side of caution' to protect public health with an adequate margin of safety" and, therefore, that the Agency "considered suspected, but not yet demonstrated, chronic effects." EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 27 (quoting Lead Indus. v. EPA, 647 F.2d 1130, 1153 (1980)).

[234] Memorandum from Harvey M. Richmond, Risk and Exposure Assessment Group, to Karen Martin, Group Leader, Health Effects and Standards Group 10 tbl.3 (Feb. 11, 1997) (on file with author).

[235] The only relevant change in the Agency's risk assessment from the proposed rule to the final rule came from "several technical changes" that were "based on insights gained from the initial analyses." EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,861.

[236] Memorandum from Harvey M. Richmond, *supra* note 234, at 10 tbl.3. For the two other health endpoints EPA evaluated (decreased lung function at a greater forced expiratory volume and moderate-to-severe chest pain), the 0.08 ppm standard resulted in only a somewhat lower number of occurrences than the 0.12 ppm standard. In considering all four endpoints together, the combined residual health effects for the 0.12 ppm standard, which EPA found unacceptable in response to its final risk assessment, were not clearly higher than the residual effects under the proposed 0.08 ppm standard, which EPA found acceptable after its initial risk assessment. *Id.*

proposed rule, why in the final rulemaking did it need to revise the old standard that resulted in only 931,000 similar cases? If 74,000 cases of cough were acceptable in the proposed rule, why were 58,000 cases of cough not acceptable in the final rule? The Agency offered no explanation.

In a brief filed in the D.C. Circuit in 1998, EPA essentially admitted that it had shifted its position on the level of acceptable risk, but it argued that this was irrelevant because "[t]he relative differences are of greater import than the absolute numbers for purposes of comparing alternative standards."[237] In effect, EPA's brief acknowledged that agency decision makers had simply made up their minds to adopt a lower standard, rather than establish any particular level of acceptable health protection. Such an approach is inconsistent with the conventional understanding of the Clean Air Act, which calls for setting a standard that protects the public health with an adequate margin of safety, rather than setting a standard that is simply more stringent than the existing standard—a point EPA has acknowledged in other contexts.[238]

More significantly, EPA failed to provide any adequate explanation for why it turned its back on harms that some citizens would continue to suffer even under the Agency's new standards. EPA's own findings indicated that further reduction of the ozone standard from 0.08 ppm to 0.07 ppm would have provided additional incremental health benefits that, in at least some cases, were even more substantial than the benefits of the 0.08 ppm standard that EPA selected.[239] In its rulemaking, EPA did not directly dispute those commentators "who argue[d] that similarly large improvements in public health protection would result from a standard set at 0.07 ppm as compared to the proposed standard, such that, based on the same reasoning, the evidence warrants a standard set at 0.07 ppm."[240] For example, EPA estimated that the incremental risk reduction to children would be greater if an 0.07 ppm standard was adopted:

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[237] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 37 n.34.

[238] EPA rejected industry's argument that the implementation of the current ozone standard would have resulted in cleaner air, stating that such a factor "is irrelevant to the issue here, *i.e.*, what the level *should* be to protect public health with an adequate margin of safety." EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 48; *see also* EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,652 ("The overriding consideration in selecting a standard is how well it protects public health, not its relative stringency as compared to the previous standard.").

[239] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868.

[240] *Id.*

> [T]he median percent of outdoor children estimated to experience FEV_1 decrements greater than 15 percent is reduced from about 7.7 percent for a 0.09 ppm, 8-hr standard to about 6.8 percent for a 0.08 ppm, 8-hr standard. Attaining a 0.07 ppm, 8-hr standard results in a further reduction to about 3.0 percent of outdoor children estimated to experience this effect.[241]

In other words, EPA's own 0.08 ppm standard would reduce the median percentage of children experiencing lung function decrements by less than 1% (0.9%) relative to an 0.09 ppm standard (which is roughly equivalent to the preexisting one-hour, 0.12 ppm, standard).[242] In contrast, an 0.07 ppm standard would reduce this same health endpoint by an additional 3.8% or would provide more than *four times* the health benefits of the 0.08 ppm standard. If reducing this endpoint by 0.9% is "requisite to protect the public health,"[243] then consistency should have dictated that reducing the same endpoint by 3.8% would also be "requisite."

EPA's attempt to justify its decision to reject the lower 0.07 ppm standard marked a departure from the past interpretations that EPA and the courts had given to section 109 of the Clean Air Act. NAAQS traditionally have been understood not only to protect healthy persons, but also to protect the health of sensitive subgroups.[244] EPA identified several ozone sensitive groups, including children playing outdoors on hot summer days and children suffering from asthma and other respiratory illnesses. Moreover, even among healthy individuals, there is substantial variability in the response to

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[241] OZONE STAFF PAPER, *supra* note 163, at 203. FEV_1 refers to "forced expiratory volume," which is the volume of air that can be expired in one second by a subject and a frequently used measure of lung function. In the proposed rule, EPA states that the 0.08 ppm standard will reduce the median percent of outdoor children experiencing 15% FEV_1 decrements to 5.1%, rather than the 6.8% figure cited in the Staff Paper, while the figures for the 0.09 and 0.07 ppm standards remain the same in the two documents (7.7% and 3.0%, respectively). National Ambient Air Quality Standards for Ozone, 61 Fed. Reg. 65,716, 65,725 (Proposed Dec. 13, 1996) (to be codified at 40 C.F.R. pt. 50) [hereinafter EPA, Ozone Proposed Rule]. No explanation is given by EPA for this discrepancy. Even if the figure cited in the proposed rule is the correct one, it means that the benefit of reducing the standard from 0.09 ppm to 0.08 ppm is a 2.6% (7.7% minus 5.1%) reduction in children with such lung decrements, whereas to reduce the standard to 0.07 ppm would produce a further 2.1% (5.1% minus 3.0%) reduction in this health effect. *Id.* EPA would be hard-pressed to justify why a 2.6% percent reduction in this health effect is important while a further 2.1% reduction is not, and EPA did not attempt to provide any such justification.

[242] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,858.

[243] 42 U.S.C. § 7409(b)(1) (2000).

[244] *Supra* notes 193-97 and accompanying text.

ozone.[245] The existence of susceptible subgroups and the variability of responses makes it impossible to identify an ozone exposure level at which no significant adverse health effects would ever occur.

EPA purported to justify its selection of an 0.08 ppm ozone standard based on its claim that "an estimated 40-65% more children would experience health effects that could limit their activity and in some cases require medical treatment" at an 0.09 ppm ozone standard.[246] The Agency noted that "[t]hese effects would occur an estimated 70-120% more times per year—a significant consideration given concerns about repeated exposures."[247] EPA relied on scientific evidence showing that under the 0.09 ppm standard (which approximated the preexisting standard) an estimated 41,000 children in the nine cities studied would suffer moderate-to-severe pain upon deep breathing at least once per year.[248] The Agency estimated a reduction in this number to 27,000 children under the 0.08 standard it selected.[249] However, at the 0.07 ppm standard rejected by EPA, only about 9000 children would experience moderate or severe pain from breathing.[250] EPA's estimates were similar for large decreases in lung function (i.e., decreases of at least 20%). At the 0.09 ppm level, 97,000 children in the nine cities studied would suffer these large decreases in lung function, while only 58,000 cases were predicted at the 0.08 ppm level chosen by EPA.[251] Yet, at the rejected 0.07 ppm level,

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[245] *E.g.*, EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 15-16 ("[A]pproximately 5–20% of healthy individuals appear to be unusually sensitive to ozone. For these 'hyper-responders,' even low ozone exposures may trigger responses that interfere with normal activity." (citations omitted)); CRITERIA DOCUMENT, *supra* note 163, at 9-4 ("There is a large range of physiological responses among humans, with at least a 10-fold difference between the most and least responsive individuals."); OZONE STAFF PAPER, *supra* note 163, at 69 ("[T]here is wide variability in the severity of response to O_3 among both healthy individuals and those with impaired respiratory systems.").

[246] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 23 (citing Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38865, 38868).

[247] *Id.* at 23-24 (citation omitted).

[248] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,865; EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,725; *see also* Brief of Amici Curiae Senator Orrin Hatch and Representative Tom Bliley in Support of Respondents at 28-29, Browner v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (No. 99-1257) (citing this evidence to exemplify EPA's arbitrary line drawing).

[249] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,865.

[250] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,725 tbl.1 (0.3% of 3.1 million outdoor children in the nine urban areas).

[251] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,865.

only about 12,000 children would suffer similar effects.[252] EPA never offered the public any reason for why it believed it needed to lower the standard to protect 14,000 children from moderate-to-severe pain from breathing but at the same time it could reject an even lower standard that would have protected still 18,000 more children from the same effects. Nor did it explain why protecting an additional 39,000 children from decreases in lung function justified lowering the standard but protecting still 46,000 more children did not.

As the Agency proceeded through several rounds of litigation over the ozone revisions, a purported explanation for EPA's choice of an 0.08 ppm standard did appear to emerge. In the initial round of review, a panel of the Court of Appeals for the District of Columbia held that EPA failed to articulate an "intelligible principle" to constrain its discretion.[253] Dissenting from that panel's holding, Judge David Tatel articulated a science-based argument that EPA would refine and advance in subsequent rounds of litigation.[254] He argued that the scientific evidence and advice on ozone did indeed provide a clear basis for EPA's choice of a new NAAQS standard. Judge Tatel argued that "different types of health effects [are] observed above and below [0].08 ppm," the level selected by EPA.[255] Specifically, he opined that the health effects below 0.08 ppm were qualitatively different in that they were "transient and reversible."[256] He also claimed that the scientific evidence indicated that normal background levels of ozone sometimes occur at 0.07 ppm but not at 0.08 ppm.[257]

In petitioning the D.C. Circuit for a rehearing and advancing arguments on further appeal, EPA resurrected Judge Tatel's arguments

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[252] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,725 tbl. 1 (0.4% of 3.1 million outdoor children in the nine urban areas).

[253] Am. Trucking Ass'ns v. EPA, 175 F.3d. 1027, 1034 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) The court stated that "EPA's explanations for its decisions amount to assertions that a less stringent standard would allow the relevant pollutant to inflict a greater quantum of harm on public health, and that a more stringent standard would result in less harm," and fails to set a specific "requisite" pollution level to "protect the public health." *Id.* at 1035.

[254] *Id.* at 1057-62 (Tatel, J., dissenting); *see* Pierce, *supra* note 18, at 75 (Judge Tatel's "dissenting opinion in *ATA* . . . contains a typical symptom of the science charade,").

[255] *Am. Trucking*, 175 F.3d at 1059 (Tatel, J., dissenting).

[256] *Id.*

[257] *Id.* at 1059-60. Not surprisingly, Judge Tatel accepted these same arguments in the final round of litigation, authoring the panel opinion that upheld EPA's actions under the "arbitrary and capricious" standard of review. Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 358 (D.C. Cir. 2002).

in defending its air quality standards.[258] EPA came to argue that it "sets primary NAAQS at levels that provide protection from medically significant risks and *not* at levels that protect against any and all risks, or any and all effects."[259] EPA also asserted that the standards should be set at the lowest level at which studies indicated a statistically significant increase in "adverse effects," which the Agency redefined as health effects that are not "transient and reversible."[260] EPA thus argued to the court that the scientific evidence on ozone indicated a break point at 0.08 ppm, even though EPA also acknowledged, and the record showed, that there was no known threshold for health effects from ozone.[261]

EPA purported to identify "important and meaningful differences in the character of the scientific evidence regarding risks—including the estimated frequency and duration of adverse health effects—associated with levels above and below 0.08 ppm."[262] For example, EPA argued to the Supreme Court that the scientific evidence did not support setting an ozone standard below 0.08 ppm:

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[258] Petition for Rehearing and Petition for Rehearing En Banc for the United States Environmental Protection Agency at 15-17, Am. Trucking Ass'ns v. EPA, 283 F.3d 355 (D.C. Cir. 2002) (Nos. 97-1440, 97-1441) [hereinafter EPA, Petition for Rehearing]; *see also*, EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 28-30 (stating the EPA's argument on which Judge Tatel relied in his dissenting opinion in *American Trucking Ass'ns*).

[259] EPA, Supreme Court Respondents' Brief, *supra* note 60, at 33; *see also id.* at 36 ("Section 109(b)(2) [of the Clean Air Act] clearly directs that EPA must set NAAQS at levels requisite to protect the general population, or identifiable groups within communities, from medically significant effects.").

[260] EPA, Petition for Rehearing, *supra* note 258, at 16.

[261] *Id.* at 13.

[262] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 33; *see also* EPA, Petition for Rehearing, *supra* note 258, at 17 ("[T]he character of the scientific evidence differed for levels above and below 0.08 ppm, and supported the selection of the 0.08 ppm level as 'requisite' to protect public health."). This argument was not made in this form in the proceedings below. In the rulemaking itself, and in the original D.C. Circuit litigation, EPA summarily dismissed an 0.07 ppm alternative with the simple assertion that "[b]ecause health impacts below 0.08 ppm were less certain and likely to be less serious, the Administrator focused on the 0.08 and 0.09 ppm alternatives." EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 23 (citing EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863, 38,868). As with the PM rulemaking, EPA again invoked uncertainty as a wild card. Even though uncertainty was ostensibly a barrier to the adoption of the 0.07 ppm standard, it did not keep EPA from defending its decision to lower the standard to 0.08 ppm based on "suspected, but not yet demonstrated, chronic effects" and an obligation to "err on the side of caution." EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 27 (quoting Lead Indus. v. EPA, 647 F.2d 1130, 1153 (1980)).

> [T]he record showed that average responses caused by exposures even at 0.08 ppm were "typically small or mild in nature." The Administrator recognized that repeated exposures at the 0.08 ppm level could potentially produce adverse effects for some unusually sensitive individuals, but the record indicated that the "most certain" ozone-related effects at and below that level, even when adverse, are "transient and reversible." Moreover, the quantitative exposure and risk assessments showed that a standard set at 0.08 ppm would significantly reduce the number of such exposures. As for more serious health effects, EPA lacked clinical data indicating the existence of an exposure-response relationship at ozone levels below 0.08 ppm.[263]

While rejection of an 0.07 ppm standard may have been sound or even compelling on policy grounds, the "character of the scientific evidence" alone did not, nor could not, justify rejection of a standard lower than 0.08 ppm.[264]

After all, according to EPA, there was no scientifically established threshold at which no "adverse effects" occurred. In promulgating its final ozone standard, EPA stated that it did not "seem possible, in the Administrator's judgment, to identify a level at which it can be concluded with confidence that no 'adverse' effects are likely to occur."[265] EPA's own brief in the Supreme Court acknowledged that "[t]he evidence showed a continuum of risk within the range considered [i.e., 0.07 to 0.09 ppm], with statistically significant decreases in risk and corresponding increases in public health protection for successively more stringent eight-hour ozone standards."[266] Similarly, in the preamble to the proposed ozone standard, EPA concluded that "[w]ithin any given urban area, statistically significant reductions in exposure and risk associated with functional and symptomatic effects result from alternative 8-hour standards as the level changes from 0.09 ppm to 0.08 ppm to 0.07 ppm."[267] EPA acknowledged that the science showed "no break point or bright line that differentiates between acceptable and unacceptable risks within this range."[268]

In rejecting industry arguments that there appeared to be a threshold for respiratory effects at 0.08 ppm, EPA argued that there were moderate decrements in lung function (FEV_1) in a significant

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[263] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 14 (citations omitted).

[264] For purpose of the following analysis, we assume the validity of EPA's conclusions on the results and meaning of the scientific evidence.

[265] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,863.

[266] EPA, Supreme Court Respondents' Brief, *supra* note 60, at 12.

[267] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,728.

[268] *Id.*

percentage of the population at 0.08 ppm and that, moreover, "the response rates at 0.07 ppm are only slightly less than these values."[269] EPA also found "clear evidence from hospital admission studies that effects may continue down to background [0.04 ppm]."[270] Indeed, although the relationship between ozone levels and hospital admissions appeared somewhat less certain at lower levels, the Agency concluded that there was "a consistency between studies which supports the associations at all levels studied" (that is, down to background levels of 0.04 ppm).[271] Thus, for the very health effects on which EPA based its selection of the 0.08 ppm ozone standard, namely respiratory effects and hospital admissions, EPA's own findings in the record demonstrated that such effects occur at ozone levels well below 0.08 ppm.

Moreover, while the record showed a continuum in the frequency and severity of respiratory effects at successively lower ozone levels, it did not show a discernible discontinuum at 0.08 ppm between those effects that were transient and reversible and those that were more permanent, as Judge Tatel and EPA argued.[272] The majority of the respiratory effects on which EPA relied to lower the primary ozone standard down to 0.08 ppm were also transient and reversible.[273] Most significantly, by invoking a distinction between effects that were transient and reversible and those that were not, EPA again shifted its position without offering any justifications. When EPA last revised the ozone standard in 1979, it relied on the same types of transient respiratory health effects to support its standard, expressly finding that such effects were of concern and "adverse," "[e]ven when reversible" and "even though transitory."[274] Similarly, when the Agency previously

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[269] EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 82.

[270] *Id.* at 84.

[271] *Id.* Moreover, even if the effects at the lower levels may have appeared less certain, EPA was supposed to adopt a margin of safety to protect against less certain, or even unknown, risks. For our previous extensive discussion on EPA's ad hoc approach to the margin of safety requirement under the Clean Air Act, see *supra* notes 186-90 and accompanying text.

[272] *See* Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1059 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001) (Tatel, J., dissenting) (arguing that health effects below 0.08 ppm were qualitatively different in that they were "transient and reversible").

[273] As the majority opinion in the D.C. Circuit noted, "it is far from apparent that any health effects existing above the [0.08 ppm] level are permanent or irreversible." *Id.* at 1035.

[274] EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207. One of the key studies relied upon by EPA in 1979 found that subjects were uncomfortable when exercising while exposed to higher levels of ozone, but that "[t]he discomfort disappeared shortly after the termination of the experiment." *See* LESTER B. LAVE, THE

revised the PM standard in 1987, it set the standard "in the lower portion of the range where sensitive, *reversible* physiological responses of *uncertain health significance* are *possibly*, but not definitely, observed in children."[275] EPA's attempt to construct a scientific demarcation based on whether effects are transient and reversible was therefore neither supported by the record nor consistent with its own past decisions.

EPA has treated health effects as relevant when they could justify the standard that EPA preferred, but then discounted these same health effects in explaining why it did not adopt a more stringent alternative. For example, in its 1993 decision not to revise the 0.12 ppm ozone standard, EPA determined that lung function decrements in the range of ten to twenty percent, even "when accompanied by symptoms," were not "adverse effects."[276] Yet, in revising the same standard in 1997, EPA shifted its position concluding that a moderate lung decrement in the range of ten to twenty percent was indeed an "adverse effect."[277] In defending its most recent ozone standard against industry attacks that it was based on nonserious and reversible lung effects, EPA accused industry of "seek[ing] to trivialize lung function

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STRATEGY OF SOCIAL REGULATION: DECISION FRAMEWORKS FOR POLICY 104 (1981) (describing the DeLucia and Adams study relied upon by EPA in the 1979 revision of the ozone standard).

[275] EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,643 (emphases added).

[276] EPA, 1992 Ozone Proposal, *supra* note 198, 57 Fed. Reg. at 35,549. The proposal also states:

> [I]ndividuals exposed to lower levels of O_3 (e.g., 0.12 to 0.15 ppm) typically experience only mild and transient functional decrements [anywhere from a –9 to –16 percent decline in FEV_1, *id.* at 35,548.] . . . [This] may be accompanied by symptoms such as cough, chest tightness, pain on deep inspiration, and throat irritation . . . .
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> . . . Although there is a difference of opinion among the EPA's scientific advisors as to the significance of decrements in lung function in the range of 10 to 20 percent when accompanied by symptoms, it is the Administrator's judgment that the lesser effects associated with exposure to O_3 in the range of 0.12 ppm to 0.15 ppm observed in the controlled human studies do not constitute adverse effects for purposes of section 109 of the Act.

Id.

[277] *See* EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 17 (noting that EPA "concluded that 'moderate' effects . . . experienced by asthmatics [defined as 10 to 20 percent FEV_1 decrements] would likely be adverse because they could interfere with normal activity."). Likewise, in its 1979 revision of the ozone standard, EPA concluded that lung function decrements in the range of 5 to 15% were adverse effects. *See* EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207 ("[T]he experts' judgments varied as to the point at which adverse effects would begin, but fell within the range of a 5 to 15 percent decrease.").

decrements and respiratory symptoms, . . . [when] these effects can be sufficiently severe to disrupt the normal activity of both healthy individuals and asthmatics."[278] Similarly, when EPA revised its ozone standard in 1979, it concluded that physical discomfort and pulmonary function changes, "[e]ven when reversible" and "even though transitory," were "adverse effects" that needed to be taken into account "in selecting the level of the primary standard."[279] Yet, in defending its 1997 revision to the ozone standard, EPA argued that it was justified in disregarding the health effects that occur at levels below 0.08 ppm since "these effects (*e.g.*, lung function decreases and coughs) are less serious because they are 'transient and reversible.'"[280] The same kind of health effects seemed relevant when they supported EPA's decision to lower standards, but irrelevant when EPA needed to defend its decision not to lower standards still further.

EPA also justified its rejection of the 0.07 ppm standard by stating that the lower standard "would be closer to peak background levels that infrequently occur in some areas due to nonanthropogenic sources of O_3 precursors, and thus more likely to be inappropriately targeted in some areas on such sources."[281] Of course, it bears noting initially that any argument about setting standards to avoid naturally occurring background levels departs from a purely health-focused justification for a risk standard. It speaks to the standard's feasibility, a factor that EPA has otherwise claimed is impermissible to use in setting air quality standards.[282] Indeed, in previous NAAQS rulemakings, EPA specifically rejected industry arguments that EPA should consider the feasibility problems created by setting air quality standards too

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[278] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 33 (citation omitted).

[279] EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8207. Likewise, in its 1987 revision to the PM standards, EPA set the standard at a level where "reversible" effects of "uncertain health significance" may "possibly, but not definitely" occur. EPA, 1987 PM Rule, *supra* note 193, 52 Fed. Reg. at 24,643.

[280] EPA, Petition for Rehearing, *supra* note 258, at 16. Elsewhere in the litigation over its NAAQS revisions, EPA emphasized the transient and reversible nature of health effects observed at lower levels in defending its decision to reject a more stringent standard. *See* EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 69, at 28-30 (arguing that while a 0.08 ppm standard may lead to adverse effects, they are transient and reversible and, therefore, "less serious").

[281] EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868.

[282] *See, e.g.*, EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,683 ("For more than a quarter of a century, EPA has interpreted section 109 of the [Clean Air] Act as precluding consideration of the economic costs or technical feasibility of implementing NAAQS in setting them.").

close to the background levels.[283] If health is the only permissible consideration under the Clean Air Act, as EPA has argued and the courts have affirmed, then it should not matter whether a standard is set near or even below background levels.[284]

Even if background levels were considered to be relevant, EPA's concern about an 0.07 ppm standard approaching background levels was not supported by the Agency's own estimates in the rulemaking record. In conducting its risk assessment, and again in making its argument to the D.C. Circuit, EPA assumed a background level of 0.04 ppm—not 0.07 ppm.[285] The Agency's Staff Paper indicated that "it is reasonable to estimate that the 8-hour daily maximum O_3 during the summer is also in the range of 0.03 to 0.05 ppm."[286] Moreover, EPA specifically rejected arguments made by industry during rulemaking that background levels may approach 0.08 ppm.[287] In doing so, EPA stated that:

> While background concentrations of O_3 can be as high as 0.05 ppm, unless O_3 concentrations are affected by anthropogenic VOC and/or NOx emissions, 8-hr O_3 background concentrations will typically be much lower than 0.05 ppm. A reasonable estimate of the 8-hr daily maximum O_3 background during the summer season is 0.03-0.05 ppm.[288]

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[283] *See, e.g.*, Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1190 (D.C. Cir. 1981) (upholding EPA's refusal even to docket evidence submitted by industry claiming that attainment of an ozone standard would be precluded by background ozone areas in many parts of the country because "the EPA position that attainability is not central to a rulemaking of this type is correct").

[284] In other regulatory programs, EPA has sought to reduce pollutants to below background levels. For example, EPA's recently promulgated standard for arsenic levels in drinking water primarily controls naturally occurring levels of arsenic. *See* EPA, National Primary Drinking Water Regulations: Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976 (Jan. 22, 2001) (to be codified at 40 C.F.R. pts. 9, 141, 142) (establishing "a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero"). EPA has also taken steps to address radon, another naturally occurring pollutant. *See generally* EPA, *Indoor Air-Radon (Rn)*, http://www.epa.gov/iaq/radon/index.html (last updated Feb. 10, 2004) (describing EPA activities in addressing radon). In any case, EPA added a new provision into 40 C.F.R. pt. 50 app. I, that created a compliance exemption for peak ozone concentrations if they are associated with forest fires, stratospheric ozone intrusion, or "other natural events." *See* EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 95 (setting forth the justifications for adding the compliance exemption). The existence of an exemption such as this one undercuts the claim that EPA could not set the standard lower than 0.08 ppm because of background ozone levels.

[285] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 20 n.19, 47 (footnote omitted).

[286] OZONE STAFF PAPER, *supra* note 163, at 23.

[287] EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 86.

[288] *Id.*; *see also id.* at 93-94 (arguing that background levels will be below 0.05 ppm unless affected by anthropogenic emissions).

EPA did acknowledge that "at remote or rural sites O_3 concentrations can exceed 0.07 ppm," but dismissed the relevance of this finding because most of these concentrations were, in the Agency's view, caused by human activities.[289] EPA's claim that it could not adopt an 0.07 ppm standard because it was too close to background level did not comport with past positions taken by the Agency, nor with the Agency's own positions adopted earlier in the rulemaking.[290]

In its rulemaking and subsequent rounds of litigation, EPA offered one remaining defense of its decision to reject the lower 0.07 ppm standard. The Agency claimed it was justified in its decision not to set a NAAQS below 0.08 ppm based on the fact that no member of EPA's CASAC supported a standard below 0.08 ppm.[291] Of course, the statute delegates the authority to select a standard to the EPA Administrator, not to CASAC.[292] In its subsequent brief before the Supreme Court, EPA acknowledged that CASAC "did not relieve the Administrator of her duty to reach decisions on specific NAAQS

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[289] *Id.* at 86; *see also id.* at 94 (asserting that it is "clear that the component consisting of natural background O_3 is only a fraction of rural O_3 concentrations, which are clearly increased by human activities throughout the U.S.").

[290] *See* Oren, *supra* note 18, at 10,659 (arguing that the Agency's reasoning in adopting its ozone standard was flawed because it failed to explain why the background level was relevant).

[291] EPA, Supreme Court Petitioners' Brief, *supra* note 57, at 14 (noting that "none of the CASAC advisors recommended setting the revised NAAQS at a level below 0.08 ppm"). Judge Tatel had advanced this point in his dissent in *American Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1059 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001), and used it again in the panel opinion in the D.C. Circuit's second round of review in the case. *See* Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 379 (D.C. Cir. 2002) ("EPA is entitled to give 'significant weight' to the fact that no committee member advocated a level of 0.07 ppm." (quoting EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868)); *see also* Am. Petroleum Inst. v. Costle, 665 F.2d 1176, 1188 (D.C. Cir. 1981) (stating that EPA is required "to submit the criteria document and standard to the SAB [Science Advisory Board] for comment, but it was not obligated to obtain SAB approval of either before promulgation of a final standard"). This decision was made under the same statutory provision that provides CASAC authority, but before the relevant subcommittee of SAB was renamed CASAC. H.R. REP. NO. 95-722, at 16 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3293, 3295 (stating that the SAB's review of EPA's air quality standards and criteria documents "is intended to be advisory only").

[292] *Whitman*, 531 U.S. at 462-63 (2001) ("Once a NAAQS has been promulgated, the Administrator must review the standard (and the criteria on which it is based) 'at five-year intervals' and make 'such revisions . . . as may be appropriate.'" (quoting 42 U.S.C. § 7409(d)(1) (2000))); *see also Am. Trucking Ass'ns*, 283 F.3d at 358 (describing CASAC as an advisory committee).

levels."[293] The function of CASAC is to provide scientific advice, not to make the risk management choices necessary for selecting a standard.[294]

Admittedly, some members of CASAC did express their "personal preferences" for specific levels for the revised standards.[295] As EPA has recognized elsewhere, however, the individual preferences of CASAC members are distinct from the collective findings of the entire committee, which comprise the official advice that EPA must consider.[296] CASAC as a whole expressly concluded that the selection of the ozone standard was a policy choice for the Administrator, rather than a scientific determination within the expertise of the committee.[297] Even though the individual views of CASAC members provided neither a legal basis for, nor a limitation on, the Administrator's decisions, it is interesting to note that more than half of those members who expressed a view actually supported a level higher than 0.08 ppm.[298] In the end, EPA effectively claimed that it was entitled to give

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[293] EPA, Supreme Court Respondents' Brief, *supra* note 60, at 11. EPA acknowledged that the official CASAC consensus view was limited to providing scientific advice, not advising on the ultimate selection of a regulatory standard: "Once the Administrator had concluded that the NAAQS required revision, she—unlike CASAC—had to resolve the uncertainties associated with those decisions." *Id.*

[294] *See* EPA, No. A-95-54, RESPONSES TO SIGNIFICANT COMMENTS ON THE 1996 PROPOSED RULE ON THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER 26-27 (1997) [hereinafter EPA, PM RESPONSE TO COMMENTS] (rejecting comments that CASAC's failure to reach consensus on the Agency's chosen standards undermines the basis for those standards because such arguments "appear to rest on questionable assumptions about the role and purposes of CASAC review," which is to provide scientific advice that the Administrator must consider "but is not bound" by).

[295] EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 37 (describing the views of individual CASAC members as "personal preferences"); *see also Am. Trucking Ass'ns*, 283 F.3d at 379 (noting that ten CASAC members expressed opinions about where the revised standard should be set).

[296] April 23, 1997 Hearing, *supra* note 74, at 370 ("While ten of the 16 CASAC members who reviewed the ozone staff paper expressed their preferences as to the level of the standard, all believe it is ultimately a policy decision for EPA to make."); EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 37 ("CASAC recognized that these views were just that—'personal preferences'—and distinguished them from the committee's consensus view that the selection of a standard was a 'policy judgment' for the Administrator."); EPA, PM RESPONSE TO COMMENTS, *supra* note 294, at 29 ("[I]t is important to separate the personal opinions that individual members might express on particular policy choices such as standard levels from their scientific conclusions on the range of options that is supported by the science and should be considered by the Administrator.").

[297] *Supra* notes 143-45, 179 and accompanying text.

[298] EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,729 (noting that "while some CASAC members supported the choice of the proposed 0.08 ppm, fully

significant weight to individual views of CASAC members when it bolstered the Agency's decision not to lower the standard to 0.07 ppm, but that it did not need to give them this same weight when it was less supportive of the Agency's position.

In sum, EPA's attempt in litigation to argue that science compelled it to reject any ozone standard below 0.08 ppm was inconsistent with numerous other Agency positions. The Agency disregarded the health effects from exposures below 0.08 ppm, abandoning the position it took in previous NAAQS rulemakings that transient and reversible effects warranted regulatory protection. EPA's position on background levels in litigation was inconsistent with its analysis of background levels in the rulemaking record and with its previous dismissal of industry concerns about background levels. Finally, EPA's position was inconsistent with its purported health-only construction of the Clean Air Act, as presumably would have been any decision to set a standard other than zero for a non-threshold pollutant. Rejecting an 0.07 ppm ozone standard may well have been an appropriate decision, but it could only be defended on public policy grounds, not based on scientific evidence or expertise. EPA identified no such policy reason to justify why it effectively turned its back on the adverse effects that some citizens will continue to experience even if all parts of the country come into compliance with the Agency's new standards.

D. *Comparing the Health Benefits of the Ozone and Particulate Matter Standards*

One of the most striking examples of regulatory incoherence in EPA's NAAQS revisions lies in the disparity between the health benefits from the revised ozone standards and the revised particulate matter standard.[299] In refusing a more stringent alternative for the PM

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half or more of the CASAC panel members expressing views on a specific level supported a specific level or range of levels that include 0.09 ppm"). Furthermore, EPA did not defer in the same way to the views of CASAC members when it came to setting the level of its revised PM standard. Of the twenty-two members of the CASAC panel, only four expressed a preference for the more stringent PM alternatives in EPA's proposal. Robert W. Crandall, *The Costly Pursuit of the Impossible*, BROOKINGS REV., Summer 1997, at 41, 45.

[299] *See, e.g.*, Lester B. Lave, *Clean Air Sense*, BROOKINGS REV., Summer 1997, at 41, 43 (noting that EPA estimated its ozone standard would provide at most $1.5 billion annually in health benefits, while its particulate standard would offer as much as $110 billion in health benefits). EPA's starkly disparate responses to health benefits across the two standards is an example of comparative incoherence. *See* Cary Coglianese, *Bounded Evaluation: Cognition, Incoherence, and Regulatory Policy*, 54 STAN. L. REV. 1217, 1223 (2002) (noting that comparative incoherence arises when one regulation "turns

standard, EPA rejected an option that would have achieved a much greater gain in health benefits than the gain EPA anticipated from its revision of the ozone standard. If protecting the public health with an adequate margin of safety did not require the Agency to lower the PM standard still further, then it is far from clear why the Agency was justified in revising its ozone standard at all.

Based on staff analysis, and consistent with CASAC's advice, the Agency assumed that the new ozone standard would not achieve any reduction in mortality.[300] In quantifying the nonmortality health benefits of the new ozone standard, EPA estimated the total monetized value to be $0.06 billion.[301] In contrast, EPA estimated that lowering the daily $PM_{2.5}$ standard from the selected 65 $\mu g/m^3$ level to 50 $\mu g/m^3$ would produce an additional $1.64 billion in *nonmortality*

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out to be inconsistent with other regulations of either the same general type or other types altogether").

[300] In setting the ozone standard, EPA found that there was insufficient evidence of any association between ozone exposure and mortality, and therefore it did not rely on any reduction in mortality to justify its new ozone standard. *See, e.g.*, OZONE STAFF PAPER, *supra* note 163, at 71 (concluding that "only limited, suggestive evidence" exists that "[a]n increase in daily mortality [is] associated with O_3 exposure"); *id.* at 72 (noting that "associations between O_3 exposure and chronic health impacts have not been sufficiently demonstrated in humans"). EPA identified and used some recent scientific studies identifying a mortality risk from ozone in its Regulatory Impact Analysis, which had the effect of substantially increasing the Agency's estimate of the benefits of the revised ozone standard while making clear that "this evidence was not used in the NAAQS standard setting process." EPA, REGULATORY IMPACT ANALYSES FOR THE PARTICULATE MATTER AND OZONE NATIONAL AMBIENT AIR QUALITY STANDARDS AND PROPOSED REGIONAL HAZARD 2-9 (1997), [hereinafter RIA] *available at* http://www.epa.gov/ttn/oarpg/naaqsfin/ria.html. The EPA's response to ozone comments stated:

> [P]remature mortality associated with O_3 was not given substantial consideration during this review of the O_3 primary NAAQS. Because some of the new studies were considered in the Regulatory Impact Analysis, some commenters may have believed mistakenly that they were considered in review of the NAAQS . . . . EPA did not give significant weight to that mortality evidence.

EPA, OZONE RESPONSE TO COMMENTS, *supra* note 136, at 48-49.

[301] RIA, *supra* note 300, at 12-70 tbl.12-19 (estimating health benefits of the new standard using an assumption of a constant annual PM standard of 15 $\mu g/m^3$). In the RIA, EPA claimed that some new studies not reviewed by CASAC strengthened the evidence for some reduced mortality benefits from the ozone standard. Although the RIA made clear that EPA did not rely on reduced mortality in selecting the ozone standard, *id.* at 12-15, 12-19, it included an estimate of potential mortality reduction benefits to produce a "high-end" ozone benefits estimate. *Id.* at 12-20 to 12-21. The estimated reduced mortality would increase the health benefits of the ozone standard from $0.06 to $1.76 billion. *Id.* at 12-70 tbl.12-19. Even this latter figure, however, is smaller than the incremental benefits of the revisions to the $PM_{2.5}$ standard previously discussed.

health benefits.[302] EPA's analysis did not permit a direct comparison of the mortality benefits of the two $PM_{2.5}$ alternatives, but given that most of the health benefits from the $PM_{2.5}$ standards are from reduced mortality, the total marginal health benefits of reducing the $PM_{2.5}$ standard from 65 to 50 $\mu g/m^3$ would likely have been much larger than $1.7 billion. The incremental benefits of reducing the daily PM standard still further to 25 $\mu g/m^3$ would have been even larger, but they were not calculated by EPA.

EPA's analysis clearly indicates that the health benefits foregone by EPA's decision not to tighten the $PM_{2.5}$ daily standard below the 65 $\mu g/m^3$ level dwarfed the total health benefits of the ozone standard (by a factor of approximately 50).[303] EPA claimed that its ozone revision was necessary in order to protect public health with an adequate margin of safety, but it also argued that a further tightening of the PM standard to achieve significantly greater health benefits was *not* necessary to protect public health with an adequate margin of safety. EPA offered no explanation for why its treatment of health risks should vary markedly from one pollutant to another.[304]

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[302] RIA, *supra* note 300, at 12-44 tbl.12.5 (listing high-end estimated monetized health benefits for partial attainment of each of the two $PM_{2.5}$ standards). EPA calculated the mortality benefits of the two standards using slightly different methodologies, so a direct apples-to-apples comparison is not possible, although the monetized mortality health benefits of the 50 $\mu g/m^3$ standards appear, as expected, to be larger than the benefits for the 65 $\mu g/m^3$ standard.

[303] Furthermore, this inconsistency cannot be explained based on the uncertainty contained in any risk analysis. Both the ozone and PM risk assessments involve substantial uncertainty, as EPA acknowledges. EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,860 (indicating that "the Administrator and CASAC recognized that there are many uncertainties inherent in such [risk assessment] analyses" of ozone exposure); EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,656 (noting that the "quantitative risk estimates include significant uncertainty"). Moreover, the $PM_{2.5}$ risk estimates for the regulatory increments not adopted by EPA come from the same studies and data sets that EPA used to justify the $PM_{2.5}$ standard it did select. Given that there is no qualitative break point in the extent of uncertainty in those data, EPA cannot on one hand say that the data above its selected standard is sufficiently certain to support regulation, but the data, produced with the same method and in the same studies, below its standard is too uncertain to be treated as credible. *See also supra* notes 229-32 and accompanying text (discussing EPA's use of uncertainty as claim for disregarding data that did not support its policies).

[304] *See* Sunstein, *supra* note 18, at 330 ("EPA's own calculations showed that a tighter particulates standard would have produced far greater health benefits than the ozone standard; this leaves a serious unexplained anomaly in the two standards taken together."); Sunstein, *supra* note 20, at 6 ("[T]ighter regulation of particulates, going well beyond the EPA's rule, would appear to do a great deal more to protect public health than would the new regulation of ozone.").

III. TOWARD MORE PRINCIPLED RISK MANAGEMENT

EPA's effort to rely exclusively on science may have effectively conveyed the impression to its overseers that the Agency had a sound basis for revising its standards, but in fact, by relying on science-based rhetoric, the Agency had only disguised a series of ad hoc and incoherent decisions. Positions adopted in previous rulemakings, or at previous points in the same rulemaking, shifted in the course of the Agency's defense of the new standards. Findings or assumptions made in the rulemaking record were set aside in order to support the Agency's positions in litigation. Nowhere during the entire rulemaking and litigation process did EPA articulate a clear policy rationale to justify how the NAAQS standards should be set, other than to assert that they were set at the "appropriate" level.[305]

Given the way that section 109 of the Clean Air Act has been construed over the years, the Agency has found itself navigating untenable conceptual terrain. Following the dictates of the Clean Air Act, EPA has claimed to select standards that protect the public health with an adequate margin of safety and, hence, has proceeded to defend revisions of its standards by marshaling scientific evidence of health effects at levels below its previously set standards.[306] Yet, similar evidence considered by the Agency demonstrated that health effects would still persist even at levels below the revised standards.[307] Indeed, with non-threshold pollutants, these effects will by definition persist at any level above zero.[308] The Agency has admitted that it need not, even cannot, set its standards at zero, but it has never provided any consistent and meaningful set of reasons that justify its decision to lower its standards to protect against one increment of adverse effects but not to lower them further to protect against another increment of adverse effects.

In this final Part, we highlight what needs to be done if air quality standard setting is to proceed in the future with more coherent justification. We present four principled approaches to standard setting in the Section that follows, with the aim of showing what has been missing from EPA's decision making as well as pointing toward better ways

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[305] *See* Sunstein, *supra* note 18, at 327 ("EPA's presentation of all the relevant data shows reason for concern about adverse health effects at current levels, but leaves many doubts about why EPA chose the particular standards it did, rather than standards somewhat higher or somewhat lower.").

[306] *Supra* Parts I.A, II.A.

[307] *Supra* Part II.B–C.

[308] *Supra* Part I.C.

of setting air quality standards in the future. Unfortunately, some of the most promising of these approaches are no longer permissible under EPA's, and now the Supreme Court's, interpretation of the Clean Air Act and therefore raise important implications for future legal developments. In this Part, we show how achieving a more candid and coherent policy justification for environmental decisions will require a significant change in EPA's existing approach toward setting NAAQS standards, including an abandonment of the fundamental fiction that costs do not and should not enter into the Agency's decision making. Of course, given the Supreme Court's affirmation of this fiction,[309] moving toward principled standard setting will now require legislative change, not only to overcome the restrictive interpretation EPA and the courts have given to section 109 of the Clean Air Act, but also to direct EPA to develop a set of general policy guidelines for use in making future decisions about its air quality standards.

A. *Risk Management Principles*

Regulatory decisions, such as the selection of air quality standards, involve enormous stakes in terms of both health consequences and economic burdens. How can EPA provide a more coherent justification for these significant decisions than it offered in its most recent NAAQS revisions? A regulatory agency such as EPA has four basic approaches available that it can use to provide a consistent justification for making risk management decisions such as setting ambient standards: (1) eliminate all risks (or all nonnaturally occurring risks); (2) avoid unacceptable risks; (3) avoid unacceptable costs (sometimes described as the feasibility approach); and (4) balance costs and benefits.[310] Although these approaches are not all equally

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[309] *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 465 (2001) (affirming that EPA is not permitted by statute to consider costs in setting ambient air quality standards).

[310] For a similar taxonomy of approaches, see FRANK CROSS, ENVIRONMENTALLY INDUCED CANCER AND THE LAW 69-95 (1989). While the four approaches we outline represent the major justification strategies available to risk regulators, they do not represent an exhaustive list of all possible principled approaches. Another principled approach would be to eliminate all costs of regulation, but this would be as misguided as eliminating all risks. Some level of government intervention is needed to address environmental risk and thereby impose an appropriate level of costs on those actors that have not fully internalized all the social costs of their action. For discussions of the rationales for governmental regulation, see NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 3-7 (1994); CASS R. SUNSTEIN, AFTER THE RIGHTS REVOLUTION 45-46 (1990); V. KIP VISCUSI ET AL., ECONOMICS OF REGULATION AND ANTITRUST 2-3 (2000). Other principled approaches

sound strategies—nor are they all currently permissible under the Supreme Court's interpretation of the Clean Air Act—they do illustrate the range of possible ways to provide a consistent explanation for risk management decision making.[311]

1. Eliminate All Risks

The first approach is conceptually straightforward: eliminate all risks. This principle could be consistently applied if EPA set its standards at levels at which it believed there would be absolutely no health risks. The Agency also could take a consistent risk management approach if it chose to minimize risk by setting standards at background levels, thereby opting to eliminate all risks except those that are naturally occurring (a zero *additive* risk approach).

More generally, the EPA could decide to follow an approach aimed at minimizing all risk. A minimize risk approach could in some cases lead to a *nonzero* risk level if a pollutant provides some beneficial health effects that countervail its adverse health effects. For example, commentators in the ozone rulemaking alleged that, despite the adverse pulmonary effects of ground level ozone, concentrations of the pollutant also screen out harmful ultraviolet radiation.[312] If a

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take into account issues of distributional equity—deploying a consistent strategy to promote fairness and equality in the distribution of costs and benefits across different individuals and groups within society. *See* NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 40 (1996) (noting that in some cases "managing environmental risks has become a question of fairness, moral responsibility, and distributional equity"); K.S. SHRADER-FRECHETTE, RISK AND RATIONALITY: PHILOSOPHICAL FOUNDATIONS FOR POPULIST REFORMS 183 (1991) (arguing for weighing "egalitarian values, social obligations, and rights" as a part of risk management decision making).

[311] Our focus here is on developing consistent general approaches to risk management decision making, not on all the choices that enter into risk decision making, such as the treatment of uncertainty. Much has been written about the development of principled approaches to risk assessment, and government agencies have issued guidelines for assessing and characterizing risk with the aim of increasing consistency. *See, e.g.*, EPA, DRAFT GUIDELINES FOR CARCINOGEN RISK ASSESSMENT 1 (1999) (offering guidance to EPA staff and decision makers on how to develop and use risk assessments), *available at* http://www.epa.gov/ncea/raf/pdfs/cancer_gls.pdf. Our aim, in contrast, is to focus on the core principles needed to justify the central risk management question that science by itself simply is unable to answer, namely the level at which ambient risk standards should be set.

[312] *See, e.g.*, Randall Lutter & Howard Gruenspecht, *Assessing Benefits of Ground-Level Ozone: What Role for Science in Setting National Air Quality Standards*, 15 TUL. ENVTL. L.J. 85, 87 (2001) (arguing that in setting its 1997 ozone standard EPA focused only on the ozone's harmful effects without taking into account its potential benefits). The D.C. Circuit, in the first round of litigation over EPA's ozone revision, directed the Agency

reduction of the pollutant would create offsetting risks, such as an increase in skin cancer, then a standard that minimizes health risks would be set above zero.[313] In cases with such so-called risk-risk tradeoffs, EPA could opt for a standard set at a level that achieves the lowest possible adverse health effects, namely the level at which the marginal adverse health effects equal the marginal beneficial health effects.[314]

Minimizing risk would appear to resonate with the conventional interpretation of the Clean Air Act, with its emphasis on a preventative approach to health protection through a margin of safety.[315] As the D.C. Circuit Court directed in *Lead Industries*, EPA should set its NAAQS standards in a way that ensured "an absence of adverse effect"

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to take these possible beneficial health effects of ozone into consideration. Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1051-53 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

[313] This assumes that the dose-response curves of the health benefits and health risks of the pollutants have different shapes. If the two dose-response curves are parallel, it may be that the health risks or the health benefits dominate the other at all dose levels as they both decrease in step with exposure. In this case, the standard that maximizes net health benefits would be set at zero (if health risks are greater than health benefits at all exposure levels) or no standard should be set (if health benefits are greater than health risks at all exposure levels).

[314] *Cf. Whitman*, 531 U.S. at 495 (Breyer, J., concurring) ("A rule likely to cause more harm to health than it prevents is not a rule that is 'requisite to protect the public health.'"). *See* LAVE, *supra* note 274, at 15-17 (outlining methods for weighing the risks of exposure to a carcinogen versus the risks of eliminating it); John D. Graham & Jonathan Baert Wiener, *Confronting Risk Tradeoffs*, *in* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT 1-4 (John D. Graham & Jonathan Baert Wiener eds., 1995) (advocating a "more rigorous framework for analyzing risk tradeoffs" that arise when countervailing risks emerge from attempts to reduce target risks); Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533, 1535-38 (1996) (arguing that individuals and regulators suffer from "selective attention" that allows them to overlook ancillary risks and, therefore, advocating that policymakers act to minimize net risks). There are obvious affinities between such an approach and one that balances all benefits and costs of a risk standard, but because the "maximize risk reduction" approach focuses only on costs and benefits as measured in health effects, it should be distinguished from an approach that aims to maximize net social benefits. In those cases where the existence of some amount of a pollutant offers no offsetting health benefits whatsoever, the "maximize risk reduction" approach equates with the "zero risk" approach.

[315] *See supra* notes 194-95 and accompanying text (noting EPA's claim that the protection of public health is the predominant goal of its air quality standards). The language in the Clean Water Act that commands the elimination of all discharges into the nation's waterways also exemplifies this approach. *See* 33 U.S.C. § 1251(a) (2000) (stating that the national goal underlying the prevention of water pollution is to protect the use of water by individuals and fish and wildlife). The regulation of food additives under the Delaney Clause also followed this approach for many years. *See* Pub. Citizen v. Young, 831 F.2d 1108, 1109 (D.C. Cir. 1987) (finding that the Delaney Clause, which prohibits use of color food additives "found . . . to induce cancer in man or animal," does not contain a de minimus exception).

on members of the public.[316] Of course, for non-threshold pollutants that lack countervailing health benefits, the minimize risk principle can only be applied consistently if EPA sets its standards at a zero or background concentration level, something that would effectively call for the elimination of all economic activities.[317] Quite sensibly, the Agency has expressly disavowed any intention of adopting a zero-risk approach, and the Supreme Court has also recognized the folly of such an approach.[318] Moreover, while EPA has raised concerns about background levels (when it would appear expedient), it has neither adopted nor applied consistently any principle of eliminating all human-created pollution.[319] It has also so far rejected calls for making health-health tradeoffs in setting NAAQS standards under a minimize risk principle.[320] Consequently, if EPA is to make its risk management decision making more coherent, it will almost certainly need to choose a principle other than eliminating all risk.

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[316] Lead Indus. v. EPA, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

[317] *See* W. KIP VISCUSI, RISK BY CHOICE: REGULATING HEALTH AND SAFETY IN THE WORKPLACE 136-38 (1983) (using EPA's lead standard requiring that 99.5% of the most sensitive group be exposed to levels below a zero-risk threshold as an example of the economic inefficiencies that result from the exclusion of cost-benefit tradeoffs in risk management decision making); *see also supra* Part I.C (arguing that eliminating pollution entirely would have the universally undesirable effect of prohibiting economic activity).

[318] *See supra* notes 164-65 and accompanying text (stating that neither EPA nor any other major participant in environmental policymaking has ever argued for a zero-risk standard, as it would call for the elimination of the industrialized economy); *see also Whitman*, 531 U.S. at 494 (Breyer, J., concurring) (noting that the Clean Air Act should not be construed as requiring "a world that is free of all risk—an impossible and undesirable objective"); Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 642 (1980) (noting that "safe" does not necessarily mean "risk-free").

[319] *See supra* notes 282-91 and accompanying text (showing the inconsistencies in EPA's argument that it set the standard at a level approximating "naturally occurring background levels").

[320] National Ambient Air Quality Standards for Ozone: Final Response to Remand, 68 Fed. Reg. 614, 618 (Jan. 6, 2003) (to be codified at 40 C.F.R. pt. 50) (noting that any increase in risks associated with reductions in ground-level ozone levels, such as from increased exposure to ultraviolet radiation, is "too uncertain at this time to warrant any relaxation in the level of public health protection previously determined to be requisite to protect against the demonstrated adverse respiratory effects of direct inhalation exposure to O_3 in the ambient air").

2. Avoid Unacceptable Risks

A second approach would be for the Agency to establish a level of acceptable risk for its air quality standards.[921] Rather than minimizing all risks, the Agency would only reduce risks to a consistent and tolerable level. As with the minimize risk principle, the acceptable risk approach focuses exclusively on the benefits to be reaped from a risk standard.[922] It does not try to maximize those benefits, but simply to deliver a desirable level of health benefits.

The acceptable risk approach has been used in other regulatory contexts. For example, in setting standards for hazardous air pollutants, EPA has presumptively defined "acceptable risk" to mean a maximum individual mortality risk of no greater than one in ten thousand.[923] The Agency has similarly set acceptable risk targets in other contexts, including the regulation of water quality, hazardous wastes, and pesticides.[924] The Occupational Safety and Health Administration (OSHA) follows a similar approach, using a benchmark mortality risk of one in one thousand as the level of "significant risk"

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[921] *See* Baruch Fischhoff, *Acceptable Risk: A Conceptual Proposal*, 5 RISK 1, 4-8 (1994) (proposing an analytical procedure for determining and implementing an acceptable risk approach); Gary E. Marchant & Dawn P. Danzeisen, *'Acceptable' Risk for Hazardous Air Pollutants*, 13 HARV. ENVTL. L. REV. 535, 540-42 (1989) (summarizing the four approaches proposed by EPA to develop a level of acceptable risk on which to base emissions standards for hazardous air pollutants).

[922] *See* Cass R. Sunstein, *Cost-Benefit Default Principles*, 99 MICH. L. REV. 1651, 1664 (2001) (describing the acceptable risk approach as "entirely benefits-based" (emphasis omitted)).

[923] National Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants, 54 Fed. Reg. 38,044, 38,045 (Sept. 14, 1989) (codified at 40 C.F.R. pt. 61) [hereinafter National Emission Standards]. This risk level slides down towards one in one million as the size of the exposed population increases. *Id.* at 38,044-45. In addition, the Clean Air Act now authorizes EPA to remove categories of sources of hazardous air pollutants from the list of regulated sources whenever it finds "that no source in the category . . . emits such hazardous air pollutants in quantities which may cause a lifetime risk of cancer greater than one in one million to the individual in the population who is most exposed to emissions of such pollutants from the source." 42 U.S.C. § 7412(c)(9)(B)(i) (2000).

[924] *See* March Sadowitz & John D. Graham, *A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy*, 6 RISK 17, 25-30 (1995) (outlining the risk standards that EPA has created with respect to water quality and hazardous wastes). The legislative history of the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, stipulates that EPA should apply an acceptable risk level of one in one million for certain pesticide residues. H.R. REP. NO. 104-669, pt. 2, at 41 (1996).

on which it bases its occupational health standards.[325] If EPA adopted a similar, approach, it could then use an acceptable risk criterion to select a set of consistent air quality standards.

Extending an acceptable risk approach to NAAQS decision making would not be easy, however, since criteria pollutants such as ozone and PM cause varied types of health effects other than mortality. Most acceptable risk benchmarks established by EPA under other regulatory programs focus exclusively, or at least primarily, on cancer mortality.[326] Mortality is a binary effect, but many of the health effects of pollutants, like ozone, involve continuous health effects (e.g., respiratory irritation) that vary in intensity from a minor nuisance to a serious illness. It is generally harder to define an acceptable risk level for such continuous effects because it is necessary to address both the frequency and the severity of the disease.[327] Moreover, a common metric for morbidity is needed to compare alternative standards, each of which may vary along multiple dimensions of predicted health effects (such as if exposure contributed to circulatory as well as to pulmonary problems).[328]

Another issue raised by the acceptable risk approach is whether to focus on the risks to individuals, to the population, or to both.[329] EPA has yet to adopt a clear and consistent position on whether to base its NAAQS decisions on maximum individual or population risk.[330] In its

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[325] *E.g.*, Occupational Exposure to Formaldehyde, 52 Fed. Reg. 46,168, 46,230 (Dec. 4, 1987) (codified at 29 C.F.R. pts. 1910, 1926); Occupational Exposure to Ethylene Oxide, 49 Fed. Reg. 25,734, 25,764 (June 22, 1984) (codified at 29 C.F.R. pt. 1910); Occupational Exposure to Inorganic Arsenic, 48 Fed. Reg. 1864, 1902 (Jan. 14, 1983) (codified at 29 C.F.R. pt. 1910); *see also* Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 655 (1980) (determining that OSHA should use a mortality risk of one in one thousand as a benchmark for significant risk); Int'l Union v. OSHA, 37 F.3d 665, 670-71 (D.C. Cir. 1994) (upholding OSHA's decision to use a single risk standard applicable to all general industry employers, rather than to disaggregate industries).

[326] *See, e.g.*, Sadowitz & Graham, *supra* note 324, at 19-21 (discussing EPA's analysis of risk based on cancer rates).

[327] *See* Reilly, *supra* note 44, at 1365-66 ("The search for the Holy Grail of risk management—the so called 'bright line' that would let policy makers determine, under any and all circumstances, whether a particular level of risk is 'acceptable' or not—seems doomed to failure.").

[328] *See infra* notes 338-40 and accompanying text (analyzing EPA's comparative analysis of continuous health effects).

[329] *See* Sunstein, *supra* note 20, at 9 ("[I]t is not clear if the agency should focus on the probability of harm faced by each individual, or instead on some statistical measure of aggregate harms, faced by the population as a whole.").

[330] In the late 1980s, EPA defined "acceptable risk" for exposure to hazardous air pollutants under section 112 of the Clean Air Act by considering only maximum

recent ozone revision, EPA appeared in some ways to accept a population risk approach.[351] Yet, in a previous NAAQS rulemaking, EPA explicitly indicated that the number of people exposed was not relevant, since "[s]tandards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect with given concentration levels."[352] The problem with relying only on levels of risk to individuals, of course, is that it overlooks the number of people exposed to the risk, something that clearly affects overall health benefits.

If EPA were to measure and compare the overall benefits of different regulatory alternatives, it would need to use consistent methods to quantify all the benefits that it predicted from each proposed standard and its alternatives. Such a careful "benefits analysis," as Professor Cass Sunstein has called it, would enable the Agency to determine whether any given regulatory option can be expected to achieve an acceptable level of risk.[353] A benefits analysis would detail all the health effects associated with different levels of exposure as well as report the predicted incidence of these effects on all exposed individuals, including those in any sensitive subgroups within the overall population.[354] Such a benefits analysis would contain EPA's best range (or point) of estimates for the number of people likely to be exposed to the pollutant under an alternative standard, the probabilities that they will suffer various health effects, and the severity of those effects.[355] These benefits could be monetized using willingness-to-pay (WTP) measures, a standard way of aggregating different kinds of environmental health effects across an entire population.[356]

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individual risk or only total population risk before ultimately selecting a hybrid approach that considered both measures. National Emission Standards, *supra* note 323, 68 Fed. Reg. at 38,045.

[351] EPA justified its selection of the 0.08 ppm ozone standard over the 0.09 ppm standard based largely on the argument that greater numbers of people would be exposed to unhealthy air quality under the 0.09 ppm standard than under the 0.08 ppm standard. EPA argued that under the 0.08 ppm standard "an estimated 40–65% more children would experience health effects that could limit their activity and in some cases require medical treatment." EPA, D.C. Cir. Ozone Brief, *supra* note 59, at 23-24 (citing EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,868).

[352] EPA, 1979 Ozone Rule, *supra* note 196, 44 Fed. Reg. at 8210.

[353] Sunstein, *supra* note 18, at 363-65.

[354] *Id.*

[355] CASS R. SUNSTEIN, RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT 245 (2002).

[356] For a recent discussion of WTP measures, see James K. Hammitt, *QALYs Versus WTP*, 22 RISK ANALYSIS 985 (2002); Cass R. Sunstein, *Lives, Life Years, and Willingness to Pay*, 104 COLUM. L. REV. 205 (2004). EPA used willingness to pay metrics to estimate

Alternatively, EPA could consider using other metrics for aggregation such as quality adjusted life years (QALY)—a measure used more commonly in health care analyses.[337] Whatever their relative merits, measures like WTP and QALY serve as a common basis for measuring the total health benefits associated with different regulatory standards.[338]

By using a common measure, EPA could improve the consistency of outcomes across different standards. For example, more explicit and detailed attention to benefits analysis might have made EPA decision makers—as well as the American public—more aware that the Agency was passing up an opportunity to secure greater health gains, through increased tightening of the particulate matter standard, than it reaped altogether from its revisions to the ozone standard.[339] In this way, a benefits-based approach could help ensure that different standards reduce risks to comparable (and acceptable) levels, achieving comparable (and desirable) levels of health benefits.[340]

While a benefits-based approach may help in identifying inconsistencies across rules, by itself such an approach still skirts the underlying question: What makes a particular level of risk "acceptable" (or a particular level of benefits "desirable")? An acceptable risk approach

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the health benefits of its recent ozone and PM standards in its Regulatory Impact Analysis for its rulemaking, although it was not permitted to consider these estimates in making its regulatory decision. RIA, *supra* note 300, at 12-34 to 12-37. For example, EPA calculated that the value of a life saved was $4.8 million, a case of chronic bronchitis prevented was $260,000, and a case of shortness of breath prevented was $5.30. *Id.* at 12-40.

[337] In its decision in *American Trucking*, the D.C. Circuit suggested that another possible way to aggregate health effects would be to define a generic unit of harm, such as through QALY. Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1039-40 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001). For a discussion of the QALY measure in the context of EPA's air pollution policy, see BRYAN J. HUBBELL, ENVIRONMENTAL PROTECTION AGENCY, IMPLEMENTING QALYS IN THE ANALYSIS OF AIR POLLUTION REGULATIONS (Innovative Strategies and Econ. Group, EPA, Working Paper May 2002), *available at* http://www.epa.gov/ttn/ecas/workingpapers/ereqaly.pdf; SUNSTEIN, *supra* note 335, at 246-47; *see also* Richard J. Zeckhauser & Donald Shepard, *Where Now for Saving Lives?*, LAW & CONTEMP. PROBS., Autumn 1976, at 5, 11 (providing the original treatment of the QALY metric).

[338] For comparative assessments of these measures, see Hammitt, *supra* note 336; Janice Clair Wright, Investments that Save Lives: The Norms of Environmental and Medical Decision Making 2-1 to 2-59 (1997) (unpublished Ph.D. dissertation, Harvard University) (on file with author).

[339] *Supra* Part II.D.

[340] *See* SUNSTEIN, *supra* note 335, at 245 ("A chief advantage of this approach is that it should ensure interregulation consistency . . . .").

seems to envision that government makes risk management decisions in individual proceedings according to some predetermined level of acceptable risk. A benefits analysis can reveal whether a particular standard meets this predetermined level. It does not, however, provide a basis for determining what that level should be. After all, any detailed benefits analysis, such as the kind that Professor Sunstein proposes, is really just a highly professional risk assessment and not the risk management judgment called for in standard setting.[341] Selecting an acceptable risk level still requires making a reasoned judgment about the optimal appropriate level.[342]

The acceptable risk approach suffers from another notable limitation: it directs that standards be set based solely on the level of benefits to be gained—regardless of the costs of meeting those standards.[343] To follow this approach would require that EPA set standards based on benefits even when the costs of compliance were disproportionately high.[344] Moreover, the consistent application of this approach

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[341] *See id.* (noting the "inevitable judgment of value" involved in setting standards).

[342] *See id.* (proposing not only careful benefits analysis, but also that EPA "explain why one set of savings . . . justifies regulation, whereas other sets of savings do not"). Justice Stephen Breyer has suggested that one approach would be for the Agency to base an acceptable level on "the public's ordinary tolerance" of similar health risks. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 494 (2001) (Breyer, J., concurring). Comparative risk analysis can be used to provide information about other benchmark risks. *See* M. Granger Morgan et al., *A Proposal for Ranking Risk Within Federal Agencies*, *in* COMPARING ENVIRONMENTAL RISKS 112-15 (J. Clarence Davies ed., 1996) (noting that ranking risks reveals society's priorities about which risks are of immediate concern). For a discussion of some of the difficulties in defining an "acceptable" level of risk, see Adam Babich, *Too Much Science in Environmental Law*, 28 COLUM. J. ENVTL. L. 119, 146-57 (2003); Sanford E. Gaines, *Science, Politics, and the Management of Toxic Risks Through Law*, 30 JURIMETRICS 271, 283 (1990); Marchant & Danzeisen, *supra* note 321, at 548-57.

[343] For a discussion of the weight given to the level of benefits, see Feller, *supra* note 127, at 873-74:

> [R]elatively large risks may be tolerated if they yield comparably large benefits. With respect to air quality, the benefit of tolerating a certain level of air pollution is the pollution control expense saved by foregoing reductions in pollution below that level. . . . [A] rational selection of an acceptable level of air quality requires consideration of the costs required to attain various levels.

Id.

[344] *Cf.* Roy E. Albert, *Carcinogen Risk Assessment in the U.S. Environmental Protection Agency*, 24 CRITICAL REV. TOXICOLOGY 75, 84 (1994) ("[T]here is no acceptable risk in the absence of benefits. Risks at virtually any level can be ignored, depending on circumstances.").

would also lead the Agency to reject risk reductions below the "acceptable level" even when the costs of achieving them were trivial.[345]

Of course, however desirable or undesirable an acceptable risk approach may be, EPA has so far not even tried to use it in setting or revising any of its NAAQS standards. The Agency has so far eschewed responsibility for offering a consistent account of its decisions, claiming that the range of health effects associated with criteria pollutants makes it too difficult to follow any "generalized paradigm" in explaining its NAAQS decisions.[346] As a result, it is hardly surprising that the recently revised ozone and PM standards will achieve markedly disparate levels of health benefits.[347]

3. Avoid Unacceptable Costs

A third approach to consistent risk management is the mirror image of the acceptable risk approach. Instead of focusing exclusively on benefits, the cost of a regulation should be the key factor. In other words, EPA could set its standards as low as possible while keeping the costs of compliance below an acceptable level.

This approach typically has been couched in terms of feasibility—what can be achieved without high costs or severe economic disruptions.[348] Saying that a standard is feasible implies that its costs are acceptable. For example, OSHA is charged by statute with developing regulations to protect workers from exposure to toxic substances "to the extent feasible."[349] Of course, just stating that a regulatory standard is "feasible" or "infeasible" is rather imprecise.[350] However, just as agencies have defined the concept of acceptable risk by setting

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[345] *See* Sunstein, *supra* note 18, at 377 (suggesting that when a nontrivial risk reduction "would be a trivial expense, surely it should be required"); *see also* Int'l Union v. OSHA, 938 F.2d 1310, 1322 (D.C. Cir. 1991) ("[E]ven a slight risk might be considered significant if it could be reduced or eliminated at a cost (including costs of enforcement and compliance) less than the resulting benefits.").

[346] *See* EPA, Ozone Final Rule, *supra* note 8, 62 Fed. Reg. at 38,883 (arguing against a "generalized paradigm" and for a case-by-case approach to setting NAAQS); *see also supra* Part II.A (describing EPA's ad hoc approach to decision making).

[347] *Supra* Part II.D.

[348] *See, e.g.*, Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729, 744 (arguing that "society may choose to limit its protection of workers only at the point where the protection would cause industry substantial economic dislocation"); Wendy E. Wagner, *The Triumph of Technology-Based Standards*, 2000 U. ILL. L. REV. 83, 93-94 (defending a standard-setting approach that is based on the use of feasible technology).

[349] 29 U.S.C. § 655(b)(5) (2000).

[350] Sunstein, *supra* note 322, at 1691, 1703.

specific risk targets, they could similarly develop precise standards establishing acceptable levels of costs and then reduce risk to the point at which compliance costs reached the specified level.[351]

Such an approach, it should be noted, would disregard the benefits of risk standards. If a standard with exceedingly high costs (or that would cause severe economic disruption) would also save thousands of lives, then society almost certainly would be better off even if the costs might seem unacceptably high.[352] For example, government regulations eliminating lead from gasoline resulted in hundreds of millions of dollars in annual costs and appeared to threaten not only layoffs in the industrial firms that produced lead additives but also gasoline shortages during the transition to unleaded fuels.[353] Nevertheless, these regulations also resulted in dramatic health benefits that substantially dwarfed the costs.[354] If regulatory agencies had adhered to an approach that avoided all regulations that imposed costs exceeding a specified level or threatened economic dislocation, without any

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[351] Regulators already use a cost ceiling as a trigger for certain legal requirements. For example, when a proposed regulation is expected to impose $100 million or more in annual costs, agencies are required to conduct formal regulatory impact analyses. 2 U.S.C. § 1532(a)(2) (2000); *see also* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, § 6, at 51,740-43 (Sept. 30, 1993) (outlining the cost-benefit analysis required for agency regulatory action). Professor Sunstein has suggested that agencies could define feasibility in terms of a specific number of bankruptcies, business closures, or job losses. Sunstein, *supra* note 322, at 1703.

[352] *See* Sunstein, *supra* note 322, at 1701-02 (noting that regulations that are not "feasible" still can result in enormous social benefits). A ban on tobacco sales, for example, might be one such case where a seemingly infeasible governmental intervention arguably could be justified. *See* DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY 392 (2001) ("[T]he solution to the smoking problem rests with the bottom line, prohibiting the tobacco companies from continuing to profit from the sale of a deadly, addictive drug.").

[353] Albert L. Nichols, *Lead in Gasoline*, *in* ECONOMIC ANALYSES AT EPA: ASSESSING REGULATORY IMPACT 49, 56-57, 59, 74 (Richard D. Morgenstern ed., 1997).

[354] In its final RIA, EPA estimated that the benefits of the lead phase-down rule would be over ten times greater than the costs. RIA, *supra* note 300, at 7-1, 12-1. In a retrospective study conducted by EPA in the mid-1990s, the Agency's average monetized estimate of health benefits from the elimination of lead emissions amounted to about two trillion dollars, with ninety-four percent of the reductions in lead emissions attributed to the phase-out of lead in gasoline. OFFICE OF AIR & RADIATION, EPA, NO. 410-R-97-002, FINAL REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF THE CLEAN AIR ACT, 1970 TO 1990, at 17, 52 (1997) [hereinafter EPA, FINAL REPORT TO CONGRESS], *available at* http://www.epa.gov/air/sect812/chptr1_7.pdf. These benefits exceeded, by approximately four times, the estimated costs of *all* the regulations EPA issued under the Clean Air Act between 1970 and 1990 ($0.5 trillion), not just the costs of the lead phase-out. *Id.* at 8.

concern for the level of corresponding benefits, they may well have delayed or avoided phasing out lead additives in gasoline.[355]

When regulatory agencies justify their risk management decisions based only on either costs or benefits, they can achieve consistent, principled decision making simply by using the same level of acceptable costs or risks across different rulemakings. Nevertheless, all the approaches we have discussed so far truncate the range of risk management criteria and may therefore lead regulatory agencies, in some cases, to make decisions that make little sense, even though they are consistent.[356] Under the acceptable risk approach, however, agencies can affirm standards that impose significant costs without proportional health protection gains. Under the acceptable cost approach, agencies can reject opportunities to achieve significant net social benefits simply because costs are high.

4. Balance Costs and Benefits

With precisely these kinds of perverse outcomes in mind, a fourth approach for risk management would take both benefits and costs into consideration and seek to achieve a consistent balance of the two.[357] By considering both costs and benefits, regulators could set

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[355] The use of cost-benefit analysis in developing the lead phase-down rule has been credited with hastening the elimination of lead emissions:

> Without quantitative analysis, it would not have been possible to make a compelling case for the accelerated phase down because it would not have been possible to show how much more important lead in gasoline was relative to the vast majority of other rules competing for attention, many of which involved congressional or court-imposed deadlines, in contrast to lead.

Nichols, *supra* note 353, at 78. The lead phase-down rule also took advantage of a market-like trading program designed to make the phase-down more cost-effective. Robert W. Hahn & Robert N. Stavins, *Incentive-Based Environmental Regulation: A New Era from an Old Idea?*, 18 ECOLOGY L.Q. 1, 17 (1991).

[356] *See* Coglianese, *supra* note 299, at 1223 (distinguishing between instrumental and comparative coherence and the need to consider multiple dimensions of regulatory policies).

[357] *See* William H. Rodgers, Jr., *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191, 214, 226 (1980) (evaluating the role for cost-benefit analysis in setting risk standards); Sunstein, *supra* note 322, at 1691 (arguing that a reasonable approach to risk regulation involves a comparison of costs against benefits); Edward W. Warren & Gary E. Marchant, *"More Good than Harm": A First Principle for Environmental Agencies and Reviewing Courts*, 20 ECOLOGY L.Q. 379, 419-25 (1993) (describing how courts have interpreted the reasoned decision making requirement in the Administrative Procedure Act to include at least a loose balancing of costs and benefits).

risk management standards to maximize net benefits.[358] Several environmental statutes other than the Clean Air Act actually require agencies to balance benefits and costs when they are setting risk standards.[359] Indeed, absent statutory prohibitions to the contrary (such as now in the Clean Air Act), regulatory agencies are directed by Executive Order 12,866 to assess both costs and benefits of significant proposed regulations and to "propose or adopt a [new] regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."[360]

Of course, in practice, there will be important issues regarding measurement, valuation, and discount rates that must be treated consistently.[361] But this is true for any other approach to risk management

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[358] For a general discussion of the use of cost-benefit analysis, see COST-BENEFIT ANALYSIS: LEGAL, ECONOMIC, AND PHILOSOPHICAL PERSPECTIVES (Matthew D. Adler & Eric A. Posner eds., 2001); RISKS, COSTS, AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION (Robert W. Hahn ed., 1996); Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489 (2002).

[359] *See, e.g.*, 7 U.S.C. § 136a(c)(2) (2000) (requiring the EPA administrator to consider both the costs and benefits prior to adoption of regulations on pesticides); 15 U.S.C. § 2605(c) (2000) (requiring EPA administrator to consider both costs and benefits in promulgating rules with respect to the regulation of hazardous chemicals); 42 U.S.C. § 300g-1(b)(3)(C)(i) (2000) (requiring EPA administrator to seek public comment on the costs and benefits of a proposed maximum contaminant level for national drinking water regulation). Even when the statute calls for balancing costs and benefits, the Agency possesses considerable discretion in how the balancing actually takes place, which may still permit the Agency to make incoherent, inconsistent, or costly decisions. *See* George Van Houtven & Maureen L. Cropper, *When is a Life Too Costly to Save? The Evidence from U.S. Environmental Regulations*, 30 J. ENVTL. ECON. & MGMT. 348, 367 (1996) (noting that even though "Congress may require that the costs of a regulation be balanced against the benefits, . . . as long as EPA has discretion in the weights it assigns to costs and benefits, regulations issued under balancing statutes may still be very costly").

[360] Exec. Order No. 12,866, § 1(b)(6), 58 Fed. Reg. 51,735, 51,736 (Sept. 30, 1993); *see also id.* § 6(a)(3)(C), 58 Fed. Reg. at 51,741 (detailing the required assessments of costs and benefits). The Unfunded Mandates Reform Act also requires agencies to prepare statements of costs and benefits of significant proposed rules. 2 U.S.C. § 1532 (2000). The Act generally directs agencies in these rulemakings to adopt the "least costly, most cost-effective or least burdensome" alternative that achieves the regulatory objective. *Id.* § 1535(a).

[361] *See generally* RAYMOND J. KOPP ET AL., COST-BENEFIT ANALYSIS AND REGULATORY REFORM: AN ASSESSMENT OF THE SCIENCE AND THE ART 14-31 (Research for the Future, Discussion Paper No. 97-19, 1997) (reviewing the state of the art in cost-benefit methodology); Steve P. Calandrillo, *Responsible Regulation: A Sensible Cost-Benefit, Risk Versus Risk Approach to Federal Health and Safety Regulation*, 81 B.U. L. REV. 957, 986-1007 (2001) (discussing some of the challenges of using cost-benefit analysis). For a discussion of the issue of the discount rate in particular, see Richard L. Revesz, *Environmental*

decision making, and regulators have developed guidelines for approaching these operational issues in consistent ways.[362] When conducted responsibly, cost-benefit analysis can prove quite valuable in explaining regulatory agencies' decision making.[363] It offers a consistent and systematic approach to risk management.

What is most striking is that EPA has not only rejected a cost-benefit approach but also all of the other general policy principles for risk management. It has explicitly ruled out zero-risk and acceptable-risk approaches, and it has successfully argued that the Clean Air Act precludes it from adopting a feasibility or cost-benefit balancing approach.[364] Instead, EPA has taken an explicitly ad hoc approach.[365]

Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives, 99 COLUM. L. REV. 941 (1999).

[362] *See* EPA, NO. 240-R-00-003, GUIDELINES FOR PREPARING ECONOMIC ANALYSES, FACT SHEET 1 (2000) (providing "a sound scientific framework for performing economic analyses of environmental regulations and policies"), *available at* http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/guidelines.html/file/FactSheet.pdf; Memorandum from Jacob J. Lew, Director, Office of Management and Budget, to the Heads of Departments and Agencies, Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements 3-16 (Mar. 22, 2000) (providing guidelines for the preparation of cost-benefit analyses), *available at* http://www.whitehouse.gov/omb/memoranda/m00-08.pdf; *see also* KOPP ET AL., *supra* note 361, at 14-31 (discussing the methodological issues surrounding cost-benefit analysis).

[363] *See* SUNSTEIN, *supra* note 168, at 65 (noting that "any reasonable judgment will ordinarily be based on some kind of weighing of costs and benefits"); Kenneth J. Arrow et al., *Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?*, 272 SCIENCE 221, 221-22 (1996) (explaining the appropriate use of cost-benefit analysis). This does not mean that a formal cost-benefit analysis will by itself determine where to set a standard in any strict algorithmic sense, for there will be uncertainties associated with it as with any other kind of analysis. EPA has mistakenly accused critics of its ad hoc approach to NAAQS rulemakings as advocating "a determinate formula" that would "straightjacket" its discretion. EPA, 2001 D.C. Cir. Ozone Brief, *supra* note 70, at 17-26. Reliance on a cost-benefit principle provides a coherent guide for agency discretion and a consistent basis for justifying its air quality standards. Such an approach "could improve both the regulatory decisionmaking process by making it more transparent and the regulatory decision by allowing all relevant information to be considered explicitly." Brief of Amici Curiae AEI-Brookings Joint Center for Regulatory Studies et al. at 12, Am. Trucking Ass'ns v. Browner, 530 U.S. 1202 (2000) (No. 99-1426).

[364] *See supra* notes 165-66, 282 and accompanying text (noting that EPA has interpreted the Clean Air Act to preclude consideration of economic costs or technical feasibility but not to require a zero-risk standard).

[365] *See supra* Part II.A (highlighting EPA's reliance on its ad hoc judgments rather than a consistent set of principles to guide its NAAQS decision making).

Given this predicament, it is by no means surprising that the EPA's account of its recent NAAQS decisions has been so inconsistent.[366] At the core of EPA's position lies a fundamental inconsistency: The Agency rejects any need to achieve a level of zero risk, but the reason to reject a zero-risk approach is its complete infeasibility.[367] Thus, an important step toward achieving a more principled and consistent account of EPA's air quality standard would be to free the Agency from its conceptual straightjacket. As we show in the next

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[366] *See* SHRADER-FRECHETTE, *supra* note 310, at 182 (arguing that any stance that rejects "systematic risk decisions . . . leaves room for arbitrary, dishonest, purely political, or irrational hazard assessment").

[367] *See* John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 275 (1991) (noting the "difficulty of determining an appropriate nonabsolute level of safety in the absence of cost considerations"); Christopher H. Schroeder, *In the Regulation of Manmade Carcinogens, If Feasibility Analysis is the Answer, What is the Question?*, 88 MICH. L. REV. 1483, 1493 (1990) ("Any regulation short of the zero-risk paradigm depends upon there being some countervailing value, one that conflicts with pure [risk] prevention, that merits a role in policy formation."); Sunstein, *supra* note 18, at 378 ("[I]t is impossible to assess 'safety' in a cost vacuum."); *cf.* LON L. FULLER, THE MORALITY OF LAW 179 (1964) ("[P]roblems of weighing costs run throughout our legal and political life."). Even the decision to pursue an acceptable risk approach and to set that level at something above zero would seem implicitly to recognize the need to balance health protection with economic costs or other considerations. Of course, as Justice Breyer has pointed out, a concern for infeasibility need not be entirely unrelated to a concern for public health. Breyer conceded that eliminating all risk would be "impossible," but suggested that EPA could defend its rejection of a zero-risk approach on health considerations since "[p]reindustrial society was not a very healthy society . . . [and therefore] a standard demanding the return of the Stone Age would not prove 'requisite to protect the public health.'" Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 494, 496 (2001) (Breyer, J., concurring). EPA has not taken seriously the "minimize risk" approach suggested by Justice Breyer, *supra* note 320 and accompanying text, since adhering to such an approach would necessitate that EPA take into account the possible health effects associated with the costs its regulations impose on the economy. Since the Agency's position is that it does not take costs into consideration at all in setting air quality standards, then it cannot consider the possibility that "the economic cost of implementing a very stringent standard might produce health losses sufficient to offset the health gains achieved in cleaning the air." *Whitman*, 531 U.S. at 466. For discussions of the estimated health effects associated with the costs of regulation, see ROBERT W. HAHN ET AL., DO FEDERAL REGULATIONS REDUCE MORTALITY? 12-22 (2000); Frank B. Cross, *When Environmental Regulations Kill: The Role of Health/Health Analysis*, 22 ECOLOGY L.Q. 729, 772-84 (1995); Ralph L. Keeney, *Mortality Risks Induced by the Costs of Regulations*, 8 J. RISK & UNCERTAINTY 95, 97-109 (1994); Randall Lutter et al., *The Cost-Per-Life-Saved Cutoff for Safety-Enhancing Regulations*, 37 ECON. INQUIRY 599 (1999); Paul R. Portney & Robert N. Stavins, *Regulatory Review of Environmental Policy: The Potential Role of Health-Health Analysis*, 8 J. RISK & UNCERTAINTY 111, 115-19 (1994); W. Kip Viscusi, *Risk-Risk Analysis*, 8 J. RISK & UNCERTAINTY 5, 9-12 (1994); Ralph L. Keeney & Kenneth Green, Estimating Fatalities Induced by Economic Impacts of Ozone and Particulate Standards 6-11 (June 1997) (unpublished manuscript, on file with author), *available at* http://www.rppi.org/environment/ps225.html.

Section, EPA most certainly does consider feasibility and costs when setting its air quality standards, even though it claims otherwise. By acknowledging the fiction that its risk management decisions are made regardless of cost considerations, EPA could pave the way for a clear, systematic justification for its NAAQS decision making.[368]

B. *Abandoning the Fiction of Ignoring Costs*

The estimated costs of the recently revised ozone and particulate matter standards make them among the most expensive federal regulations ever promulgated in the history of the United States. EPA estimated that by 2010 the standards would impose incremental costs exceeding forty-five billion dollars per year[369]—an amount larger than the combined annual cost of all the other Clean Air Act regulations in

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[368] *See* Pierce, *supra* note 134, at 1255 ("I do not believe it is possible to make many regulatory decisions in a rational manner without considering costs in some way.").

[369] EPA estimated that the costs of full attainment of its revised ozone and particulate matter NAAQS would be about $47 billion per year ($9.6 billion for ozone and $37 billion for PM) by 2010. RIA, *supra* note 300, at 9-1. EPA was only able to identify technologies that could partially attain the ozone and PM standards; thus, it simply assumed that new technologies will be developed in the future that will enable full attainment of the two standards at a cost of $10,000 per ton. *Id.* at ES-9. Other cost estimates that relaxed this assumption and addressed technological change empirically were substantially higher. For example, the President's Council of Economic Advisors estimated that the costs of the ozone standard alone could approach $60 billion per year. *See* Peter Passell, *The Air Standards Are Set, but How Clean Is Clean Enough?*, N.Y. TIMES, July 3, 1997, at D2 (citing an estimate that meeting the ozone standard could cost $11 to $60 billion per year); *see also* RANDALL LUTTER, IS EPA'S OZONE STANDARD FEASIBLE? 11 (AEI-Brookings Joint Ctr. for Regulatory Studies, Regulatory Analysis 99-6 1999) (finding that compliance with EPA's ozone standard would be seven-fold more expensive than EPA estimated for most cities, and would be infeasible for one city), *available at* http://www.aei.brookings.org/admin/authorpdfs/page.php?id=93; ANNE E. SMITH ET AL., COSTS, ECONOMIC IMPACTS, AND BENEFITS OF EPA'S OZONE AND PARTICULATE STANDARDS 2 (Reason Pub. Pol'y Inst., Policy Study No. 226, 1997) (estimating that compliance costs will range from $20 billion to $60 billion per year for the ozone standard and $70 to $150 billion per year for the $PM_{2.5}$ standard), *available at* http://www.rppi.org/environment/ps226.html; Darrell A. Winner & Glen R. Cass, *Effect of Emissions Control on the Long-Term Frequency Distribution of Regional Ozone Concentrations*, 34 ENVTL. SCI. & TECH. 2612, 2617 (2000) (deducing that compliance with the new 0.08 ppm ozone standard would be physically impossible even with the most stringent emissions controls). Of course, some have hypothesized that as a general matter ex ante estimates of regulatory compliance costs may tend to be overstated to some extent. For a discussion of research on the accuracy of compliance cost predictions, see Cary Coglianese, *Empirical Analysis and Administrative Law*, 2002 ILL. L. REV. 1111, 1121-22; Richard B. Stewart, *A New Generation of Environmental Regulation?*, 29 CAP. U. L. REV. 21, 45-48 (2001).

effect at the time.[370] The high costs of the air quality standards might appear to support EPA's claim that it did not consider costs in setting the standards.[371] Yet, these high costs notwithstanding, it is widely acknowledged that the EPA does, and indeed must, consider costs when deciding where to set air quality standards.[372]

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[370] EPA has estimated annual costs of $19 billion (1990 dollars) resulting from all of the Clean Air Act's requirements during the period from 1990 to 2000, an analysis that excluded the costs of the recent ozone and particulate matter NAAQS revisions. EPA, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT 1990 TO 2010, at iii (1999), *available at* http://www.epa.gov/oar/sect812. In its retrospective study of the costs and benefits of the Clean Air Act from 1970 to 1990, EPA estimated the annual compliance costs associated with all its air pollution regulations ranged from $19.0 to $25.7 billion. EPA, FINAL REPORT TO CONGRESS *supra* note 354, at A-15.

[371] EPA, Supreme Court Respondents Brief, *supra* note 60, at 44 (asserting in a heading that "The Administrator Did Not Base Her NAAQS Decisions On Consideration Of Compliance Costs.").

[372] *See, e.g.*, Graham Testimony, *supra* note 116 ("When multi-billion dollar rulemaking decisions are made, it is inevitable that regulators will consider the consequences of their actions as well as the reasonableness of the relationship between risks, benefits and costs."); DAVID L. FAIGMAN, LEGAL ALCHEMY: THE USE AND MISUSE OF SCIENCE IN THE LAW 183 (1999) ("In practice, therefore, despite the legal technicality limiting EPA to promulgating regulations solely to promote health, costs are an integral part of the policy-making process at EPA."); LANDY ET AL., *supra* note 108, at 238 ("[I]n the absence of any threshold for risk, some balancing between costs and benefits had to be implicit in the standard setting decision—a reality EPA neither acknowledged nor forced the Congress to confront."); THOMAS O. MCGARITY, REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY 253 (1991) ("[EPA] has considered costs and benefits, and the advice that the Administrator receives orally from subordinates reflects those considerations."); MELNICK, *supra* note 155, at 297 ("Regulators inevitably consider cost [in setting air quality standards]. But presently they cannot explain how they do so."); David W. Barnes, *Back Door Cost-Benefit Analysis Under a Safety-First Clean Air Act*, 23 NAT. RES. J. 827, 856 (1983) (criticizing the "subterfuge of back door cost-benefit analysis" in setting clean air standards); George Eads, *The Confusion of Goals and Instruments: The Explicit Consideration of Cost in Setting National Ambient Air Quality Standards*, *in* TO BREATHE FREELY: RISK, CONSENT, AND AIR 222, 229 (Mary Gibson ed., 1985) (noting that it is a "policy fiction" that costs are not considered in setting NAAQS); Feller, *supra* note 127, at 833 ("If all costs were truly ignored, then no risk would be acceptable."); Barbara A. Finamore & Elizabeth E. Simpson, *Ambient Air Standards for Lead and Ozone: Scientific Problems and Economic Pressures*, 3 HARV. ENVTL. L. REV. 261, 274 (1979) ("[E]conomic pressures were obviously present and arguably influential in the formulation of the new ozone [1979] and lead [1978] standards."); C. Boyden Gray, *The Clean Air Act Under Regulatory Reform*, 11 TUL. ENVTL. L.J. 235, 235 (1998) ("The plain fact is that the EPA has for a long time considered costs and benefits in setting ambient standards—only it has done so behind closed doors . . . ."); James E. Krier, *On the Topology of Uniform Environmental Standards in a Federal System—and Why it Matters*, 54 MD. L. REV. 1226, 1231 n.12 (1995) ("Congress has nominally insisted that costs be ignored in setting most environmental standards . . . even though everyone knows this is a fiction."); Howard Latin, *Regulatory Failure, Administrative Incentives, and the New Clean Air Act*, 21 ENVTL. L. 1647, 1658 (1991) (observing "EPA's great reluctance to cause serious social dislocation, even if

EPA has certainly acknowledged the significant economic impacts of its NAAQS decisions.[373] Even the amicus briefs filed in favor of EPA in the recent NAAQS litigation admitted that the EPA Administrator "will naturally have before her information on the implementation of standards even as she sets them."[374] This awareness of the costs appears to have influenced the Agency's decision making by creating a reluctance to make standards too stringent, even when doing so would provide still greater public health protection.[375] After all, as Professor

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that result appears clearly mandated by the statute"); Gary E. Marchant, *Turning Two Blind Eyes: The EPA's Failure to Consider Costs and Health Disbenefits in Revising the Ozone Standard*, 11 TUL. ENVTL. L.J. 261, 268 (1998) (stating that EPA failed "to 'come clean' about the true nature of its decision-making"); Oren, *supra* note 18, at 10,662 ("EPA inevitably must therefore consider costs in standard-setting to help decide how stringent to make the standards."); Pierce, *supra* note 134, at 1239 ("[A]ll participants in this decision making process know [that] the EPA Administrator always considers costs when making decisions pursuant to [the Clean Air Act] section 109."); Pierce, *supra* note 18, at 85 ("I am confident that the EPA did, in fact, consider its CBA [cost-benefit analysis] of the ozone and particulate rules, notwithstanding its claims to the contrary."); Sunstein, *supra* note 18, at 308 ("There is reason to think that at least in some cases, an understanding of costs has affected EPA's decision about appropriate standards—but that the cost-benefit balancing has been left implicit and free from public scrutiny and review."); Sunstein, *supra* note 20, at 11 (noting "the apparent fact, urged by credible observers, that the EPA had in fact considered costs, although tacitly and without public supervision"); ALAN J. KRUPNICK & DEIRDRE FARRELL, SIX STEPS TO A HEALTHIER OZONE POLICY 6 (Resources for the Future, Discussion Paper 96-13, 1996) ("[C]osts must implicitly be playing a role."), *available at* http://www.rff.org/rff/Documents/RFF-DP-96-13.pdf. Without confronting either the academic record or the logical necessity of EPA at least implicitly considering costs in setting NAAQS, the Supreme Court dismissed the argument that EPA was "secretly considering the costs of attainment without telling anyone" as mere speculation. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 471 n.4 (2001).

[373] *See, e.g.*, EPA, 1993 Ozone Decision, *supra* note 192, at 13,013 (noting that "implementation of the NAAQS can have profound economic and social as well as environmental consequences"); EPA, 1979 Ozone Rule, *supra* note 196, 52 Fed. Reg. at 8213 (admitting that "controlling ozone to very low levels is a task that will have significant impact on economic and social activities"); Oren, *supra* note 18, at 10,662 (stating that "EPA decisionmakers have admitted that they examine cost data when deciding on the levels of the standards."). The estimated costs of the air quality standards have been included in the *Federal Register* notice signed by the Administrator. *See, e.g.*, EPA, Ozone Proposed Rule, *supra* note 241, 61 Fed. Reg. at 65,746 (showing estimates of NAAQS benefits and costs).

[374] Massachusetts and New Jersey Brief, *supra* note 161, at 44; *see also* MCGARITY, *supra* note 372, at 162 (noting that "[t]he artificiality of [EPA's] attempt to shield the decisionmaking process from analysis is apparent"); EPA, Douglas M. Costle: Oral History Interview, *at* http://www.epa.gov/history/publications/print/costle.htm (last updated June 10, 2002) (acknowledging that the former EPA Administrator considered costs in his decision-making process over the 1979 ozone NAAQS revisions).

[375] *See supra* Part II.B–C (indicating that EPA could have saved thousands of additional lives per year by setting more stringent standards).

Joseph Feller, a former EPA attorney, has noted, "[i]f all costs were truly ignored, then no risk would be acceptable."[376]

Even if the Administrator did not explicitly consider the cost estimates that EPA analysts had gone to great lengths to prepare, she and her staff could not have been unaware that the regulations EPA promulgated were among the most expensive ever adopted.[377] After all, an implicit recognition of cost considerations would seem to be the only way to explain EPA's new standard for fine PM.[378] The only apparent reason why EPA would accept thousands of additional predicted deaths per year was because of concern about the costs of tightening the standards even further,[379] which would have imposed unacceptable economic burdens on society.[380]

In explaining its decision to reject the tougher PM standard, EPA asserted that setting more stringent standards "*might* result in regulatory programs that go beyond those that are *needed* to effectively reduce risks to public health."[381] But under a precautionary approach that is supposed to "err on the side of safety," the mere possibility that

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[376] Feller, *supra* note 127, at 833; *see also* Eads, *supra* note 372, at 228 ("*No* level of ambient exposure above zero could be ruled out if consideration was given just to health effects.").

[377] Furthermore, the intensity of industry lobbying efforts undoubtedly signaled to EPA the economic impact at stake in its decisions. *See* Jason Scott Johnston, *A Game Theoretic Analysis of Alternative Institutions for Regulatory Cost-Benefit Analysis*, 150 U. PA. L. REV. 1343, 1353 (2002) (deploying a game-theoretic model to show that even where agency is precluded from taking costs into account, "the agency generally will internalize some of the compliance costs its regulation will impose" through the political process of rulemaking).

[378] *Supra* Part II.B.

[379] *See* Sunstein, *supra* note 18, at 317 n.51 ("EPA's failure to require more stringent regulation of particulates provides some evidence of cost consideration. On EPA's own numbers, more stringent regulation might have provided $4 billion in increased benefits . . . . If these benefits were possible, why did EPA not require greater stringency, if not because of some cost consciousness?").

[380] A recent New England Journal of Medicine editorial, which accompanied a review generally supportive of EPA's scientific analysis of $PM_{2.5}$, stated that significant further reductions in the 24-hour $PM_{2.5}$ standard would have been particularly burdensome, if not impossible. James H. Ware, *Particulate Air Pollution and Mortality—Clearing the Air*, 343 NEW ENG. J. MED. 1798 (2000). The article states that:

> The epidemiologic evidence suggests that the association between fine-particle concentrations and mortality is linear across the entire range of current concentrations. Although substantial reductions can be achieved at a reasonable cost, a reduction in 24-hour exposures to levels consistently below the current range would be prohibitively costly, if not impossible, in the foreseeable future.

Id. at 1799.

[381] EPA, PM Final Rule, *supra* note 9, 62 Fed. Reg. at 38,675 (emphasis added).

a standard "might" exceed the level of health protection "needed" should not prevent the Agency from adopting it.[382] Indeed, by definition, erring on the side of safety would require going beyond what might appear to be needed.

EPA advanced a similar argument in its petition for rehearing in the D.C. Circuit, stating that section 109 requires that a NAAQS standard be set at a level "*necessary* for public health protection: neither *more* nor *less* stringent than necessary, but 'requisite.'"[383] Given that particulate matter appears to present a continuum of risk down to background levels (or at least to levels well below EPA's selected standard), it is far from clear how the Agency can show that its selected standard was neither more nor less stringent than necessary. Each increment of additional stringency will protect against some additional unit of risk (some perhaps unknown or uncertain). In the case of fine PM, additional stringency would have protected against additional human mortality predicted by the Agency's own risk assessment.[384] If standards are supposed to be set solely to protect public health, and if the Agency is supposed to be precautionary by erring on the side of safety, then it is not possible under EPA's risk model to have a PM standard that was too stringent.[385] Indeed, a more stringent standard would have been "necessary" to prevent the loss of thousands of additional lives, according to the Agency's own analysis.[386] When this evidence is taken into consideration, there is no escaping the conclusion that there must have been some other factor—presumably cost—that kept EPA from lowering the standard even further.[387]

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[382] *See supra* notes 194-95 and accompanying text (citing EPA's Supreme Court brief, which stated that the predominant purpose of its standards was to be preventative and precautionary).

[383] EPA, Petition for Rehearing, *supra* note 258, at 8.

[384] *Supra* Part II.B.

[385] In the case of non-threshold pollutants, where discernible harm to human health is believed to occur down to levels just above zero, then by definition no level can be said to be completely "safe," thus eliminating any room for erring on the side of safety. *See* Pierce, *supra* note 18, at 74 (describing non-threshold pollutants as having "no level at which [they] do not kill some people"); *supra* notes 128, 131-34 and accompanying text (discussing the policy implications of regulating non-threshold air pollutants).

[386] *See supra* text accompanying notes 209-17 (discussing how up to 860 additional lives in Philadelphia and 1080 lives in Los Angeles would have been saved with more stringent standards).

[387] As the National Academy of Sciences and National Academy of Engineering concluded in a 1974 report to Congress, in setting air quality standards "[t]here is no escape from a reasoned judgment, containing an unavoidable subjective element, as to the level at which the possible benefits from reducing pollution further no longer

Given that EPA almost certainly considers costs implicitly when determining the level of its standards, the question arises whether society would be better served if the Agency began to consider cost estimates explicitly.[388] Express consideration of cost data may provide important information that can be used to set standards that are more cost-effective without sacrificing health protection. This is because costs and benefits from air quality standards, like other regulatory standards, may exhibit discontinuities and nonlinearities that can only be discerned through careful analysis of cost functions. For example, EPA's draft Regulatory Impact Analysis (RIA) for ozone, published at the time of the Agency's proposed rule, indicated that an eight-hour ozone standard set at 0.08 ppm based on the fifth rather than the fourth highest annual concentration would provide roughly equivalent health protection but at approximately twenty percent lower cost.[389] This analysis suggests that there is a disconnect in the cost-effectiveness of tightening the standard from the fifth to the fourth highest annual concentration. Had EPA been able to consider this evidence openly and explicitly, the Administrator could have based the standard on the fifth highest annual concentration and saved the nation over $1 billion per year without sacrificing health protection.[390]

Such an open consideration of costs would not only likely ensure more cost-effective policy decisions, it would also better serve some of

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justify the high probable costs of bringing about such further reduction." NAS/NAE, *supra* note 132, at 18.

[388] *See* Barnes, *supra* note 372, at 857 ("Given the presence of a cost-minded administration, society might be better off with explicit cost-benefit analysis in setting the air quality standards from the start and abandoning as giving an inferior result the safety-first approach.").

[389] Partial attainment costs would decrease from $1.10 to $0.89 billion per year. RIA, *supra* note 300, at 7-12. EPA's analysis also indicates that there would be little, if any, health decrement in basing the standard on the fifth highest annual concentration. EPA calculated that total monetized health benefits would actually increase if the standard was based on the fifth rather than the fourth highest annual concentration under one method of controlling for $PM_{2.5}$ benefits, while slightly decreasing under an alternative method. *Id.* at 12-46; *see also* OZONE STAFF PAPER, *supra* note 163, at 212 ("Risk analyses . . . indicate that for most of the health endpoints analyzed there is little difference in health risk, at a given level of the standard, within the ranges of 1- to 5-expected-exceedances and the second to the fifth highest 8-hr daily maximum concentration forms of the O_3 primary standard.").

[390] EPA's RIA calculated the cost savings of a standard based on the fifth rather than the fourth highest annual concentration for partial attainment of the ozone standard, but not full attainment. But given that EPA estimated that the fifth highest concentration would save $0.2 billion of the $1.1 billion attainment costs, it would almost certainly save over $1 billion of EPA's estimated $9.6 billion full compliance estimates. RIA, *supra* note 300.

the core principles that undergird administrative law.[391] As John Graham has noted, EPA's "legal fiction" of not considering costs when setting NAAQS "reduces political accountability for value judgments and political choices, [and] hides from public scrutiny claims that are made about risks, benefits and costs (since such claims are driven 'underground' in the course of regulatory deliberations)."[392] Put more simply, as Professor David Faigman has recently argued, the "real loser in the PM/ozone drama was candor."[393] By framing the standard-setting decision as one for which costs cannot be taken into consideration, EPA, Congress, and the courts have endorsed a misleading and ultimately fictional basis for setting air quality standards.[394]

In testimony to Congress on the revised ozone and PM standards, EPA Administrator Carol Browner argued that "to allow costs and related factors to influence the determination of what levels protect public health would be to mislead the American public in a very

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[391] *See supra* notes 1, 5 and accompanying text (describing the fundamental principle of administrative law as reasoned decision making).

[392] Graham, *supra* note 116. Graham also writes that:

> Although regulators might prefer to pass the buck by hiding behind a cloak of quantitative risk assessment, it is important for a representative democracy to deliberate explicitly about the political aspects of chemical regulation. If regulators are not compelled to be explicit about the nature of their policy judgments, then it is unlikely that an informed public discussion of ethics and values will occur.

GRAHAM ET AL., *supra* note 89, at 198; *see also* Barton H. Thompson, Jr., *People or Prairie Chickens: The Uncertain Search for Optimal Biodiversity*, 51 STAN. L. REV. 1127, 1156 (1999) (concluding, in a related context, that "no one can argue that our current system of covert, indirect consideration of costs is better than open and direct consideration").

[393] FAIGMAN, *supra* note 372, at 187; *see also id.* ("The debate was phrased almost entirely in terms of science when the science played a decidedly minor role in the actual decision . . . . Science should not be used to hide what are essentially the true bases for decision.").

[394] *See* J. CLARENCE DAVIES & JAN MAZUREK, POLLUTION CONTROL IN THE UNITED STATES: EVALUATING THE SYSTEM 30 (1998) ("Statutory prohibitions of considering costs in setting environmental standards encourage dishonest, pseudoscientific debates that are really about policy choices (that is, who will we protect, and from what)."); LANDY ET AL., *supra* note 108, at 316 (lamenting that EPA has "sought refuge" in "the Clean Air Act's prohibition against using cost considerations to decide on standards" and that "[a]s a result the public often has an unrealistic picture of environmental uncertainty"); Eads, *supra* note 372, at 231 (noting that EPA's refusal to consider costs explicitly means that the public sees "only the shadow, not the substance" of EPA's decisions); Portney, *supra* note 166, at 77, 117 ("[I]t seems disingenuous to have a law that has been interpreted to prohibit costs from being considered in setting the NAAQSs when, in fact, virtually everyone knows that costs do—and should—get factored into decisionmaking anyway.").

fundamental way."[395] Yet, as we have indicated, when EPA considers costs at least implicitly in setting air quality standards, and then denies that it is doing so, it is actually the Agency's refusal or inability to reveal the full basis for its decision making that "misleads the American public."[396]

C. *Reforming EPA's Air Quality Risk Management*

What steps can be taken that might lead EPA to adopt a more candid and coherent account of its risk management decision making? One possible option would be to look to the courts, while another would be to encourage greater awareness of the limits of science in risk management by Agency scientists, policy advisors, and decision makers. As we discuss below, however, each of these options is unlikely to result in any real improvements in the foreseeable future given the prevailing construction of the Clean Air Act. Under the Supreme Court's interpretation of the Act, the Agency is essentially locked into an ad hoc approach to its standard setting.[397] We conclude that if the aspiration of well-reasoned agency decision making is

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[395] *Clean Air Act: Ozone and Particulate Matter Standards: Hearings Before the Subcomm. on Clean Air, Wetlands, Private Prop., and Nuclear Safety of the Senate Env't and Pub. Works Comm.*, 105th Cong. 282 (1997) (statement of Carol M. Browner, Administrator, EPA).

[396] It is not enough simply to say that EPA can always take costs into account when the states develop implementation plans seeking to bring their air quality into compliance with the national standards. *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 470 (2001) (suggesting that, by statute, the appropriate place to consider costs and feasibility is in the state implementation process). While there is nothing wrong with taking costs into account during implementation, the fact that costs can potentially be considered later does not resolve the core question of how EPA should set the national standards that the states must implement. Consideration of costs during implementation cannot provide a principled explanation for how EPA sets those standards, any more than the justice of a law imposing the death penalty for parking tickets can be established by pointing to the potential for jury nullification. Moreover, even if costs were considered during state implementation, this would at best only partially address the economic impacts of the standards, for the Clean Air Act requires the automatic application of certain regulatory requirements in nonattainment areas and states have no authority to grant exemptions from these requirements. *See supra* note 115 and accompanying text (noting that areas of the country failing to attain air quality standards are subject to more stringent regulations).

[397] Admittedly, even under the existing interpretation of the Clean Air Act, EPA could have improved the comparative coherence of its recent NAAQS revisions by opting to aim for a consistent level of residual risk (or a consistent level of health benefits). In other words, adhering to a predetermined level of risk could have reduced the incoherence between the ozone and PM standards. *Supra* Part II.D. This still would leave unanswered, however, how to justify the predetermined risk level (as opposed to other levels), a decision that would essentially remain ad hoc if costs or feasibility are not considered.

to become a reality for risk management of non-threshold air pollutants, Congress will need to step in to authorize and encourage EPA to break free from its current, incoherent approach. The Clean Air Act itself will need amendment if EPA is ever to pursue a principled approach to air quality standard setting.

Judicial review once would have been considered an option for encouraging EPA to adopt a more candid and consistent justification for its decision making. The availability of judicial review long has been viewed as a mechanism for ensuring that regulatory agencies provide reasoned explanations for their actions.[398] In judging agency decisions under the arbitrary and capricious standard of the Administrative Procedure Act,[399] courts are expected to make a "searching and careful" review of the agency record and to dismiss "post hoc rationalizations" offered by the agency.[400] The prevailing doctrine imposes a "strict and demanding requirement" on an administrative agency that it "must cogently explain why it has exercised its discretion in a given manner."[401] Moreover, even though many judges may lack the expertise to scrutinize scientific research, they should be able to determine where an agency's science ends and its policy reasoning needs to

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[398] *See, e.g.*, Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (applying the "arbitrary and capricious" standard and holding that the agency must "articulate a satisfactory explanation for its action"); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415-17 (1971) (subjecting administrative action to "a thorough, probing in-depth review" to ensure it is not arbitrary or capricious); Air Transp. Ass'n of Can. v. FAA, 254 F.3d 271, 279 (D.C. Cir. 2001) ("[W]ith its delicate balance of thorough record scrutiny and deference to agency expertise, judicial review can occur only when agencies explain their decisions with precision."); Am. Petroleum Inst. v. EPA, 216 F.3d 50, 58 (D.C. Cir. 2000) (holding that an EPA decision was arbitrary and capricious "because the agency failed to provide a rational explanation for its decision"); *see also* JERRY L. MASHAW, BUREAUCRATIC JUSTICE: MANAGING SOCIAL SECURITY DISABILITY CLAIMS 50 (1983) (observing that most of "administrative law has to do with judicial oversight of administrative rationality").

[399] 5 U.S.C. § 706(2)(A) (2000) ("The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . .").

[400] *Overton Park*, 401 U.S. at 416, 419.

[401] *State Farm*, 463 U.S. at 48; *see also* SEC. OF ADMIN. L. & REG. PRAC., AM. BAR ASS'N, THE ADMINISTRATIVE PROCEDURE ACT PROJECT: FINAL BLACK LETTER STATEMENT 23 (2001) (noting that courts may reverse an agency action when it "is unsupported by any explanation or rests upon reasoning that is seriously flawed" or where "[t]he action is, without legitimate reason and adequate explanation, inconsistent with prior agency policies or precedents") [hereinafter ABA, BLACK LETTER STATEMENT], *available at* http://www/abanet.org/adminlaw/apa/home.html.

begin, and, thus, compel the agency to justify its risk management choices with coherent reasoning.[402]

Although an entrenched doctrinal tradition in American administrative law requires agencies to give reasoned explanations,[403] there also exists an equally substantial tradition of judicial deference to agency action.[404] Notwithstanding widely held claims that judicial review under the arbitrary and capricious standard has ossified the rulemaking process, judges actually only review a small fraction of agency rules and, typically, defer to administrative agencies in conducting such review.[405] Moreover, even though the courts have

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[402] *See* ABA, BLACK LETTER STATEMENT, *supra* note 401, at 20 (noting that courts commonly "review agency findings that may be termed factual but actually embody a degree of normative judgment"); Bazelon, *supra* note 42, at 279 ("[A]t the interface of fact and value, courts can help ensure that the value component of decisions is explicitly acknowledged, not hidden in quasi-scientific jargon."). Wendy Wagner suggested an amendment to the Administrative Procedure Act requiring regulatory agencies to clearly demark scientific from policy judgments. *See* Wagner, *supra* note 11, at 1711 (suggesting that such an amendment would "correct the courts' current inclination to interpret the APA to require more, rather than less, quantitative and technical justifications"). While such an amendment might be helpful, it does not seem necessary, since a reviewing court presumably should be able to strike down a regulation as arbitrary and capricious if the agency misrepresents a policy decision as a scientific determination.

[403] This general administrative law tradition has been reflected in judicial decisions reviewing air quality standards. *See supra* note 5.

[404] *See, e.g.*, Natural Res. Def. Council v. EPA, 902 F.2d 962, 968, 973 (D.C. Cir. 1990) (stating that the court must "defer to the agency's interpretation of equivocal evidence, so long as it is reasonable," when reviewing predictions that are within the agency's area of expertise and at the frontiers of science); Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir. 1976) (characterizing the arbitrary and capricious standard of review as "a highly deferential one" that "presumes agency action to be valid").

[405] *See* Coglianese, *supra* note 369, at 1129 ("[I]t appears that judicial review blocks the EPA from taking action in only about 0.5% of all its rulemakings."). Overall, the D.C. Circuit upholds EPA rulemakings in their entirety almost as often as it finds even a single reason to remand the rule to the agency. *See* Cary Coglianese, *Assessing Consensus: The Promise and Performance of Negotiated Rulemaking*, 46 DUKE L.J. 1255, 1308-09 n.249 (1997) (noting that, from 1979 to 1990, EPA rules were affirmed in their entirety in fifty-one percent of the cases decided by the D.C. Circuit); Patricia M. Wald, *Regulation at Risk: Are Courts Part of the Solution or Most of the Problem?*, 67 S. CAL. L. REV. 621, 636-39 (1994) (reporting that agency rules were upheld in their entirety in over fifty percent of the cases decided by the D.C. Circuit during the 1992–1993 term). Moreover, these judicial remands do not appear to be too demanding, as EPA is usually able to take some action to see that its original decision is carried out. *See* William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393, 422-24 (2000) (finding that EPA was able to overcome twenty-seven of thirty-nine remands from the D.C. Circuit from 1985 to 1995 and concluding that judicial review causes "relatively little interference with agency attempts to achieve regulatory goals").

required agencies to give reasons for their regulatory actions, in practice this does not necessarily compel agencies to give sound or consistent reasons, even where judges purport to give them a "hard look."[406]

As the litigation over EPA's recent NAAQS revisions demonstrates, when it comes to reviewing decisions purportedly based on highly specialized scientific analysis, judges tend to give agencies a deferential pass. Particularly in rulemakings that generate a large volume of scientific analysis, agencies can readily appeal to the authority of scientific studies and can look for (and usually find) some pattern in the scientific evidence that appears to rationalize their decision. This rationalization holds even if in the next, similar rulemaking the pattern of the same kind of evidence aligns differently. By practicing this "science charade," agencies can escape the need to provide a consistent, reasoned account of the core policy issues imbedded in risk management.[407]

That is what happened, in the end, with EPA. Of course, in the initial round of litigation, Judge Stephen Williams recognized that EPA's emperor had no clothes. Despite a voluminous record of scientific analysis, all of which was reviewed by the Clean Air Science Advisory Committee, Judge Williams concluded that EPA had provided "no intelligible principle by which to identify a stopping point" for its air quality standards.[408] Unfortunately, Judge Williams's insight came accompanied with a novel constitutional argument that the Supreme Court quickly rejected, and that may have made the significance of his core observation easier to discount.

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[406] Offering "a reason" is not necessarily the same as offering "a good reason." For example, Frederick Schauer explains:

> [A] judge who says she has decided for the plaintiff because it is raining in Calcutta offers a reason . . . even though the reason, unconnected to any sound basis for decision, is a bad one. . . . [A]lthough it is a bad reason, it still exhibits the feature . . . of offering a justification or explanation for the result reached.

Frederick Schauer, *Giving Reasons*, 47 STAN. L. REV. 633, 636 (1995). EPA prepared lengthy documents that purported to offer a justification or explanation for its NAAQS, but because it has not adopted any principle with respect to the core policy issues, and because science by itself cannot address these issues, the agency's proffered explanation is akin to the judge deciding for the plaintiff "because it is raining in Calcutta."

[407] *See* Wagner, *supra* note 11, at 1664 (noting "the tendency of many courts to defer to the agency as expert when the issue is framed as scientific in nature").

[408] Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1037 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

The Supreme Court, in an opinion by Justice Antonin Scalia, interpreted the Clean Air Act in such a way as to preclude the administrator from considering costs.[409] The Court concluded that the Act directed EPA to use "information about health effects . . . to identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an 'adequate' margin of safety, and set the standard at that level."[410] The Court held that this prosaic understanding of the statute provided adequate guidance to sustain the constitutionality of the Clean Air Act. Dismissing concerns about the inability to take a principled health-only approach for non-threshold pollutants, the Court declared that it was simply "not conclusive for delegation purposes" that ozone and PM were non-threshold pollutants with health effects occurring at levels below EPA's promulgated standards.[411] With the Supreme Court effectively affirming the incoherent approach embedded in the longstanding interpretation of the Clean Air Act, it was not surprising that the D.C. Circuit, on remand, upheld EPA's revised standards under the arbitrary and capricious test and deferred ultimately to the agency's "expert judgment."[412] In the end, EPA prevailed and secured judicial approval for its explicitly ad hoc decision making.

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[409] *See Whitman*, 531 U.S. at 471 ("The text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the [Clean Air Act] as a whole, unambiguously bars cost considerations from the NAAQS-setting process . . . ."). In his concurrence, Justice Breyer drew extensively on the legislative history of the Clean Air Act to conclude that EPA may not consider technological or economic feasibility in setting NAAQS:

> [T]he legislative history shows that Congress intended the statute to be "technology forcing." Senator Edmund Muskie, the primary sponsor of the 1970 amendments to the Act, introduced them by saying that Congress' primary responsibility in drafting the Act was not "to be limited by what is or appears to be technologically or economically feasible," but "to establish what the public interest requires to protect the health of persons," even if that means that "*industries will be asked to do what seems to be impossible at the present time.*"

Id. at 490-91 (Breyer, J., concurring) (quoting 116 CONG. REC. 32, 901-02 (1970) (statement of Sen. Muskie))

[410] *Id.* at 465. Interestingly, this language by the Court indicates that EPA must take a "two-step" approach according to the statute in setting its air quality standards, first identifying a "safe" level and then adding an adequate margin of safety. In the past, EPA has expressly rejected any need to follow this "two-step" or any other consistent approach in setting its air quality standards. *See supra* text accompanying notes 186-90 (noting that EPA has continually refused to offer a policy justification in setting the margin of safety and instead has claimed that the administrator has sole discretion in determining how it is addressed).

[411] *Whitman*, 531 U.S. at 475.

[412] Am. Trucking Ass'ns v. EPA, 283 F.3d 355, 373 (D.C. Cir. 2002). For a careful analysis of the Supreme Court's approach to statutory interpretation in *Whitman*, see

If judicial review no longer ensures coherent reasoning by EPA, another possible option would be for EPA professionals to commit themselves to candor about the role and limits of science in making risk management decisions. The Agency has, after all, recently initiated several efforts to improve its scientific analysis.[413] In particular, EPA has made reliance on "sound science" one of its agency-wide strategic goals,[414] creating an office of science advisor[415] and taking steps to ensure that its analysis meets the standards for reliable scientific evidence provided in the Information Quality Act.[416] These efforts to improve the quality of agency science are certainly important in their own right, but by themselves are insufficient to prevent future attempts to stretch the limits of what science can bear.[417] Indeed, calls for a "science-based" approach to risk regulation, however warranted, may mistakenly reinforce the tendency of EPA and other agencies to cloak their policy decisions in scientific terms.[418] What the Agency

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Pierce, *supra* note 134, at 1251 ("[T]he Court seemed to announce and to apply a new canon that is inherently inconsistent with all of the pre-existing law applicable to interpretation of agency-administered regulatory statutes.").

[413] For a discussion of the need to improve scientific analysis and its role within EPA decision making, see E. Donald Elliott et al., *Science, Agencies, and the Courts: Is Three a Crowd?*, 31 Envtl. L. Rep. (Envtl. L. Inst.) 10,125, 10,125-128 (Jan. 2001).

[414] EPA, FY 2003 ANNUAL PERFORMANCE PLAN, at VIII-1 (2002), *at* http://www.epa.gov/ocfo/budget/2003/2003ap/2003ap.htm.

[415] *See* Press Release, EPA, Whitman Appoints Gilman Science Advisor (June 2002) (quoting Administrator Whitman as directing the EPA Science Advisor to "ensure that the highest quality science is better integrated into the Agency's programs, policies and decisions"), *available at* http://www.epa.gov/ord/htm/sci-advi.htm.

[416] Pub. L. No. 106-554, § 515, 114 Stat. 2763A-154 (2001); *see also* OFFICE OF ENVTL. INFO., EPA, NO. EPA/260R-02-008, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY 4 (2002) ("Our Guidelines reflect EPA's best effort to present our goals and commitments for ensuring and maximizing the quality of information we disseminate. . . . EPA's intention is to fully implement these Guidelines in order to achieve the purposes of Section 515."), *available at* http://www.epa.gov/oei/qualityguidelines/EPA-OEI-IQG-FINAL-10.2.pdf.

[417] That said, one recent proposal for improving the use of science at EPA would encourage science advisors to make explicit policy recommendations, under the theory that allowing scientists to express policy advice openly might discourage disingenuousness. E. Donald Elliott, *Strengthening Science's Voice at EPA*, 66 LAW & CONTEMP. PROBS. 45 (2003). Elliott argues that "[i]f told that it is improper to make policy recommendations, scientific groups are much more likely to smuggle in their policy predilections covertly, either consciously or unconsciously." *Id.* at 58. He believes "[w]e would be far better advised to invite scientific advisory bodies to *separate* their scientific conclusions from their policy recommendations, and to empower them to address both." *Id.*

[418] *See, e.g.*, Press Release, Office of Management and Budget, OMB Announces Science-Based Regulatory Review Framework (Sept. 25, 2001) (calling for "high-quality

needs is not only "sound science," but also sound policy reasoning regarding its risk management decisions.[419] Part of the mandate of the new science advisor should include a duty to notify the Administrator when the Agency is overemphasizing the role of science in justifying its policy recommendations.

Even with better and more circumspect scientific advice, however, the Agency still may shirk from providing consistent reasons for its risk management decisions. After all, EPA already had the benefit of science advisors who explained that the choice of where to set its new air quality standards was not a question that science could answer.[420] CASAC clearly explained to the Administrator that the decision about what alternative NAAQS standard it selected was a "policy judgment."[421] In other recent regulatory proceedings, EPA's science advisory committees have pointed out the limitations of science within regulatory decision making, specifically warning EPA when it was overrelying on science.[422] Notwithstanding the sound advice it has

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cost-benefit analyses, science-based risk assessments, peer review, consultation with state and local governments, and specific consideration of the welfare of small businesses"), *available at* http://www.whitehouse.gov/omb/pubpress/2001-38.html. Even though those who call for a "science-based" approach to regulation generally mean to increase the rigor and reliability of scientific research that forms the basis of agency risk assessments (surely a noteworthy aim), such calls may unintentionally increase the incentives for couching policy decisions in terms of "listening to the science." *See supra* Part I.A (describing the rhetorical use of science to hide arbitrary policy decisions); *see also* Kunreuther & Slovic, *supra* note 108, at 123 ("[T]echnical analysis is vital for making risk decisions better informed, more consistent, and more accountable. However, value conflicts and pervasive distrust in risk management cannot be reduced by technical analysis. Trying to address risk controversies with more science, in fact, is likely to exacerbate conflict.").

[419] *See supra* Part III.A (detailing a more principled approach to justifying risk management decisions). In setting environmental standards, "[v]alue judgments must be made about how much health protection is feasible and affordable and who should pay the costs of cleanup." John D. Graham, *Science and Environmental Regulation*, *in* HARNESSING SCIENCE FOR ENVIRONMENTAL REGULATION 1, 2 (John D. Graham ed., 1991). Making these judgments requires hard thinking about risk management principles, even more than perfecting scientific techniques. Obviously, the Agency needs to invest in both.

[420] *See supra* notes 143-45, 179, 297 and accompanying text (detailing CASAC's repeated statements that the setting of the NAAQS standards was a policy judgment rather than a scientific determination).

[421] Wolff, *supra* note 139, at 2.

[422] For example, in commenting on EPA's proposed methodology for setting "residual risk" standards for hazardous air pollutants, the Interim Chair of EPA's Scientific Advisory Board (SAB) advised the Administrator on behalf of the SAB Executive Committee that "while we certainly endorse the concept of science-based decisionmaking at the Agency, we also recognize that no one is well served by asking science to take on an impossible task." Letter from Dr. Morton Lippmann, Interim Chairman, EPA

received about the limits of science, EPA has continued to use science as a fig leaf for its policy choices.[423]

If neither science advisors nor judicial overseers can ensure that EPA will strive for principled, risk management decision making, perhaps we should simply accept that EPA will set its standards in an ad hoc manner and take steps to enhance the democratic basis for the policy choices embedded in the Agency's risk management.[424] After all, even if it makes sense to delegate to agencies on issues requiring scientific expertise, it is much harder to claim that agencies like EPA possess comparable expertise in making social policy judgments, such as determining an acceptable level of risk. Consequently, even if agency expertise is needed to assess and characterize risks, the policy judgments embedded within any risk management decision arguably should be made by a more democratically accountable decision maker or through more direct democratic means.[425] Dean Elena Kagan, for example, has argued that the President should play a greater role in regulatory decision making because agencies do not possess any special expertise to make value judgments and the President is more directly accountable to the citizenry.[426]

While there is much to the idea of holding regulatory agencies more accountable to elected officials, that position only makes it more

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Science Advisory Board, to Carol M. Browner, Administrator, EPA 2 (July 25, 2000), *available at* http://www.epa.gov/sab/pdf/eccm005.pdf.

[423] Wagner, *supra* note 11, at 1617 ("[A]gencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions.").

[424] *See, e.g.*, Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1698 (1975) (theorizing that a major thrust of contemporary administrative law in the United States has been to foster a more pluralistic and transparent process by which agencies develop regulations).

[425] For the standard exposition of this general argument, see THEODORE J. LOWI, THE END OF LIBERALISM: THE SECOND REPUBLIC OF THE UNITED STATES (2d ed. 1979). *But see* Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 95-99 (1985) (arguing that executive branch agencies should be given more power in deference to the electorate's choice in electing the president).

[426] *See* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2353 (2001) ("[A]gency experts have neither democratic warrant nor special competence to make the value judgments—the essentially political choices—that underlie most administrative policymaking."). Reliance on political intervention as a reason for administrative policymaking would represent a shift in the traditional direction of administrative law, which has generally favored independent reasoning by agency decision makers. *See* Mashaw, *supra* note 1, at 21 ("[A] retreat to political will or intuition is almost always unavailable to modern American administrative decisionmakers. The electoral connection is generally unavailable as a justification for administrative action.").

important that agencies respect the limits of science in setting risk standards. After all, even those who favor greater involvement by the President or Congress in regulatory decision making acknowledge a need for relying on agency expertise, particularly on scientific questions.[427] As Dean Kagan writes, "there is no good reason for a President to displace or ignore purely scientific determinations" because "[t]he exercise of presidential power in this context would threaten a kind of impartiality and objectivity in decisionmaking that conduces to both the effectiveness and the legitimacy of the administrative process."[428] As a result, rather than curing the problems with how EPA set its recent air quality standards, any argument for improving the democratic basis for the policy choices in risk management actually makes it all the more imperative that regulatory agencies openly acknowledge science's limits.[429] Using science to justify nonscientific decisions only serves to shield agency decision making from the political institutions that oversee the agency.[430]

Given how EPA has proceeded in its NAAQS rulemakings, citizens are left with a fundamental question unanswered: What justifies the revisions of the ozone and PM standards?[431] Those who will continue

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[427] *See* Kagan, *supra* note 426, at 2353 ("However much political judgment pervades administration and however much political actors should take the lead as to these questions, an important place for substantive expertise remains in generating sound regulatory decisions.").

[428] *Id.* at 2357.

[429] *See id.* at 2332 ("[T]he need for transparency, as an aid to holding governmental decisionmakers to account, here reaches its apex."); *see also* GRAHAM ET AL., *supra* note 89, at 218 ("[S]cience cannot answer the ultimate regulatory questions . . . . Only by recognizing the limited role of science as resolver of conflict can [the policy considerations underlying regulatory decisions] be addressed explicitly and democratically.").

[430] *See* Wagner, *supra* note 11, at 1617 ("Although camouflaging controversial policy decisions as science assists the agency in evading various political, legal, and institutional forces, doing so ultimately delays and distorts the standard-setting mission, leaving in its wake a dysfunctional regulatory program.").

[431] *See* SUNSTEIN, *supra* note 335, at 240-41 ("The EPA's own public justification was . . . in important respects vague and conclusory . . . . Hence any reader is likely to be puzzled about exactly why EPA chose the particular regulations it did—about why it did not regulate either somewhat more or somewhat less."). Dean Kagan argues that sometimes presidential intervention should count as an answer to a question such as this one. Kagan, *supra* note 426, at 2382. In the case of EPA's NAAQS revisions, even that answer was not offered and instead the Agency sought to shield itself within the cloak of science. *Supra* Part I.A. It is not clear, furthermore, whether the President would have intervened to make the critical policy decision. *See* Kagan, *supra* note 426, at 2356-57 (noting President Clinton's "frequent practice of sidestepping involvement" in cases where regulators would "confront the question, which science alone cannot

to suffer from environmentally induced respiratory problems or whose family members will die prematurely due to the levels of pollution permitted under EPA's standards are entitled to a coherent reason why the Agency did not set lower standards in the face of evidence of remaining health effects.[452] Similarly, those who lose out on jobs or forego an increased standard of living as the result of the high costs of the revised standards can also reasonably demand a clear and candid explanation.[453] Yet right now, EPA cannot say anything sensible to those who will be affected by its air quality standards. The Agency is locked into a fictional framework that presumes that pollutants have clear threshold health effects (which they do not) and that costs can be ignored (which they cannot).[454] The law now prohibits the Agency from clearly explaining why it draws the line where it does.

How can EPA achieve greater candor and consistency in its NAAQS rulemakings? Given the prevailing legal structure as well as the incentives agencies have to hide behind the perceived objectivity of science, it seems unlikely that improvements will result from anything other than legislative change.[455] Since EPA does not have a strong incentive to abandon its scientific rhetoric and articulate policy principles, legislative change must do more than simply reject the current interpretation of section 109. It seems unlikely that EPA would take up such an initiative on its own accord, so legislative amendments are needed to spur meaningful change. Such amendments must either provide EPA with a preferred policy approach, such

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answer, of how to make determinate judgments regarding the protection of health and safety in the face both of scientific uncertainty and competing political interests").

[452] *See* Daniel A. Farber, *Risk Regulation in Perspective:* Reserve Mining *Revisited*, 21 ENVTL. L. 1321, 1340 (1991) ("When the decision is being made by an administrator or a judge, we would like to have a little more guidance than simply the decision maker's gut reaction. Too many different kinds of people get jobs as administrators and judges for us to simply trust their intuitions.").

[453] SUNSTEIN, *supra* note 335, at 7-8 ("When the costs of regulation are high, real people will be hurt, through increased prices, decreased wages, and even greater unemployment . . . . [T]he costs should be placed 'on-screen,' so that if they are to be incurred, it is with knowledge and approval rather than ignorance and wishful thinking.").

[454] *See supra* notes 133-36, 166, 368 and accompanying text and Part III.B (discussing the lack of threshold levels in the health effects of pollutants to air and the necessity of considering costs when setting air quality standards).

[455] *See* Wagner, *supra* note 11, at 1651 (arguing that without some external mandate "no rational agency or administrative official acting in her own self-interest would expose the underlying policy choices when faced with the numerous benefits of engaging in the science charade and the high price to be paid for proceeding any other way").

as by directing the Agency to balance benefits and costs, or by imposing a mandate on the Agency to articulate a principle to explain its NAAQS decision making.

Legislative change will not come easily, to be sure, but it may become more viable when the absurdity of the Clean Air Act's outmoded legislative model becomes still clearer to those across the political spectrum. This was the case with the Delaney Clause, which Congress amended after many years, once the Act was interpreted to require the elimination of all cancer risks from pesticide residues in food.[456] If the Clean Air Act follows a course similar to that taken with the Delaney Clause, then ever-advancing knowledge about the adverse effects from still lower levels of air pollutants may force EPA and Congress to confront the absurdity of the current interpretation of the Clean Air Act. For example, the recent identification of genetic susceptibilities to pollutants such as particulate matter and ozone may well heighten the demand under the existing statutory framework to set even more

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[456] The Delaney Clause, adopted in the late 1950s, required agencies to prohibit all carcinogens in food additives. Food Additives Amendment of 1958, 21 U.S.C. § 348(c)(3)(A) (2000). For decades, EPA and the Food and Drug Administration attempted to evade the harsh and unrealistic absolutism of the Delaney Clause by applying various exceptions and limitations. *See* Edward Dunkelberger & Richard A. Merrill, *The Delaney Paradox Reexamined: Regulating Pesticides in Processed Foods*, 48 FOOD & DRUG L.J. 411, 416-18 (1993) (describing EPA's efforts to ameliorate the extreme effects of a strict interpretation of the Delaney Clause, including a short-lived effort to establish a de minimus exception); Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 YALE J. ON REG. 1, 21-41 (1988) (describing how, by circumscribing and reinterpreting the statute in a number of instances, the "FDA chipped away at the edges of the Delaney Clause"). Once the courts confirmed that the Delaney Clause would require zero-risk standards that would impose unacceptable burdens on society, Congress stepped in to amend the food safety laws. *See, e.g.*, Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (legislating additive and pesticide levels in food and applying a "reasonable certainty" standard instead of the Delaney Clause's zero tolerance policy); Les v. Reilly, 968 F.2d 985, 990 (9th Cir. 1992) (rejecting the Agency's interpretation of the Delaney Clause intended "to bring about a more sensible application of the regulatory scheme" because "[r]evising the existing statutory scheme . . . is neither our function nor the function of the EPA"); James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENVTL. L.J. 273, 289-333 (1998) (detailing the repeated congressional attempts to legislate around the strict prohibitions of the Delaney Clause, culminating with the passage of the Food Quality Protection Act in 1996). *But see* James S. Turner, *Delaney Lives! Reports of Delaney's Death Are Greatly Exaggerated*, 28 Envtl. L. Rep. (Envtl. L. Inst.) 10,003, 10,004 (Jan. 1998) (arguing that the Food Quality Protection Act of 1996 "neither removes the protections provided by the Delaney Clause prohibition against adding cancer-causing substances to food nor reflects a public policy rationale or political consensus to do so").

stringent standards.[437] As scientific research continues to document the public health effects that EPA already acknowledges still exist under its revised standards, the pressures to lower air quality standards ever closer to zero will persist and likely increase over time, as will, of course, the costs for complying with more stringent standards. Perhaps fortunately, at least for those who value reason and candor in governmental policymaking, this dynamic will most likely result, eventually, in a broader recognition of the need for statutory reform. If this is correct, then perhaps it is only a matter of time before Congress steps in and adopts a more realistic legislative approach that will bring clarity to this important domain of risk management.

CONCLUSION

The recent revisions to the ozone and PM standards confirm what has been widely known since at least the mid-1970s, namely that section 109 of the Clean Air Act is unrealistic.[438] As scientific knowledge has expanded, health risks have been identified at decreasing levels of exposure. In light of this evolving evidence, it is no longer possible to

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[437] *See generally* GEORGE D. LEIKAUF ET AL., HEALTH EFFECT INST., RESEARCH REPORT NO. 105, PATHOGENOMIC MECHANISMS FOR PARTICULATE MATTER INDUCTION OF ACUTE LUNG INJURY AND INFLAMMATION IN MICE (2001) (reporting that genetic factors contributed to the response of mice to inhaled nickel particles); Enrico Bergamaschi et al., *Polymorphism of Quinone-metabolizing Enzymes and Susceptibility to Ozone-induced Acute Effects*, 163 AM. J. RESPIRATORY CRITICAL CARE MED. 1426 (2001) (demonstrating a link between human genotype and lung function after ozone exposure); Steven R. Kleeberger et al., *Linkage Analysis of Susceptibility to Ozone-Induced Lung Inflammation in Inbred Mice*, 17 NATURE GENETICS 475 (1997) (finding a genetic factor that increased susceptibility to lung damage brought on by ozone exposure); William F. McDonnell, *Individual Variability in Human Lung Function Responses to Ozone Exposure*, 2 ENVTL. TOXICOLOGY PHARMACOLOGY 171, 175 (1996) (finding widespread interindividual variation in response to ozone exposure and speculating that genetic factors may explain some of this variation); Yoshinori Ohtsuka et al., *Genetic Linkage Analysis of Susceptibility to Particle Exposure in Mice*, 22 AM. J. RESPIRATORY CELL & MOLECULAR BIOLOGY 574 (2000) (identifying a genetic trait in mice linked with increased susceptibility to immune dysfunction induced by particulate exposure). As the susceptible subgroups carrying these genetic variants become better characterized, EPA will likely be confronted with an even clearer choice to either set more stringent standards to protect such sensitive subgroups, perhaps even adopting standards approaching zero, or to recognize that other factors such as cost need to be taken into consideration in providing a rationale for decisions about standards set at levels above zero. Gary E. Marchant, *Genomics and Toxic Substances: Part II—Genetic Susceptibility to Environmental Agents*, 33 Envtl. L. Reptr. (Envtl. L. Inst.) 10641, 10656 (Sept. 2003).

[438] *See supra* notes 147-52 and accompanying text (noting that even members of Congress have acknowledged the disingenuousness of the Clean Air Act's framework during past deliberations over legislative amendments).

select a standard that protects the public health, with an adequate margin of safety, from all the adverse effects of non-threshold pollutants, at least not without imposing dire economic costs on the nation.[439] As a practical matter, EPA has had little choice but to disregard evidence about substantial adverse effects on a public whose health the Agency is directed by law to protect.

But EPA has been neither candid nor consistent about the policy choices it has made in revising the nation's air quality standards. The Agency has so far succeeded in shielding its policy decisions behind the language of science and expertise, but it has done so at the expense of consistent and principled public management. These consequences are the less widely acknowledged, but no less significant, lessons to be drawn from EPA's recent experience in revising its air quality standards. Although these rulemakings will likely be remembered for the vigorous arguments that they engendered about the nondelegation doctrine,[440] the more enduring and significant lesson for administrative law concerns the limitations of science in justifying risk management decisions. When agencies rely on science to explain the policy decisions they make, they not only escape their duty to provide a principled account of their decision making, but they also can find themselves submitting to expediency and post hoc rationalization in their efforts to defend their actions.

Examination of the ozone and particulate matter rulemakings reveals that EPA's invocation of science enabled it to ignore numerous inconsistent positions and incoherent results. The same kind of scientific evidence that EPA relied on to tighten its standards also indicated that significant adverse effects—including, in the case of fine PM, substantial mortality—would persist even at the levels of exposure permitted by the revised standards.[441] EPA failed to offer any meaningful rationale to justify both the enormous costs of these rules and the significant adverse effects that they still permit. Without any justification, EPA adopted positions in these rulemakings that shifted from

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[439] *See supra* notes 166, 317 and accompanying text (illustrating the impossibility of eliminating all risks associated with exposure to non-threshold pollutants, short of setting a standard at zero).

[440] *See, e.g.*, Coglianese, *supra* note 18, at 33-35 (noting the tendency of courts and commentators to focus on the constitutional issues raised in the litigation over EPA's revised standards).

[441] *Supra* Part II.B–C.

earlier positions the Agency had taken—both in other NAAQS rulemakings as well as even earlier in these same proceedings.[442]

We have argued that the courts' acceptance of a dysfunctional legislative framework means that to achieve greater consistency in setting air quality standards, Congress must compel EPA to come clean about what science can and cannot say and about what policy principles justify its standards. The Agency cannot simply "listen to the science" to tell it how to make policy choices about how many adverse health effects or how much regulatory cost should be tolerated in society. Risk management calls for value judgments about which it is both possible and desirable for public officials to defend through policy analysis and normative reasoning.[443]

It will probably take new legislation before EPA will begin to adopt a more principled approach to setting air quality standards, but the lessons from the recent experience need not await future legislation to be applied in other contexts. Whenever policymakers find themselves tempted to "listen to the science," they should be careful to consider what science really can and cannot tell them. Embedded within any bare claim that a policy decision is "based on" science, or that science "leads to" a particular policy choice, will be some underlying normative position.[444] If the core normative dimension to any policy decision is camouflaged in science, the resulting policy outcomes, as well as any explanations or rationalizations offered in their defense, will likely be inconsistent if not unreasonable. To be sure, high-quality scientific analysis is vitally needed to inform decision makers about policy problems and to predict the consequences of different solutions, but appeals to science are no substitute for clear and careful reasoning about the normative choices inherent in public policymaking.

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[442] *See supra* Part II (exposing EPA's "veil of science" in its decision making).

[443] *See* Brown, *supra* note 36, at 338 ("The attempt to expunge values is not only doomed to failure or partiality but is harmful to the objectivity and usefulness of the resulting endeavor."); Mashaw, *supra* note 1, at 26 ("'Expertise is no longer a protective shield to be worn like a sacred vestment. It is a competence to be demonstrated by cogent reason-giving.").

[444] *See* Mashaw, *supra* note 1, at 32-33 ("Administrators by and large claim not to be making value judgments . . . . But we know this administrative claim to be hollow.").

Inside EPA's

Risk Policy Report

Guest Perspective

The Legacy of John Graham: Strait-Jacketing Risk Assessment

DATE: MAY 23, 2006

By Rena Steinzor

Economists at Every Table

Risk assessment is the coin of the environmental realm, figuratively and literally. It is also the primary source of the most draining, counterproductive disputes preoccupying the Environmental Protection Agency (EPA). Risk assessment is not the only regulatory methodology used by EPA and other agencies assigned to protect public health, safety, and the environment. Different tools—most notably the technology-based controls that underlie the great successes of statutes such as the *Clean Water Act*—have accomplished more protection, in many cases for less money. But beginning in the mid-1980's, decision-makers have felt disgraced if they do not take a run at conducting a risk assessment on a problem, translating the results into numbers that are deceptively precise. Curtailing this trend is not in the cards for the foreseeable future.

Given its importance, it was no surprise when John Graham's parting salvo as the Director of the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) was a *Proposed Risk Assessment Bulletin* (bulletin) that was intended to be the most prominent aspect of his legacy.[17] The 26-page document would establish uniform, government-wide standards for risk assessments regarding human health, safety, or the environment.[18] OMB will accept comments until June 15, 2006 and a National Academy of Sciences (NAS) panel is conducting a review of the proposal.[19]

Graham's assertion that OMB is qualified to define what constitutes an acceptable risk assessment displays misplaced confidence of the first order. Despite his aspiration to enlarge OIRA's role in science policy, Graham cannot possibly have added more than a handful of scientists to a staff overwhelmingly dominated by economists and budget analysts. If OIRA succeeds in this remarkable power grab, unqualified economists will take their seats beside toxicologists, epidemiologists, pediatricians, neurologists, engineers, statisticians, and other qualified experts as the complex implications of scientific uncertainty are debated.

By raising the "expertise" question, I do not mean to pick a shop-worn, counterproductive fight about whether OMB is entitled to conduct regulatory oversight on behalf of the President. Risk assessment is a cornerstone of many important decisions that OIRA reviews. Yet this effort to control every form of risk assessment *pre*-rule-making goes far beyond that basic function, even assuming that the polarized spectrum of OIRA's constituencies could agree on its appropriate oversight role.

Under the bulletin, any assessment, no matter what its nature or scope, must estimate the "central" risk likely to result from exposure, using a formula for "weighting" model results that is as vague as it is pseudo-scientific. Agencies will be compelled to fast forward to the end of their decision-making process, determining all available options for managing risk before they complete assessments. Risk assessments will be rejected unless they are based on research determining "No Observed Adverse Effects Levels" (NOAELs), as opposed to the long-standing practice of determining "No Observed Effect Levels" (NOEL). And any perceived misstep along the way could trigger challenges to agencies' compliance with the *Information Quality Act* (IQA) (or *Data Quality Act*), one of the worst appropriations riders enacted by Congress. OMB claims legal authority to interfere with the scientific process in this aggressive and inappropriate manner under the IQA, although the one-page law says nothing specific about its authority in this arena.

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[17] *Bulletin* at 20.
[18] *Id.*
[19] *Id.*

Tobacco for Everything

The IQA says that information "disseminated" by the government must be "correct" and of high "quality, objectivity, utility and integrity."[20] The concept for such a mandate originated with EPA's report on second-hand smoke.[21] Philip Morris Inc. was fighting a rear-guard battle against further controls of tobacco and was heavily invested in picking apart every detail of the report. The company hired Jim Tozzi, a Reagan-era OIRA veteran, to persuade his former colleagues to accomplish this charmingly over-simplistic mandate administratively. After all, who could oppose the idea that government should establish a process for outside parties to challenge its dissemination of incorrect information?

As it turned out, seasoned bureaucrats could easily harbor misgivings about this new approach to obstruction and Clinton-era OMB officials were no exception. Frustrated by their indifference, Tozzi went to Capitol Hill where he achieved relief via a rider on 2001 "must pass" appropriations legislation. From these modest origins, the IQA has spawned guidance from every federal agency and department for how they will consider requests for correction of a wide variety of information.

Of course, "truth" and "correctness" are elusive concepts when the science, technology, and economics underlying such decisions become ever more complex. As the tobacco industry well understood, challenging any debatable assertion, no matter how minor, contained in every piece of unfavorable research is the best way to muddy the waters to confound regulators, stalling decisions until the tide of research turns completely and washes away these last outposts of resistance.

Enforcing the Bulletin

This "corpuscularization" of science, to use the term coined by Professor Thomas McGarity,[22] is the foundation of the "sound science" movement that is in full swing both in the U.S. and internationally. Its central tactic is the fly-specking of scientific studies to find individual "errors" of three distinct kinds: (1) clear misstatements of fact; (2) decisions that could have been made differently; and (3) science policy judgments that are unpopular with special interests.

The problem with the discovery of factual mistakes is that corpuscularists demand the exclusion of an entire study whether the error is major or minor, preventing scientists from using their expertise in a "weight of evidence" evaluation that takes mistakes into account in evaluating—but nevertheless using—such research. As for the second and third categories, the sound science movement's has achieved great, if undeserved, rhetorical success by labeling as "incorrect" scientific judgments regulated industries do not like, regardless of whether such judgments are legitimate, common, and transparent. Scientists adopt assumptions all the time in order to proceed with their work. They may decide to use groups of 25, not 40, rats in a bioassay. By challenging such judgments as mistakes that should discredit a study, corpuscularists put everyone on a treadmill of controversy with no easy escape. Similarly, such science policy judgments as the use of "safety factors" to compensate for uncertainties in animal testing may be a legitimate concern in deciding how to evaluate a study but are not a sensible reason to ignore it entirely.

The campaign to deconstruct science in order to gain the upper hand in regulatory decision-making has continued at a rapidly quickening pace in all arenas—from rule-making to judicial proceedings to the scientific literature. Thus far, the IQA has played only a supporting role. Government-wide, IQA "Requests for Correction" number in the hundreds, not thousands, and agencies have rejected most of them in short order. All that could change, however, if the IQA provides a route to judicial review, especially for studies, reports, toxicological profiles, and risk assessments issued before or apart from rule-making. Whether or not regulated industries win such appeals, opportunities to undermine the validity of adverse information and delay decision-making could well be worth the litigation costs.

A few weeks ago, the U.S. Court of Appeals for the Fourth Circuit made short shrift of a bid to obtain judicial review of agency IQA decisions under existing language. Judge J. Michael Luttig wrote that the IQA does not create a cause of action for any particular person or group to challenge the correctness of information in court because Congress did not specify who would have standing in such circumstances.[23] Of course, Congress could fix this problem and the Chamber of Commerce has pledged to go this route. If the matter is debated fully, and industry lobbying does not win out over the long-standing concerns of the House and Senate ju-

[20] **Footnote missing.**
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diciary committees about acute docket overload in the federal courts, the IQA could be transformed from nuisance to major wrench in the works of health and safety regulation. In effect, it would then amount to a codification of corpuscularization, especially with respect to documents such as risk assessments covered by the bulletin, which was supposedly written to implement the IQA.

One Small Size Does Not Fit All

The threshold problem with the bulletin is that it reflects the naïve belief that uniform, government-wide standards would improve a process that has almost as many iterations as it does results. The bulletin requires agencies to include a "central or expected" risk estimate whenever a "quantitative characterization of risk" is made available, and mandates that quantitative estimates should be done "whenever possible."[24] Just how would one calculate this central estimate?

This bulletin uses the terms *'central'* and *'expected'* estimates synonymously. When the model used by assessors is well established, the central or expected estimate may be computed using *standard statistical tools.* When model uncertainty is substantial, the central or expected estimate may be a *weighted average of results* from alternative models. *Formal probability assessments* supplied by qualified experts can help assessors obtain central or expected estimates of risk in the face of model uncertainty.[25]

Suppose we must conduct a risk assessment of a single toxic substance (think arsenic, dioxin, perchlorate, mercury, or vinyl chloride) and have available chemical structure analyses, animal and epidemiological studies, and fate and transport models. Each piece of research has its strengths and weaknesses, including the inevitable policy-laden, default assumptions about the shape of the dose response curve, the level of exposure of both animal and human populations, and the pharmacokinetics of what happens to the chemical once it enters the body.

The bulletin appears to require that the numeric results of specific subgroups of models be averaged together. One example is the hotly contested area of dose-response curve models that use either traditional, "no threshold" assumptions or assume that low doses of specific chemicals are "acceptable." But the bulletin does not stop there. Instead, it appears to require that the numeric results of the full range of "apples and oranges" models somehow be subject to number crunching, also yielding a single estimate of risk.

Given the right, balanced, and suitably skillful risk assessor, a reference dose (RfD) for a single chemical can be calculated, although the calculation will require a series of scientific findings *and* science policy judgments that must remain fully transparent so that they can be debated fully. These difficulties are the reason why NAS panels routinely wring their hands over such numbers and either add a series of safety factors to hedge their bets[26] or pronounce the EPA RfD "justifiable,"[27] as they did with EPA's mercury and arsenic reviews.

Now suppose that we are doing a risk assessment that has considerably more dimensions: an assessment of the risks posed by a substantial expansion of nuclear energy or the implications of a terrorist attack on the chemical industry. Anyone familiar with the practice of risk assessment in this broader context would recognize the foolishness of attempting to calculate a central number that reflects the wide variety of models and other methodologies used by multi-disciplinary approaches. Reducing such disparate pieces of data to one number can only produce the "junk" science that sound science advocates assure us they are determined to eradicate. Even constructing a meaningful *qualitative* statement summarizing central risk poses substantial challenges.

The Great Conflation

The fact is that risk assessments come in all shapes and sizes. They can take weeks, months, years, or decades. The perceived magnitude of the risk inevitably plays a crucial role in determining an assessment's nature and scope, and OMB wisely advises risk assessors to be transparent about these decisions.[28] But it is one thing to acknowledge that science policy-makers cannot help but think about the importance of a problem and what they might be able to do about it when they design an assessment and quite another to say that they must identify and assess those

[24] **Footnote missing.**
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solutions *before* the nature of the risk is established. And yet the bulletin demands that they undertake exactly this task:

"[R]isk assessments that will be used for regulatory analysis . . . shall include . . . an evaluation of alternative options, clearly establishing the baseline risk, as well as the risk reduction alternatives that will be evaluated [and] a *comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered."*[29] (italics added)

Distinctions between risk *assessment* and risk *management* have provoked many a lengthy and esoteric argument in the rarified circles that undertake this troublesome work. Across the political spectrum, many believe that there is no clear line between the two, especially in the sense that policy-making, as opposed to "pure" science, infects both aspects of any problem. "Hard" science informs the design of experiments and determines the results, while "trans-science" permeates everything that happens to those results before they affect human affairs.

Acknowledging this reality is not the same thing as accepting the very large stride that is necessary to get to the idea that risk assessors must worry about the difficulty of finding a remedy before they have assessed the risk. One especially pungent example is testimony by Colonel Dan Rogers, a lawyer by training and Department of Defense's point person on perchlorate, before the NAS panel reviewing EPA's RfD on perchlorate:

> Thousands of men and women in the uniformed services of the United States of America eagerly await the results of your careful and considered and objective deliberations, for what you decide will have a greater impact on their lives than on any others. *[T]here is no room for reliance on science policy* precaution for its own sake . . . Every layer of science *policy* precaution inhibits our ability to train . . . *[putting] our combat forces and, ultimately, our nation at risk.* (italics added)
>
> —Colonel Daniel Rogers, U.S. Air Force.[30]

Or, in other words, the bulletin supports Colonel Rogers' demands that the panel consider his dire warnings about diminution of national security at the same time that it grapples with how perchlorate might pose a risk to public health.

Prove Rather Than Prevent Harm

One of the well-established practices used to both simplify and ensure the protectiveness of risk assessments is to apply the "No Observed Effect Level" (NOEL) as a starting point for dose-response analysis. The reasoning is that since we do not have a firm handle on why certain chemicals cause disease, or how diseases like cancer are initiated and spread, *any* change detected in an organism following exposure is the right place to begin charting whether additional exposure will cause harm. However, science has evolved in some cases to allow us to consider that some organisms can endure such changes without suffering damage. In those instances, it may well be appropriate to begin charting a dose-response curve at the "No Observed *Adverse* Effect Level" (NOAEL).

Rather than allow this approach to evolve at the same pace as the science, however, OMB waves a wand and transforms it to the default assumption in all risk assessments.[31] With respect to human health effects, measuring the concentration of a chemical metabolite in a target tissue is "not a demonstration of an adverse effect" although it does indicate exposure.[32] Nor does measurement of a "biological event in the human body" demonstrate an adverse effect.[33] Instead, "adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges."[34]

At least two things are notable about these stark instructions. First, this aspect makes it clear, if there was any doubt, that the bulletin is not a summary of consensus risk assessment principles, however carefully OMB hedges the language in most sections. If OMB actually uses this language to ride herd over assessments, much less if the courts become involved, the bulletin will skew risk assessments in the direction favored by regulated industries.

Second, OMB is obviously preoccupied with EPA risk assessments dealing with toxic chemicals where NOELs and NOAELs are relevant to decisions whether to

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control exposure. Rather than simply pursue this narrow, albeit controversial, goal, OMB does its best to camouflage its intentions with lofty expressions of overall concerns about improving the quality of assessments government-wide.

Politicized Double Standard

As added evidence that OMB is pursuing a political, as opposed to a scientific or even objective agenda, the bulletin *exempts* from coverage risk assessments prepared by regulated industries, including new drug approvals, pesticide registrations, and the licensing of individual (e.g., nuclear or chemical) plants. In these contexts, risk assessments are used to determine whether to allow activities to occur, from the marketing of Vioxx to the use of pesticides to the operation of Three Mile Island. If OMB sincerely perceives a problem with risk assessment used in a regulatory context, and believes it has the legal authority and scientific expertise to define and police the preparation of such analyses, this double standard is as unwarranted as it is unexplained.

Conclusion

OMB's foray into peer review was a misadventure of sizeable proportions. The bulletin shows that OMB learned little from that experience, although it is also possible that OMB is cheerfully immune to such controversy and expects to be barraged by the same wide variety of stakeholders as those that attacked its peer review proposal. Given the relative importance of the bulletin, we can only hope that it is not disappointed.

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Saving Science from Politics:

Nine Essential Reforms of the Legal System

By Rena Steinzor, Wendy Wagner, and Matthew Shudtz

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About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information. The Center for Progressive Reform is grateful to the Bauman Foundation, the Beldon Fund, and the Deer Creek Foundation for their generous support of its work in general.

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In developing these proposals, we enlisted the expertise of our colleagues in the academic, public interest, government, and private sectors. We circulated draft proposals and invited the recipients to join us for a one-day workshop to vet these ideas. These individuals provided invaluable advice that has helped us refine and improve our proposals. They are listed below because we want to express our gratitude for their time and effort, not to suggest that as a group, as individuals, or as representatives of their organizations they have endorsed all of our recommendations.

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Defending Clean Science

Sound policymaking depends on open access to unbiased science. In recent years, however, the scientific process has been pollured by politics and ideology, calling into doubt the credibility of the science and scientists that inform the regulatory process. Center for Progressive Reform Member Scholars have written extensively on the laws and regulatory policies that can help ensure researchers are free to develop, share, and debate their work without interference from special interests whose power or profits might be affected.

Our work in this area includes:

- Rescuing Science from Politics: Regulation and the Distortion of Scientific Research
  Edited by Wendy Wagner and Rena Steinzor
  Cambridge University Press, 2006

CPR Member Scholars with expertise in law, science, and philosophy contributed chapters to this book, exploring the ways that special interests can abuse the law to intrude on the way that scientists conduct research. Wagner and Steinzor close the book with an examination of the principles that should support any reforms aimed at protecting scientists (independence, transparency, and a public infrastructure for science) and suggest some concrete legal and regulatory changes.

- Sequestered Science: Secrets Threatening Public Health
  by Rena Steinzor and Matthew Shudtz
  <<http://www.progressivereform.org/articles/Secrecy_703.pdf>>

In this White Paper, we explain how the legal system enables, and often promotes, a culture of secrecy that obscures science on the adverse effects of consumer products and toxic chemicals. Key provisions of several environmental, health, and safety laws are compared, with a focus on their disparate treatment of confidential business information. The paper also debunks several justifications typically offered to support the argument that information relevant to public health should be sequestered.

- Strategies for Closing the Chemical Data Gap
  by John S. Applegate and Katherine Baer
  <<http://www.progressivereform.org/articles/Closing_Data_Gaps_602.pdf>>

Following up on an earlier CPR report ("Overcoming 'Environmental Data Gaps:' Why What EPA Doesn't Know about Toxic Chemicals Can Hurt," CPR White Paper 510), we analyze the underlying causes of the gap between the legal system's demand for information about chemicals and the existing supply of available data. We examine the relative advantages and disadvantages of a variety of ways to fill or bridge the data gap, keeping in mind the ultimate goal of protecting people and the environment.

Executive Summary

Several years ago, a group of scholars at the Center for Progressive Reform (CPR) set out to develop legal reforms that would reshape the legal and political dynamics that determine how scientific research informs regulatory decisions. The impetus for this project was the recognition that opponents of protective regulations did not limit their objections to policy debates, but also attacked the research supporting such decisions in ways that undermine scientific integrity.

Private sponsors recruit prominent scientists to sign ghost written articles based on skewed research (as in the Vioxx episode) or try to censor research results that they do not like. Researchers face spurious claims of scientific misconduct and peer review panels lack balance or include members with blatant financial conflicts of interest. Special interests seeking to influence the policymaking debate submit studies without the underlying data that is critical to evaluating their validity or claim that information crucial to understanding a chemical's toxicity is a trade secret and must be withheld from the public. Even when companies know that exposures to their products have caused harm, they fail to file "adverse effects reports" so the problems can be investigated. These political assaults on regulatory science have already cost us dearly, delaying the battle to control climate change and prolonging government efforts to protect people and the environment.

Two years ago, we wrote a book, *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research* (Cambridge 2006), which explains these phenomena and analyzes their adverse effects on the development of disinterested and complete research. *Rescuing Science* also proposed some initial ideas for how Congress, the courts, and federal agencies could restore the independence of science in the regulatory process. The book is based on three fundamental and incontrovertible principles that should guide any legal reforms designed to promote clean science: independence, transparency, and a robust public infrastructure to support research.

This white paper is the logical next step in developing concrete, workable reforms to federal law and regulation based on those broad principles. In Table 1 (next page), we recommend major changes to law and legal practice to launch a full-fledged rescue of science from politics.

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TABLE 1.
Nine Essential Reforms

Recommendation	Problem	Reasoning/ Means of Implementation
1. Level the playing field for publicly funded and privately funded science.	Scientists conducting federally funded research must make available all of their underlying data pursuant to a statute known as the "Shelby Amendment" or the "Data Access Act." But privately funded research used to inform the regulatory process is exempt from these requirements, creating a sharply tilted playing field for informing regulatory policymaking.	The requirements that apply to publicly funded science should also apply to privately sponsored science.
2. Require Disclosure of Sponsor-Controlled Research	Special interests routinely demand that agencies use "sound" science to make regulatory policy, which should mean that such science is conducted by disinterested researchers who are able to operate independently in designing, conducting, and reporting the results of their studies. Over the last three decades, however, the bulk of research that informs health and safety policymaking is privately sponsored. Empirical studies have shown that private sponsorship skews the outcome of the research, especially when sponsors insist on control over study design and impose pre-publication review requirements. Despite this evidence, most regulatory agencies remain ignorant of these conditions, which could affect the weight the government gives to privately sponsored studies.	Studies submitted to federal agencies should always be accompanied by statements disclosing the amount of control sponsors had over the design and publication of research. Federal officials should request this information when researchers do not submit it voluntarily, and if they are unable to obtain this information, they should explain how they assessed the reliability of the research and the weight they ultimately afforded the conclusions.
3. Strengthen adverse effects reporting	Companies that manufacture toxic chemicals have substantial amounts of information regarding the potential risks those chemicals pose to workers, the public at large, and the environment. Yet, as in the case with DuPont's failure to disclose risks posed by perfluorooctanoic acid (PFOA, a chemical used in manufacturing Teflon), companies withhold significant amounts of information from federal regulators. EPA considered DuPont's failure to report sufficiently serious to trigger the unusually high penalties of $10.25 million in fines and another $6.25 million in compulsory Supplemental Environmental Projects.	Public and private entities that become aware of potentially significant risks caused by hazardous substances in in consumer products, chemicals sold in commerce or used in manufacturing, or disposed in a manner that causes human exposure must disclose any known information regarding these risks to regulatory authorities. Exposure data, research related to environmental transport, and studies on toxicogenomics must be shared. EPA should explore new methods for gathering adverse effects information that seek the assistance of the medical profession, the insurance industry, and the plaintiffs' bar.
4. Separate science from policy	In 2007, the Department of Interior Inspector General reported on the case of Julie MacDonald, a political appointee who routinely instructed conservation biologists to change their research reports so that Endangered Species Act protections could be undermined. MacDonald is the most egregious example of a pattern of behavior in this and other federal agencies.	Scientific studies used to inform regulatory policy should be disclosed and docketed in the administrative record before the decisionmaking process begins to prevent political appointees and other interested parties from pressuring scientists to edit or distort their findings.

TABLE 1.
Nine Essential Reforms (continued)

Recommendation	Problem	Reasoning/ Means of Implementation
5. Protect whistleblowers	Many of the worst abuses of regulatory science were brought to public attention by courageous agency employees who risked their careers in protest of the politicization of independent research. Too often, whistleblowers cannot protect themselves from harsh retaliation as a result of loopholes in existing laws.	Whistleblowers who disclose instances of interference or suppression that compromise the conduct and reporting of science used in the regulatory process must be protected from retaliation by expanding record-keeping requirements so that political interference may be detected more easily, changing the allocation of federal positions between the career and excepted service, establishing federal scientific integrity regulations, and improving and expanding existing whistleblower protections.
6. Establish a legal cause of action for harassed scientists	When epidemiologists began to prove links between inhalation of second-hand smoke and lung disease, tobacco company representatives called their superiors to question their competence. Academic scientists have been threatened with lawsuits, subpoenaed by courts, and compelled to withdraw articles submitted from publication, all without receiving legal support from their institutions.	Scientists subject to harassment, including frivolous charges of scientific misconduct or open record requests and other legal processes (e.g., subpoenas, interrogatories) that are unreasonable in scope or demand, should have the right to seek damages by filing an action in federal court.
7. Restore balance and transparency to the peer review process	Congress passed the Federal Advisory Committee Act (FACA) to ensure that when private sector parties gather in committees to advise the government, such consultations are disclosed to the public and the committees reflect a balance of views on the issues. These protections have been eroded in practice and by the courts, exempting too many peer review panels from transparency requirements and resulting in stacked advisory panels. For example, in 2002, then-Secretary of Health and Human Services Tommy Thompson re-shuffled Center for Disease Control's (CDC)'s Advisory Committee on Childhood Lead Poisoning Prevention to eliminate long-serving experts on the consequences of infant and toddler exposure, replacing them with people who had never done any work on the subject.	All members of outside committees that advise federal agencies must disclose a full suite of information about their propensity for conflicts of interest or bias. Agency efforts to screen for these biases and conflicts of interest must be subject to public notice and comment. Finally, agencies empanelling advisory committees should sharply limit their use of conflict-of-interest waivers and prohibit those with waivers from voting on committee recommendations.
8. Prevent overbroad trade secret claims from compromising public health and natural resources	When companies submit research about chemicals in commerce, they routinely stamp it "confidential business information" (CBI), sequestering even basic toxicological information from public release. EPA requires companies to provide upfront substantiation for such claims in the context of its Toxic Substances Control Act (TSCA) § 8(e) program, with the result that the number of CBI claims drops sharply.	Crucial toxicological and eco-toxicological information should be exempt from CBI claims. Any entity claiming CBI must provide upfront substantiation regarding why the protection is warranted. CBI protections should expire within five years unless a compelling case for a limited extension is made.
9. Create an environmental science registry	The FDA's clinical studies registry is designed to prevent duplication of research and prevent private sponsors from suppressing studies that do not turn out as well as they hoped – for example, by showing that a chemical could have an adverse effect on public health or the environment. No comparable disclosure requirement applies to studies conducted on the environmental effects of common chemicals or pesticides.	A registry of scientific studies modeled on the Food and Drug Administration's clinical-trials registry should be established for chemicals and pesticides.

Introduction

Many of the statutes Congress has enacted to protect the health and safety of consumers, workers, and the environment depend in part on scientific research to inform federal agencies' implementation of their mandates. The statutes recognize that agencies sometimes must act before "definitive" science documenting the nature and scope of the harm is available because taking precautions is far preferable to allowing pollution to kill or otherwise threaten public health and natural resources. Staff at the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), National Highway Transportation Safety Administration (NHTSA), and other federal agencies are expected to gather the scientific research relevant to their decisionmaking process and then use this science to set protective standards. Inevitably, the available science is uncertain and incomplete, complicating the task of creating workable regulations that properly manage risks.[1] This entire process must be accomplished under the watchful eye of the regulated community and public interest organizations. As a result, the science behind agency decisions often becomes the center of vehement, if sometimes obscure, debates about how best to manage risks.

Even though the science used for regulation is highly contentious, surprisingly few guidelines govern the agencies' use of this science, particularly with respect to research sponsored by private sector entities ("private science"). Science supported by the government ("public science") is subject to a number of oversight mechanisms. But private science used for regulation is generally exempt from examination with respect to inappropriate sponsor control over decisions regarding study design and publication, scientific misconduct, data transparency, and other crucial qualities. Additionally, federal agency officials often are not required to share internal, agency-generated research and scientific analyses, and are not compelled to docket internal debate about the available science. Consequently, several obscure procedures, or policymaking "black boxes," surround the integration of science into agency policy that undercut both the reliability and legitimacy of the resulting policy decisions.

The two touchstones of clean science are transparency and independence. The concept of transparency affects three stages in the production and use of research. First, regulatory agencies depend on scientific research that can be and has been validated because the data, models, methods, and other critical pieces of the research are open to review. Second, all research relevant to public health and environmental regulation must be communicated to the appropriate agency in a timely and accurate manner, ensuring that the "best available science" is truly available to the agency. Finally, open access to the government's decisionmaking process - transparency as to *how* the science is used - is an essential component of clean science. Combining these three elements of transparency promotes broader involvement in the regulatory process, ideally improving the end result.

The principle of independence is equally important because the credibility of a researcher's work is closely tied to her ability to follow science where it leads her without regard to outside economic or political pressures. Scientists engaged in research that could affect public health or the environment and impose costs on the regulated community must be allowed to conduct their research free of any impediments or restrictions on their rights to publish or otherwise communicate their results to outside parties. They must have the opportunity to choose research projects, design neutral studies, assess their data, and report their results based solely on their best scientific judgment.

The reforms we propose are progressive responses to the problems that surround the integration of science into agency policy and emanate from the two fundamental principles of promoting transparency and protecting independence in regulatory science. These proposals are important steps, designed to staunch misuse of the legal system so that scientists have space to develop their own responses to these inevitable pressures. However, the ultimate solutions to the pervasive and debilitating politicization of science must come from within the scientific community itself.

The Data Access Act's lopsided approach frustrates the fundamentals of scientific and regulatory transparency.

Improving the Data Access Act

The asymmetrical design of the federal Data Access Act (DAA) is the first problem that Congress and federal policymakers should address. This statute, sometimes referred to as the "Shelby Amendment," in honor of its author, Sen. Richard Shelby (R-AL), instructs the White House Office of Management and Budget (OMB) to amend the rules governing *federal* grant disbursement to make scientific data created with the support of federal funds publicly available through the Freedom of Information Act (FOIA). Enacted as a rider to a 4,000-page omnibus appropriations bill, the DAA reads in full:

> Provided further, That the Director of OMB amends Section _.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act: Provided further, That if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data.[2]

As the text reveals, the Act does not address accessibility of the growing amounts of data generated by the *private* sector that is used to justify positions on regulatory policies. This lopsided approach frustrates the fundamentals of scientific and regulatory transparency, which apply to all research - not just research supported by the government - if participants in the regulatory process want to use it to influence a final action.

Writing in the *Harvard Journal on Legislation* shortly after the DAA was signed into law, Senator Shelby explained his rationale for introducing the amendment.[3] While acknowledging the importance of transparency of regulatory science, Senator Shelby said that his primary motivation for sponsoring the legislation was a dispute with EPA over access to the underlying data in a federally funded study used to support revisions to the ozone and particulate matter National Ambient Air Quality Standards.[4] The "Six Cities Studies" showed adverse effects on respiratory and pulmonary functions among human subjects who exercised in chambers contaminated by these pollutants at levels comparable to ambient air in some major cities. Senator Shelby was incensed when neither EPA nor the researchers would disclose the underlying data.[5] Thus the DAA was born, applicable only to federally funded research.

In its effort to devise guidance explaining to agencies how they should implement the DAA, OMB proposed several ideas that ignited a firestorm of protest from the scientific community. Specifically, the scientific commenters raised concerns about the statute's inattention to human subject privacy concerns, intellectual property protection as related to the Bayh-Dole Act's award of patent rights on the basis of federally funded research, potential harassment by those who might be subject to more stringent regulation as a result of federally funded research, and the possibility that the timing of data accessibility could disrupt the traditional rhythm of scientific discovery. After two rounds of proposed

revisions. OMB's final changes, embodied in Circular A-110, were adopted with the following key features that limited the reach of the Act in a way more consistent with the views of the scientific community:

- The public can use FOIA to access only research data (1) "relating to published research findings" that are (2) "used by the Federal Government in developing an agency action that has the force and effect of law."[6]
- Research data that scientists must divulge upon request from any agency do not include:
  - "Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
  - "Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy..."[7]

The constraints on the DAA imposed by OMB in response to public comments reflect an effort to promote transparency in the scientific process while at the same time allowing for speedy development of regulation and protection of confidential information and scientific independence. Apparently OMB did an adequate job of balancing these competing interests, because the scientific and public interest communities - who had initially lobbied for repeal of the DAA - abandoned that position after the final revisions to Circular A-110. Given that the Circular A-110 limitations to the DAA's scope appear generally to protect scientists in a reasonable way while advancing the goals of regulatory transparency, we propose expanding the coverage of the DAA to a broader range of scientific studies.

First, we recommend that Congress extend the DAA to cover the results of privately funded research. This proposal, on its own, is relatively uncontroversial. The American Association for the Advancement of Science, the Association of American Universities, and the National Research Council have expressed support for sharing research data relevant to public policy debates,[8] and the public interest community has maintained that the DAA's asymmetrical applicability runs contrary to principles of transparency and accountability. Industry groups also support equal treatment for all science. The American Chemistry Council's Long-Range Research Initiative, which sponsors new research aimed at improving chemical risk assessment, requires grantees to make their data accessible.[9]

We further recommend that the Act's coverage extend to data that support regulatory actions beyond those with "the force and effect of law." This reform is necessary because regulatory agencies use scientific research to support many decisions that may not rise to the level of having "the force and effect of law" but nonetheless have a significant impact on their efforts to protect human health and the environment. For example, risk assessments developed for EPA's Integrated Risk Information System (IRIS) database do not have any legal effect on their own but are highly influential in regulatory decisions throughout the world. Similarly, U.S. climate change policy is in its infancy, and the scientific basis for decisions about whether and how to act is under intense scrutiny. The substitution of voluntary or

incentive-based programs for binding legal requirements in various other fields puts a premium on the transparency of the science used to justify such decisions. The same is true for decisions to refrain from addressing health and safety problems on the grounds that they are not pressing concerns (e.g., OSHA's failure to regulate diacetyl, a toxic chemical used in the manufacture of popcorn sold to consumers).[10] In the field of endangered species protection, the decision to not list an imperiled species as threatened or endangered should be supported by research that is subject to transparency rules.

We recommend that Congress extend the Data Access Act to cover the results of privately funded research.

Rather than limiting data access to research supporting the vaguely worded "agency action with the force and effect of law," we recommend that coverage should instead reference the Administrative Procedure Act (APA) definitions of "agency action" and "agency proceeding." Under the APA an agency action is defined as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[11] An agency "proceeding" means "any regulatory process as defined by [the terms 'rule making,' 'adjudication,' or 'licensing.']"[12] The advantage of using these terms is that years of agency practice and legal precedent will help inform decisions about whether particular data should be accessible. Additionally, the inclusion of instances where the agency fails to act based on scientific research will now be subject to greater accountability. However, these reforms do not adequately expand the universe of regulatory decisions that trigger FOIA-based data access procedures.

To bring a broad universe of regulatory decisions under the umbrella of a revised DAA, we further recommend expanding data access rights to cover research that informs "significant guidance documents," as defined by Executive Order 13422.[13] A "guidance document" is "an agency statement of general applicability and future effect other than a regulatory action that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue."[14] We suggest expanding data access requirements only to cover *significant* guidance documents as a way of promoting transparency without excessively impinging on administrative flexibility.[15] Most agency actions that are not finalized through the rulemaking process are of limited applicability and significance – they guide internal deliberations or clarify minor ambiguities in more formal regulations. It is important to protect the agencies' ability to develop these documents quickly so that they can be revised continually to reflect new information. But at the same time, the public has a legitimate interest in the accessibility of data that support things like influential risk assessments and reports on "education, health care, drug usage, crime, welfare, the environment, and Social Security"[16] that in turn support regulation or legislation. The definition of "significant guidance document" in Executive Order 13422 provides a workable starting point for striking a balance between transparency and efficiency.

During the public comment period on proposed revisions to Circular A-110, OMB considered broader data access rights akin to those we have just suggested, but backed off the idea after determining that the proposal was "burdensome and time-consuming, and would intrude into the agency's deliberative process."[17] However, this conclusion was based on an

incorrect assumption about the timing of data access rights. The DAA states that data access rights take effect when an agency has "used" the research. OMB correctly determined that in the context of notice and comment rulemaking an agency can be viewed as having "used" research findings when those findings are publicly and officially cited in a *Federal Register* rulemaking notice.[18] But when agencies undertake less formal actions without preparing explanatory documents for the *Federal Register*, OMB found it "unclear" how the statute would operate.[19] OMB considered only one admittedly unworkable approach to solving the problem:

> [A]n agency might be viewed as having "used" research findings if those findings: (1) were relied upon in an internal agency memorandum sent to a decisionmaker; (2) were discussed in an agency staff level communication, such as an email message; or (3) were simply available for the agency staff to read, regardless of whether there was any evidence that the staff relied upon the findings in carrying out their work.[20]

This scheme would certainly be burdensome, time-consuming, and an intrusion on agencies' deliberative process, but these problems arise because this scheme would shift the determination of whether research findings were "used" to a premature point in the decisionmaking process. As in the context of notice and comment rulemaking, an agency should not be considered to have "used" research findings unless they are publicly and officially cited. That is, outside the context of notice and comment rulemaking, an agency has only "used" research findings when a document citing those findings is published in final form or in draft form for public comment.

To summarize, the DAA should be considered the starting point from which Congress launches a broader program to ensure transparency in the creation and use of all regulatory science, not just publicly funded science. An improved data access policy should have the following characteristics: all research data, regardless of funding source, should be publicly accessible if research findings based on that data are used by the federal government in support of an agency action, agency proceeding, or significant guidance document. Research findings are "used by the federal government" when the agency publicly and officially cites them. These principles, clarified by the discussion above, strike an appropriate balance between transparency and efficiency.

Private funding increases the likelihood that the researcher will have significant financial ties to a person, corporation, or other organization that could benefit either directly or indirectly from her research.

Eliminating Funding Bias and Sponsor-Controlled Research

The most recent estimates from the National Science Foundation indicate that private funders were responsible for more than fifty percent of the $143 billion dollars spent on basic and applied research in the US in 2006.[21] The objectivity of this work might legitimately be questioned for multiple reasons. For one, private funding increases the likelihood that the researcher will have significant financial ties to a person, corporation, or other organization that could benefit either directly or indirectly from her research. Meta-analyses of research results in the fields of pharmaceuticals, toxics, and pesticides often suggest that the identity of the sponsor affects the outcome of scientific studies.[22] Researchers suggest that the problems run deeper than simple bias in interpreting data - privately funded science sometimes suffers from methodological biases that corrupt the data. In the field of pharmaceuticals, these methodological biases can include enrollment of relatively healthy patients, insufficient selection or dosage of comparator drug, inadequate sample size, or inappropriate length of patient follow-up.[23] Besides these predetermined methodological decisions, during the study itself, researchers have discretion in making decisions about which effects are recorded and analyzed.[24] At each stage in the research process, funding bias can affect the outcome of a study.

Skepticism about the objectivity of privately funded research also has roots in sponsors' attempts to put limitations on researchers' independence. In hopes of protecting the financial interests implicated by the research they sponsor, private funders have engaged in a practice of contracting with researchers who will agree to allow their sponsors to dictate aspects of their work. Examples include sponsor-prescribed trial design, limited access to data, restricted participation in data interpretation, and incomplete editorial and publication rights.[25] Though the problem is most acute in fields of research where studies are linked directly to big-market consumer products (e.g., pharmaceuticals), the problem is not limited to private research sponsors. Government agencies including the Department of Defense and Federal Aviation Administration are also guilty of attempting to limit researchers' rights to data and results.[26]

Private sector sponsors advance numerous justifications for limits on scientists' independence. One line of reasoning is that sponsors deserve the opportunity to capture returns on investment before copycat products are developed. Another is the argument that private sector sponsors will have less incentive to fund research if they cannot control the dissemination of results that could trigger liability or more stringent regulatory standards. Firms that have large-scale, diversified research programs (e.g., Merck, the manufacturer of Vioxx) also want to be able to halt some research projects at "critical development milestones" in order to optimize allocation of research money.[27] Regardless of the justification, these impediments to independent scientific research are harmful because they reduce the credibility of individual projects by creating a presumption of sponsor manipulation.

Two groups with an institutional interest in maintaining independence in scientific research have adopted policies designed to create incentives that will encourage both researchers and

their sponsors to avoid contractual limitations on independence. Major research universities have developed policies that prohibit engaging in research projects contingent on limited publication rights,[28] thus shrinking the pool of accomplished researchers available to sponsors who want to constrain scientific independence. In addition, the International Committee of Medical Journal Editors (ICMJE) has adopted a policy that requires authors to submit a written declaration regarding their level of control over the research that supported an article submitted for review.[29] *The New England Journal of Medicine, the Journal of the American Medical Association (JAMA)*, and other major journals have said that they will not review or publish articles unless the authors' disclosure statement indicates a substantial level of control over the research and reporting of results.

Despite these efforts, sponsor control over research and publication continues to be a problem because the interplay between researchers, funders, and the researchers' home institutions is much more complex than it might seem at first blush. To begin, university policies that protect publication rights may be less complete than is needed to significantly affect contract negotiations. A survey of the 100 U.S. institutions with the most funding from NIH in 1998 uncovered only 11 university policies that specified a time limit for delay of publication or presentation of research results to allow review by corporate sponsors.[30] However, a more recent study, conducted after the ICMJE revised its policy on authors' autonomy, found that a vast majority of medical schools "would not approve provisions giving industry sponsors the authority to revise manuscripts or decide whether results should be published."[31] Former Harvard University President Derek Bok suggests that enforcement may be the real problem, noting that "company research directors report that they seldom have difficulty obtaining as much secrecy as they want."[32] A shift in the types of institutions that are obtaining funding is also a factor. Nonacademic research groups (contract research organizations, or CROs) that "can do the job for less money and with fewer hassles than academic investigators" are getting an increasing share of research funding because they are more likely to accept limitations on independence and are not as motivated by the potential for publication in research journals.[33]

Despite the growing body of evidence suggesting funding bias is a serious problem, regulatory agencies still use research to support regulatory action without necessarily knowing the source of funding for that research or whether the authors had complete research and publication independence. Some leading biomedical journals have adopted a policy of requiring disclosure of sponsor control over any research submission.[34] The information requested from researchers provides transparency as to the identity of sponsors, the types of support provided, the role of the sponsor in the research process, and the researchers' level of control over the study and data.[35] ***To improve transparency in regulatory science, federal agencies should follow this model, requiring that studies submitted to the agency be accompanied by disclosure statements that provide all of this information. When agency officials want to use a study that they discovered in searching the literature, they should be required to contact the principal investigator and request this information.***

Improving Adverse Effects Reporting

Congress inserted provisions in TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that require regulated parties to inform EPA when they develop or discover information that suggests threats to public health or the environment. But these requirements have not been updated in decades and are increasingly inadequate.[36] Under TSCA, for example, registration of a chemical with EPA triggers a continuing obligation on regulated firms to submit to EPA any information they obtain that "reasonably supports the conclusion" that a chemical or mixture they manufacture, import, process, or distribute "presents a substantial risk of injury to health or the environment."[37] Similarly, FIFRA § 6(a)(2) states that pesticide registrants have an ongoing duty after registration to submit to EPA any "additional factual information regarding unreasonable adverse effects on the environment" caused by the pesticide.[38] Failure to adhere to these disclosure mandates can lead to significant civil or criminal penalties,[39] but the government must discover the withheld information before it can punish the firm that keeps it secret.

These legal standards depend too much on the discretion of the firms who manufacture, sell or use the products that pose the risk. Under TSCA, reporting is triggered by three judgments: whether the information (1) reasonably supports (2) a conclusion that the substance presents (3) a substantial risk of injury. Under FIFRA, three alternative factors govern whether information is reportable: whether it is (1) additional, (2) factual information (3) regarding adverse effects.[40]

To strengthen these requirements and ensure that evidence of adverse effects is reported to the government, we recommend four reforms:

- *Promulgation of new TSCA regulations that require regulated parties to disclose any research that provides significant knowledge that would allow scientists to assess the risk of a chemical circulated widely in commerce;*
- *Issuance of EPA "safety net" guidance under FIFRA specifying that information beyond specifically enumerated types of studies must be submitted if it would serve the same purpose as the listed data;*
- *Enactment of a free-standing, cross-cutting requirement that manufacturers and users of hazardous agents in the form of either products or wastes must report instances where exposures - estimated using either reasonable worst-case methods or methods to estimate the expected value of exposure - could pose a significant threat to human health; and*
- *Expansion of efforts to collect risk data from private institutions, including the plaintiffs' bar, the insurance industry, and the medical profession.*

The PFOA Episode

The December 2005 settlement agreement between EPA and DuPont over DuPont's failure to comply with TSCA § 8(e) highlights the problems with compliance. In 1978, DuPont began studying the human health effects of perfluorooctanoic acid (PFOA, a chemical used in manufacturing Teflon).[41] By 1981, the company had compiled reports about PFOA in pregnant workers and their offspring, developing "the first direct human evidence of PFOA crossing the placenta in humans,"[42] a startling discovery that greatly increased the risks posed by exposure to even low doses of the chemical. In addition, DuPont conducted two different studies of PFOA in the blood of residents of the community surrounding a West Virginia plant where the chemical was used and three inhalation exposure studies using rats and chemicals similar to PFOA. The company failed to submit the results of any of these studies to EPA upon completion.

The first evidence of these studies did not reach EPA until 2001, when attorney Robert Billott discovered documentation of the studies while investigating a class action lawsuit against DuPont for suspected PFOA contamination of groundwater surrounding a West Virginia plant. Billott sent copies of the studies to EPA, which began a § 8(e) enforcement action soon thereafter.[43] EPA and DuPont settled the enforcement case for penalties totaling $10.25 million and Supplemental Environmental Projects worth $6.25 million,[44] unusually heavy penalties in an unfortunately rare type of enforcement action. The precise number of injuries that could have been prevented by more timely disclosure has yet to be determined, but we do know that one child born to a DuPont employee working in the PFOA plant "was born with a severe nostril and eye defect and another was born with an unconfirmed eye and tear duct defect,"[45] and that workers in a Minnesota PFOA plant have exhibited an increased risk of death from prostate cancer and stroke.[46]

New TSCA Section 8(e) Regulations

The PFOA settlement highlights the potential for abuse of TSCA § 8(e).[47] The only legally enforceable reporting standard is the statute itself, since EPA has never issued any regulations that clarify what types of information the agency expects to be reported, giving companies too much room to evade these requirements on the grounds that they did not "expect" a risk to be "substantial." EPA has two guidance documents on the subject,[48] but the history of § 8(e) non-compliance suggests that the guidance is insufficient.

Between February 1991 and May 1996, EPA ran a Compliance Audit Program that encouraged companies to search for and disclose any TSCA-relevant risk information by establishing a $1 million ceiling on penalties that would be imposed against any single company for failure to comply with § 8(e).[49] Eighty-nine companies participating in the program found over 11,000 previously unreported studies,[50] suggesting that there is a serious problem of non-compliance.

Scrapping existing guidance and beginning anew with legally enforceable regulations would allow EPA to make a strong policy statement in favor of transparency in privately funded research.

A problem with § 8(e) highlighted by the DuPont case is the fact that the statute and guidance are susceptible to circumvention by corpuscularization. "Corpuscularization" is the tactic of highlighting the inherent and unavoidable incompleteness of any given scientific study to frame it as not scientifically valid.[51] DuPont argued that the evidence of cross-placental PFOA exposure and PFOA contamination of water supplies do not reasonably support a conclusion of substantial risk because the information pertained to exposure alone and did not make a causative link between exposure and harm.[52] To put the argument in stark terms, the company seems to suggest that scientific studies are only subject to § 8(e) reporting if the results of the study reach definitive conclusions that a given number of people became ill as a result of exposure. If that argument were true, it would give short shrift to the fact that evidence of a chemical's ability to cross the placenta and reach a fetus dramatically expands the potential for adverse exposure to babies in utero.

Moreover, DuPont's reasoning contradicts well-established scientific standards for regulatory risk assessment, which involve taking a "weight-of-the-evidence" approach. Scientists of relevant disciplines consider all available studies that will improve our understanding of release, fate and transport, exposure, cellular response, and many other factors.[53] Properly understood, TSCA § 8(e) reflects the principle that a broad range of scientific research is necessary for proper risk assessment and that no study can survive the test of proving causation on its own. Therefore, any study that could play an important role in assessing risk should be covered by adverse effects reporting requirements.

The disconnect between regulated parties' understanding of the § 8(e) requirements and the EPA enforcement office's understanding of the requirements (as exemplified by the DuPont case) could be resolved by improvements to EPA guidance or establishment of new regulations. We recommend the latter option. Scrapping the existing guidance and beginning anew with legally enforceable regulations would allow EPA to make a strong policy statement in favor of transparency in privately funded research. It would also better implement Congress' mandate for disclosure of any scientific research that could provide significant knowledge about toxic substances that would allow scientists to assess risk.

EPA should develop new TSCA regulations that require regulated parties to disclose any research that provides significant knowledge that would allow scientists to assess the risk of a chemical circulated widely in commerce, especially High Production Volume chemicals (those produced or imported into the U.S. in quantities of one million pounds or more per year). Exposure data, research related to environmental transport, studies on toxicogenomics, and a host of other research not necessarily disclosed under the current guidance would be shared.

Adding a FIFRA 'Safety Net' Provision

Under FIFRA, Congress used different language to describe the adverse effects information that should be reported to EPA. For pesticides, a particular scientific study should be submitted under FIFRA § 6(a)(2) if it presents "information regarding unreasonable adverse effects." Unlike the TSCA adverse effects reporting program, EPA actually established a

detailed set of regulations governing adverse effects reporting under this vague statutory standard.[54] Since the first iteration of the regulations in 1978, EPA has taken "a very broad view of the statutory scope of section 6(a)(2)," explaining "that reportable information need only 'pertain or relate to unreasonable adverse effects on the environment; it does not have to indicate, establish, or prove the existence of such effects.'"[55] Despite espousing this viewpoint, EPA adheres to an enforcement policy that greatly limits the statute's effectiveness.[56]

Instead of crafting regulations that would implement the "broad view" of § 6(a)(2)'s coverage, EPA chose to limit coverage to only that information which "the Agency considers relevant to determining whether a registered pesticide continues to meet the standards of registration."[57] The regulations thus list certain types of toxicological, ecological, and human epidemiological studies that EPA wants registrants to submit "and essentially exempts from the reporting requirements information not covered by the Rule."[58] Under threat of civil and criminal liability, registrants must submit:

- Toxicological studies...[59]
  - Showing toxic effects in a different tissue than previously reported;
  - Showing toxic effects at a lower dose, after a shorter exposure period, or after a shorter latency period;
  - Showing toxic effects at a higher frequency;
  - Showing toxic effects in a different species/strain/sex/generation of test animal; and
  - Leading to a lower toxicity indicator like an LD50, LC50, or irritation index.
- Ecological studies...[60]
  - Leading to a lower LD50, LC50, or EC50 than previously reported;
  - Showing chronic effects at lower levels; and
  - Using different test species and indicating lower LD50 or LC50.
- Human epidemiological studies...[61]
  - Showing any correlation between exposure and adverse effects, regardless of whether the registrant considers the correlation significant.
- Surface or ground water screening studies...[62]
  - Measuring the chemical in a concentration higher than an EPA-established Maximum Contaminant Level (MCL), Health Advisory Level (HAL), reference dose (RfD), or reference concentration (RfC).

This regulatory scheme has the benefit of making reporting requirements objective, thereby limiting the discretion afforded to registrants in deciding whether to submit a specific piece of research. However, such specificity also limits the utility of the statute. By limiting itself to a "laundry list" approach, EPA indirectly encourages the sequestration of information that would be useful to scientists and the public in studying and managing the risks posed by toxic chemicals.

EPA should supplement existing FIFRA disclosure requirements with a "safety net" provision that requires disclosure of evidence not specifically listed that would provide the equivalent function of informing re-registration risk assessments of covered pesticides.

Cross-cutting Adverse Effects Reporting of 'Significant Threats'

Recent headlines make it abundantly clear that a great deal of critical health and environmental risk information has been suppressed, leading to delays in appropriate government response.[63] At least some of this suppression can be blamed on incomplete and ineffective regulatory requirements governing adverse effects reporting. ***We recommend that Congress pass a free-standing law that requires any entity, including the federal government, that produces goods in commerce within the United States to report any information that suggests a "significant threat" is posed by exposure to any "hazardous agent" contained in those products and the wastes they become.***

The two fundamental challenges in creating this new reporting requirement will be ensuring broad coverage of hazardous agents and establishing a low reporting threshold. At a minimum, the reporting requirement should cover "hazardous substances" as defined in Superfund,[64] the active and inactive ingredients of pesticides,[65] substances covered by the Federal Hazardous Substance Act,[66] petroleum products, and materials regulated by the Atomic Energy and Nuclear Regulatory Commissions. This proposal would expand existing Superfund reporting requirements by eliminating exemptions for petroleum products, the normal use of pesticides, and nuclear materials. However, it is considerably narrower than the Superfund requirement that any "release" or "threatened release" into the "environment" trigger reporting obligations.[67] Instead, application of the new law would depend on an "objectively reasonable belief" that potential exposure levels could pose a significant risk. Potential exposure levels should be estimated using either reasonable worst case methods or methods to determine the expected value of exposure. Companies should be encouraged to over-report in the first years of the statute. Agencies must undertake routine enforcement from the new law's effective date, with penalties gradually increasing as its parameters are defined by relevant agencies and the courts.

We recommend that reports would be submitted to agencies with primary authority over the product or waste in question: environmental risk information would go to EPA, workplace risk information to OSHA, consumer product risk information to CPSC, and pharmaceutical and food risk information to FDA. Each agency would have a uniform set of remedies available and would coordinate cross-media exposures. We recognize that reviewing adverse effect reports would be time-consuming and demand additional resources above and beyond what agencies now have available. In comparison to the costs of unrecognized risks, we believe these additional expenditures would be a bargain.

New Approaches to Gathering Risk Information

Another important point highlighted by the PFOA case is that manufacturers are not the only sources of adverse effects information. In fact, the case illustrates the importance of the tort system as a source of information.[68] But while the discovery powers available to plaintiffs' attorneys and the incentives to find "smoking gun" documents increase the likelihood of uncovering information that an agency might like to use in crafting protective regulation, those attorneys are also obligated to work toward their clients' best interests, which sometimes means exchanging sealed settlements for larger payouts. EPA and Congress should consider working with other entities, especially the medical profession, the insurance industry, and the plaintiffs' bar, to access risk information.[69]

The FDA Amendments Act of 2007 provides an example of an agency-driven program designed to uncover new information that would be useful to further supplement agencies' current primary reliance on regulated parties to produce post-market information on the adverse effects of their products. This new statute instructs FDA to develop "active post-market risk identification and analysis methods" for all approved pharmaceuticals that will enable the agency to identify trends and patterns in adverse events caused by the drugs.[70] FDA is supposed to collect data from insurance claims, patient survey data, and any other data source deemed appropriate. The data collection methods developed by FDA under new amendments to its authorizing statute might have the potential to be modified to improve EPA's ability to identify adverse events resulting from exposure to environmental toxins.

Improving Whistleblower Protections

Effectively protecting whistleblowers is another way to identify suppression and manipulation of science used for regulation. Generally speaking, whistleblower-protection laws are designed to ensure that employees who speak out against improper or illegal activities are not fired, demoted, or otherwise retaliated against by their employers. The laws could be a useful tool for protecting scientists who make good faith allegations of research misconduct or disclose in some other fashion evidence of impediments to independent scientific inquiry.

Unfortunately, existing laws do not provide adequate protection for scientific whistleblowers.[71] For instance, the Whistleblower Protection Act, the main statute protecting federal employees from retaliation, prohibits adverse employment actions in response to a federal employee's disclosure of information that she reasonably believes evidences either (1) "a violation of any law, rule, or regulation;" or (2) "gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety."[72] A federal employee who has evidence of interference with scientific integrity might claim that disclosure of that information would be covered by the protection for speaking out against an abuse of authority, but that is not an argument clearly supported by the statute.

For privately employed scientists, existing whistleblower statutes are even more ambiguous. Several environmental statutes - for example the CAA, CERCLA, and the CWA - extend whistleblower protections to privately employed individuals who participate in the enforcement of those laws (e.g., by testifying before Congress or a judicial proceeding or by assisting in regulatory proceedings).[73] But the availability of the protections afforded by statutes will often turn on whether the employee's whistleblowing results in the commencement of a proceeding to administer or enforce some other provision of statute. Disclosing evidence of interference with scientific integrity is not clearly covered by these statutes.

Finally, the structure of whistleblower protection, insofar as it relies primarily on back-end, reactive protections, is an unsatisfactory system. Federal scientists should be able to rely on well-designed decisionmaking procedures and clearly defined role boundaries for political appointees so that the need to become a whistleblower does not arise.

Front-End Protections: Improving Administrative Recordkeeping

Recent rulemakings are littered with examples of White House staff and agency political appointees secretly rewriting draft rulemaking notices and scientific reports to distort the candid opinions of career scientists and even outside peer reviewers. These alterations were revealed only through whistleblowers and persistent investigative reporting. Endangered species decisions,[74] climate change reports,[75] and the Bush Administration's proposals to control mercury from power plants[76] have all been compromised by ideological re-drafting

of scientists' work. Expanded administrative recordkeeping requirements could prevent – or at least minimize – such inappropriate interference by creating a public record of the evidence whistleblowers need to support their claims.

The Administrative Procedure Act (APA) requires federal agencies to keep a paper trail of their decisionmaking process in an administrative record, but the record compiled by an agency is often suspiciously limited to a collection of documents that justify the agency's final decision. Conspicuously absent from the record are documents that indicate what the scientists said before the policymaking debate began. ***In the interest of regulatory transparency and as a way to protect federal scientists, we suggest that agencies consider revising their record-keeping policies to memorialize agency scientists' pre-decisional findings.***

"We ought to protect scientists from those that would try to suppress or distort their scientific work."

— Rep. Henry Waxman, March 14, 2007

The requirements governing what materials must be included in an administrative record come from a variety of sources. The APA itself simply says that a court "shall review the whole record" when reviewing agency decisions but does not describe the types of documentation that must be in the record.[77] Some statutes, like the CAA and CERCLA, enumerate certain materials that must be kept in the administrative record for particular rulemakings.[78] DOJ has issued a guidance document on compiling an administrative record which implores agency staff to include a broad range of materials in the record. The guidance states that officials should include "documents and materials whether they support or do not support the final agency decision" and "documents and materials that were before the agency at the time of the challenged decision, even if they were not specifically considered by the final agency decisionmaker."[79] Yet the inclusionary tone of the DOJ guidance and the broad language of the APA do not ensure a fully developed administrative record. Entrenched agency practice, supported by the longstanding legal privilege for documents that could expose the deliberative process, is unduly generous in providing agency staff excess discretion to limit the documentation of pre-decisional internal debate regarding scientific documents.

The contours of the deliberative process privilege have been explored by the federal courts in lawsuits over agencies' rejection of FOIA requests. FOIA defines the deliberative process privilege as protecting "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency."[80] As defined by the FOIA case law, this privilege shields from public view documentation of agency work that is "pre-decisional" (generated prior to adoption of agency policy) and "deliberative" (reflective of the give-and-take of the consultative process).[81] The justifications for the deliberative process exemption are three: (1) to protect "creative debate and candid consideration of alternatives," (2) to protect "the public from confusion that would result from premature exposure to discussions occurring before the policies affecting it had actually been settled upon," and (3) to protect "the integrity of the decisionmaking process itself by confirming that 'officials would be judged by what they decided[,] not for matters they considered before making up their minds.'"[82] It is the first of these three justifications - a desire to protect candor in agency deliberations - that is generally

considered the "key question" in deliberative process cases.[83] In the words of Chief Justice Warren Burger, "[h]uman experience teaches that those who expect public dissemination of their remarks may well temper candor with a concern for appearances and for their own interests to the detriment of the decisionmaking process."[84] Based on this common experience, the federal courts continue to uphold agency officials' discretion to limit the administrative record to a fraction of the documentation that would provide a clear picture of the decisionmaking process.

Our proposal to expand the publicly available administrative record sits at the interface of two opposing public policy norms: the desire to increase regulatory transparency in order to maximize accountability, public trust, and engagement in the regulatory process versus the desire to protect internal deliberations in order to encourage candor and flexibility, which in turn improve job satisfaction among career staff. We are sensitive to concerns about maintaining independence in agency deliberations, but we also recognize that the status quo, which favors limited recordkeeping, is contributing to the growing distrust of federal regulatory agencies.

Important administrative law court cases support our proposal to require fuller disclosure of the deliberative process. Under the *United States v. Nova Scotia Food Products Corp.* case, agencies must disclose enough of the scientific data that support a rule to enable interested parties to provide meaningful comments on proposed rules and courts to assess whether the rule is based on administrative consideration of all relevant factors.[85] Fuller disclosure of deliberative documents would assist agencies in satisfying these procedural requirements.

What types of records should expanded recordkeeping requirements reach? ***Agencies should consider explicitly exempting the products, analyses, and discussions of scientific research from the deliberative process privilege, even if they are produced by agency scientists. Given the recent problems with political interference with scientific reports, however, it may ultimately rest with Congress to adopt statutory requirements that agencies docket all pre-decisional scientific studies and analyses by agency experts if the agencies do not increase disclosure in this area on their own. This approach would help protect whistleblowers by minimizing the blurring of lines between science, science policy, and pure policy.***[86]

Front-End Protections: Reforming the Civil Service

Improving administrative recordkeeping requirements is a first step in clearly delineating between the roles of agency scientists and policymakers, improving the integrity of federal decisionmaking and, ultimately, preventing whistleblower problems.[87] However, recordkeeping requirements alone are insufficient. Limiting the depth of political appointments into agencies' management structures would help empower career staff. In addition to preventing individuals beholden to changing administrations from intruding in the technical work of agency scientists, congressionally mandated limits on political appointments could improve agency morale and lead to stronger resistance to improper political pressure.[88] Congress should consider changing the allocation of federal positions between the career and excepted service.

Front-End Protections: Establishing Federal Scientific Integrity Regulations

Finally, to prevent cases of political manipulation of science that lead to whistleblower protection problems, federal agencies need to establish unambiguous statements about the rights and responsibilities of all employees with respect to scientific integrity. On several occasions - most recently following the scandal of Julie MacDonald abusing her power and manipulating endangered species decisions[89] - the Department of Interior has attempted to create enforceable ethics guidelines; however, the initiatives have failed to produce useful standards of practice. Congress should consider mandating that all federal agencies adopt regulations that prohibit agency officials from "coercing or intimidating scientists or altering or mischaracterizing scientific conclusions and information."[90] Requiring the adoption of regulations through notice and comment rulemaking will ensure transparency in the process and will result in the creation of legally binding rights and duties.

Back-End Protections: Improving and Expanding Existing Whistleblower Protections

Rep. Henry Waxman (D-CA) has introduced legislation to address scientific integrity by adding a new provision to the Whistleblower Protection Act that defines illegal "abuse of authority" as, among other things, "any action that compromises the validity or accuracy of federally funded research or analysis" and "the dissemination of false or misleading scientific, medical, or technical information."[91] This change is essential to adequately protect federal employees from retaliation. ***Amendments to other statutes (e.g., CAA, CWA, CERCLA) based on the proposed changes to the Whistleblower Protection Act might be a good solution to problems of political interference with science in the private sector. Private sector employees should be protected when they adhere to their ethical duty to report actions that compromise the validity or accuracy of research or result in the dissemination of false or misleading information.***

Expanding whistleblower protection statutes requires changes to the bureaucratic mechanisms relied upon to investigate whistleblower cases. These cases are funneled through the Labor Department's Occupational Safety & Health Administration (OSHA), which, along with the Federal Circuit Court of Appeals, has greatly curtailed the protections available through whistleblower protection statutes.[92] ***Congress and the federal agencies should consider establishing alternative ways for whistleblowers to lodge complaints.*** Congress could create a specialized scientific ombudsman's office staffed by people trained in the distinctions between and potentials for overlap of scientific and policy judgments. Ombudsmen could be empowered to insist on review of a scientist's complaints by top-level officials, take their concerns directly to legislative oversight committees, or even prepare reports that would become part of the administrative record available to reviewing courts.[93] Agencies' inspectors general might also be able to provide the independence and will to investigate allegations of whistleblower retaliation that OSHA lacks.

Establishing a Legal Cause of Action for Harassed Scientists

Congress should also address the use of legal processes to harass scientists. A prominent example is the case of Dr. Paul Fischer, a researcher at the Medical College of Georgia, who investigated the effect of Camel cigarette advertising campaigns on children.[94] When San Francisco attorney Janet Mangini sued the R.J. Reynolds Tobacco Company because it had failed to put warning labels on promotional products, Reynolds subpoenaed Dr. Fischer's records. He was not a party to the case or a witness for either side, and his study had not been cited in Mangini's filings, yet Reynolds' lawyers ordered him to produce mountains of materials, from original test materials to "all correspondence relating to the research" to "the names and telephone numbers of all of the children who participated in the study."[95] Concerned about violating confidentiality agreements signed with each of the participants' parents before conducting the research, Dr. Fischer hired a lawyer to have the subpoena quashed because it was overbroad and unjustified. Reynolds then pursued the same strategy of obtaining all of Dr. Fischer's research documents using the State of Georgia's Open Records statute, and this time Reynolds succeeded. Throughout these legally sanctioned attacks, the Medical College of Georgia refused to support Dr. Fischer. Ultimately he resigned from his tenured position in disgust.

The abuse of Dr. Fischer is only one example of legally backed harassment of independent scientists.[96] Rep. Joe Barton's inquiry into the work of climate scientist Michael Mann, abusive use of state open record requests against public university researchers, and defamation claims filed against scientists provide other recent examples of how special interests have abused legal processes to attempt to intimidate them and deter them from pursuing their research.[97] As Donald Kennedy, the editor of *Science*, observes:

> Many [scientists] are wary of work that may find use in some regulatory proceeding. They wonder whether the data underlying their findings may be subject to examination and reinterpretation, perhaps with some "spin" supplied by the revisionists. They know that charges of research misconduct could arise from hostile access to their scientific work. They know they are vulnerable to personal attack from those whose interests may be adversely affected by the product of their research.[98]

Scientific misconduct allegations have also been filed against federally funded researchers by those who were adversely affected by the researchers' work.[99] Even though the scientists are generally exonerated, these non-meritorious allegations of research misconduct financed by special interests can still have a serious and lasting impact on the accused. In the short-term, productive work is interrupted while the accused devotes time and energy to responding to the allegations. Notebooks, computers, and other lab equipment are sometimes off-limits during the investigation, and interactions with colleagues can become strained. In the longer term, even scientists who have been exonerated have had their labs

closed down, lost their jobs, and accumulated staggering legal debts.[100] Any allegation of misconduct can cast a pall over a scientist's work, harming her reputation and prospects for future grants.

The common thread running through all of these examples of scientific harassment is that the affected researcher has little recourse other than to wait out the often tedious legal proceedings. ***Creating a limited cause of action that would allow harassed scientists to recover compensatory and punitive damages for unduly burdensome subpoenas, spurious allegations of research misconduct, bad faith open records requests, or any other abuse of legitimate legal processes would give scientists a tool that they could use to ensure compensation for their inconvenience.***[101] It would also have the important effect of raising the costs to those engaged in these types of excessive activities. However, because we do not want to inadvertently outlaw vigorous disagreement over unsettled science, there must be a high and clear threshold for this limited cause of action.

Any allegation of misconduct can cast a pall over a scientist's work, harming her reputation and prospects for future grants.

Improving the Federal Advisory Committee Act

Stronger legal and regulatory controls on agencies' use of science advisory boards are essential to counter the trend toward political manipulation of this vital stream of science advice to the policy process. One of the most important institutional devices for translating scientific studies into public policy is the federal advisory committee. Agencies engaged in complex rulemakings that require application of advanced scientific research often seek advice and counsel from experts in the field who are not full-time government employees. Through the use of advisory committees, agencies are able to get the best advice from scientists who are well-respected in their fields and ensure that they understand how a range of disciplines interact to inform the resolution of difficult questions.[102] Advisory committees also improve accountability in agency decisionmaking by giving independent, disinterested outside experts an opportunity to critique how agency scientists are approaching a problem. Finally, and perhaps most important, the "stamp" of approval by an expert body helps insulate the agency from criticism by the political branches and the courts.[103]

Advisory committees are ubiquitous in the modern regulatory system. Thousands of advisory boards, subcommittees, and informal advisory groups meet each year to provide federal agencies with their perspectives on policy and regulation. Counting only the formally chartered advisory committees, there are some 62,000 committee members whose viewpoints help shape the regulatory landscape.[104]

The Federal Advisory Committee Act (FACA) is Congress's attempt to ensure that advisory committees include balanced viewpoints and are devoid of undue influence by special interests. FACA sets forth certain procedural requirements for the establishment and operation of advisory committees, including requirements that each committee be established by charter,[105] that all meetings and their purpose be publicized in advance,[106] that transcripts and other meeting materials be made publicly available after the meeting,[107] and that meetings be open to the public.[108] All of these requirements were designed to leverage public notice and participation as a means of ensuring that advisory committees provide neutral advice.

In its first 35 years of existence, FACA has been an effective tool for improving transparency of federal advisory bodies. Since FACA is not limited to science advisory committees, however, its effectiveness could be improved through amendments designed to address two problems unique to science advice. First, the law imposes a responsibility on federal agencies to balance the viewpoints of committee members and ensure no special interest has undue influence on the committee, but it provides little in the way of specific requirements for managing scientific conflicts of interest. Second, FACA provides insufficient guidance to agencies to ensure that their processes governing the selection and use of science advisors are transparent to the public.

Committee Composition

The committee selection process occurs in two stages. First, an agency must ensure the right mix of committee members (both from a disciplinary and intra-disciplinary perspective). Second, an agency must ensure that the individuals appointed to the committee are able to render objective judgments about the weight of evidence before them.

Choosing the Right Types of Committee Members

At the first stage, choosing the right mix of committee members involves two considerations. The first issue is that committee members can either be selected as "special government employees" (SGEs) or "representatives." Representatives are chosen to voice the opinion of a specific interest group, e.g., pesticide formulators or environmental advocates. Because they are chosen to provide a specific viewpoint - to harbor a specific bias - they are not subject to conflict-of-interest review. SGEs, on the other hand, are supposed to provide neutral advice and are subject to the same conflict-of-interest statute as full-time government employees,[109] so they are required to report financial interests that could create a real or apparent conflict of interest.

Agencies have broad discretion in choosing the employment status of advisory committee members, and agencies appear to vary in their approach to these issues. The FDA and EPA tend to employ advisors as SGEs, while GAO found that the Departments of Agriculture, Energy, and Interior rely almost exclusively on representatives to fill their advisory committees, even though many of these committees would have been better served by SGEs.[110] It may be the administrative burden of reviewing SGEs' conflicts of interest that creates an incentive to simply appoint committee members as representatives;[111] but the efficiencies gained through the use of advisory committees[112] and the value of their recommendations should counterbalance those concerns.

General Services Administration (GSA) regulations state that agency heads are responsible for ensuring that committee members' interests and affiliations are reviewed for compliance with federal conflicts-of-interest statutes,[113] and for making the decision as to whether committee members are appointed as representatives or SGEs.[114] ***Seating representatives of special interests as advisory committee members can threaten the balance of the panel. All members of science advisory boards should therefore be SGEs. GSA regulations could be clarified by explaining that agency heads can best assure compliance with federal conflicts-of-interest statutes by maximizing the number of committee members appointed as SGEs, particularly on committees whose charges focus on scientific issues.***

The other committee membership issue that agencies need to address at a general level is the task of ensuring balanced viewpoints. Under current GSA regulations, agencies must develop a plan that ensures a committee will be balanced according to the functions and

tasks to be performed.[115] The guidance provided to agencies implementing this requirement instructs the agencies to consider the following factors in developing the plan:

- The advisory committee's mission;
- The geographic, ethnic, social, economic, or scientific impact of the advisory committee's recommendations;
- The types of specific perspectives required, for example, such as those of consumers, technical experts, the public at large, academia, business, or other sectors;
- The need to obtain divergent points of view on the issues before the advisory committee; and
- The relevance of state, local, or tribal governments to the development of the advisory committee's recommendations.[116]

Seating representatives of special interests as advisory committee members can threaten the balance of the panel.

Ideally, this list would also include an express requirement that agencies consider the scientific disciplines necessary to proper resolution of their charges. So, for example, if a committee is charged with evaluating the toxicity of a chemical based on a host of clinical and epidemiological studies, that committee should have members who are experts in clinical toxicology and epidemiology. This compelling need for the correct mix of scientific disciplines seems rudimentary, but its fulfillment has become more difficult as the complexity of scientific risk assessments has grown.

Choosing the Right Individuals: Screening for Bias and Conflicts of Interest

Moving on from the general goal of ensuring that agencies seek out the right types of committee members, we need to address the subsequent problem of ensuring that specific appointments do not threaten the committee's integrity. To that end, agencies must screen potential committee members for biases and conflicts of interest. At this stage a new statute and a new agency take control. Each committee member who is seated as an SGE is subject to the federal conflict-of-interest statutes enforced by the Office of Government Ethics (OGE). These statutes include the criminal conflict-of-interest prohibitions in 18 U.S.C. §§ 201 et seq. and the Ethics in Government Act of 1978,[117] which requires government employees to file reports regarding their financial and other interests. However, these statutes were designed to address ethical concerns related to all government employees, including full-time employees, Members of Congress, the President, and federal judges. Thus they are not a tight fit for prospective advisory committee members and each agency has had to develop its own policies for ensuring FACA committees comply with the statutes. The absence of clear guidance from OGE has led to a plethora of differing committee selection processes in the various federal agencies.

Optimizing the advisory committee selection process across federal agencies will require reforms that focus on a problem that is at its root one of definitions. What is bias? What is a conflict of interest? And when agency officials go to seat committee members, are there *de*

minimis biases or conflicts that they can safely assume will not color an advisor's work? FACA, the federal criminal conflicts-of-interest statutes, and the GSA and OGE implementing regulations all fail to answer these questions. Most federal agencies have only done so in a roundabout way, by using bias and conflict-of-interest screening policies that require prospective committee members to disclose certain limited information about their beliefs and financial interests. But these information disclosure requirements vary from agency to agency, meaning that the definitions of bias and conflict of interest are not uniform. Clearer guidance from GSA on what financial interests and biases are objectionable in the context of advisory committee appointments might help agencies.

The National Academies have a policy statement that addresses the definitional issue wisely and would be a good starting point for amending GSA's regulations. It reads:

> Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group.
>
> [T]he term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.[118]

Other agencies have neglected to articulate what sorts of interests they are trying to uncover with their bias and conflicts screening policies. ***Clear and concise statements like those quoted above, if printed at the beginning of every agency's conflicts disclosure form, would send an unambiguous signal to potential committee members that advisory committees are meant to produce neutral and disinterested advice. Moreover, it would set the tone for broad information disclosure that will help agency staff properly compose advisory committees' overall composition.***

The National Academies' policy statement is based on fundamental distinctions between bias and conflicts of interest. As the guidelines recognize, some degree of bias is unavoidable. Over time, through education and experience, everyone develops a degree of bias with regard to how common questions in their line of work should be answered. In fact, it is precisely this experience that makes experts valuable to peer review. On the other hand, when biases become so strong that they impinge on an individual's ability to objectively answer new questions, that person should not be given the institutional power of an advisory committee member. The process of choosing committee members should involve screening potential members to ensure that their biases are not threats to objectivity.

Improperly designed procedures aimed at uncovering biases are dangerous because of their potential to slide down the slippery slope toward the "political litmus tests" that infringe on a person's privacy and were improperly used by some federal officials in recent years.[119] The

National Academies' statement on bias and lack of objectivity above hints at the types of information that a legitimate committee-selection process should be designed to uncover. For one, the focus should be on views stated and actions taken in a public forum. Examples are analyses and conclusions published in research articles, statements made at conferences and other public speaking engagements, and any statements made as an expert witness. These statements are most likely to reflect an individual's most strongly held beliefs and do not invoke privacy interests. Screening for biases and potential problems with objectivity should also focus on whether an individual's public statements reflect a close tie to the positions or perspectives of a particular group's extreme views. If such a tie exists, it would cut against the principle of ensuring that FACA committees are not unduly influenced by special interests.

The National Academies' definition of conflict of interest is not limited to employment or even financial benefits. Looking at such a broad spectrum of motivations is the best way to get a full picture of an individual's interests and discern whether she might be swayed in her decisionmaking. Most agencies use a conflicts screening policy that examines, as this model does, non-financial interests and interests of a potential committee member's immediate family and business partners.

The temporal aspect of conflicts disclosure, however, is an area that needs improvement across the government. Even though a plain-text reading of the definition would indicate that the Academies demand disclosure of past and future interests, the guidance that accompanies the definition states that only interests held at the time a committee meets are important.[120] But past employment relationships, divested interests, or potential future research support might create a perception of a conflict of interest or bias, which can be just as detrimental to an advisory committee's legitimacy as an actual conflict. ***Therefore, reformed conflicts policies should require prospective committee members to report potentially conflicting interests for some set period into the past (three to five years, at the least) and into the foreseeable future.***

A perception of a conflict of interest or bias can be just as detrimental to an advisory committee's legitimacy as an actual conflict.

Such a requirement is not unprecedented. FDA asks prospective committee members to disclose certain financial interests up to 12 months old.[121] Another section of the FDA conflicts-disclosure form has an indefinite "look-back" period, asking: "To your knowledge, do any of the following persons have any past involvement with the meeting/task issues: You, your spouse, minor child, general partner, organization in which you serve as an officer, director, trustee, general partner or employee."[122] OGE requires disclosure of all financial interests up to 12 months old in order to comply with the Ethics in Government Act of 1978.[123] EPA looks at financial interests from the previous two years and any interest from the past five years that might impinge on the ability to provide impartial advice.[124] And the *Journal of the American Medical Association* asks authors to disclose relationships with financially interested parties dating back five years and into "the foreseeable future."[125]

The second important concept contained in the National Academies' definition of conflicts of interest is that the definition does not set any threshold value below which conflicting

interests will be ignored. Most of the existing conflicts screening policies either set absolute thresholds for reporting (e.g., real property must be reported only if its fair market value is above $1,000) or create some linkage between the value of an interest and percentage of personal wealth (e.g., stocks and bonds valued below 5 percent of personal wealth are considered *de minimis*). ***Abolishing reporting thresholds for financial conflicts would provide a fuller picture of a prospective committee member's potential conflicts by allowing agency staff to look at an individual's cumulative investments.***

The third important concept in the NAS definition of conflicts of interest is that it turns on competitive advantages that might accrue to any firm or organization for which a prospective member is employed, thus helping to ensure disclosure of interests in firms that compete with, supply products to, or are in any other way related to a firm directly affected by an advisory committee's work. Conflict-of-interest standards should be expanded to include the competitive advantages that could be gained by an entity with which the prospective panelist is affiliated.

Another concept that deserves consideration is the possibility of vesting the power to select advisory committee members in someone other than political appointees. Current practice puts the ultimate power of committee selection in the hands of high-level agency officials who are appointed by the president. Nominations for committee membership can come from the public, career employees, and, in some cases, other government organizations like the NSE,[126] but the final decision about advisory committee membership rests with political appointees. This power structure compounds concerns about the neutrality of advisory committees by increasing the potential for political interference in the appointment process. Thus, to restore trust in the advisory committee system, changes to the bias and conflicts screening processes should be accompanied by changes to the balance of power in committee member nomination and appointment.

At one end of the spectrum is the idea of completely removing political appointees from the process of seating advisory committees. The National Academies are well respected and politically neutral and could be tasked with the responsibility of seating federal advisory committees. The Academies' membership comprises a diverse group of experts with specialties in nearly every field of research who could be a valuable resource for finding potential advisory committee members. Moreover, by moving the committee appointment process to a non-political arm of the government, committees will better survive changing Congresses and presidential administrations, thus enhancing the credibility of committee recommendations. Of course, completely eliminating political appointees from the committee selection process would pose some problems. For one, the current system maintains a level of accountability that would not be possible if politically insulated individuals were making final decisions. Furthermore, taking control of advisory committees away from administrative agencies might cause agencies to avoid seeking their advice.

A hybrid system may be a more effective way to minimize political interference in the advisory committee selection process while at the same time maintaining accountability. The

National Academies are an ideal resource for committee member nominations, so a system modeled after the FIFRA Scientific Advisory Panel might be the best option. The seven members of the FIFRA Scientific Advisory Panel are chosen from a list of twelve nominees, six of whom are nominated by NIH and six of whom are nominated by NSF.[127] Depending on the subject matter that will be addressed, the proper arm of the National Academies (either NAS, the National Academy of Engineering, the Institute of Medicine, or the National Research Council) can be polled for nominations. Then, the agency that chartered the committee can choose the committee members after screening for biases and conflicts of interest and taking into account the advice of agency staff. High-level officials should be responsible for signing off on the final choices and approving any conflicts waivers.

Conflict-of-interest Waivers

A question integral to any discussion of committee appointments is how the appointing officials should address waivers. As agencies seek the scientists most experienced in ratified fields, these scientists are more likely to be employed by - or have some financial relationship to - companies that could be affected by the advisory committee's decisions.[128] The problem becomes even more acute as the definition of "conflict of interest" expands. As a result, agencies typically grant waivers that allow the conflicted scientists to participate in committee deliberations and, occasionally, vote on the committee's final recommendations. Some public interest advocates have made the claim that advisory committees can and should be composed of only non-conflicted scientists.[129] However, a study by the Eastern Research Group, commissioned by FDA, came to a different conclusion based on a review of 124 standing advisory committee members at 16 committee meetings held between December 2005 and October 2006.[130] ERG concluded that "[t]he practical feasibility of creating conflict-free advisory committees remains uncertain."[131]

Given that the empirical research record on the issue of conflicts waivers is limited and that we have advocated for a broad definition of conflicts of interest, we will remain agnostic as to the feasibility of conflict-free advisory committees. ***Nevertheless, we are strongly in favor of limiting the number of waivers on each committee and increasing transparency as to those waivers that are issued. With respect to the limitations on waivers, concerns about biased committee recommendations could be alleviated by limiting the number of waivers available per committee to a certain fraction of the total membership, and by prohibiting committee members who receive waivers from voting on the committee's decisions. These limitations would allow committees to benefit from the conflicted individuals' expertise while simultaneously minimizing the potential for those individuals to threaten the integrity of the committee's final decisions. In terms of increased transparency, any proposed waivers should be posted on the Internet 15 days prior to any committee meeting, along with a justification for the waiver and an explanation of the decision process used to set the composition of the committee as a whole. Increased transparency about the decisionmaking process will help to eliminate questions of credibility that regularly arise when the public finds that a committee is composed of conflicted individuals.***

Transparency in the Appointment Process

Government-wide FACA regulations must also improve the transparency of agency processes governing the agencies' evaluation of potential members for biases and conflicts. The status quo lies at the least prescriptive end of the spectrum, relying on individual agencies to develop their own information collection policies. As a result, each agency has its own form that potential committee members must complete and its own interview process. Furthermore, each agency has its own policy regarding waivers of conflicts of interest. This lack of uniformity is not something that we think necessarily needs to be addressed by GSA. The process of gathering and analyzing bias and conflicts information is something that would probably benefit from regulatory flexibility. For example, an individual's real property investments deserve more scrutiny when she may be the member of an advisory committee dealing with endangered species than when she may be on an FDA drug-approval advisory committee. The more important issue is transparency in the process. GSA's regulations should be revised to ensure that, regardless of the process an agency uses, the process is the same for each potential committee member and the results of the process are publicly available. ***At the very least, a blank copy of each agency's conflicts disclosure form should be available online, along with a full description of the other methods used to collect information about conflicts and biases and how the collected information is analyzed.***

Closing a Loophole in FACA Coverage

In some instances, federal agencies avoid the difficult issues of proper advisory committee selection by simply commissioning private contractors to provide the advice they need. This loophole is an issue Congress must address because it arises out of the federal courts' interpretation of FACA's statutory language. The statute only covers committees that are "established" or "utilized" by an agency.[132] The courts have held that contractors who are paid to provide agencies with expert advice are not "established" or "utilized" by an agency - and are therefore not covered by FACA - as long as the agency does not exercise a significant level of control over the group.[133] Congress should close this loophole by redefining FACA's coverage so that it is clear that the Act is meant to ensure transparency and eliminate conflicts of interest even when a private entity is managing the advisory committee process.

Preventing Unwarranted CBI Claims

Risk information submitted to the federal government is often hidden from public view through overbroad regulatory policies designed to insulate information claimed as "trade secrets" and "confidential business information" (CBI). Statutory definitions have been incrementally expanded through agency policies and by case law in some circuits.[134] This process has turned non-mandatory and limited statutory exemptions in TSCA, FIFRA, and the FDCA into broad exclusions that routinely frustrate the statutory goal of improving regulation through information disclosure. Agencies also defer in the first instance to the regulated party to determine what information should be classified as CBI.[135] CBI claims need not be substantiated in advance, at least under most of the public health and environmental statutes.[136] Instead, the justification for a CBI classification is reviewed, if at all, by the agency only after the information has been requested under FOIA.[137] At that time, if the agency determines the CBI claim is unjustified it can release the information (after informal proceedings).[138] However, if the agency official is wrong, they could face personal civil and criminal charges for disclosing trade secret information.[139] A 2001 memo from Attorney General John Ashcroft suggests that the executive branch has reversed its longstanding policy of operating under a "presumption of disclosure."[140] In such a permissive environment, it is perfectly rational for companies to overclaim CBI in their regulatory submissions, and the evidence suggests that this is exactly what they do.[141]

The consequences of overly vigorous CBI claims are difficult to quantify, but they appear to impinge, potentially significantly, on the accessibility and utility of important research and scientific information. For example, risk information submitted to EPA could be useful to other federal and state officials, but statutory requirements to keep that information confidential often prevent efficient information-sharing. Problems arise for non-EPA staff in realizing that the information exists, getting proper security clearances, and ensuring that file rooms and computer systems provide adequate protection.[142] This secrecy limits innovation in risk prevention and risk management.[143] Keeping risk information hidden from the public also limits the credibility of agency decisions.[144] Without access to this information, the public is asked to simply trust that the agency is making appropriate and well-informed decisions.

We propose four separate reforms that address the agencies' current, permissive approach to trade secret protections for information that informs health and environmental regulation:

- *The classes of information subject to CBI protection should be explicitly limited;*
- *All information that is submitted to the government and alleged to be worthy of trade secret/CBI protection should be accompanied by a thorough explanation of why such protection is warranted;*
- *In the rare instances where the government sequesters trade secrets or CBI, protections should "sunset" unless submitters justify the extension of protection; and*
- *The Executive Branch should reestablish a "presumption of disclosure" under FOIA.*

Types of Information that Should Never Be Sequestered

Certain toxicological, ecotoxicological, and other physicochemical information should never be kept secret because of its importance to the protection of public health, worker safety, and natural resources. Both TSCA and FIFRA prohibit EPA from granting CBI protection to certain health and safety information.[145] However, the TSCA and FIFRA prohibitions have exceptions that allow CBI claims when the health and safety information could possibly be used to understand a firm's manufacturing processes or the composition of a proprietary chemical mixture.[146] These exceptions, though narrowly tailored, are tied to a FOIA process that opens significant loopholes and enables firms to hide useful information from the public.[147] Under TSCA, 95 percent of § 5 premanufacture notices have CBI claims[148] and 25 percent of § 8(e) adverse effects reports have CBI claims.[149]

Amendments to domestic statutes and regulations that exempt the above classes of information from trade secret/CBI protections will ensure that useful risk information is publicly available. However, positive legislative action may not even be necessary once the EU's REACH regulations take effect.[150] The REACH legislation lists the following information as that which must be always publicly available:[151]

- The name of the substance;
- The classification and labeling of the substance: Under a prior EU directive, substances can be classified as "explosive," "oxidizing," "flammable," "toxic," "harmful," "corrosive," "irritant," "sensitizer," "carcinogenic," "mutagenic," "toxic for reproduction," or "dangerous for the environment." If classified as one or more of the preceding, the substance must be labeled as such;[152]
- Physicochemical data: information about the chemical properties of the substance,[153] as well as about pathways and environmental fate;
- Results of toxicology and ecotoxicology studies;
- Any derived no effect level or predicted no effect concentration;
- Guidance on safe use; and
- Analytical methods for detecting the substance in humans or the environment (if requested by the Chemicals Agency).

Presumably, any risk information submitted to a U.S. regulatory agency would have to be submitted to the European Chemicals Agency, would be available to the public through that Agency, and would therefore destroy any link between disclosure by the U.S. agency and any economic harm.

Nevertheless, EPA and other agencies could still go one step further and explicitly identify classes of information, as REACH does, that are not entitled to protection. For example, under 40 C.F.R. § 2.207, EPA has the authority to make "class determinations" regarding the availability of CBI protection under FOIA for clearly defined types of information. A class determination stating that the information listed above is not eligible for CBI

EPA should identify classes of information that are not entitled to CBI protection.

protection due to its public availability through the European Chemicals Agency would be a simple way for federal officials to affirm a policy of promoting scientific transparency.

Upfront Substantiation

In addition to limiting the types of information deserving confidential protection, we propose reforming the procedures that the private sector must follow to request protection. Under existing policies, requesting CBI protection is virtually cost-free, resulting in an overabundance of unwarranted CBI claims. A submitter can simply stamp a document as CBI: Only in limited circumstances are firms required to provide a justification for requesting confidential protection.[154] ***In order to ensure a proper balance between secrecy and transparency, firms should be required to provide a detailed, upfront substantiation of their claim that public disclosure of specific information would result in substantial adverse competitive impact.***

Evidence exists that requiring substantiation of CBI claims is an effective way to prevent overbroad claims. A 1992 study by the Hampshire Research Associates found that CBI claims drop by as much as 50 to 60 percent when EPA requires upfront substantiation.[155] EPA has undertaken a systematic effort to review CBI claims made under TSCA and to challenge those that seemed overbroad. Agency officials challenge about 14 TSCA CBI claims per year and firms withdraw "nearly all of the claims challenged."[156] By requiring firms to provide upfront substantiation of their CBI claims when the claims are first made, the government could avoid the administrative and public health costs of sequestering information that does not deserve confidential protection.

Requiring upfront substantiation would simply mean asking for clear documentation of the decision process firms should already be employing. The same regulations that inform firms of their right to request CBI protection for the information they submit to EPA also clearly state the substantive criteria that the Agency uses to determine whether confidentiality is warranted. Any firm that requests CBI protection should first assess the request according to the regulatory criteria.

Documenting this assessment and submitting it to EPA along with the alleged CBI should impose only minimal additional administrative costs. In fact, EPA conducted some research in the 1990s to determine the additional costs to firms if they were required to provide

TABLE 2.
Hours for Confidential Business Information Claims (in 1997 dollars)

Task	Clerical Hours ($24.33/hr)	Technical hours ($59.52/hr)	Managerial hours ($81.61/hr)	Total hours
Upfront substantiation of chemical identity	0.26 - 0.26	1.08 - 1.82	0.48 - 1.05	1.82 - 3.13
Upfront substantiation of plant site information	0.12 - 0.12	0.54 - 1.12	0.23 - 0.79	0.89 - 2.03

upfront substantiation of CBI claims related to chemical identity or plant site information submitted under the TSCA § 8(a) Inventory Update Rule and found the following:[157]

If we take these data to indicate that substantiating a CBI claim only takes a matter of hours, our proposal to impose such a small burden on firms in order to promote transparency and improve public health seems reasonable.

In 1994, EPA actually published in the Federal Register a limited proposal to improve substantiation practices. After first indicating that the Agency was considering imposing an upfront substantiation requirement on all TSCA §§ 8(c), (d), and (e) filings,[158] the final proposal in the Federal Register suggested only requiring upfront substantiation when the chemical identity is claimed confidential in these filings.[159] The final proposal was never codified, but this episode shows that EPA recognizes the utility of upfront substantiation, particularly where CBI claims are prevalent and the allegedly confidential information would be useful if disclosed to the public.[160] Congress, too, recognizes the importance of upfront substantiation of CBI claims in the toxics arena, evidenced by the fact that the Emergency Planning and Community Right-to-Know Act (EPCRA) mandates upfront substantiation of any CBI claim.[161]

Sunsets on CBI Claims

Over time, changes in market conditions and the state of technology tend to decrease the economic justification for CBI protection. The benefit to manufacturers - and therefore the justifications for sequestering risk information - decreases over time due to the high depreciation rate of information.[162] Products are reformulated, patents expire, and competitors gain access to proprietary information through other means. At the same time, hazardous products are distributed through the marketplace, increasing environmental and human exposure and, consequently, driving up the value of that risk information as a tool for eliminating hazards.

The idea of sunsets on CBI claims covering risk information was actually floated by EPA in 1994 as part of a broader initiative to change the Agency's CBI policy.[163] And the Government Accountability Office (GAO) has found that industry representatives who were asked about sunsets on CBI claims found the proposal reasonable.[164] While the justification for imposing sunsets on CBI claims under toxics law is simple, the technical details of implementing this reform are not. Research on the useful life of CBI protection in the field of risk information is essentially non-existent, likely because maintaining that protection is costless for firms under current regulation (thus eliminating the incentive to research the utility of continuing to protect information). This lack of research makes the task of choosing sunsets arbitrary. In other fields, empirical research suggests that five years is a typical useful life for patent and trade-secret protections.[165] To put this conclusion in context, the FDA typically grants five-year exclusive marketing rights for new drugs and pesticides are generally protected by 20-year patents. ***Since risk information on its own is***

unlikely to destroy a firm's competitive advantage and a sunset would allow for continued CBI protection upon proper justification, we suggest a five-year sunset on all claims made under TSCA and FIFRA.

Freedom of Information Act Retrenchment

Even if changes to the CBI policies under TSCA, FIFRA, and other information-gathering statutes decrease incentives for regulated parties to hide information, public requests for unprotected data could be rejected by agency staff who are wary of running up against officials who support recent trends in federal policy that constrict FOIA's open-government mandates.[166] FOIA Exemption 4 gives federal officials the power to withhold information requested by the public if that information is a "trade secret" or commercial or financial information obtained from a person that is privileged or confidential."[167] The breadth of information covered by this exemption has expanded in recent years as the result of troubling court decisions and shifting Justice Department policies.[168]

The overarching trend in judicial interpretation of FOIA Exemption 4 is to read the exemption "in the broadest possible manner, ignoring other interpretations that balance the economic reasons for protecting business information against the goal of promoting government transparency."[169]

Current Justice Department policy on the exemption similarly favors secrecy over open government. Attorney General John Ashcroft, in an October 2001 memo to all federal agencies, announced that decisions to disclose information through FOIA that could have been withheld by claiming a statutory exemption "should be made only after full and deliberate consideration of the institutional, commercial, and personal privacy interests that could be implicated by disclosure of the information."[170] Moreover, the memo stated that DOJ would defend all decisions to withhold information "unless they lack a sound legal basis or present an unwarranted risk of adverse impact on the ability of other agencies to protect other important records."[171]

This policy "flouts legislative intent and previous administrative practice."[172] Under Attorney General Janet Reno, the executive branch operated under a "presumption of disclosure" whereby DOJ would only defend decisions to withhold information from the public "in those cases where the agency reasonably foresees that disclosure would be harmful to an interest protected by that exemption."[173] ***Whether by Executive Order or revised Justice Department policy, the executive branch should reestablish the longstanding "presumption of disclosure" under FOIA. Congressional action may be necessary to overcome established agency policies and court decisions.***

Establishing a Science Registry

The goal of expanding access to privately funded toxics research might be best achieved through additional programs that would complement expanded adverse effects reporting requirements, specifically the creation of a national registry for studies investigating the toxicological properties of common chemicals. One such program was first developed in the pharmaceuticals arena, where researchers are required to register their work in a clinical-trials registry. A clinical-trials registry allows scientists to post a notice that they are conducting research on the effects or efficacy of a pharmaceutical product in a centralized and publicly accessible database.

The most successful clinical-trials registry is operated by the National Institutes of Health (NIH). ClinicalTrials.gov is an online database developed in accordance with the FDA Modernization Act of 1997, which mandated registration of all private and public clinical trials conducted to support investigational new drug applications for pharmaceuticals that could be used to treat "serious and life-threatening conditions."[174] The process of registering a clinical trial begins early in the research process. Before any patients are enrolled, the principal investigator must submit certain basic information about the trial's design to NIH. The details include the name of the sponsor and principal investigator, a description of the study (including information about the disease or condition being studied and intervention being tested), and the outcome measures being tested.[175]

Congress has since expanded the registration mandate to cover all controlled, clinical investigations other than Phase I studies (short-term, limited-exposure studies designed to ensure pharmaceuticals meet basic safety standards prior to further investigation to test efficacy).[176] A similar program could be designed to bring the transparency benefits of a research registry to a broader set of scientific disciplines. This idea has been implemented or proposed in a number of other fields, from genetics[177] to nanotechnology.[178]

The clinical-trials registry was designed in response to a problem that also plagues toxicological research: the suppression and selective reporting of adverse and equivocal research. In the pharmaceutical research industry, researchers, funding institutions, and medical journals are keenly interested in two types of trials: those showing that new treatments are improvements over existing clinical practices, and those showing that two approaches to treatment are equivalent.[179] Equivocal trials and those showing that a new treatment is inferior are less likely to boost pharmaceutical manufacturers' profits or affect physicians' practices or Medicare and Medicaid coverage and, as a result, are more likely to get scuttled while in progress or left unpublished once the data are analyzed. In other fields of research, suppression of adverse results is also pervasive, though it is motivated more by manufacturers' desire to avoid additional regulation than by publication incentives. Examples include the DuPont/PFOA case cited previously[180] and the tobacco industry's persistent sequestration of studies related to nicotine pharmacology.[181]

Presumably, many of the benefits of a clinical-trials registry that accrue to the pharmaceutical field would be transferable to other fields of research if the registry concept were expanded.

NIH has made ClinicalTrials.gov indexed and searchable, so once researchers have registered their work (which they are generally required to do prior to enrollment of the first patient), any member of the public can access certain details about the goals of the trial, its status, its sponsor, and other useful information. This design was originally conceived as a recruitment tool for investigators and potential patients. But it is the other benefits that would be most useful in the context of other research fields.

By knowing what their colleagues and competitors are doing, scientists can design new work to resolve the questions left unanswered by existing work.

For scientists, the primary benefit might be providing insight into the state of ongoing research that has not yet reached the publication stage. By knowing what their colleagues and competitors are doing, scientists can design new work to resolve the questions left unanswered by existing work (e.g., does an alternate exposure pathway change the toxicology of a certain chemical?). For organizations that fund research, the registry could be a useful tool for avoiding redundant work. For state and federal regulators, it could be a resource for finding experts at the cutting edge of research in a particular area. Interested parties can also track individual studies to ensure that they are continuing toward completion and not abandoned when results do not conform to expectations.

A threshold problem in designing and implementing an expanded science registry is defining the scope of the registry - the types of research that must be registered. Outside the field of pharmaceuticals, studies are not identified as "Phase I" through "Phase IV," so that aspect of simple design in the ClinicalTrials.gov database cannot be duplicated. Instead, coverage could be defined based on intended outcomes. For instance, the database could initially be limited to studies designed to develop or refine a carcinogenicity profile or other toxicological profile for a substance in the TSCA Inventory or covered by a pesticide registration under FIFRA. This approach fails to cover research on new substances and on the fundamental principles of toxicology, but it promotes transparency in those studies that could be the most useful in toxics regulation.

A second significant issue is enforcement. When the clinical-trials registry first came online, it was plagued by infrequent registration of trials. FDA staff found that, from January to September 2002, only 49 percent of industry-sponsored clinical trials that should have been registered were.[182] During its first five years, from its inception in February 2000 until May 20, 2005, researchers registered 13,153 clinical trials on the registry.[183] But then between May 20, 2005 and October 11, 2005, another 9,561 trials were registered (a 73-percent increase in the size of the database in less than five months).[184] This dramatic spike in the number of registered trials has been linked to a policy shift by the ICMJE.[185] In September 2004, the editors of *JAMA, The New England Journal of Medicine, The British Medical Journal*, and numerous other influential publications announced that they would refuse to accept articles based on unregistered trials that began patient enrollment after July 2005.[186] A similar statement by a group of prominent journal editors in other fields of research might be the best way to expand the use of research registries.

One final question about implementation that ties the idea of expanded registries back to the adverse effects reporting and Shelby Amendment discussions is the question of whether expanded research registries should be "results registries." Unlike ClinicalTrials.gov, a results registry has all of the information about the design of a trial, plus a summary of the results once the trial has run its course. Results could be posted in many different ways, each with potential pitfalls, but the simplest way may be the best: When a registered study is the basis for a peer-reviewed article, a link to the article or an abstract should be posted on the registry. Though this method makes it less likely that the results will be posted in language that is clear and comprehensible to the lay public, it ensures that only peer-reviewed conclusions are posted.

Conclusion

Congress and the Executive Branch have developed a system in which decisions about how to set protective standards are guided in large part by objective scientific evidence. So long as this is the case, these two branches of government, along with the judiciary, must do what they can to limit distortion of science and harassment of scientists by ideological and economic special interests. The proposals described in these pages are rooted in the bedrock principles of scientific independence and transparency, and, if implemented, would improve the integrity of the science policy decisions that shape our environmental and public health protections.

End Notes

[1] Oliver Houck, *Tales from a Troubled Marriage: Science and Law in Environmental Policy*, 302 SCIENCE 1926 (Dec. 12, 2003).

[2] Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, Title III, 112 Stat. 2681 (1998).

[3] Senator Richard Shelby, *Accountability and Transparency: Public Access to Federally Funded Research Data*, 37 HARV. J. ON LEGIS. 369 (Summer 2000).

[4] *Id.* at 370-76.

[5] *See id.*

[6] OFFICE OF MANAGEMENT AND BUDGET, OMB Circular A-110, "*Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals and Other Non-Profit Organizations*," 64 Fed. Reg. 54926, 54930 (October 8, 1999).

[7] *Id.*

[8] AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, *AAAS Resolution: Expressing Concern About Legislation Opening all Federally Funded Research Awards to Freedom of Information Act (FOIA) Demands* (January 24, 1999), *available at* http://archives.aaas.org/docs/resolutions.php?doc_id=400 (accessed May 9, 2008); Association of American Universities letter to OMB re: Against proposed revision to OMB Circular A-110 (March 23, 1999), *available at* http://www.theore.com/ipd/access/agency/1999-03-23.html (accessed May 9, 2008); National Research Council, SHARING RESEARCH DATA 29-30 (1985), *available at* http://www.nap.edu/catalog.php?record_id=2033 (accessed May 9, 2008).

[9] See, e.g., American Chemistry Council Long-Range Research Initiative Request for Proposals, RfP Title: Providing a Science-based understanding of low-dose risk; RfP Number: MTD-08-01, at 5, *available at* http://www.americanchemistry.com/s_acc/bin.asp?CID=1295&DID=5710 (accessed May 9, 2008).

[10] *See* Stephen Labaton, *OSHA Loses Worker Safety in Hands of Industry*, N.Y. TIMES, A1, Apr. 25, 2007.

[11] 5 U.S.C. § 551(13) (emphasis added).

[12] 5 U.S.C. § 551(12).

[13] Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review," 72 Fed. Reg. 2763 (January 25, 2007).

[14] A "regulatory action" exempted from this definition is "any substantive action by an agency (normally published in the *Federal Register*) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking." *Id.*

[15] A guidance document is considered "significant" if it is disseminated to regulated entities or the general public and may reasonably be anticipated to:
(A) lead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
(B) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
(C) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or
(D) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in [Executive Order 12866]...
Id.

[16] Shelby, *Accountability and Transparency*, *supra* note 4 at 385.

[17] OMB, *OMB Circular A-110 "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,"* 64 Fed. Reg. 43786, 43790 (August 11, 1999).

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *See* NATIONAL SCIENCE FOUNDATION, DIVISION OF SCIENCE RESOURCES STATISTICS, *National Patterns of R&D Resources: 2006 Data Update* 26, 30 (Sept. 2007), available at http://www.nsf.gov/statistics/nsf07331/pdf/nsf07331.pdf (accessed May 9, 2008); see also, CONGRESSIONAL BUDGET OFFICE, *Federal Support for Research and Development* 11 (June 2007), available at http://www.cbo.gov/ftpdocs/82xx/doc8221/06-18-Research.pdf (accessed May 9, 2008).

[22] Friedberg et al., *Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology*, 282 J. AM. MED. ASS'N. 1453 (Oct. 20, 1999); Perlis et al., *Industry Sponsorship and Financial Conflict of Interest in the Reporting of Clinical Trials in Psychiatry*, 162 AM. J. PSYCHIATRY 1957 (Oct. 2005); Frederick S. vom Saal and Claude Hughes, *An Extensive New Literature Concerning Low-Dose Effect of Bisphenol A Shows the Need for a New Risk Assessment*, 113 ENVT'L. HEALTH PERSP. 926 (August 2005); Deatfield et al., *A survey of EPA/OPP and open literature data on selected pesticide chemicals tested for mutagenicity*, 297 MUTATION. RES. 197 (Oct. 1993); Tyrone Hayes, *There is no denying this defiance of the conflict of interest*, 54 BIOSCIENCE 1138 (Dec. 2004). See generally, Wendy Wagner and David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 80 AM. J. L. & MED. 119, 123-26 (2004).

[23] Sameer S. Chopra, *Industry Funding for Clinical Trials: Benefit or Bias?* 290 J. AM. MED. ASS'N. 113 (July 2, 2003).

[24] Wagner and Michaels, *Equal Treatment for Regulatory Science*, *supra* note 23, at 124.

[25] Davidoff, DeAngelis, Drazen, et al., *Sponsorship, Authorship, and Accountability*, 345 NEW ENGL. J. MED. 825 (Sept. 13, 2001).

[26] Paul Powell and Julie Norris, Massachusetts Institute of Technology and Robert Hardy, Council on Government Relations, "Selected Troublesome/Unacceptable Clauses Related to Information Release and Foreign Nationals," *available at* http://www.columbia.edu/cu/opp/policies/troublesome-clauses.pdf (accessed May 9, 2008).

[27] Lawrence Hirsch, *Randomized clinical trials: What get published, and when?*, 170 CAN. MED. ASS'N. J. 681 (Feb. 17, 2004).

[28] *See, e.g.*, JOHNS HOPKINS UNIVERSITY, "Policy on Classified and Otherwise Restricted Research" (Oct. 25, 2005) (prohibiting classified research on the University's academic campuses and noting that classified research cannot be used to satisfy criteria for faculty appointments or promotions), *available at* http://fjtresearch.jhu.edu/JHU_Classified_Research%20Policy.pdf (accessed May 9, 2008); *see also, e.g.*, UNIVERSITY SYSTEM OF MARYLAND, Consolidated USMH and UM Policies and Procedures Manual, § IV-2.00 - Policy on Solicitation and Acceptance of Sponsored Projects, *available at* http://www.usmh.usmd.edu/regents/bylaws/SectionIV/IV200.html (accessed May 9, 2008).

[29] Davidoff et al., *Sponsorship, Authorship, and Accountability*, *supra* note 26.

[30] Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at US Universities*, 284 J. AMER. MED. ASS'N. 2203 (Nov. 1, 2000).

[31] Michelle M. Mello et al., *Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry*, 352 NEW ENGL. J. MED. 2202 (May 26, 2005).

[32] Derek Bok, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION 65 (2003).

[33] Davidoff et al., *Sponsorship, Authorship, and Accountability*, *supra* note 26.

[34] INT'L. CMTE. OF MED. J. EDS., *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication* (Oct. 2007), available at http://www.icmje.org/index.html#conflicts (accessed May 9, 2008).

[35] *See, e.g.*, AM. MED. ASS'N., JAMA - *Instructions for Authors* at http://jama.ama-assn.org/misc/ifora.dtl#ConflictsofInterestandFinancialDisclosures (accessed May 9, 2008).

[36] TSCA, FIFRA, and the FDCA also have adverse event reporting requirements, but these provisions relate more to basic regulatory reporting than to scientific transparency so they will not be addressed in this paper.

[37] 15 U.S.C. § 2607(c).

[38] 7 U.S.C. § 136d(a)(2).

[39] 15 U.S.C. § 2615 (TSCA); 7 U.S.C. § 136l (FIFRA).

[40] ENVT'L. PROT. AGENCY, *Reporting Requirements for Risk/Benefit Information*, 62 Fed. Reg. 49370, 49371 (Sept. 19, 1997).

[41] Thomas O. McGarity, *The Complementary Roles of Common Law Courts and Federal Agencies in Producing and Using Policy-Relevant Scientific Information*, 57 ENVT'L. L. 1027, 1038 (2007).

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[42] Memorandum re: Consent Agreement and Proposed Final Order to Resolve DuPont's Alleged Failure to Submit Substantial Risk Information Under the Toxic Substances Control Act (TSCA) and Failure to Submit Data Requested Under the Resource Conservation and Recovery Act (RCRA), from Granta Y. Nakayama to Environmental Appeals Board, 3 (December 14, 2005), *available at* http://www.epa.gov/compliance/resources/cases/civil/tsca/eabmemodupontpfoasettlement121405.pdf (accessed May 9, 2008).

[43] *Id.* at 7-11.

[44] *Id.* at 1. The settlement agreement also covered a Resource Conservation and Recovery Act violation that could have brought a penalty of over $500,000.

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[46] Ken Ward, Jr., *Higher cancer stroke risk found in C8 workers*, Charleston Gazette (Mar. 8, 2008), *available at* http://wvgazette.com/News/200803080087 (accessed May 9, 2008).

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48 Envt'l Prot. Agency, TSCA *Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance*, 68 Fed. Reg. 33129 (June 3, 2003); Envt'l Prot. Agency, TSCA *Section 8(e) Reporting Guide* (June 1991), *available at* http://www.epa.gov/oppt/tsca8e/pubs/rguide.htm (accessed May 9, 2008).

[49] Envt'l Prot. Agency, *Registration and Agreement for TSCA Section 8(e) Compliance Audit Program*, 56 Fed. Reg. 4128-4130 (February 1, 1991).

[50] Envt'l Prot. Agency, *News Release: EPA TSCA Enforcement Action Secures New Chemical Risk Data*, April 25, 1997, *available at* http://yosemite.epa.gov/opa/admpress.nsf/e5ab1f0f0b1c39348525701d005e1573/1babc3c8f4a802c8525648400594f58?OpenDocument (accessed May 9, 2008).

[51] *See generally*, Thomas O. McGarity, *Science in the Regulatory Process: On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 L. & Contemp. Probs. 155, 172-76 (2003); Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 Kan. L. Rev. 897, 921-23 (2004).

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[53] Vincent T. Covello and Miley W. Merkhofer, Risk Assessment Methods: Approaches for Assessing Health and Environmental Risks 5-7 (1993); *see generally*, National Research Council, Risk Assessment in the Federal Government: Managing the Process (1983).

[54] 40 C.F.R. Part 159 (2007).

[55] Envt'l Prot. Agency, *Reporting Requirements for Risk/Benefit Information*, 62 Fed. Reg. 49370, 49371 (Sept. 19, 1997).

[56] *See id.* at 49371-72.

[57] *Id.* at 49372.

[58] *Id.*

[59] 40 C.F.R. § 159.165(a) (2007).

[60] 40 C.F.R. § 159.165(b) (2007).

[61] 40 C.F.R. § 159.170 (2007).

[62] 40 C.F.R. § 159.178(b) (2007).

[63] *See, e.g.*, Jad Mouawad, *550,000 More Chinese Toys Recalled for Lead*, N.Y. Times, Sept. 27, 2007, at C2; Gardiner Harris, *Regulation Redefined: The F.D.A. Shifts Focus: At F.D.A., Strong Drug Ties and Less Monitoring*, N.Y. Times, Dec. 6, 2004, at A1; Ken Ward, Jr., *DuPont's C8 Risks Above Acceptable Limits, Feds Find*, Charleston Gazette, Mar. 28, 2003, at D3.

[64] 42 U.S.C. § 9601(14).

[65] 7 U.S.C. §§ 136(a)-(m).

[66] 15 U.S.C. § 1261.

[67] 42 U.S.C. §§9601(22) (defining "release") and (8) (defining "environment").

[68] McGarity, *The Complimentary Roles of Common Law Courts and Federal Agencies in Producing and Using Policy-Relevant Scientific Information*, *supra* note 42.

[69] *See generally id.*; *see also* Wendy Wagner, *When All Else Fails: Regulating Risk Products Through Tort Litigation*, 95 GEO. L.J. 693 (2007).

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[82] *Jordan v. Dept. of Justice*, 591 F.2d 753, 772-73 (D.C. Cir. 1978) (en banc) (citation omitted).

[83] *Petroleum Information Corp. v. U.S. Dept. of Interior*, 976 F.2d 1429, 1435 (D.C. Cir. 1992).

[84] *United States v. Nixon*, 418 U.S. 683, 705 (1974).

[85] *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2nd Cir. 1977).

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[87] Doremus, *Scientific and Political Integrity in Environmental Policy*, *supra* note 72, at n.214 and accompanying text.

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[89] Public Employees for Envtl. Responsibility, *News Release - Interior Ethics Initiative Evaporates Behind Closed Doors* (Dec. 18, 2007), *available at* http://www.peer.org/news/news_id.php?row_id=960 (accessed May 9, 2008).

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[91] Whistleblower Protection Enhancement Act of 2007, H.R. 985 (110th Cong.), § 13. This bill has been passed by the House and by a Senate committee, but will not be called for a vote on the Senate floor until Sen. Coburn's hold has been removed. Sen. Coburn's hold is in place over a concern that another section of the bill, which would overturn an Executive Order regarding presidential documents, might be unconstitutional.

[92] *See* Doremus, *Scientific and Political Integrity in Environmental Policy*, *supra* note 72, at n.66 and accompanying text; *see also*, James Sandler, *The war on whistleblowers*, SALON (Nov. 1, 2007), at http://www.salon.com/news/feature/2007/11/01/whistleblowers/ (accessed May 9, 2008).

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[98] Donald Kennedy, "Prologue," in Wagner and Steinzor, eds., RESCUING SCIENCE, *supra* note 96, at xix.

[99] See Herbert L. Needleman, *Safety Comes to the National Institutes of Health: Notes from Inside the Crucible of Scientific Integrity*, 90 PEDIATRICS 977; Paul M. Fischer, "Science and Subpoenas: When do the Courts Become Instruments of Manipulation?" in Wagner and Steinzor, eds., RESCUING SCIENCE, *supra* note 96, at 86.

[100] Glenn Harlan Reynolds, "*Thank God for the Lawyers*": *Some Thoughts on the "Multiregulative" of Scientific Misconduct*, 66 Tenn. L. Rev. 801, 808-09 (1999) (describing the case of Dr. Rameshwar Sharma, whose laboratory was closed during a federal misconduct investigation that eventually vindicated him); *see also*, Kuehn, *Suppression of Environmental Science*, *supra* note 97, at 348 (noting that the editor of the *Journal of Medical Primatology* accumulated over $2 million in legal expenses, including $70,000 he had to pay out of pocket).

[101] Some state legislatures have enacted statutes that protect public policy advocates whose participation in the regulatory process leads to harassing lawsuits by powerful commercial interests. Victims of Strategic Litigation Against Public Participation (SLAPP) suits have convinced some states to pass "anti-SLAPP" legislation that gives them recourse somewhat like what we are proposing for harassed scientists. *See* Wagner & McGarity, BENDING SCIENCE, *supra* note 97 at 157-80.

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[103] *See, e.g.*, *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000).

[104] U. S. GOV'T ACCOUNTABILITY OFFICE, *Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance*, GAO-04-328, 9 (April 2004).

[105] 5 U.S.C. App. 2, § 9(c).

[106] 5 U.S.C. App. 2, § 10(a)(2).

[107] 5 U.S.C. App. 2, §§ 10(b) - (c).

[108] 5 U.S.C. App. 2, § 10(a)(1).

[109] 5 U.S.C. App. IV (Ethics in Government Act) 18 U.S.C. § 208 (conflicts of interest statute).

[110] U.S. GOV'T. ACCOUNTABILITY OFFICE, *Federal Advisory Committees: Additional Guidance Could Help Ensure Independence and Balance*, GAO-04-328, 20-23 (April 2004).

[111] *Id.* at 20.

[112] *See generally*, Sidney A. Shapiro and Rena I. Steinzor, *The People's Agent: Executive Branch Secrecy and Accountability in an Age of Terrorism*, 69 U. COLORADO PROBS. 99 (2006).

[113] 41 C.F.R. § 102-3.105(b) (2007).

[114] 41 C.F.R. Part 102-3, Appendix A to Subpart C (2007); GENERAL SERVICES ADMIN., *Federal Advisory Committee Management - Final Rule*, 66 Fed. Reg. 37728, 37744 (July 19, 2001).

[115] 41 C.F.R. § 102-3.60(b)(3) (2007).

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[117] 5 U.S.C. Appendix 6.

[118] NATIONAL ACADEMIES, "Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports" (May 12, 2003), *available at* http://www.nationalacademies.org/ coi/bi-coi_form-0.pdf (accessed March 18, 2008).

[119] Rep. Brian Baird Letter to Attorney General Requesting Investigation of Improper Review of Advisory Committee Candidates, Oct. 26, 2004, *available at* http://science.house.gov/press/PRArticle.aspx?NewsID=446 (accessed March 18, 2008).

[120] NATIONAL ACADEMIES, "Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," *supra* note 110 at 4.

[121] FDA Form 3410, *available at* http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3410.pdf (accessed May 9, 2008).

[122] *Id.*

[123] OGE Form 450, *available at* http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/forms/oge450_2006/oge450_fillable.pdf (accessed May 9, 2008).

[124] EPA Form 3110-48, *available at* http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/Form3110-48/$File/epaform3110-48.pdf (accessed May 9, 2008).

[125] JAMA, "Instructions for Authors," http://jama.ama-assn.org/misc/ifora.dtl#ConflictsofInterestandFinancialDisclosures (accessed May 9, 2008).

[126] By law, the seven members of the FIFRA Scientific Advisory Panel are chosen from a list of 12 nominees, 6 of whom are nominated by NIH and 6 of whom are nominated by NSF. 7 U.S.C. § 136w(d).

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[131] *Id.* at 7-11.

[132] 5 U.S.C. Appendix II, § 3(2)(C).

[133] *See generally*, Steven P. Croley and William F. Funk, The Federal Advisory Committee Act and Good Government, 14 Yale J. on Reg. 451, 477-85 (1997); *see also*, Byrd v. EPA, 174 F.3d 239 (D.C. Cir.) (holding that FACA did not apply when EPA hired Eastern Research Group to convene a peer review panel tasked with reviewing EPA's updated report on the carcinogenic effects of benzene, despite the fact that EPA gave ERG a list of potential panelists, had the opportunity to modify ERG's choice of panelists, submitted a list of specific questions the panel must answer, and sent an employee to provide introductory remarks at the peer review panel's public meeting), *cert. denied* 529 U.S. 1018 (2000).

[134] McGarity, *The Complementary Roles of Common Law Courts and Federal Agencies in Producing and Using Policy-Relevant Scientific Information*, *supra* note 42; Mary L. Lyndon, *Secrecy and Access in an Innovation Intensive Economy: Reinforcing Information Privileges in Environmental, Health and Safety Law*, 78 U. COLO. L. REV. 465 (2007); Wendy E. Wagner, *Common Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1699-1705 (2004).

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[136] *See* 40 C.F.R. § 2.203 (2007).

[137] *See id.* at § 2.204 (2007).

[138] *Id.*

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[140] *See infra* note 174 and accompanying text.

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[142] U.S. GOV'T. ACCOUNTABILITY OFFICE, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, GAO/RCED-94-103, 55 (Sept. 1994).

[143] *See generally*, Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, *supra* note 135.

[144] ENVT'L. PROT. AGENCY, *Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule*, V-28 (July 29, 1999), *available at* http://yosemite.epa.gov/ee/epa/eaflile.nsf/vwAN/T99-8.pdf/$File/T99-8.pdf (accessed May 9, 2008).

[145] 15 U.S.C. § 2613(b)(1) (TSCA § 14(b)(1)); 7 U.S.C. § 136h(d)(1) (FIFRA § 10(d)(1)).

[146] *Id.*

[147] Wagner, *Common Ignorance*, *supra* note 135, at 1699-1705; Thomas O. McGarity, *The Complementary Roles of Courts and Agencies in Producing and Using Policy-Relevant Scientific Information*, *supra* note 42, at 1055-56.

[148] U.S. GOV'T. ACCOUNTABILITY OFFICE, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458, 33 (June 2005).

End Notes

[149] Robert Gottlieb, REDUCING TOXICS: A NEW AGENDA IN POLLUTION AND INDUSTRIAL DECISIONMAKING 65 (1995). Gottlieb notes that 80 percent of the CBI claims made in § 8(e) notices are claims to protect the identity of the chemical.

[150] REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No. 1907/2006). The legislation creates a unified regulatory scheme for EU nations whereby all chemicals manufactured and imported into the EU must be registered with the European Chemicals Agency. The registration process mandates that each chemical be screened for toxicity and ecotoxicity and empowers the Chemicals Agency to ban or restrict the sale of the most dangerous substances.

[151] EU Regulation (EC) 1907/2006 Article 119(1). Though Article 119(1) mandates that this information "shall be made available, free of charge, over the Internet," registrants may request confidential treatment of the information. *Id.* at 10(a)(h). This request must be accompanied by "a justification as to why publication could be harmful for his or any other concerned party's commercial interests." *Id.*

[152] EU Directive 67/548/EEC.

[153] Properties that must be reported include physical state at standard temperature and pressure, boiling point, flash point, flammability, explosive properties, vapor pressure, solubility, evaporation rate, fat solubility, etc. *See* EU Regulation (EC) 1907/2006 Annex II. § 9; Annex VII, § 7; Annex IX, § 7.

[154] *See* 40 C.F.R. § 2.203 (2007); *see also* Wagner and Michaels, *Equal Treatment*, *supra* note 25, at 329-35; and Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, *supra* note 135, at 519.

[155] Wagner and Michaels, Equal Treatment, *supra* note 25, at 334, citing HAMPSHIRE RESEARCH ASSOCIATES, INC., *Influence of CBI on TSCA Implementation* (1992), at figs. 2, 6.

[156] U.S. GOV'T. ACCOUNTABILITY OFFICE, Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program, GAO-05-458, 33 (June 2005).

[157] ENV'T'L. PROT. AGENCY, *Economic Analysis of Proposed Amendments to the TSCA Section 8(e) Reporting Update Rule*, *supra* note 145, at III-9, III-30.

[158] ENV'T'L. PROT. AGENCY, *Final Action Plan: TSCA Confidential Business Information Reform*, 9 (June 20, 1994) (on file with the authors).

[159] ENV'T'L. PROT. AGENCY, *Proposed Rule: Public Information and Confidentiality Regulations*, 59 Fed. Reg. 60436, 60459 (Nov. 23, 1994).

[160] *See* ENV'T'L. PROT. AGENCY, *Final Action Plan: TSCA Confidential Business Information Reform*, *supra* note 159.

[161] 42 U.S.C. § 11042(a)(2)(A)(ii).

[162] Kitch, *The Law and Economics of Rights in Valuable Information*, 9 J. LEGAL STUD. 683, 713 (1980).

[163] ENV'T'L. PROT. AGENCY, *Public Information and Confidentiality Regulations*, 59 Fed. Reg. 60466, 60450 (Nov. 23, 1994).

[164] U.S. GOV'T. ACCOUNTABILITY OFFICE, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, GAO/RCED-94-103, 58 (Sept. 1994); U.S. GOV'T. ACCOUNTABILITY OFFICE, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458, 84 (June 2005).

[165] Richard Levin et al., *Appropriating the Returns from Industrial Research and Development*, BROOKINGS PAPERS ON ECONOMIC ACTIVITY, 785 (1987).

[166] *See generally*, Shapiro and Steinzor, *The People's Agent*, *supra* note 113, at 116-18.

[167] 5 U.S.C. § 552(b)(4).

[168] Shapiro and Steinzor, *The People's Agent*, *supra* note 113, at 117; Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, *supra* note 135, at 509-09.

[169] *Id.* at 117, citing Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1825 (1989) and Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secrecy Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 857-92 (1980).

[170] Memorandum from John Ashcroft, Attorney General, to Heads of All Federal Departments and Agencies, The Freedom of Information Act (Oct. 12, 2001), *available at* http://www.usdoj.gov/04foia/011012.htm (accessed May 9, 2008).

[171] *Id.*

[172] Shapiro and Steinzor, *The People's Agent*, *supra* note 113, at 118.

[173] Memorandum from Janet Reno, Attorney General, to Heads of Departments and Agencies, The Freedom of Information Act (Oct. 4, 1993), *available at* http://www.fas.org/sgp/clinton/reno.html (accessed May 9, 2008).

[174] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 113, 111 Stat. 23(1).

[175] 42 U.S.C. § 282(j)(2)(A)(ii).

[176] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, §§ 304(a), 801(a), 1104(2); 121 Stat. 868, 904, 975; 42 U.S.C. § 282(j).

[177] NIH operates GenBank, an annotated collection of all publicly available DNA sequences. *See* NIH, *GenBank Overview*, at http://www.ncbi.nlm.nih.gov/Genbank/ (accessed May 9, 2008).

[178] OECD has established a Working Group on Manufactured Nanomaterials, which is planning to develop a database of all environmental, health, and safety research being conducted on nanotechnology. OECD, *Safety of Manufactured Nanomaterials: Work of OECD Chemicals Committee*, 9, *available at* http://www.oecd.org/dataoecd/34/6/37852582.ppt (accessed May 9, 2008); Pat Rizzuto, *Science Policy: Improving Tox. Risk Assessment, Continued Work on Nanotech Key Focus*, 39 ENV. REPORTER 193 (Jan. 18, 2008).

[179] INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, Editorial: *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, *available at* http://www.icmje.org/clin_trial.pdf (accessed May 9, 2008).

[180] *See supra*, notes 126-7 and accompanying text.

[181] Stanton Glantz et al., THE CIGARETTE PAPERS, 15, 58-107 (1996).

[182] Robert Steinbrook, *Public Registration of Clinical Trials*, 351 NEW ENGLAND J. MED. 515, 516 (2004).

[183] Deborah A. Zarin, Tony Tse, and Nicholas C. Ide, *Trial Registration at ClinicalTrials.gov between May and October 2005*, 353 NEW ENGLAND J. MED. 2779 (2005).

[184] *Id.*

[185] *Id.*

[186] INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, Editorial: *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, *available at* http://www.icmje.org/clin_trial.pdf (accessed May 9, 2008).

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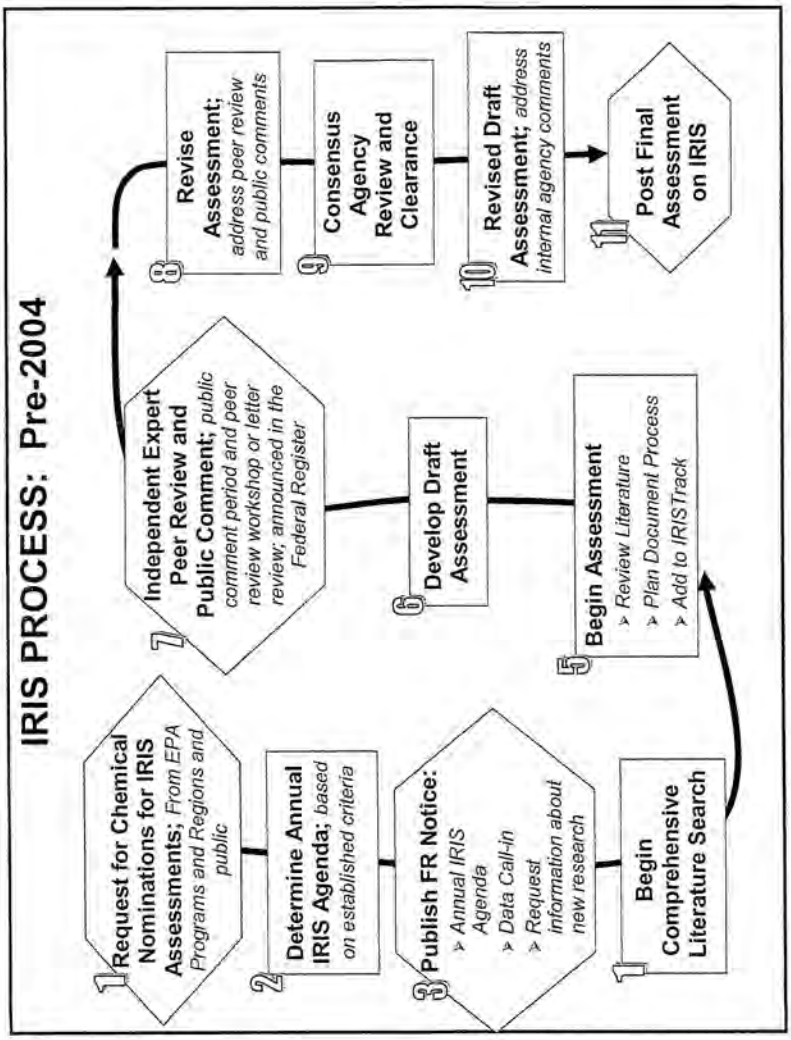
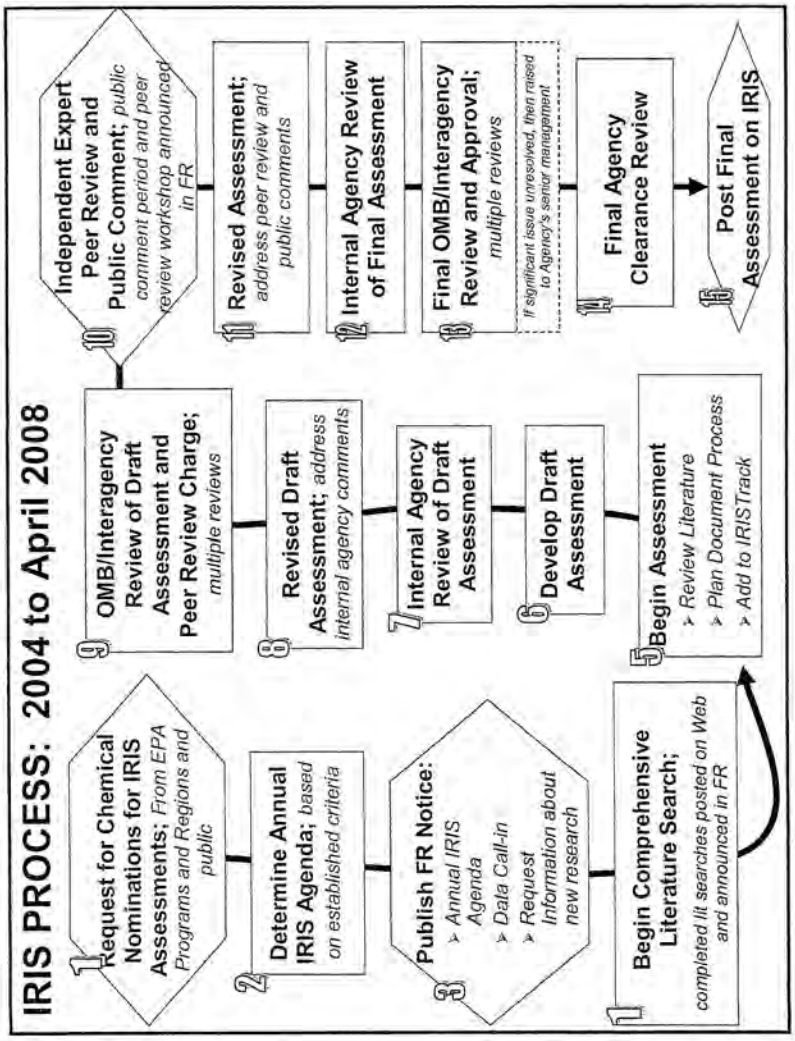
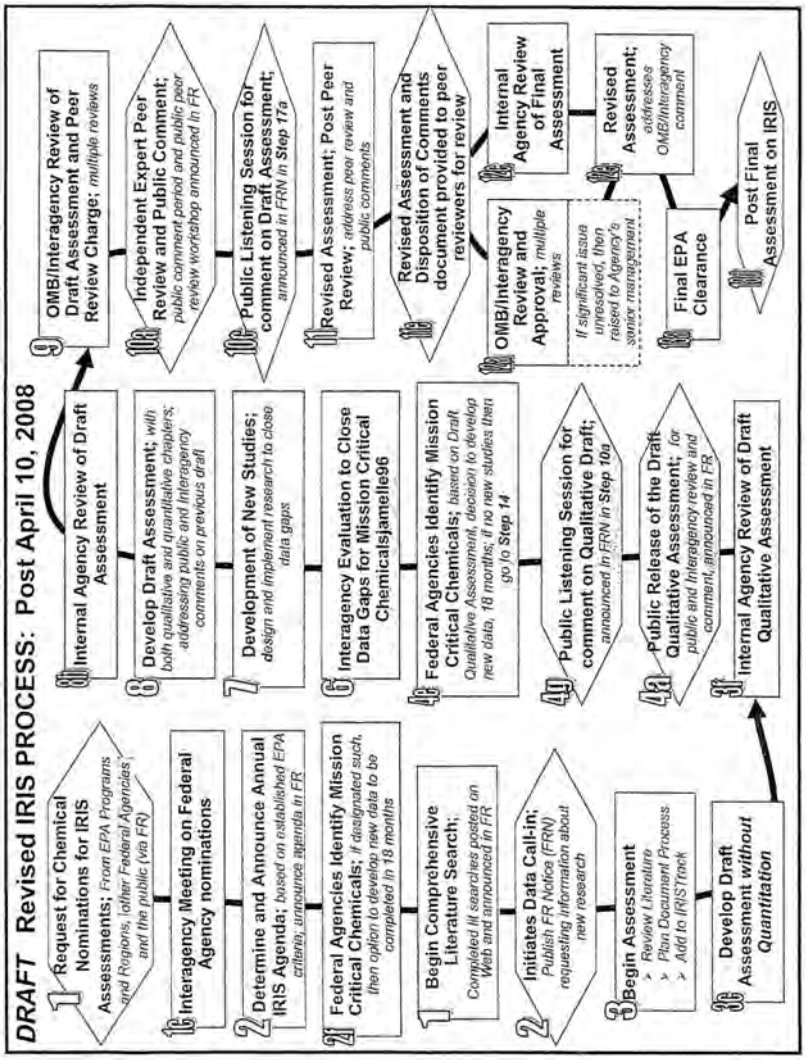

IRIS PROCESS: Pre-2004
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions and public
2 Determine Annual IRIS Agenda; based on established criteria
3 Publish FR Notice:
Annual IRIS Agenda
Data Call-in
Request information about new research
4 Begin Comprehensive Literature Search
5 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
6 Develop Draft Assessment
7 Independent Expert Peer Review and Public Comment; public comment period and peer review workshop or letter review; announced in the Federal Register
8 Revise Assessment; address peer review and public comments
9 Consensus Agency Review and Clearance
10 Revised Draft Assessment; address internal agency comments
11 Post Final Assessment on IRIS


IRIS PROCESS: 2004 to April 2008
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions and public
2 Determine Annual IRIS Agenda; based on established criteria
3 Publish FR Notice:
Annual IRIS Agenda
Data Call-in
Request Information about new research
4 Begin Comprehensive Literature Search;
completed lit searches posted on Web and announced in FR
5 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
6 Develop Draft Assessment
7 Internal Agency Review of Draft Assessment
8 Revised Draft Assessment; address internal agency comments
9 OMB/Interagency Review of Draft Assessment and Peer Review Charge; multiple reviews
10 Independent Expert Peer Review and Public Comment; public comment period and peer review workshop announced in FR
11 Revised Assessment; address peer review and public comments
12 Internal Agency Review of Final Assessment
13 Final OMB/Interagency Review and Approval; multiple reviews
If significant issue unresolved, then raised to Agency's senior management
14 Final Agency Clearance Review
15 Post Final Assessment on IRIS


DRAFT Revised IRIS PROCESS: Post April 10, 2008
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions, other Federal Agencies, and the public (via FR)
1b Interagency Meeting on Federal Agency nominations
2 Determine and Announce Annual IRIS Agenda; based on established EPA criteria, announce agenda in FR
2a Federal Agencies Identify Mission Critical Chemicals; if designated such, then option to develop new data to be completed in 18 months
1 Begin Comprehensive Literature Search; Completed lit searches posted on Web and announced in FR
2 Initiates Data Call-in; Publish FR Notice (FRN) requesting information about new research
3 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
3b Develop Draft Assessment without Quantitation
3a Internal Agency Review of Draft Qualitative Assessment
4a Public Release of the Draft Qualitative Assessment; for public and interagency review and comment, announced in FR
4 Public Listening Session for comment on Qualitative Draft; announced in FRN in Step 10a
4b Federal Agencies Identify Mission Critical Chemicals; based on Draft Qualitative Assessment, decision to develop new data, 18 months; if no new studies then go to Step 14
6 Interagency Evaluation to Close Data Gaps for Mission Critical Chemicals/jamelle96
7 Development of New Studies; design and implement research to close data gaps
8 Develop Draft Assessment; with both qualitative and quantitative chapters; addressing public and interagency comments on previous draft
8a Internal Agency Review of Draft Assessment
9 OMB/Interagency Review of Draft Assessment and Peer Review Charge; multiple reviews
10a Independent Expert Peer Review and Public Comment; public comment period and public peer review workshop announced in FR
10c Public Listening Session for comment on Draft Assessment; announced in FRN in Step 17a
11 Revised Assessment; Post Peer Review; address peer review and public comments
11a Revised Assessment and Disposition of Comments document provided to peer reviewers for review
12a OMB/Interagency Review and Approval; multiple reviews
If significant issue unresolved, then raised to Agency's senior management
12 Final EPA Clearance
12b Internal Agency Review of Final Assessment
13 Revised Assessment; addresses OMB/Interagency comment
13a Post Final Assessment on IRIS