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Before

The Committee on the Judiciary
Subcommittee on Commercial and Administrative Law
U.S. House of Representatives

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on
"Changes to OMB Regulatory Review by Executive Order 13422"

Chairman Sanchez, Ranking Member Cannon, and Members of the Subcommittee, my name is Paul Noe. Thank you for the honor to testify before you on recent changes to the regulatory review process.

Although I am now in the private sector, I have had the privilege to spend most of my career in public service -- much of it on efforts to improve the regulatory process. From 1995 to 2001, I worked in Congress on regulatory reform and administrative law issues as counsel for Chairmen Bill Roth, Ted Stevens and Fred Thompson on the Senate Governmental Affairs Committee. Then, until last May, I worked as counselor to Administrator John Graham at OMB's Office of Information and Regulatory Affairs. From the vantage points of Congressional oversight and legislating, as well as Executive Branch management, I developed a deep appreciation for the importance of a coordinated, interagency regulatory review process. I also know that the public could not ask for more talented and dedicated public servants than those I worked closely with while at OMB. I should note that my testimony is solely my personal opinion, and in my view, the recent amendments to Executive Order 12866 and the accompanying OMB Bulletin on Good Guidance Practices are important and salutary steps toward good governance.

Justice Scalia once quipped, "Administrative law is not for sissies." To be sure, agency rules can be voluminous, arcane and mind-numbingly complex. When well-designed, they provide important and substantial benefits, such as improvements in environmental quality, health and safety. When poorly designed or inconsistent, agency rules can impose wasteful and needless burdens, frustrate the public, or even lead to unintended harms. Accordingly, it is essential that the regulatory process be coordinated by sensible "rules of the road" and be transparent, accountable and effective.

On January 18, President Bush issued amendments to clarify and strengthen Executive Order 12866, which was issued by President Clinton to establish principles for regulatory planning and review. President Bush's Order was reinforced by an OMB Bulletin on Good Guidance

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Practices. The OMB Bulletin fits hand-in-glove with the provision in the new Executive Order to coordinate the development and use of agency guidance documents.

The reactions from some to the Executive Order were remarkable compared with the actual language. To assist in the consideration of the new Order, an attachment to my statement shows how the main Bush amendments modified President Clinton's Order. I would now like to review the most important provisions of Executive Order 13422 and the OMB Bulletin on Good Guidance Practices and to explain how I think they can improve the regulatory process.

1. Coordinated Review and Procedures for Guidance Documents

In my view, extending the existing regulatory review process to significant guidance documents is a critical step toward good governance.

President Reagan's Executive Order 12291, which firmly established OMB regulatory review, was quite broad in scope and applied to virtually all rules – and there are thousands issued annually. When President Clinton replaced the Reagan Order in 1993 with E.O. 12866, it honed in on "significant" regulatory actions. Given the vastness of federal regulatory activity, and the limited resources of OIRA, it was eminently sensible to try to sort the significant agency activity from the insignificant. The problem is that while the Clinton Order applied to significant legally binding regulations, it neglected guidance documents: interpretive regulations and agency statements of policy. And there is no doubt that guidance documents can be significant. A cursory review of the Preamble to the Bulletin, the comments on OMB's website, and the scholarly literature[2] provides many examples.

Although guidance documents may not properly carry the force of law, they are a key component of regulatory programs. As the scope and complexity of regulatory programs has grown, agencies increasingly have relied on guidance documents to provide direction to their staff and to the public. That generally is to the good.

But concerns have been raised by many quarters that agency guidance practices should be better managed and more consistent, transparent and accountable. Moreover, there is growing concern that guidance documents essentially are being used in lieu of regulations – without observing the procedural safeguards for regulations. As the D.C. Circuit put it:

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance

[2] See, e.g., Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals and the Like – Should Federal Agencies Use Them to Bind the Public?" 41 Duke L.J. 1311 (1992); Robert A. Anthony, "'Interpretive' Rules, 'Legislative' Rules and 'Spurious' Rules: Lifting the Smog," 8 Admin. L.J. (Spring 1994).

> document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.[3]

Together, Executive Order 13422 and the OMB Bulletin establish the first government-wide "rules of the road" to manage the development and use of guidance documents. The Executive Order gave clear authority to OMB to review significant agency guidance documents, just as OMB reviews significant agency regulations. The agencies, in turn, are required to give OMB advance notice of their upcoming significant guidance documents. OMB will be responsible for ensuring that other interested agencies in the federal family have notice, and occasionally, an opportunity to provide input into the most important guidance documents.

The OMB Bulletin on Good Guidance Practices supplements President Bush's Executive Order. First, agencies must implement written procedures for the approval of significant guidance documents by appropriate senior officials. Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence. Second, significant guidance documents must have standard elements, such as information identifying the document as guidance, the issuing office, the activity and persons to whom it applies, the date of issuance, title and docket number.

Most important, agencies are directed to avoid inappropriate mandatory language. This provision will help curb the problem of "regulation by guidance document" criticized in the Appalachian Power decision. It also will obviate wasteful litigation and increase fairness and accountability in the exercise of regulatory power.

The Bulletin also establishes public access and feedback procedures. For example, agencies are required to maintain on their Web sites a current list of their significant guidance documents, and to provide a means for the public to electronically submit comments on significant guidance documents, or to request that they be created, reconsidered or modified. Finally, the Bulletin establishes pre-adoption notice and comment requirements for guidance documents that rise to the level of being "economically" significant.

There is a strong foundation for the good guidance practices reflected in President Bush's Executive Order and the OMB Bulletin. This foundation includes the work of many authorities – including Congress, the courts, the Executive Branch, the former Administrative Conference of the United States, the American Bar Association, and the work of administrative law scholars.[4]

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[3] Appalachian Power Co. v. EPA, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (striking down emissions monitoring guidance as requiring notice and comment through legislative rulemaking procedures).

[4] See OMB Bulletin on Good Guidance Practices, at pp. 2-3 & n. 2, 6.

Indeed, Congress produced what became the model for OMB's Good Guidance Practices.[5] In the Federal Food and Drug Administration Modernization Act of 1997, Congress directed the FDA to issue regulations establishing good guidance practices.[6] Congress was particularly concerned about public knowledge of, and access to, FDA guidance documents; the lack of a systematic process for adopting guidance documents and for allowing public input; and inconsistency in the use of guidance documents.[7] Those same concerns apply to other agencies as well.

2. Identifying the Problem Requiring Regulation

President Clinton's E.O. 12866 required each agency to "*identify the problem* it intends to address *(including, where applicable, the failures of private markets* or public institutions that warrant new agency action) *as well as assess the significance of that problem*." (Sec. 1(b)(1)) (Emphasis added). President Bush's Order uses equivalent language, but requires that each agency *in writing* "identify . . . *the specific market failure (such as externalities, market power, lack of information) or other problem* that it intends to address, as well as assess the significance of that problem, *to enable assessment of whether any new regulation is warranted*." (Emphasis added). It is sensible to ask the agencies to be clear about their intentions and to say so in writing.

The Bush Order's language on market failure is not new or radical, as some have suggested. In fact, the focus on market failure and the delineation of externality, market power, and lack of information was thoroughly detailed in the Clinton's Administration's 1996 guidelines for economic analysis under Executive Order 12866.[8] The concept of market failure has permeated OMB guidelines for decades – in both Democratic[9] and Republican[10] Administrations.

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[5] As OMB stated in its Preamble (pp. 4-5), FDAMA and FDA's implementing regulations, as well as the recommendations of the former Administrative Conference, informed the development of the Bulletin.

[6] Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 371(h) (establishing FDA good guidance practices as law).

[7] "Food and Drug Administration Modernization and Accountability Act of 1997," S. Rep. 105-43, at 26 (1997).

[8] OMB, "Economic Analysis of Federal Regulations Under Executive Order 12866" (Jan. 11, 1996) (delineating at length market failures, including externality, natural monopoly, market power, and asymmetric information).

[9] OMB, M-00-08, "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements (March 22, 1990), at pp. 653-54 ("Since the existence of a market failure is not sufficient to justify government intervention, you should show that government intervention to correct market failure is likely to do more economic good than harm. If the problem is not a significant market failure, you should provide an alternative demonstration of compelling public need."); OMB, "Economic Analysis of Federal Regulations Under Executive

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In my view, both the Clinton and Bush principles make the same point: agencies should identify a problem that justifies regulation before proceeding -- whether the problem is a market failure or something else. While I think that the Clinton language was adequate, identifying the problem more precisely and in writing – to clarify the merits of going forward -- is a helpful but modest change.

Finally, while allegations have been raised that the Bush Administration focuses on market failure to the exclusion of other reasons to regulate, those allegations are misplaced. The Administration has clearly stated that there are additional justifications for regulations other than market failures – including the protection of civil rights, privacy, personal freedom, and other concerns.[11]

Carefully considering market failures is hardly a subversive way of thinking. Indeed, some of the greatest regulatory successes were made possible by market-based approaches that are based upon an understanding of market failure. For example, in the 1990 Clean Air Act Amendments, Congress established a sulfur dioxide emissions trading regime that is one of the greatest success stories in the history of environmental law. The results of that program were so compelling that the Administration adopted this approach in its Clear Skies legislative proposal. When Clear Skies stalled in Congress, OMB supported EPA accomplishing its goals through an innovative regulatory approach. The resulting Clean Air Interstate Rule will cut power plant emissions by about 70% without the economic disruption and hardships associated with traditional "command-and-control" regulation by clearly identifying the market failure and targeting regulation to remedy it.

It would be most unfortunate if market failure analysis, and market-based approaches that flow from it, become politicized when they are such important tools in the regulatory policy toolkit.

3. Responsibility of Regulatory Policy Officers

Some have alleged that the concept of Regulatory Policy Officers is a radical change from established practice. I respectfully disagree. President Clinton's Executive Order required each agency head to designate a Regulatory Policy Officer, who in turn had to report back to her. The

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Order 12866" (Jan. 11, 1996) (detailing market failures, including externality, natural monopoly, market power, and asymmetric information).

[10] See OMB, Circular A-4 (Sept. 17, 2003), at pp. 3-5 (delineating market failures, including externality, market power, and inadequate or asymmetric information); Regulatory Program of the United States (April 1, 1990 – March 31, 1991), at pp. 653-54 (describing market failure, including externality, natural monopoly and inadequate information, and noting that "[e]nvironmental problems are a classic case of externality").

[11] See OMB Circular A-4, at p. 5.

Regulatory Policy Officer had the duty to 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 in the Order.

President Bush's Order also delegates to the agency head the designation of the Regulatory Policy Officer. The Order further specifies that the Regulatory Policy Officer should be one of the agency's Presidential Appointees. Some critics have raised alarm that this provision is "political."

Yet, one of the benefits of centralized regulatory oversight is democratic accountability. The Regulatory Policy Officer presumably should help to ensure that the agency's rulemaking priorities are consistent with those of the President and with the requirements of Congress.

To my knowledge, the Bush provision only codifies prior practice in both the Bush and Clinton Administrations. There is a practical reason for Regulatory Policy Officers to be political appointees: anyone with the duty to oversee the functioning of the regulatory process should be at the top of the management pyramid, someone with a bird's eye view of the agency's regulatory agenda who could fairly be held accountable for such a broad responsibility. Typically, this would be a high-level appointee – such as the agency's general counsel. Moreover, if the Regulatory Policy Officer were a civil servant, it might be awkward for Congress to expect him to testify on behalf of the President. And Congress might have difficulty obtaining authoritative information on presidential priorities.

Under the Clinton Order, each agency's Regulatory Plan had to be "*approved personally by the agency head*." Under the Bush Order, no rulemaking may commence or be included in an agency's Regulatory Plan unless approved by the Regulatory Policy Officer.

To the extent that the new provisions are criticized as "political," it is unclear to me why the Clinton provisions were less so. Requiring the agency head – someone particularly close to the President – to personally approve the Regulatory Plan would seem at least as political as requiring the elements of the Plan to be approved by a less senior Presidential Appointee.

4. Agency Assessment of Annual Regulatory Costs and Benefits

The Clinton Order required agencies to estimate the anticipated costs and benefits of each rule. Under the Bush amendments, agencies also must provide an estimate of the combined aggregate costs and benefits of all of its regulations planned for the calendar year. The simple toting up of already required information is sensible because OMB is required by Congress to provide an annual report on the costs and benefits of Federal regulation under the "Regulatory Right-to-Know Act." This information should help agencies to prioritize and help OMB to fulfill its statutory obligation in a more efficient and accurate manner.

5. Formal Rulemaking Procedures

Executive Order 12866 directed each agency to provide for meaningful public participation in the regulatory process, including an opportunity for comment. Executive Order 13422 adds that

"each agency may also consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations." Of course, agencies always have had the discretion to opt for formal rulemaking procedures, but they rarely do because these trial-type procedures can be time-consuming and expensive. I doubt that this provision will significantly change the status quo.

Conclusion

Regulatory policy is important and often controversial. It is commendable that the Subcommittee is making the effort to assess the recent changes to the regulatory review process. While some raised concerns about these changes, I think a close reading of the language should allay those concerns. I hope that this hearing helps to foster a better understanding of the changes – and that the regulatory process can be improved as a result.

Madam Chairman, this concludes my prepared statement. I would be happy to answer any questions you may have.

Key Changes to Executive Order 12866, as amended by Executive Order 13422

1. Coordinated Review of Guidance Documents -- 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.

2. Identifying the Problem Requiring Regulation -- Sec. 1(b)(1)

Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.

Deleted: Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

3. Regulatory Policy Officers

a. Designation – Sec. 6(a)(2)

Within 60 days of the date of this Executive Order, each agency head shall designate one of the agency's Presidential Appointees to be its Regulatory Policy Officer, advise OMB of such designation, and annually update OMB on the status of this designation. 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.

Deleted: Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head

b. Responsibilities – Sec. 4(c)(1)

As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. 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

Deleted: The Plan shall be approved personally by the agency head

4. Aggregate Costs and Benefits of Regulations -- Sec. 4(c)(1)

As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. . . and the Plan 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;

5. Formal Rulemaking Procedures – Sec 6(a)(1)

Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. In consultation with OIRA, each agency may also consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations