OMB WATCH

A Failure to Govern:

Bush's Attack on the Regulatory Process

An OMB Watch report

March 2007

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Acknowledgements

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About OMB Watch

OMB Watch, a nonprofit research and advocacy organization, was formed in 1983 to lift the veil of secrecy shrouding the White House Office of Management and Budget (OMB).

OMB Watch exists to increase government transparency and accountability; to ensure sound, equitable regulatory and budgetary processes and policies; and to protect and promote active citizen participation in our democracy.

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Executive Summary

On January 18, 2007, the Bush White House released two documents that will take effect in late July. The documents will change the current regulatory review process conducted by federal agencies and the Office of Management and Budget (OMB). This report describes the changes and analyzes the potential impacts on the regulatory system.

One document, Executive Order 13422, amends Executive Order 12866, which currently prescribes the review process. The amendments to E.O. 12866 will further centralize regulatory power in OMB's Office of Information and Regulatory Affairs (OIRA), shifting it away from agencies that are granted this power by legislative enactments. Among the changes:

- The executive order shifts the criterion for promulgating regulations from the identification of a problem like public health or environmental protection to the identification of a "specific market failure (such as externalities, market power, lack of information)…that warrant new agency action."
- It makes the agencies' Regulatory Policy Officer a presidential appointee and gives that person the authority to approve any commencement or inclusion of any rulemaking in the Regulatory Plan, unless specifically otherwise 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."
- It requires "significant" guidance documents to go through the same OMB review process as proposed regulations before agencies can issue them.
- It also requires "economically 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.

The new Executive Order that results from these amendments will further threaten public protections. 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 public values of health, safety, and environmental protections, and substitutes executive authority for legislative authority. In the process, it further tilts the regulatory playing field in favor of corporate interests.

The second document is OMB's Final Bulletin for Agency Good Guidance Practices. The Bulletin sets forth policy and procedures agencies should follow internally when formulating guidance documents. The Bulletin works in concert with the amendments, outlining ways in which agencies can write guidelines that better meet the new E.O. procedures. This report addresses the Bulletin in a separate section.

BACKGROUND

The Federal Rule Making Process

The growth in the number of federal agencies during the administration of President Franklin D. Roosevelt resulted in a proliferation of rulemaking. Subsequently, Congress created a framework for regulatory procedure in 1946: The Administrative Procedure Act (APA).

The APA defines a "rule" as:

> [T]he 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…

The APA also outlines two types of rulemaking; formal and informal. Formal rulemaking calls for a trial-like, on-the-record proceeding. However, informal rulemaking is far more common. According to the APA, the main requirements for informal rulemaking are:

- Publication of a "Notice of Proposed Rulemaking" (NPRM) in the Federal Register;
- Opportunity for public participation by submission of written comments;
- Consideration by the agency of the public comments and other relevant material; and
- Publication of a final rule not less than 30 days before its effective date, with a statement explaining the purpose of the rule.[1]

In 1981, and again in 1985, President Ronald Reagan signed executive orders placing the White House Office of Management and Budget (OMB) squarely in the middle of the federal regulatory process. The Reagan executive orders called for regular agendas of agency regulatory action; cost-benefit analyses of proposed rules and alternatives; a detailed review of major rules performed by OMB's Office of Information and Regulatory Affairs (OIRA); and an annual agenda of proposed regulations that reflected the administration's regulatory priorities. OIRA became the coordinating entity for these actions. [2]

Executive Order 12866

On September 30, 1993, President Bill Clinton signed Executive Order 12866 – Regulatory Planning and Review. E.O. 12866 replaced the two Reagan executive orders by combining and revising them. E.O. 12866:

- States a regulatory philosophy and set of principles for the federal government;
- Defines the regulatory roles of federal agencies, OMB, and the Executive Office of the President;
- Outlines a process for the coordination of regulatory priorities;
- Requires of each agency the regular development of a regulatory agenda (the Unified Regulatory Agenda) and a list of planned significant regulatory actions (Regulatory Plan);
- Calls for the formation of a Regulatory Working Group to include agency, OMB, and Executive Office personnel;
- Outlines the process by which OIRA will conduct reviews of both regulations and significant regulations; and
- Creates within each agency the position of Regulatory Policy Officer to shepherd regulations.

Much like the Reagan executive orders before it, E.O. 12866 became standard operating procedure for federal rulemaking. It does not supplant the Administrative Procedure Act, but adds to it in a way that allows the White House to exert substantial influence at various stages in the rulemaking process.

Industry Influence

Over the past three decades, there has been a concerted deregulatory effort led by industry and industry associations. The argument against regulations is that they are costly, too burdensome, and hurt the competitive stance of US companies compared to international companies. The argument is much the same today[3] despite significant evidence to the contrary.[4] Nevertheless, the myths about regulatory burdens continue to be voiced. Increasingly, the regulatory process, especially executive orders that mandate the development and review of agency-promulgated regulations, has become more focused on calculating regulatory costs to the private sector.

In addition, OMB Watch, other public interest groups and the media have documented the unusually business-friendly attitude of the current Bush administration. From the development of its energy policy early in its first term by Vice President Cheney's Energy Task Force to nominating and placing industry representatives in critical regulatory positions, this administration has opened the door to allowing regulated interests control over writing and influencing regulations.[5]

AMENDMENTS TO E.O. 12866

Introduction to the Amendments

President George W. Bush's administration operated under E.O. 12866 without substantial amendment until January 2007. The administration made a minor modification on February 26, 2002, to exclude the Vice President from regulatory planning and review, giving those responsibilities to the Director of OMB. This change did not have a substantive effect on the rulemaking process.

On January 18, 2007, Bush issued Executive Order 13422, which amended E.O. 12866. The amendments will change several aspects of the federal government's regulatory process when they take effect in late July 2007. This report focuses on four of those changes:

- Increasing the emphasis on the determination of a "specific market failure" before regulating;
- Adding an aggregated costs and benefits component to the cost-benefit analyses agencies must perform for the annual Regulatory Plan;
- Expanding the role of agencies' Regulatory Policy Officer, and mandating those officers be presidential appointees;
- Expanding OIRA's influence over agency guidance documents, in tandem with the release of OMB's Good Guidance Practice Bulletin. (This change is addressed in the section on "Guidance Documents" below.)

Market Failure Criterion

Section One of E.O. 12866 is the "Statement of Regulatory Philosophy and Principles." It is a broad Clinton administration dictate outlining when regulation is necessary and how agencies should go about developing and promulgating rules.

The first principle listed in Section One relates to the identification of problems in need of regulation. The identification of problems is to include "where applicable, the failures of private markets or public institutions that warrant new agency action." The E.O. gives no further guidance on identifying problems, market failures or otherwise.

The Bush amendments altered the first principle of regulation to state: "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."

The original E.O. 12866	Amended E.O. 12866
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.

Impact

The revision places an added emphasis on identifying a market failure before regulating. The new language will institutionalize an anti-regulatory approach by using a market failure criterion in place of actually identifying threats to public health and safety. It will diminish standards Congress requires agencies to use, such as the best control technology, by elevating a new market failure standard Congress has never required.

The market failure criterion will be yet another layer added to agency analysis. An agency must comply with statutory criteria 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. This new standard will favor the regulated community by placing another hurdle for agencies promulgating health, safety, and environmental regulations, and creating more delay.

Not only will the market failure test be 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 will force the agency to reconsider inaction and will provide OIRA with another justification, or assessment, for halting or

delaying regulations. The regulatory process set out in prior executive orders applies after Congress has passed legislation determining that a problem exists and needs to be addressed. Although Congress may legislate, without implementing regulation, agencies may not be able to enforce the law. Thus, OIRA will be able to stifle regulations of which it disapproves – or at least shape them in ways that are less objectionable to OMB.

Furthermore, the definition of "specific market failure" in this context is unclear. The amendment gives only examples: externalities, market power, lack of information. Economic interpretations of the definition of market failure vary greatly. Interpretations on when government should intervene vary as well, ranging from government action only on free-rider problems (such as national defense) to intervention any time the market is operating with inefficiency.

> "The amendments will further substitute economics for all other values the American public consistently says are important."

A number of questions and concerns are associated with the market failure criterion. Do market failures exist when invaluable public goods, such as civil rights, are threatened? Even if a regulation proves cost-effective, will agencies be able to regulate absent a market failure? OMB Watch believes that the market failure criterion is a furtherance of the economic criteria which OIRA has increasingly required over three decades as justification for taking regulatory action. The amendments will further substitute economics for all other values the American public consistently says are important.

The language of this revision may be purposefully vague. The current nominee to head OIRA, Susan Dudley, holds an interpretation of market failure that falls outside of any mainstream economic definition. Dudley rarely acknowledges any market inefficiency. She is more likely to presume the public has chosen an unsafe or unhealthy status quo than recognize the unchecked excesses of the free market as threatening the public.[6] If the Senate does not confirm Dudley, the E.O. amendments will become a way to implement her ideas and, in effect circumvent the will of Congress.

Presumably, federal agencies are also perplexed over how to implement the new market failure assessment. Some in the agencies have wondered whether it will be possible to prove a market failure or, if that is not what OMB intends, then exactly what specific analyses will be required of them. At least one agency employee hoped that this requirement

becomes nothing more than submitting boilerplate language to OMB about the market failure analysis. "It's just going to be more paperwork," the employee lamented.

Clarity on what OIRA expects from agencies will likely come in the form of guidelines on how to interpret this market failure criterion. This guidance needs to be closely monitored when it appears.

The Regulatory Plan

E.O. 12866 requires each agency to "prepare a Regulatory Plan (Plan) of the most important significant regulatory actions the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter." The Plan is included in the fall publication of the semiannual Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda).

The Plan is more focused than the Unified Agenda. Whereas the Unified Agenda is to include "all regulations under development or review," the Plan includes only "significant" regulations. Significant regulations, those expected to have "an annual effect on the economy of $100 million or more," require a more detailed submission of information to OIRA. Significant regulations are pared even further so that only the "most important" are included in the Plan. Additional requirements associated with each rule in the Plan include a statement of need and may include a summary of legal basis, alternatives to the proposed regulation, anticipated costs and benefits, and risks.

The anticipated costs and benefits section should provide a brief description of the impact the regulation is expected to have on agencies, industry, and the public. When possible, agencies often include dollar amounts to quantify these expectations, and often a quantified net impact on the economy.

Bush's amendments add a component to agencies' work on anticipating costs and benefits. As amended, the E.O. will now require agencies to submit a "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."

Agencies will now be required to develop a summation of the economic impact of all regulations included in the Plan. Presumably, each agency will quantify a combined net cost or benefit for all of the regulations the agency proposes to develop in a given year. OIRA will include the agencies' estimates in the Plan each year.

Impact

Requiring agencies to prepare an "estimate of the combined aggregate costs and benefits" of planned regulations for the calendar year may have an impact on agencies' ability to develop and promulgate regulations. This is simply a numbers game with little relevance to policymakers. The aggregation of costs and benefits is comparing apples to oranges. Each analysis employs different assumptions, methodologies, and time comparisons. Many have speculated that this is merely a political exercise to generate numbers to be used to attack regulations. Some have noted that this provides the foundation for establishing a "regulatory budget," an idea long championed by conservatives but opposed in Congress.

> "OIRA appears to be imposing the early stages of a regulatory budget policy and, in doing so, circumventing Congress."

The idea of anticipating costs and benefits of regulations has been popular for decades. Proponents present it as a reasonable way of determining whether or not regulations will benefit the public. However, determining costs and benefits is too inaccurate a process. The calculation of benefits of a regulation requires two separate analyses: an assessment of the risk posed by the harm in question, and a monetization of the potential benefits. Both factors are 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 these data the potential benefits of a regulation requires a large degree of estimation, and agencies often come up with wide ranging results on the potential health benefits.

Furthermore, costs are often overestimated because the agencies rely on industry estimates of costs for unknown requirements, and studies have shown that compliance costs decline after implementation of regulations.

The estimate of costs and benefits is a static analysis. The outcome of regulation may include benefits that inherently cannot be monetized, such as biological diversity, civil liberties, or the safety and life of a human. Therefore, a combined assessment of the cost and benefits of an agency's entire regulatory agenda will produce an unreliable product. By viewing valuation through such an economic lens, benefits of regulation are likely to be underestimated.

The estimate required by each agency is a necessary early step in the development of a regulatory budget. A regulatory budget is a cap on the impact agencies may levy on the economy when developing and enforcing regulations. When the cap is reached, regulations perceived to have a negative economic impact would have to be eliminated. Similarly, development of new regulations presented as imposing a net cost would cease.

Determining costs imposed on the economy for comparison to a regulatory budget cap would require an aggregation of the costs and benefits of all federal regulations in order to derive a net monetization. Gathering the "combined aggregate costs and benefits" of regulation may lead to such a federal-wide evaluation. Again, regulatory decisions are based on economics, without regard to health and safety issues.

Recently, there have been two major efforts to impose a federal regulatory budget through legislation. The first came in 1995 as a part of the Republican Contract with America. Under the plan, the cap would have been set as a percentage of GDP. That percentage would then have been reduced by a set amount each year – an automatic annual regulatory budget cut. The second came in 2003 when Rep. Doug Ose (R-CA) introduced legislation to create regulatory budget pilot programs in several agencies. Neither bill became law.

With Congress now in Democratic control, passage of such legislation is unlikely. Through this amendment to E.O. 12866, OIRA appears to be imposing the early stages of a regulatory budget policy and, in doing so, circumventing Congress.

The Regulatory Policy Officer

E.O. 12866 created the Regulatory Policy Officer (RPO) within each federal agency who reports generally to the agency head. The E.O. states:

> "The Regulatory Policy Officer shall be 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 this Executive order."

The role of the RPO envisioned in E.O. 12866 is to coordinate and carry out agency responsibilities in regard to regulatory planning and the OIRA review of regulations. These responsibilities include: allowing "meaningful" public participation in the regulatory process; informing stakeholders of pertinent regulations; providing OIRA with a list of planned regulatory actions; providing OIRA

with cost benefit analyses for significant regulatory actions; and making available to the public information on proposed and final regulations.

In practice, the role of the RPO evolved in a somewhat different fashion. Currently, not every agency maintains one designated RPO. In the case of the Department of Agriculture (USDA), various officials serve as de facto RPOs. Familiarity with the issue is likely to determine where responsibilities lie on a specific regulation. In the Department of Energy, the RPO also functions as an agency counselor. The RPO is not necessarily a political appointee, but the final regulatory decisions within an agency are in the hands of a political appointee, usually the agency head or his or her designee.

> "The [RPO] amendments suggest a further politicization of the regulatory process."

Two of President Bush's amendments impact the Regulatory Policy Officer. Agencies are now required to designate a political appointee as their RPO, and are to do so within 60 days of the issuance of the amendments. New text also requires OMB to verify this designation.

In addition to changing the requirements of the designated RPO, the Officer's responsibilities are increased. The RPO will now be charged with approving an agency's Regulatory Plan, a responsibility previously given to the agency head. The amendments state that "no rulemaking shall commence nor be included" for consideration in the agency's regulatory plan without the political appointee's approval. The Regulatory Plan includes the most important regulations which an agency plans in a given year.

Impact

Installing a political appointee as the Regulatory Policy Officer and increasing the responsibilities of the RPO may significantly affect an agency's ability to regulate. Bush's amendments will solidify the position of RPO as the sole regulatory manager within each agency. By requiring the Officer to be a political appointee, and approved by OMB, the amendments suggest a further politicization of the regulatory process.

In some agencies, the amendments related to the RPO may have little to no effect. In the case of the Department of Energy, the RPO is already a political appointee. The White House is unlikely to have a greater or lesser impact on the way in which regulations are formulated within that agency. Similarly, the process in the Department of Labor is likely to go unchanged.

In other agencies, however, the RPO amendments may centralize the regulatory process and allow OIRA to exert greater influence. In the case of USDA, the RPO amendments, if followed, will end the process of dividing regulatory authority based upon experience and expertise. Instead, the RPO will ultimately be responsible for all regulatory decision making and be involved in regulatory discussions from the beginning of agency considerations. Furthermore, installing a political appointee where one did not previously exist will facilitate White House input in agency regulatory matters.

> "Installing a political appointee where one did not previously exist will facilitate White House input in agency regulatory matters."

A similar approach was attempted by President Reagan through his E.O. 12498, the Regulatory Planning Process, 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 an effective approach for choking off agency ideas in their earliest stage. That approach, however, proved too cumbersome and difficult to administer.

The new Bush E.O. amendments have the same objective, but will 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. When 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 will create a process that works 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.

Moreover, a requirement that has political appointees overseeing all regulatory matters raises a public perception concern. When a political appointee instructs scientists and agency experts to change what they are doing, it will raise questions about whether politics is superseding science.

GUIDANCE DOCUMENTS

Introduction to Guidance Documents

Agencies issue guidance documents in order to clarify regulatory obligations to industry, explain complex technical issues or otherwise offer clarification or guidance on agency policies. Because the regulatory process has become so encumbered over the past several decades with increased analytical burdens, agencies have turned more frequently to guidance documents as a way of providing direction to regulated communities without being subjected to a lengthy and onerous rulemaking process. Unlike a regulation, guidance is not legally binding and therefore imposes no mandates on regulated entities.

On January 18, the White House put forward two pronouncements aimed at applying greater levels of scrutiny to agency's issuance of regulatory guidance. First, E.O. 13422, in addition to the regulatory changes described above, requires review of economically significant guidance documents by OIRA. Second, the Final Bulletin for Agency Good Guidance Practices issued by the Office of Management and Budget (with authority under the Data Quality Act) requires internal review of significant guidance documents by senior agency officials as well as public notice-and-comment on guidance documents deemed "economically significant."

Amendments to E.O. 12866 on Guidance Documents

The amendments issued to E.O. 12866 require review by OIRA of agencies' guidance documents for the first time.

Definitions added

Section 3(g) is added to E.O. 12866 and defines a guidance document as "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."

Section 3(h) defines a significant guidance document as "a guidance document disseminated to regulated entities or the general

public that, for purposes of this order, 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 this Executive order".

Beyond this definitional section, a new section is added to the end of the E.O.:

> Sec. 9. Significant Guidance Documents. Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notification of any significant guidance documents. Each agency shall take such steps as are necessary for its Regulatory Policy Officer to ensure the agency's compliance with the requirements of this section. Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when additional consultation will be required before the issuance of the significant guidance document.

Good Guidance Practices Bulletin

On Jan. 18, the White House Office of Management and Budget issued its Final Bulletin for Agency Good Guidance Practices (Bulletin). The Bulletin further clarifies the definition of significant guidance documents as well as instructs agencies on "policies and procedures for the development, issuance, and use of significant guidance documents."

The Bulletin's release was not as surprising as that of the E.O. amendments. In fact, a draft E.O. had been circulating within the agencies that appeared to focus only on

the Bulletin changes. However, it appears the E.O. changed to include other items discussed in this paper after agency reviews of the drafts.

The Bulletin first appeared in its proposed form late in 2005. It was announced in the Federal Register on Nov. 30, 2005, and was opened for public comment.[7] In those comments, public interest groups (including OMB Watch) criticized the Bulletin for its potential to allow OMB to interfere unnecessarily in agency practices. Industry organizations expressed their support for the Bulletin, citing their desire for OIRA to review guidance documents in the same way it reviews regulations.

Definitions Added

The Bulletin defines guidance documents to include "interpretive memoranda, policy statements, guidances (sic), manuals, circulars, memoranda, bulletins, advisories, and the like." Federal agencies issue thousands of guidance documents each year relating to hundreds of different types of activities.

As Section 9 of the amended E.O. also clearly states, the OIRA administrator has the power to determine which guidance documents are significant, thus submitting them to the review process, as well as when "additional consultation" is needed before a document can be issued. Section I(4) provides that the head of an agency, "in consultation and concurrence" with the OIRA administrator, may exempt categories of significant documents from the Bulletin's requirements.

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. This language applies to all four conditions in the definition of significant guidance document, and the Bulletin "makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules."

Impact

The new policies will place agency guidance documents squarely under the authority of the administration via OIRA. By subsuming guidance documents to 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, as will the influence and access of regulated sectors. All of the documents deemed significant will now come under review by OIRA's staff of 55 people.

The fourth part of this definition, raising "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. As a result, the administration has redefined the APA, which specifically exempts interpretive rules and policy statements from the notice-and comment process.

> "Subjecting guidance documents to requirements similar to the rulemaking process will undermine much of [their] utility."

Reasons for Incorporating Guidance Documents into OMB Regulatory Process

The Bulletin provides the justifications for including guidance documents. One reason is that too many of the documents are "poorly designed or improperly implemented," and they "may not receive the benefit of careful consideration" that would come from the equivalent of the regulatory review process. At the least, this is judging the documents by a different standard – OIRA's standard – and not the standard that experts in the agencies might use. At the worst, it impugns the competence of those agency employees responsible for developing guidance.

Another justification is that because "it is procedurally easier to issue guidance documents, there also may be an incentive for regulators to issue guidance documents in lieu of regulations." From the agencies' perspective, this might occur because it presents the opportunity to have people knowledgeable about the issue provide guidance to those being regulated. This differs from the regulatory process because of OIRA's intervention in and monitoring of the development of rules. Subjecting guidance documents to requirements similar to the rulemaking process will undermine much of the utility of guidance documents without addressing the reasons agencies are turning to guidance rather than using the convoluted regulatory process.

Implications on Agency Practices

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 the 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 language defining significant and economically significant guidance documents – those that "may reasonably be anticipated to lead to" the four conditions in the definition – will allow OIRA to include in its review and/or will require agencies to analyze nearly any significant guidance document OIRA wishes to review, hinder, or stop. 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 or regulated industries. Coupled with the "economic impacts" language described above, OIRA will have the potential to keep the agencies in an endless loop of analysis and lead to endless regulatory delays.

"OIRA will have the potential to keep the agencies in an endless loop of analysis and lead to endless regulatory delays."

During the public comment period, several commenters wondered what might be an example of an "economically significant guidance document." The Bulletin provides this example:

> Similarly, an agency might make a pronouncement about the conditions under which it believes a particular substance or product is unsafe. While not legally binding, such a statement could reasonably be anticipated to lead to changes in behavior by the private sector or governmental authorities such that it would lead to a significant economic effect. Unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures of section IV.

Determining the safety of a substance or product involves some scientific assessment. In reviewing scientific conclusions, OIRA will have the opportunity to substitute an economic analysis for a scientific one, and manipulate the scientific findings in the process. This substitution, or even second-guessing the scientific judgment, could lead to substantial delays in protecting the public.

For example, the Centers for Disease Control and Prevention

(CDC) recently issued guidance regarding actions businesses, urban governments, and school districts should take if an influenza pandemic occurs before a vaccine becomes available. The CDC planning document's wide-ranging recommendations could easily have a significant economic impact, which would trigger a review by OIRA under the new requirements and cause months of delays. If OIRA so chooses, the impacts of delaying regulations and guidance could affect a broad range of public protections.

After internal approval, the agency will send drafts of significant guidance documents to OIRA for review. Unlike the detailed procedures for OIRA's review of regulations, the procedures for OIRA's review of guidance is relatively vague. The Regulatory Policy Officer is responsible for ensuring that the agency sends a draft of the significant guidance to OIRA, along with an explanation of the need for the guidance and how the guidance document will meet that need. OIRA will "notify the agency when additional consultation is required before the issuance of a significant guidance document."

Beyond this grant of authority, there is little explanation in the Bulletin of OIRA's role in the review process. There are no timelines for completing the review, and there is vague language about the administrator's ability to exempt guidance for an emergency or "other appropriate consideration."

While the Bulletin itself is relatively vague, OMB hints as to how it plans to enforce the bulletin in the preamble. For instance,

- OMB states that the term "guidance document" "is not limited only to written guidance materials and should not be construed as such. Online databases, power point presentations or other materials used to communicate guidelines would also be subjected to the bulletin."
- OMB excludes "opinion letters or letters of interpretation prepared for or in response to an inquiry from an individual person or entity" from the definition of significant guidance, such as letters sent by the Department of Labor's Wage and Hour Division to employers seeking advice on wage and hour laws. OMB also excludes service announcements from the National Weather Service. However, the definition of significant guidance put forward in the bulletin would still seem to include these categories of guidance, and it would be up to the discretion of OIRA to disqualify them as such.
- More startling, OMB declares that agency pronouncements on substance or product safety could constitute "economically significant guidance." This assessment could set a dangerous standard, forcing agencies to go through burdensome procedures before

alerting the public to a potential health or safety hazard. How OMB decides that Weather Service announcements don't require significant review but consumer product warnings do is unclear.

- OMB also suggests that the agency might decide to go through multiple drafts before issuing a final guidance, potentially extending the process indefinitely:

After providing an opportunity for comment, an agency may decide, in its discretion, that it is appropriate to issue another draft of the significant guidance document. The agency may again solicit comment by publishing a notice in the Federal Register, posting a draft on the Internet and making the draft available in hard copy. . . In addition, the response-to-comments document should address the additional comments received on the revised draft.

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' authority.

Public Participation

The public feedback section of the Bulletin creates an agency notice-and-comment procedure for significant guidance documents that parallels the procedure used for regulations. Each agency must establish an electronic means of allowing public comment and requesting changes to significant and economically significant guidance documents, and provide a complaints office where concerns over "problematic guidance documents" can be directed. "At any time, the public also may request that an agency modify or rescind an existing significant guidance document." Although a formal response to comments is not required, the agency may "in consultation with the Administrator" of OIRA decide to respond to comments by "updating or altering the significant guidance document."

The notice-and-comment procedures don't have to be used, however, even though the public may request changes. The procedures provide regulated industries especially with a chance to argue against or to modify guidance. With its superior resources and access to electronic procedures, the Bulletin builds in access advantages for the regulated industries as it has done with the regulatory process. The Bulletin urges agencies to provide "pre-adoption notice-and-comment procedures" because "providing pre-adoption opportunity for comment on significant guidance documents can increase the quality of the guidance and provide for greater public confidence in and acceptance of the ultimate agency judgments." No doubt OIRA will recommend a notice-and-comment opportunity

when it wants to delay issuance even if the agency thinks it's unnecessary or impractical.

The process for economically significant guidance documents requires a notice-and-comment procedure and a "robust response-to-comments document". Unlike the process for significant guidance, this section requires an APA-like process. If an agency decides "in its discretion" to issue another draft of the economically significant guidance, then publication, notice-and-comment, and response-to-comments procedures commence again.

CONCLUSION

The Bush administration has further reduced public protections by putting special interests' concerns above the general public's concerns. For six years, administration appointees have manipulated how agencies use regulatory tools such as cost-benefit analysis and peer review. They have delayed, diminished or destroyed regulations Congress mandated agencies to promulgate.

The administration has consistently attacked the quality of scientific information, the scientific expertise of agency professionals, and the integrity of the scientific process at large.

The executive order amendments, coupled with the good guidance practices bulletin, have further concentrated control of the regulatory process in the White House, especially in OIRA, at the expense of both the separation of powers and agency discretion.

By bringing agency guidance documents under OIRA review, these amendments to the E.O. will lead to further delay of regulatory implementation. They will place the technical interpretations of legislative mandates not with the agencies but with OIRA – a clear usurpation of agencies' authority.

The real loser, however, is the public. 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, there are real consequences from these actions and inactions for public protections. Our government should be doing more, not less, to protect the public. The amended E.O. and guidance bulletin move the regulatory process in the wrong direction.

Every year, more than 40,000 people die on our nation's highways. Foodborne 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 asthma – linked to air pollution – is rising dramatically, afflicting 17 million, including six million children.

The amendments and the guidance bulletin go into effect in late July, and only then will we be able to gauge the full impacts of the changes. In the meantime, look for OIRA to issue guidance to agencies clarifying the new amendments, probably by amending Circular A-4, Regulatory Analysis, which is the current directive used by the agencies. We urge Congress to give tough scrutiny to any new directive OIRA releases and continue oversight of these important regulatory issues.

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.

Endnotes

1. OMB Watch, *Through the Corridors of Power*, 1987

2. OIRA was created by the 1980 Paperwork Reduction Act (PRA). Although established by law to implement the PRA, from its first day it also had responsibility for implementing regulatory review functions as prescribed by the president.

3. See for example, the testimony of William L. Kovacs, Vice President, U.S. Chamber of Commerce, at a Joint Hearing Before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, and the Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, U.S. House of Representatives, *Amending Executive Order 12866: Good Governance or Regulatory Usurpation?* February 13, 2007. Available at: http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/13feb/kovacs_testimony.pdf

4. OMB Watch, *Regulation and Competitiveness: Regulatory Policy issue Brief*, February 2006. The brief cites the considerable body of literature which counters these industry arguments. Available at: http://www.ombwatch.org/regs/compete/regandcompetitiveness.pdf.

5. OMB Watch has documented this on-going process. (See http://www.ombwatch.org/article/archive/235). See for example, *The New York Times* (http://www.nytimes.com/2007/03/09/business/09tax.html) about tax regulations being outsourced to the regulated industry, and *The Washington Post* (http://www.washingtonpost.com/wp-dyn/content/article/2007/03/11/AR2007031101197.html) about the financial industry fighting regulations in the post-Enron era.

6. This philosophy was evident in her comments on airbags while employed by the Mercatus Center: "If 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." Dudley believes the free market should be given time to correct problems even when a simple regulation, such as requiring airbags in new cars, could quickly and dramatically improve public safety. (From: 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. Document no longer available; see Public Citizen and OMB Watch , *The Cost is Too High: How Susan Dudley Threatens Public Protections*. (Sept. 2006), p. 17, available at: http://www.ombwatch.org/regs/2006/dudleyreport.pdf)

7. The proposed bulletin is available at: http://www.ombwatch.org/regs/2005/guidancebulletin_draft.pdf. Comments on the bulletin made by Citizens for Sensible Safeguards (a coalition run by OMB Watch) are available at: http://

List of External Appendices

APPENDIX 1: Text of E.O. 12866 as amended by E.O. 13422

Executive Order 12866 of September 30, 1993, as amended by E.O. 13258 of February 26, 2002 and E.O. 13422 of January 18, 2007: REGULATORY PLANNING AND REVIEW (http://www.sba.gov/advo/laws/eo12866.pdf)

APPENDIX 2: Text of E.O. 12866 with all parts stricken and parts added highlighted

Executive Order 12866 of September 30, 1993, as amended by E.O. 13258 of February 26, 2002 and E.O. 13422 of January 18, 2007. The original text of E.O. 12866 remains, with parts stricken and parts added by the two subsequent executive orders highlighted. (http://www.ombwatch.org/regs/PDFs/EOchangeshighlighted.pdf)

APPENDIX 3: Text of E.O. 13422

Executive Order: Further Amendment to Executive Order 12866 on Regulatory Planning and Review (http://www.whitehouse.gov/news/releases/2007/01/20070118.html)

APPENDIX 4: Text of Good Guidance Practices Bulletin

Final Bulletin for Agency Good Guidance Practices (January 25, 2007) (http://www.whitehouse.gov/omb/fedreg/2007/012507_good_guidance.pdf)

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