Testimony of
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Committee on Science and Technology
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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 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 focuses on 1) the amendments to E.O. 12866 and the impacts of the amendments, 2) the manipulation of the analytical tools used in the regulatory process as part of a broader assault by this administration, and 3) a brief description of actions Congress might take to minimize the impact of the changes just enacted.

I. Amendments to E.O. 12866: Executive Order 13422

On January 18, President Bush issued amendments to Executive Order (E.O.) 12866, which further centralize regulatory power in the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) and shift it away from the federal agencies given this power by legislative enactments. It is another brick in the foundation this administration has been building for a unitary theory of the presidency, one in which the executive is superior to the other branches in our constitutional system and one in which the White House exhibits significant control.

We are particularly concerned with three aspects of the amendments: the identification of "market failure" as the first principle in promulgating regulations, the designation of a presidential appointee as the Regulatory Policy Officer in each agency covered by the E.O., and the requirement that significant guidance documents undergo nearly the same OIRA review process required of significant regulations. Attached to this testimony is a copy of our analysis of the amendments. I want to focus on these three aspects here.

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A. The Market Failure Criterion

Through amending the regulatory process, the President is institutionalizing an anti-regulatory approach by using a market failure criterion in place of actually identifying threats to public health and safety. It diminishes standards Congress may require agencies to use, such as the best control technology, by elevating a new market failure standard that Congress has never required.

The market failure criterion is yet another layer added to the agency analysis. The agency must comply with statutory criteria (such as best available technology) as well as perform an analysis demonstrating market failures. If the agency meets OMB's standards for assessing "whether any new regulation is warranted," then the agency must also comply with other standards in the E.O., including cost-benefit analysis. We believe this new standard decidedly favors the regulated community and places another hurdle for agencies to promulgate health, safety, and environmental regulations, and creates more delay.

In addition, the language of the amendments makes clear that this economic test is front and center in the review process. Compare the language:

E.O 12866	**E.O. 13422**
Each agency shall identify the problem that it intends to address	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 private markets or public institutions that warrant agency action)	(including, where applicable, the failures of public institutions) that warrant new agency action,
as well as assess the significance of that problem.	as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.

Not only is the market failure test a primary consideration, but the agency's description of the problem will be used to "enable assessment of whether new regulation is warranted." This clearly forces the agency to think again about whether the best course is to do nothing and provides OIRA with another justification, or assessment, for halting or delaying regulations. The regulatory process set out in the executive order applies after Congress has passed legislation having determined that a problem existed and needed to be addressed. Under the amendments, agencies are directed to ask that same question again: is the problem worth addressing? Moreover, OIRA's assessment of whether any new regulation is warranted raises the question of whether OMB intends to supersede legislative intent when the market failure test does not met OIRA's satisfaction. Although Congress may have already legislated, without the implementing regulation, the legislation may not be able to be executed. Thus the executive branch has assumed a legislative function.

Adding the market failure criterion challenges the role of Congress. Theoretically, employees could contract with employers for a certain level of risk in their jobs. Nevertheless, Congress has passed workplace safety regulations (as well as consumer protections, environmental protections, and economic protections to help markets function better for

businesses) where markets might have resolved problems if given time. As Georgetown University law professor Lisa Heinzerling wrote: "Judging regulations implementing these laws based on whether the regulations respond to 'market failure' misunderstands the premises of many of the laws Congress enacts." In short, there are multiple contexts in which Congress might justify taking legislative action, market failure being only one.

The supporters of using the market failure criterion believe the free market will supply the protections the American people want without government intervention. Susan Dudley, one of these free market advocates and the nominee to head OIRA, would have preferred to leave safety to the unsteady hand of the market, hypothesizing that "[i]f air bags protect lives, and consumers demand them, it is reasonable to assume that automobile manufacturers would have installed air bags in the absence of federal requirements to do so."[1] According to Dudley, federal action requiring air bags in cars was unnecessary because the market would have provided air bags to the public absent regulation.

OMB Watch believes that the market failure criterion is a furtherance of the economic criteria which OIRA has increasingly required as justification for taking regulatory action. OIRA has substituted economics for all other values the American public has consistently said to be important to them.

B. The Regulatory Policy Officer (RPO)

The amendments require each agency to have a Regulatory Policy Office run by a political appointee and that "no rulemaking shall commence nor be included" for consideration in the agency's regulatory plan without the political appointee's approval. This will further politicize the rulemaking process and provide more White House control over the agency rulemaking process.

Section 4(c) The Regulatory Plan, is amended to place this regulatory planning authority directly in the RPO's hands. The language is changed from

> The Plan shall be approved personally by the agency head and shall contain at a minimum:

to

> Unless specifically authorized by the head of the agency, no rulemaking shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office, and shall contain at a minimum:…
>
> (B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits **of each rule as well as the agency's 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**; [emphasis added].

The amendments add the highlighted language which requires not only significantly more analysis by the agencies because of the "best estimates" requirement, but also provides a basis to allow the RPO to establish priorities.

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[1] Susan E. Dudley, *Regulatory Studies Program Comments: Advanced Air Bags* 7 (Dec. 17, 1998), *available at* <http://mercatus.org/repository/docLib/MC_RSP_PIC1998-04_NHTSAAirBags_981130.pdf>.

A similar approach was attempted by President Reagan through his E.O. 12498, the Regulatory Planning Process, which was issued January 4, 1985. Under E.O. 12498, agencies were to get approval from OMB prior to starting a rulemaking — a pre-rulemaking review. Many in the business community thought this would be a wonderful approach for choking off agency ideas before they ever really got going. That approach, however, proved too cumbersome and difficult to administer. In short order it failed.

The new Bush E.O. amendments have the same objective, but put the chokehold in the agencies, instead of at OMB. To ensure that the process works, the amendments grant authority to these new political appointees to be the eyes and ears for OMB. And it again mounts a challenge to congressional authority. In writing legislation, Congress often directs agencies to initiate a rulemaking. The presence in the agencies of these appointees by whom rulemaking must now be initiated creates a process that is as if Congress had not directed the agencies to act, or as if that direction is irrelevant if the White House appointees disagree with it.

A civil servant reacting to the new amendments provided an agency perspective (http://fromthearchives.blogspot.com/2007/01/long-and-esoteric-twice-in-one-day-just.html).

> From the perspective of a low level bureaucrat looking up the line, there are two big problems with this, independent of ideology.
>
> The first is simple. I just don't want to add a single step that adds time to management review. Honestly, you'd be shocked how long it takes for us to get anything through management review. Anything we release to the public, including our non-controversial, small scale documents, must go through six (6) levels of review. We schedule three to four weeks for management review. Yeah. Three days on each desk, if we give them advance notice that our stuff will be coming. If we were doing controversial stuff, it would be longer. If we had to route through one additional back-logged office? If they were far away, and my bossman couldn't chat with them to prep them for the document, and we were just another insignificant office on the west coast? I can't even guess.
>
> But the more important reason is that a distant political appointee, even assuming that she is not a partisan hack and that she is interested in the topic and not using the office as a stepping stone, would know exactly the wrong amount. Anyone at a distance from the process can only know enough to be dangerous. When we go to write anything that tells people what they have to do, there is an intricate multi-year negotiation between everyone involved. There are drafts, and comments, and drafts, and workshops, and drafts, and internal meetings, and drafts, and formal written comment, and more drafts. Usually, in the end, you will come down to very awkwardly written compromises that no one will sue you for.
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> Every word in there was hard fought. People snorted and sat back at the table with their arms crossed. We changed it until no one threatened to call their congressperson any more. We explained to them why we have to implement the law that way, and caved when we couldn't get more, or when we were wrong. We brought in someone's good idea. I know how people laugh at ridiculous regulations, but I swear they didn't get to be ridiculous because no one was thinking. They're ridiculous because the topics are complicated, and we have to accommodate widely divergent views, and because there were so many iterations.
>
> Anyway, a political appointee who wasn't there for the painful years of writing regulations can only disrupt a very precarious balance… Unless she was there, she can only make things worse. I don't want her in the loop.

Even worse, if the political appointee is a "partisan hack", then the integrity of the science may be compromised. The regulatory process is a complex one that involves agency

experts of all types. Imagine if a political appointee were to shape the regulatory options from the start: invariably the outcomes would be skewed.

There are two concerns with the Regulatory Policy Officer approach. First, OIRA may be creating political outposts in each agency thereby magnifying its impact. The amendments to the E.O. allow OIRA to play an active role during the pre-rulemaking stage when agencies are formulating annual plans for regulatory activities. OIRA will be able to quash any contemplated regulatory or guidance issues before agencies propose them for the Regulatory Plan. Under the amended E.O., OIRA can now engage the agency, along with other government personnel (as provided for in one amendment), in reaching a “common understanding” on regulatory efforts.

Second, the content to be collected raises questions about priorities. Collecting cumulative costs and benefits leads to little more than comparing apples and oranges. And what value does this information provide to policymakers? We believe this is leading to the creation of regulatory budgets which would be used to determine the regulatory agenda without congressional approval. Using these budgets, regulation proceeds on a cost effectiveness basis only, with agencies' budgets ranked by total costs and benefits. It completely divorces policymaking from the need for health, safety and environmental protections.

C. Guidance Document Review

The amendments issued to E.O. 12866 require review by OIRA of agencies' guidance documents for the first time. These documents are issued to clarify how regulated parties are expected to implement legally binding regulations. By subsuming guidance documents into a review process almost identical to the review process OIRA uses to review and approve regulations, the extent of OIRA's reach into agencies' responsibilities will be at an all-time high.

By requiring agency guidance documents to come under OIRA review, and to treat “significant” guidance in the same way as “significant” regulations, the E.O. amendments will lead to further delay in providing information to the public about compliance with regulations, as well as with general guidance on agency policies.

If it is true that more and more agencies are using guidance as a means of avoiding the regulatory process, then that should be a signal to Congress and the public that the rulemaking process is seriously flawed. If agencies are looking for faster ways of doing their job and have turned to guidance, the solution is certainly not to require guidance to go through the same regulatory process that agencies were trying to avoid in the first place.

The *Final Bulletin for Agency Good Guidance Practices*, issued the same day as the E.O., defines guidance documents to include "interpretive memoranda, policy statements, guidances (sic), manuals, circulars, memoranda, bulletins, advisories, and the like." Federal agencies issue thousands and thousands of guidance documents each year relating to hundreds of different types of activities. All of these documents deemed significant will now come under review by OIRA's staff of 55 people.

The fourth part of the "significant guidance document" definition, whether the issue raises "novel legal or policy issues arising out of legal mandates, the President's priorities, or principles set forth in this Executive order", is nearly broad enough to permit OIRA to sweep into its review any guidance it wishes to review.

Section I.5 of the Bulletin adds a further category of guidance document, the "economically significant guidance document" which is:

> "a significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant guidance documents do not include guidance documents on Federal expenditures and receipts."

The definitions of both significant and economically significant guidance documents include documents that "may reasonably be anticipated to lead to" certain conditions. The Bulletin "makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules." In other words, it will be even easier to reasonably anticipate that a guidance document will have a significant effect on the economy than will a regulation. The reasonable people doing the anticipating no doubt work for OIRA.

Furthermore, according to the Bulletin, the "relevant economic impacts include those that *may be* [emphasis added] imposed by Federal agencies, state, or local governments, or foreign governments that affect the U.S. economy, as well as impacts that could arise from private sector conduct." This creates a largely speculative analysis to be conducted by the agencies even assuming reasonably anticipated effects by a third parties. The Bulletin does not, however, require a formal regulatory impact analysis, so it is unclear just how this determination is to be conducted.

The example cited in the Bulletin of an economically significant guidance document is an agency pronouncement that a particular product or substance is unsafe. In this instance, "Unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures". The determination that a substance or product is unsafe involves some scientific assessment. This provides an example of OIRA reviewing a scientific conclusion and having the opportunity to substitute an economic analysis for a scientific one. This substitution, or even second-guessing the scientific judgment, could lead to substantial delays in protecting the public.

In the end, the review of guidance documents by OIRA will simply result in more delay and more White House control over the substantive work of the agencies. It will inevitably lead to a usurpation of agencies' powers.

II. Manipulation of Regulatory Tools

A great deal of attention has been given to the tools of the regulatory process, especially cost-benefit analysis (CBA). More recently, risk assessment (RA), peer review, and federal advisory committees (FAC) have also been the focus of attention from a regulatory standpoint. I want to address each of these briefly and to convey to the members that these tools have been manipulated by OIRA and administration appointees to achieve results-oriented processes and biased decisions that have delayed, dismantled or diminished public protections.

A. Cost-benefit Analysis

CBA is a policymaking tool by which the costs of imposing a regulation are weighed against the potential benefits of reducing the harm. For example, in the case of pollution regulation, cost is generally construed as the cost of implementing technology to comply with regulation. These costs are more easily quantifiable than other factors, although some evidence exists that costs are often inflated.

The benefits of a regulation require two separate analyses: an assessment of the risk posed by the harm in question as well as a monetization of the potential benefits. Both factors prove to be difficult to calculate; many benefits resist monetization, and risk assessments can be hindered either through incomplete datasets or a large degree of indeterminable factors. In order to estimate the health effects of a regulation, for example, agencies generally must rely on laboratory data on other species or on human experience with much higher levels of exposure. To extrapolate from this data the potential benefits of a regulation requires a large degree of guesswork, and agencies often come up with wide ranging numbers on the potential health benefits.

CBA is often touted by the administration and conservative think tanks as a neutral tool in policymaking, but recent studies by legal scholars show that CBA is inherently political and may even advise against what we consider our most immutable public protections.[2]

I would argue that there are several shortcomings in the way that CBA is used, and these deficiencies have been exacerbated by actions during the Bush administration:

- The overriding criterion of CBA is efficiency, but efficiency doesn't mean fairness. The net benefit calculation that results from using CBA is without regard for who wins and who loses, and without regard for any public participation. This focus on efficiency is critical to business but doesn't work for government because there is no single, public sector measurement comparable to profit maximization in the private sector.
- CBA tends to overestimate costs for a variety of reasons. Agencies generally rely on the regulated industries to provide them with costs of compliance over a certain number of years. Studies show compliance costs drop after regulation due to the decline in the costs of technology (like pollution controls), management efficiencies, and business innovations. These cost savings, however, are not calculated into the analysis generally; and CBA takes a snapshot of one point in time resulting in a static analysis.
- The major objection I have to relying on CBA as the determinative factor in rulemaking is that it does such poor job of calculating benefits. How do you monetize benefits like clean drinking water, good health, being alive? There are certain values we hold dear that cannot be adequately monetized. A decision making process that doesn't provide for the expression of these nonquantifiable benefits is critically flawed.[3]

CBA has been part of the rulemaking process since the Reagan administration. Prof. Sally Katzen spoke at a September 2006 panel on presidential rulemaking and stated that, although E.O. 12866 kept the CBA requirements of the earlier Reagan era executive orders, during her tenure as OIRA administrator,

> we explicitly recognized that non-quantifiable costs and benefits are essential to consider. That not everything can be counted and it is very important to take into account those things which can't be counted. We also made it clear that this economic analysis was not dispositive, but simply informative.[4]

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[2] See, for example, Lisa Heinzerling, Frank Ackerman and Rachel Massey's "Applying Cost Benefit Analysis to Past Decisions: Was Environmental Protection Ever a Good Idea?," David Driesen's "Is Cost-Benefit Analysis Neutral?," and Richard Parker's "Is Government Regulation Irrational? A Reply to Morall and Hahn".

[3] See for example, Heinzerling and Ackerman's *Priceless: On Knowing the Price of Everything and the Value of Nothing*. NY: The New Press, 2004. Chapter 2.

[4] Panel 4: A PRESIDENTIAL REVIEW OF RULEMAKING: REAGAN TO BUSH II. Part of a symposium on "Presidential, Congressional, and Judicial Control of Rulemaking," conducted at the Congressional

In the hands of the Bush administration, and particularly in those of John Graham, OIRA administrator from 2001-2006, CBA has risen to a position of primacy in the rulemaking process. In September 2003, OIRA issued final guidance that instructed federal agencies on specific analytical methods for regulatory decisions. This guidance committed agencies to increased emphasis on cost-effectiveness analysis as well as benefit-cost analysis and raised the bar on new health, safety and environmental protections. Specifically, the guidance

- pushes for health and safety benefits to be expressed in terms of dollars and cents, so agencies can calculate and demonstrate "net benefits" (benefits minus costs);
- uses cost-effectiveness analysis which does not monetize benefits. Rather, it looks at the ratio of costs to units of benefits (i.e., number of lives saved). The Clinton guidance allowed agencies to use cost-effectiveness analysis in place of a "net benefits" analysis if they have difficulty monetizing. The new guidance requires both types of analyses for all major health and safety rules.
- requires discounting of lives saved in the future. "Discounting" -- already common practice in monetizing benefits -- rests on the premise that a life saved today is worth more than a life saved tomorrow. The further in the future a life is saved as a result of regulatory action today, the more it will be discounted from its "present value," and the less likely the action will pass a cost-benefit test.
- promotes use of "life years" in evaluating fatality benefits**.** Agencies commonly base benefit estimates on the "value of a statistical life" (VSL), drawn from the number of lives expected to be saved by regulatory action. On top of VSL estimates, OIRA's guidance asks agencies to consider using "value of statistical life years" (VSLY), which looks at the number of life years saved as opposed to the number of lives. This would skew against protections for the elderly, who have fewer life years remaining.

These CBA and cost-effectiveness requirements are offensive for the devaluation of lives, health and safety. Elderly and minority communities frequently suffer the consequences of a lifetime's exposure to industrial contaminants, including heart or lung failure from smog and soot, and cancer from toxic chemicals. Tens of thousands die prematurely every year as a result. They are offensive also for their elevation of economic and statistical manipulation that results in extremely high barriers to implementing public protections under the guise of regulatory relief for special interests.

B. Risk Assessment (RA)

A second regulatory tool that OIRA tried to manipulate was the use of risk assessments. In January 2006, Graham issued OMB's *Proposed Risk Assessment Bulletin* (RAB) which contained a set of guidelines to govern all risk assessments and included technical standards for all federal agencies to use when conducting risk assessments, as well as other scientific documents. The OMB guidelines would apply to risk assessments conducted as part of issuing or revising health, safety and environmental rules, as well as important scientific studies. OMB asked the National Research Council (NRC) to review the document after its release. NRC suggested the Bulletin be withdrawn completely.

The NRC defined RA as "the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations." There are components to

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Research Service on September 11, 2006 as part of the Administrative Law project of the Subcommittee on Commercial and Administrative Law of the House Judiciary Committee

conducting a public health RA: hazard identification, dose-response assessment, exposure assessment, and risk characterization.[5] Even without knowing the scientific definitions of these terms, it's clear from the definition and its elements that a risk assessment is an evaluative process.

In its review of the RAB, the Council found that OMB's new definition of risk assessment was "too broad and in conflict with long-established concepts and practices." The Bulletin defined a risk assessment as a document instead of a process and the goals outlined, when considered together, indicated "that a risk assessment should be tailored to the specific need for which it is undertaken." The emphasis, according to the NRC evaluation, was on efficiency over quality and stated that the goals outlined did not "support the primary purpose of the bulletin — to enhance the technical quality and objectivity of risk assessments."

The report also recommended that OMB leave technical risk assessment guidelines and standards to each federal agency because one size does not fit all when it comes to risk assessments. The Council stressed concerns over "the likely drain on agency resources, the extended time necessary to complete risk assessments that are undertaken, and the highly likely disruptive effect on many agencies."

As OMB has done with other regulatory tools, the risk assessment approach called for in this release would have created unnecessary delays in the rulemaking process by adding to the already cumbersome process that OMB oversees. The ability of government agencies to protect the public would be compromised by attempts to manipulate science and the risk assessment process. For example, the proposed standards called for the use of central estimates or tendencies instead of statistical ranges. Using this approach puts the most vulnerable populations, who fall outside these "central estimates," at risk in some analyses.

The rebuke by the NRC is one of the strongest commentaries issued on the trend over the last six years to centralize power over the regulatory process within OMB and move it away from agencies responsible for protecting health, safety and the environment. The administration has consistently used regulatory tools like RA to manipulate science for its own ends, attempted to impose a one-size-fits-all framework on the agencies' use of these tools, and has shifted the criteria for defining when regulations are necessary away from a health or safety problem and toward market-based criteria. The strongly-worded NRC evaluation should provide a Congress interested in executive oversight with a strong example of the dangers of this regulatory trend.

C. Peer Review

As happened with the two tools described above, OMB developed a bulletin establishing government-wide requirements for scientific peer review. The *Final Information Quality Bulletin for Peer Review* was issued December 2004 after OMB took comments from the public regarding a proposed bulletin that was issued in April 2004. OMB again attempts a one-size-fits-all approach that doesn't consider different agency functions and expertise required to implement legislation. In the final bulletin, OMB asserts that its authority for the peer review policies is implied in the Information Quality Act and OMB's general authorities. None of the laws or executive orders referenced provide any specific instructions on peer review. No new authority is referenced by the agency and OMB did not seek any clarifying or supporting language from Congress.

[5] National Research Council. 1983. *Risk Assessment in the Federal Government: Managing the Process*. Washington, DC: National Academies Press. This publication established the parameters for using RA.

In OMB Watch's comments on the proposed bulletin, we argued that OMB had not identified a peer review problem that justified this government-wide approach. OMB implied that a problem had been identified and defined by citing several studies and reports. However, none of these documents actually claim that an overarching problem or failure of peer review policies has occurred at federal agencies. Nor do the studies recommend the establishment of uniform requirements for scientific peer review. Instead, the referenced materials address the importance of peer review, the need for changes at certain agencies, or types of reviews. Yet, without a clear understanding of any problem in peer review standards, OMB finalized these policies assuming they will do more good than harm.

OMB granted itself an oversight role in the peer review process. OMB has never overseen peer review and holds very little scientific or peer review expertise – only a handful of recently-hired scientists. This grant of authority involves OIRA personnel in the technical and scientific discussions that often lead to a pre-rulemaking process. This part of the regulatory process is already dominated by OIRA's gatekeeper function by which it develops acceptable agency rulemaking submissions even before the public process.

OMB is a political office working directly for the administration, not an unbiased scientific office. Yet, the agency places itself in the role of supervisor for implementing scientific peer review. OMB Watch recommended oversight authority to an objective scientific body, such as the National Academy of Sciences or an interagency review panel.

In the final peer review bulletin, OMB solidified its new oversight role for scientific peer review. OMB has the authority to grant exemptions, approve alternative peer review processes, and designate information for stricter review requirements. The final proposal also adds a stipulation that all federal agencies submit an annual report to OMB detailing the use of peer review for the fiscal year. OMB Watch continues to believe that the bulletin grants far too much influence over the scientific peer review process to the politically motivated offices of OMB and the Office of Science and Technology Policy. Such power would enable an administration to easily influence peer reviews and in turn, the rulemakings that follow.

For the most important peer reviews, OMB created a double standard in which agency employees, who may peer review more basic information, are essentially barred from serving as reviewers. However, experts associated with affected industries are allowed to serve as peer reviewers with only a requirement that their affiliations be disclosed. Highly influential scientific information has much stricter peer review requirements, and OMB explicitly states that government employees should rarely be used as reviewers. The final proposal bans any experts from the sponsoring agency from reviewing information, but makes an exception for the “rare situation in which a scientist from a different agency of a Cabinet-level department other than the agency that is disseminating the scientific assessment has expertise, experience and skills that are essential but cannot be obtained elsewhere.” The unequal standards for private sector scientists remains, but the final bulletin instructs agencies to “consider barring participation by scientists with a conflict of interest.”

The peer review process outlined in the final bulletin creates delay by excessive bureaucratic information requirements and certifications, and rounds of public comments. While we generally support providing public access, the very definition of a peer review is to collect assessments from experts. Adding repeated public comment periods is inappropriate for peer reviews and can only result in delaying important research.

D. Federal Advisory Committees (FAC)

There are many instances during the Bush administration in which candidates for advisory panels have been passed over, or members replaced, or resigned. While it is common for new administrations to replace members of these committees, there is a trend towards making sure that those people who might disagree with the administration's opinions are not appointed. The scientific community has often argued that by appointing people from the regulated industries as members of these committees, as the Bush administration has done consistently, the advice the committees offer to an agency might create real dangers to public health and safety.

In the fall of 2002, a series of reports and articles began to be published charging the administration with manipulation of these committees to assist hazardous substances manufacturers especially. [6] According to DefendingScience.org, a website of The Project on Scientific Knowledge and Public Policy,

> Groups accused the Bush Administration of manipulating activities in two federal committees advising the Centers for Disease Control and Prevention's National Center for Environmental Health (NCEH).
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> - Several well-respected scientists were dropped from the Pediatric Lead Poisoning Prevention Panel. Nominees suggested by staff scientists at CDC were rejected and replaced by individuals who later reported that the lead industry had contacted them initially to ask if they would be willing to serve on the committee.
> - Scientists employed by the chemical industry or industry advocacy groups, including the Heritage Foundation and the Annapolis Institute (established in 1993 by the National Association of Manufacturers to challenge EPA proposed regulations) replaced 15 of 18 renowned university-based scientists on the advisory committee to the Director of NCEH.

We've begun to see more resignations by respected scientists as these FACs have become more politicized. For example, last October, three of the fifteen members of the EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) resigned because they felt major problems with the Toxic Substances Control Act were not being addressed due to industry influence.

The impacts of this political approach to using FACs are real dangers to public health, safety and the environment. One example was provided in the February 6, 2007 testimony before the Senate Committee on Environment and Public Works of Dr. John Balmes, testifying on behalf of the American Lung Association.[7] The focus was on the changes EPA has made to the scientific review process for the National Ambient Air Quality Standards (NAAQS). EPA's Clean Air Scientific Advisory Committee (CASAC) participates in the review process of these standards. The review was a multi-step process the end of which was a Staff Paper reviewed by CASAC and open to public comment. According to Dr. Balmes testimony, " [m]any regard the preparation and finalization of the Staff Paper, which is done by EPA's scientific staff, as the

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[6] David Michaels, Eula Bingham, et al. "Advice Without Dissent", *Science*, Vol 298, 25 October 2002. p.703. (www.sciencemag.org, or http://www.defendingscience.org/public_health_regulations/upload/Advice-Without-Dissent.pdf).

[7] Dr. John Balmes testimony before the U.S. Senate Environment and Public Works Committee, February 6, 2007. Available at http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=78a52250-802a-23ad-4274-59a54b06a447

most crucial step" because it is the final analysis of the scientific information on which standards are based. It is not a political process.

According to Dr. Balmes testimony:

> It is the elimination of the Staff Paper that we fear will lead to the diminishment of science in the standard setting process. The staff paper is to be replaced with a "Policy Assessment" which according to a memorandum by EPA's Deputy Administrator Peacock, "reflect the Agency's views, consistent with EPA's practice in other rulemakings." However, the EPA does not set standards exclusively based on the protection of health using the latest scientific research in any other rulemaking. In sum, a unique standard demands a unique process, not EPA's "usual" practice. We believe the elimination of the Staff Paper is being done precisely because the science underlying protection of public health from air pollution is in conflict with what policy makers in EPA want to do in the implementation of the Clean Air Act. The elimination of the Staff Paper will make it easier for policy staff to fuzz the lines in public health protection and present the basis for alternative standards and the alternatives themselves in a way that favors the outcomes they are seeking rather than what the science says is needed. Substituting an Advanced Notice of Proposed Rulemaking for the Staff Paper will put policy make[r]s (sic) at EPA and the White House in the driver'[s] (sic) seat by enabling them to review and edit before it is reviewed by CASAC and the public.

The process has been specifically influenced by the American Petroleum Institute which suggested the Staff Paper be replaced with an Advanced Notice of Proposed Rulemaking, which the EPA has adopted. And the lead industry recommended that the Staff Paper be replaced by a new Policy Assessment which argues that lead should be eliminated as a criteria pollutant.

This is one example of the growing influence of regulated industries in the rulemaking process. Like the tools discussed above, FACs specifically, and the processes in which they are used, are being manipulated to achieve results desired by political considerations, not science, health, safety, or environmental protection.

E. Information Quality Act

The final issue I would like to address briefly is the Information Quality Act (IQA), or as it is often called, the Data Quality Act (DQA). This is an issue in the discussion of manipulation of regulatory tools because the guidelines issued by OMB regarding the use of the DQA has led to delays in the promulgation of public protections through challenges to the science agencies rely on to fulfill their mandates.

The DQA allows challenges to the information disseminated by agencies that can dilute, dismantle and remove essential pieces of the scientific information that go into creating a body of scientific knowledge. OMB published a report in 2004 evaluating the first year of implementation of DQA, a report that OMB Watch criticized as "inaccurate", "misleading", and "flawed". OMB understated the number of challenges, the source of those challenges (mostly industry), and drew conclusions about the impact of the DQA without the data to support its conclusions. OMB Watch's analysis shows that the Act has had a significant impact on agency actions, yet the law was added as a last minute rider without Congressional hearings.[8]

[8] OMB Watch. *The Reality of Data Quality Act's First Year: A Correction of OMB's Report to Congress*. July 2004. Available at http://www.ombwatch.org/info/dataqualityreport.pdf.

A report issued by the Congressional Research Service (CRS) calls for oversight and investigation of the impacts of DQA, a call OMB Watch argued for in our report as well. CRS recommends

> either Congress or OMB could better define the scope of the act or the issues to be included in any future report. Clarification could also be provided regarding whether correction requests that the agencies determine to involve issues outside the scope of the IQA (e.g., a challenge to the minutes of a federal advisory committee meeting) should be included in a report that is supposed to list correction requests under the act.[9]

III. Congressional Action

OMB Watch has several concerns about the trends in the regulatory process that have occurred over the last few decades. Societal problems have become more complex and their solutions are often less obvious and straight forward than, for example, a command and control approach. The role of the federal government has become more limited in its perspective of what is appropriate for government action. Responsibility has increasingly devolved to the states, or been the target of privatization. We believe that the time has come to change this limited government perspective to one in which the government plays a more positive role in protecting health, safety, environmental and civil rights safeguards. A major part of this movement to positive government must be a focus on the regulatory process.

The Bush administration has further reduced the federal government's general welfare protections by putting special interests' concerns above the general public's concerns. The problems outlined in this testimony have eroded the government's role in public protections. They have delayed, diminished or destroyed regulations that agencies are mandated to promulgate. There has been a sustained attack on scientific integrity – on the quality of scientific information, on the scientific expertise of agency professionals, and on the integrity of the scientific process. The tools have been manipulated and the executive order amendments just issued, coupled with the good guidance practices bulletin, have further established control of the regulatory process in the executive branch, and OIRA especially, at the expense of both congressional power and agency discretion.

The real loser, however, is the public. The regulatory process is highly partisan and politicized. In the end, less regulation means less protection. Instead of a regulatory "cop on the beat", we have none. Instead of addressing regulatory gaps, we operate based on whether these gaps have political consequences. Unfortunately, now government doesn't act until there is national news about people being hurt or, in the case mine workers, dying. If you are parents, you don't want to gamble that the weekend barbeque results in your child becoming ill or dying from *E. coli*. The point is, there are real consequences from these actions and inactions. Our government should be doing more, not less, to protect the public. The amended E.O. moves in the wrong direction.

Every year, more than 40,000 people die on our nation’s highways. Food borne illnesses kill an estimated 5,000 and sicken 76 million. Nearly 6,000 workers die as a result of injury on the job, with an additional 50,000 to 60,000 killed by occupational disease. And

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[9] Congressional Research Service *The Information Quality Act: OMB’s Guidance and Initial Implementation*. September 17, 2004. p. CRS-18. Available at http://www.defendingscience.org/public_health_regulations/upload/Congressional-Research-Service-Information-Quality-Act-Report-2004.pdf

asthma – linked to air pollution – is rising dramatically, afflicting 17 million, including six million children.

There is real danger to our constitutional system from this arrogation of power. Equally significant, in our opinion, is the real danger presented to the American public from the delay or refusal to regulate dangerous activities. I want to leave you with just one example of the danger.

The Transportation Recall Enhancement, Accountability and Documentation (TREAD) Act, passed by Congress in November 2000, required that "Not later than 1 year after the date of the enactment of this Act, the Secretary of Transportation shall complete a rulemaking for a regulation to require a warning system in new motor vehicles to indicate to the operator when a tire is significantly under inflated. Such requirement shall become effective not later than 2 years after the date of the completion of such rulemaking."[10]

The National Highway Transportation Safety Administration (NHTSA) determined that a direct tire pressure monitoring system should be installed in all new vehicles. OMB sent a return letter to NHTSA, after meetings with the auto industry, deciding this action was an inappropriate one, claiming its cost-benefit calculations provided a basis for delaying a requirement for direct systems. The final rule, issued May 2002, would have allowed automakers to install ineffective Tire Pressure Monitoring Systems (TMPS) and would have left too many drivers unaware of dangerously under-inflated tires. NHTSA was sued because its final rule would have allowed manufacturers to choose to install either an effective (direct) system or an inferior (indirect) system. In August 2003, the US Court of Appeals for the Second Circuit ordered NHTSA to rewrite the rule because NHTSA acted in an arbitrary and capricious manner by writing a standard that would allow installation of a clearly faulty (indirect) system.

In July 2004, the groups that had sued NHTSA returned to court because the agency had not issued a revised rule. In April 2005, NHTSA finally issued a rule requiring automakers to install tire pressure systems in all new passenger cars and trucks by the 2008 model year, beginning a phase-in with 2006 model year vehicles. The new rule, however, still does not meet the requirements set by Congress. Although better systems exist, the TPMS could allow tires to be 30 percent below proper inflation before the alert is provided, costing approximately 150 lives and countless injuries each year. In June 2005, Public Citizen, the Goodyear Tire & Rubber Company, Bridgestone Firestone North American Tire, Cooper Tire & Rubber Co., Pirelli and the Tire Industry Association, filed suit in the U.S. Court of Appeals for the District of Columbia, arguing that the new rule is inadequate and should be overturned. Tire pressure alert systems regulations that were required by law to be in place by the end of 2003 have, as the tire manufacturers legal action implies, not been adequately developed.[11]

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[10] Public Law 106-414, The Transportation Recall Enhancement, Accountability and Documentation Act, Nov. 2000. Section 13.

[11] For another example of the danger to the public from regulatory manipulation, see the testimony of John B. Stephenson, Director of Natural Resources and Environment, GAO, before the Senate Committee on Environment and Public Works, February 6, 2007. Available at www.gao.gov/cgi-bin/getrpt?GAO-07-464T. The summary findings read:

> Although we have not yet completed our evaluation, our preliminary observations indicate that EPA did not adhere to its own rulemaking guidelines when developing the proposal to change TRI reporting requirements. We have identified several significant differences between the

So what can Congress do address this process? First, if Congress concurs that the amendments to the Executive Order are as bad as we believe they are, it should act. Here are three areas to explore.

- Congress should explore the legality of the Executive Order amendments and their implementation.

- OIRA will need to provide guidance to agencies on implementing the market failure criteria. Congress could provide much needed oversight on this guidance to ensure OIRA does not create new standards or irresponsible requirements on agencies.

- Congress has the ability to alter the implementation of these amendments through a variety of vehicles, including the appropriations process. Congress should take a hard look at limiting agencies' and OIRA's spending on the specific elements of the amendments.

Second, we believe it is time for the debate over regulatory policy and process to turn toward the real need to increase public protections not protect special interest access and influence. Because this regulatory process has real consequences for our health and safety, Congress should explore legislative actions that put the regulatory presumption on safety first. Why should products and substances be approved for use before they have been determined to be safe? Why should the economics of regulation be the overriding, to the point of being nearly determinative, consideration to the exclusion of protecting the vulnerable populations like the elderly, the frail, children, and minorities exposed to flawed siting processes? Government and businesses have a responsibility to the public to uphold their parts of the social contract. Congress can lead the way by providing its critical oversight responsibilities and considering legislative proposals that renew the federal government's protection of the general welfare.

Thank you, Mr. Chairman, for providing me this opportunity to appear before you. I'm happy to respond to members' questions.

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guidelines and the process EPA followed. First, late in the process, senior EPA management directed the inclusion of a burden reduction option that raised the Form R reporting threshold, an option that the TRI workgroup charged with analyzing potential options, had dropped from consideration early in the process. Second, EPA reviewed this option on an expedited schedule that appears to have provided a limited amount of time for conducting various impact analyses. Last, the decision to expedite final agency review, when EPA's internal and regional offices determine whether they concur with the final proposal, appears to have limited the amount of input they could provide to senior EPA management.

Appendix:

Preliminary Analysis of the Amendments Executive Order 12866 on Regulatory Planning and Review

Undermining Public Protections

Preliminary Analysis of the Amendments to Executive Order 12866 on Regulatory Planning and Review

On January 18, President Bush issued amendments to Executive Order (E.O.) 12866, which further centralize regulatory power in the Office of Management and Budget (OMB) and shift it away from the federal agencies given this power by legislative enactments. Among the changes to the E.O.:

- It shifts the criterion for promulgating regulations from the identification of a problem like public health or environmental protection to the identification of "…the specific market failure (such as externalities, market power, lack of information)…that warrant new agency action."
- It requires guidance documents to go through the same OMB review process as proposed regulations before agencies can issue them.
- It also requires "significant" guidance documents (those that are estimated to have at least a $100 million effect on the economy, among other criteria) to go through the same OMB review process as "significant" regulations.
- It makes the agencies' Regulatory Policy Officer a presidential appointment and gives that person the approval authority for any commencement or inclusion of any rulemaking in the Regulatory Plan unless specifically authorized by the agency head.
- It requires each agency to estimate the "combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities," which will be overseen by the Regulatory Policy Officer.

By-Passing Congress With New Policies

Through amending the regulatory process, the President is institutionalizing an anti-regulatory approach by using a market failure criterion in place of actually identifying threats to public health and safety. It diminishes standards Congress may have required agencies to use, such as the best control technology, by elevating a new market failure standard that Congress never required. This standard has been advocated by Susan Dudley, Bush's current nominee as administrator of the Office of Information and Regulatory Affairs (OIRA). Dudley's extreme views on the use of free market standards were well-documented during her failed confirmation last year. Despite the failure to confirm her, the administration has used the Executive Order as a backdoor means to implement the Dudley philosophy.

The market failure criterion is yet another layer added to the agency analysis. The agency must comply with the statutory criteria (such as best available technology) as well as an analysis demonstrating market failures. If the agency meets OMB's standards for assessing "whether any new regulation is warranted," then the agency must also comply with other standards in the E.O., including cost-benefit analysis.

This new standard decidedly favors the regulated community and places yet another hurdle for agencies to issue regulations in pursuit of protecting the public.

More White House Control; More Delay

By requiring agency guidance documents to come under OIRA review, and to treat "significant" guidance in the same way as "significant" regulations, the E.O. amendments will lead to further delay in providing information to the public about compliance with regulations, as well as with general guidance on agency policies.

It may be true that more and more agencies are using guidance as a means of avoiding the regulatory process. But that should be a signal to Congress and the public that the rulemaking process is seriously flawed. Agencies are looking for faster ways of doing their job and have turned to guidance. The solution is certainly not to require guidance to go through the same regulatory process that agencies were trying to avoid in the first place.

In the end, this will simply result in more delay and more White House control over the substantive work of the agencies. It will inevitably lead to a usurpation of agencies' powers.

The Foxes Controlling the Hen Houses

The Bush administration has regularly appointed industry representatives or allies to oversee agency regulatory activities. Often this has been dubbed "foxes in the hen house." The E.O. amendments add a new dimension by having the foxes control the hen houses.

The amendments require each agency to have a Regulatory Policy Office run by a political appointee and that "no rulemaking shall commence nor be included" for consideration without the political appointee's approval. This will further politicize the rulemaking process and provide more White House control over the agency rulemaking process.

A similar approach was attempted by President Reagan through his E.O. 12498, the Regulatory Planning Process, which was issued January 4, 1985. Under E.O. 12498, agencies were to get approval from OMB prior to starting a rulemaking – a pre-rulemaking review. Many in the business community thought this would be a wonderful approach for choking off agency ideas before they ever really got going. That approach, however, proved too cumbersome and difficult to administer; in short order, it failed.

The new Bush E.O. amendments have the same objective, but put the chokehold in the agencies, instead of at OMB. To ensure that the process works, OMB grants authority to these new political appointees to be the eyes and ears for OMB.

Laying the Groundwork for a Regulatory Budget

The E.O. amendments also require regulatory proposals that are to be submitted to the Regulatory Policy Officer to include "aggregate costs and benefits" during the calendar year. Most experts agree that aggregating all costs and benefits is like comparing apples and oranges – and in the end has little value except to create large numbers intended to scare the public.

Another possible reason to require such information is to begin laying the groundwork for establishing a regulatory budget. This concept, proposed by conservatives since the Reagan

administration, has been criticized by Congress and never approved. Yet the amended E.O. begins to move in this direction.

Pre-Rulemaking Review

The amendments to the E.O. allow OIRA to play an active role during the pre-rulemaking stage when agencies are formulating annual plans for regulatory activities. By having OIRA involved in agencies' planning process, OIRA can quash any contemplated regulatory or guidance issues before they get proposed for the Regulatory Plan. Under the amended E.O., OMB can now engage the agency, along with other government personnel (as provided for in one amendment), in reaching a “common understanding” on regulatory efforts.

Conclusion

The revised Executive Order that results from these amendments is a further threat to public protections from an administration committed to elevating special interests over public interests. It codifies regulatory delay, further removes agency discretion over legislative implementation, and centralizes control over the regulatory process into a small executive office. It substitutes free market criteria for the public values of health, safety, and environmental protections, and substitutes executive authority for legislative authority.

We can only speculate as to why the President has issued these amendments at this time in his presidency. With Congress now in control of Democrats, it is unlikely that further anti-regulatory efforts will be supported or ignored by a compliant Congress. It is a surprising action to take in light of the Dudley nomination now pending before the Senate. It may be an admission by the administration that the nomination is not likely to succeed, and that the President has decided to advance the Dudley philosophy through the back door.

Prepared on January 18, 2007