



Testimony of
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Regarding
The Role of Science in Regulatory Reform

**Before the
Subcommittee on Investigations and Oversight
Committee on Science and Technology
US House of Representatives**

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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 in 1983 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

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.

federal regulatory agencies, 4) regulatory transparency, 5) how to improve the timeliness and responsiveness of the rulemaking 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-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.

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 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 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.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 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.

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."

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 policymakers." (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 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

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>.

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 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

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.

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 rulemaking 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 rulemaking, 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 rulemaking 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 rulemaking.

Within those dockets, the report recommended expanding disclosure of communications made by or to federal officials during the rulemaking 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 nongovernmental entity regarding rules under development or under review;" and (p. 48)

- “Agencies should disclose online all substantive communications between the agency and nongovernmental 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 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.” (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 Rulemaking Process

Delay in writing new rules is one of the most obvious and serious flaws inherent in the current rulemaking 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 rulemaking,” the report noted. (p. 14-15)

Accordingly, the report recommended that President Obama establish a blue-ribbon commission to analyze all the potential sources of delay in the rulemaking 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 rulemakings 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 rulemaking 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.

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>.