

AMENDING EXECUTIVE ORDER 12866: GOOD GOVERNANCE OR REGULATORY USURPATION?

HEARING BEFORE THE SUBCOMMITTEE ON COMMERCIAL AND ADMINISTRATIVE LAW OF THE COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES ONE HUNDRED TENTH CONGRESS FIRST SESSION

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FEBRUARY 13, 2007
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TUESDAY, FEBRUARY 13, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCIAL
AND ADMINISTRATIVE LAW,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:05 p.m., in Room 2141 of the Rayburn House Office Building, the Honorable Linda Sánchez (Chairwoman of the Subcommittee) presiding.

Ms. SÁNCHEZ. The hearing of the Subcommittee on Commercial and Administrative Law will now come to order.

I would like to begin by welcoming everyone to the first hearing of this Subcommittee of the 110th Congress, and in particular I wish to extend warm regards to the Ranking Member of the Subcommittee, Mr. Cannon. I very much look forward to our working together. I would also like to welcome the two newest Members to the Judiciary Committee, Mr. Johnson and Mr. Jordan, to the Subcommittee.

At the request of a minority Member of the Science Committee, we moved the starting time of this hearing from 1 to 2 p.m. to accommodate the Science Committee hearing that has just concluded, and I appreciate the cooperation of our Ranking Member and the indulgence of our witnesses and attendees.

I will now recognize myself for a short statement.

Over the last several weeks, I have been reading some very disturbing news reports and commentaries about an Executive Order issued last month by President Bush. The new Order substantially amends Executive Order 12866, an Order that has guided the OMB regulatory review process for the last 13 years. This new Order requires agencies to identify specific “market failures” or problems that warrant a new regulation. Furthermore, agency heads are now required to designate a presidential appointee as an “agency policy officer” to control upcoming rulemaking. In a sense, the Executive Order politicizes regulations, many of which were specifically created by experts to protect the health and safety of our citizens. I am concerned that the main thrust of this new Order appears to shift control of the regulatory process from the agencies—the entities that have the most substantive knowledge and experience to the White House.

The primary purpose of this regulatory process is to provide guidance and interpret technical policies, often at the request of industry. Unfortunately, we don't know what prompted President Bush to undertake a major overhaul of this proven process. There is some speculation as to the Administration's reasoning. The *New York Times*, for example, reported that this new Executive Order "strengthens the hand of the White House in shaping rules that have, in the past, often been generated by civil servants and scientific experts." Others claim that this is just another clandestine "power grab" by the Administration.

These thoughts and concerns are not just being expressed by the so-called liberal media or partisan hacks. CRS, for example, says that the revisions made by Executive Order 13422 "represent a clear expansion of presidential authority over rulemaking agencies." CRS also notes that the Order can be viewed as part of a broader statement of presidential authority presented throughout the Bush administration—from declining to provide access to Executive Branch documents and information to creating presidential signing statements indicating that certain statutory provisions will be interpreted consistent with the President's view of the "unitary executive."

That is a rather serious observation coming from a preeminently nonpartisan source. And the fact that Subcommittees from both the Judiciary and Science Committees are looking into this issue I think underscores the serious concerns that the Order appears to present.

To help shed some light on these issues, we have with us today a truly notable witness panel. We are pleased to have a representative from the Administration, as well as two former Administration officials. We also have the author of the CRS report that I mentioned earlier, as well as one of the leading academics on presidential review of rulemaking. Accordingly, I very much look forward to hearing their testimony, and appreciate their willingness to participate.

[The prepared statement of Ms. Sánchez follows:]

PREPARED STATEMENT OF THE HONORABLE LINDA T. SÁNCHEZ, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND CHAIRWOMAN, SUBCOMMITTEE ON COMMERCIAL AND ADMINISTRATIVE LAW

Over the last several weeks, I've been reading some very disturbing news reports and commentaries about an executive order issued last month by President Bush. The new Order substantially amends Executive Order 12866, an order that has guided the OMB regulatory review process for the last 13 years. This new Order requires agencies to identify specific "market failures" or problems that warrant a new regulation. Furthermore, agency heads are now required to designate a presidential appointee as an "agency policy officer" to control upcoming rulemaking.

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ATTACHMENT

Executive Order 12866 as amended by Executive Orders 13258 and 13422

Federal Register, September 30, 1993 (Volume 58)
[Presidential Documents]
[Page 51735]

Executive Order 12866 of September 30, 1993--Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today. With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the Laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(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."

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(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation or guidance document.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations ~~and guidance documents that are inconsistent, incompatible, or duplicative with its other regulations and guidance documents or those~~ of other Federal agencies.

(11) Each agency shall tailor its regulations ~~and guidance documents to impose the least~~ burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

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(12) Each agency shall draft its regulations and guidance documents to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty. Formatted: Font color: Red

Sec. 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people.

(a) The Agencies. Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and guidance documents and assuring that the regulations and guidance documents are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order. Formatted: Font color: Red

(b) The Office of Management and Budget. Coordinated review of agency rulemaking is necessary to ensure that regulations and guidance documents are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President, and other regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations and guidance documents, as provided by this Executive order. Formatted: Font color: Red

(c) Assistance. In fulfilling his responsibilities under this Executive order, the President shall be assisted by the regulatory policy advisors within the Executive Office of the President and by such agency officials and personnel as the President may, from time to time, consult. Deleted: the Vice President.

Sec. 3. Definitions. For purposes of this Executive order:

(a) "Advisors" refers to such regulatory policy advisors to the President as the President may from time to time consult, including, among others:

- (1) the Director of OMB; Formatted: Font color: Red
- (2) the Chair (or another member) of the Council of Economic Advisers; Deleted: The Vice President. The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order.
- (3) the Assistant to the President for Economic Policy; Formatted: Font color: Blue
- (4) the Assistant to the President for Domestic Policy; Deleted: their
- (5) the Assistant to the President for National Security Affairs; Deleted: and the Vice President
- (6) the Director of the Office of Science and Technology Policy; Deleted: and the Vice President
- (7) the Deputy Assistant to the President and Director for Intergovernmental Affairs; Deleted: ¶
- (8) the Assistant to the President and Staff Secretary; Deleted: the Assistant to the President for Science and Technology
- (9) the Assistant to the President and Chief of Staff to the Vice President; Formatted: Font color: Auto
- (10) the Assistant to the President and Counsel to the President; Formatted: Font color: Auto
- (11) the Chairman of the Council on Environmental Quality and Director of the Office of Environmental Quality; and Deleted: the Assistant to the President for Intergovernmental Affairs
- (12) the Assistant to the President for Homeland Security; Deleted: the Deputy Assistant to the President and Director of the White House Office on Environmental Policy
- (13) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President. Formatted: Font color: Blue

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(a) "Advisors" refers to such regulatory policy advisors to the President as the President may from time to time consult, including, among others:

- (1) the Director of OMB; Formatted: Font color: Red
- (2) the Chair (or another member) of the Council of Economic Advisers; Deleted: The Vice President. The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order.
- (3) the Assistant to the President for Economic Policy; Formatted: Font color: Blue
- (4) the Assistant to the President for Domestic Policy; Deleted: their
- (5) the Assistant to the President for National Security Affairs; Deleted: and the Vice President
- (6) the Director of the Office of Science and Technology Policy; Deleted: and the Vice President
- (7) the Deputy Assistant to the President and Director for Intergovernmental Affairs; Deleted: ¶
- (8) the Assistant to the President and Staff Secretary; Deleted: the Assistant to the President for Science and Technology
- (9) the Assistant to the President and Chief of Staff to the Vice President; Formatted: Font color: Auto
- (10) the Assistant to the President and Counsel to the President; Formatted: Font color: Auto
- (11) the Chairman of the Council on Environmental Quality and Director of the Office of Environmental Quality; and Deleted: the Assistant to the President for Intergovernmental Affairs
- (12) the Assistant to the President for Homeland Security; Deleted: the Deputy Assistant to the President and Director of the White House Office on Environmental Policy
- (13) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President. Formatted: Font color: Blue

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

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(1) Regulations issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

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(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations that are limited to agency organization, management, or personnel matters; or

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(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

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(f) "Significant regulatory action" means any regulatory action that is likely to result in a regulation that may:

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(1) Have an annual effect on the economy 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;

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(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

(g) "Guidance document" means an agency statement of general applicability and future effect, other than regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.

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(h) "Significant guidance document"

(1) Means a guidance document disseminated to regulated entities or the general public that, for purposes of this order, may reasonably be anticipated to:

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(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; and~~

~~(2) Does not include:~~

~~(A) Guidance documents on regulations issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;~~

~~(B) Guidance documents that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;~~

~~(C) Guidance documents on regulations that are limited to agency organization, management, or personnel matters; or~~

~~(D) Any other category of guidance documents exempted by the Administrator of OIRA."~~

Sec. 4. Planning Mechanism. In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law: (a) ~~The Director may convene a meeting of agency heads and other government personnel as appropriate to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.~~

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(b) Unified Regulatory Agenda. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

~~Deleted:~~ Agencies' Policy Meeting. Early in each year's planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year. **1**

(c) The Regulatory Plan. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (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, and the Plan shall contain at a minimum,~~

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(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(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;

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(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order, and specific citation to such statute, order, or other legal authority."

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(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies, and the Advisors. (4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency, the Advisors, and the Vice President.

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(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies, and the Advisors.

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(6) The Director may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

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(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(j) Regulatory Working Group. Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, and Advisors. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Director on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the

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methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) Conferences. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) ~~The Director~~, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

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Sec. 6. Centralized Review of Regulations. The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) Agency Responsibilities.

(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.~~ Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(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.~~

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(2)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of

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~~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. 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 natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no

material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

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Sec. 7. Resolution of Conflicts.

(a) To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President with the assistance of the Chief of Staff, with the relevant agency head (and, as appropriate, other interested government officials).

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Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

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(b) Resolution of such conflicts shall be informed by recommendations developed by the Chief of Staff, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

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(c) During the Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Chief of Staff shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

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(d) At the end of this review process, the President, or the Chief of Staff acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

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Sec. 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Director, as provided under section 7 of this order. Upon receipt of this request, the Director shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

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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

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meet that need. The OIRA Administrator shall notify the agency when additional consultation will be required before the issuance of the significant guidance document.

Sec. 10. Preservation of Agency Authority. Nothing in this order shall be construed to impair or otherwise affect the authority vested by law in an agency or the head thereof, including the authority of the Attorney General relating to litigation.

Sec. 11. Judicial Review. Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 12. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

George W. Bush
THE WHITE HOUSE,
January 18, 2007.

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Exec. Order No. 12866, 58 FR 51735, 1993 WL 388305 (Pres.)

Ms. SÁNCHEZ. At this time, I would now like to recognize my colleague, Mr. Cannon, the distinguished Ranking Member of my Subcommittee, for his opening remarks.

Mr. CANNON. Thank you, and welcome, Madame Chairman.

This is—let me just say briefly to begin that we had a few problems, I think, with notice on the hearing today, and the rule requires a week's notice for hearings. I don't mean to be petty about this, but my understanding is that we have been assured by the Majority in the future any significant aspects of hearings won't be changed without the explicit sign-off of the Subcommittee Ranking Member. I appreciate this and look forward to working with you on this and other issues.

Welcome to the world of—through the looking glass, what do we call this? The world of the APA, the Administrative Procedure Act. And let me just say that the concerns you have raised are very important, and this is the Committee where we get to work these things through. And I would hope that we would continue the process of looking at this. I think it is not so much a partisan process as it is a very important process for how we govern ourselves here in America.

Let me just say that government in the sunshine is an improved process for the development of coordination of potential regulations and significant guidance documents and hands-on management of that process by accountable public officials are the heart and soul of OMB's new amendments to Executive Order 12866. They are to be celebrated and they are what this hearing really should be about: good governance and assuring that regulation is guided by officials accountable to the people through the political process and not usurped by unaccountable Federal agency employees.

The Executive Order amendments are about government in the sunshine because they are part of OMB's commendable and sustained effort to bring about government by guidance without sufficient notice and comment by the public under control. They are also about government in the sunshine because they are specifically related to a noted and comment proceeding which provides every interested party in the Nation an opportunity to tell OMB whether they thought OMB's good guidance proposals were good or bad ones.

The response was clear. The vast majority of comments supported the effort. OMB's Executive Order, amendments, and the final bulletin for agency good guidance practices that the amendments accompanies contemporaneously formed the capstone of that process. The importance of these developments to good government should not be underestimated, as the D.C. circuit trenchantly observed in 2000 when it addressed the troubled and widespread use of government by guidance in its Appalachian Power decision "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 passed, the agency issues circulars or guidance or memoranda explaining, interpreting, defining, and often expanding the commands in regulations. One guidance 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. Laws made without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.” Appalachian Power Company, VEPA, *et cetera*.

The Executive Order amendments in OMB’s Good Guidance Bulletin are the latest positive steps toward turning that around. What better way to begin to stem this tide than to bring significant guidance statements under increased management by the accountable and responsive political process, and to assure that that same process remains engaged through the planning and development phases of regulations and significant guidance.

Those are the key innovations of the Executive Order amendments and OMB should be praised for adopting them. Indeed, that praise should be high praise.

What kind of guidance are we talking about bringing under the Executive Orders procedures? Guidance that may reasonably be anticipated to (1), lead to an annual effect of \$100 million or more; to create serious inconsistency or otherwise interfere with an action taken or planned by another agency; to materially alter the budgetary impact of entitlement grants, user fees, or loan programs, and to raise novel, legal, or policy issues arising out of legal mandates, the President’s priorities or the principles set forth in this Executive Order. These are key examples. Bringing these kinds of truly significant guidance documents under increased and standardized review by accountable officials is a large step forward in good governance and should not be questioned.

The only better approach would be for this Committee to proceed with its Administrative Procedure Act review, and solve many of these problems with clear legislation. Beyond these major improvements, the amendments largely provide useful refinements to a process where the procedure is already present in Executive Order 12866, which was issued by the Clinton administration. For example, the original Order required agencies to identify what market failure or other problem they are proposing to address. The amendments have only made that requirement more specific, to make clear that the identification must be in writing and to make clear that the purpose of the identification is to enable assessment of whether any new regulation is warranted. That is, no seen change in the Order’s terms, but it can be expected to help better governance. In addition, the amendments allow more flexibility in the timing and use of regulatory prioritization and coordination meetings with agency heads. They also sensibly call not just for a cost benefit analysis for each planned regulation, but also for a cumulative cost benefit analysis of all regulations planned for a calendar year. That is intended to assist with the identification of priorities, clearly a salutary step.

There have been allegations that the Executive Order amendments somehow usurp the regulatory process, taking it out of the hands of bureaucrats and placing it in the hands of political officials. That is not correct. The agency’s authority to regulate is an authority delegated to the agencies by Congress. OMB steps to assure that Congress’s delegated authority is watchfully overseen by

officials that are accountable through the political process, are consistent with the source of the agency's authority.

It appears that this hearing is an attempt to show that the Administration is placing politics over good policy. That is not the case. Executive Order amendments are good policy. I commend OMB for its efforts and I look forward to future hearings that focus more directly on policy solutions to the problems that concern the American people, such as updating the Administrative Procedure Act and covering some of these issues.

I look forward to the hearing for all of the witnesses, and again, Madame Chairman, congratulations, welcome, and I yield back.

Ms. SÁNCHEZ. I thank the gentleman.

It is now my pleasure to recognize at this time Mr. Conyers, the Chairman of the Judiciary Committee and a Member of this Subcommittee, for his opening statement.

Mr. CONYERS. Thank you very much. I enjoy referring to the gentlelady from California, Linda Sánchez, as the Chair of the Subcommittee on Commercial and Administrative Law, and my old friend, Chris Cannon, as the Ranking Member of this very important Committee on the occasion of your very first hearing, and I am very proud to be here with you all.

This is an important item of the President's Executive Order, a recent one altering the procedure for administrative rulemaking. To me, in effect the President has created a new obstacle to agencies doing their jobs under the law by requiring for the first time a political appointee to approve any, and maybe all, agency guidance.

Now, this is, from a wider view I say to the distinguished witnesses who have been invited here, a part of this unprecedented reach for power on the part of this White House, an attempt to control the institutions that could challenge it: the courts, the Congress, and the press, and maybe a move to upset the balance of power among the three branches of Government. In my view, the Executive Order that we are looking at today represents yet another attempt to bring more authority into the Executive Branch, and it deserves and warrants the scrutiny of this Committee on behalf of the American people.

Policies and regulations that are created to protect public health, safety, the environment, civil rights, and privacy should be created by experts in the field and in my view, not by political appointees. This deviation from past process only serves to compromise the protection of the public while enhancing presidential power.

Executive Order 13422 has a requirement that a market failure or problem to be identified to justify governmental intervention also marks a serious increase of regulatory control by the White House. It is often at the request of the industry that the agencies issue best practices and policies. To make them more complicated only seems to further interfere with the regulatory process.

And so I am concerned that Orders like this will serve as yet another barrier to oppose consumer protection, specifically against exposure to harmful environmental pollutants and other safety and health requirements. A number of companies have already stated the regulatory rules have a significant impact on their business

practices, while numerous consumer groups have complained about the Orders impact on public health and safety.

And so this hearing starts this Subcommittee, its Chairman, Ranking Member, and Members of the Subcommittee to a very auspicious and important issue, and I congratulate you all for being here today.

I thank you for the time.

Ms. SÁNCHEZ. I thank the gentleman for his statement, and I would like to acknowledge that we have been joined by Mr. Feeney and Ms. Lofgren.

In the interest of time, I would ask that other Members submit their statements for the record by close of business Friday. Without objection, all opening statements will be placed in the record.

Without objection, the Chair will be authorized to declare a recess of the hearing at any point.

We have been informed that our Administration witness, Mr. Aitken, has a tight schedule this afternoon and may need to leave before our hearing is concluded. We will hear from him first and proceed with a round of questions for him before turning to our other witnesses. Mr. Aitken is invited to stay with us as long as he is able to do so.

Mr. CANNON. Madame Chairman, could we inquire of Mr. Aitken what his timeframe is, because I think that his insights through the course of the answering of other questions would be very important.

Mr. AITKEN. I do believe that when I was coming to the hearing that I received an e-mail saying that OPM had told Government employees to go home, so I suspect since nobody will be back in the office when I arrive there that my schedule will permit me to stay longer.

Mr. CONYERS. You don't have to go home, do you, Mr. Aitken?

Mr. AITKEN. No.

Mr. CANNON. That is our gain and your loss, I suppose.

Ms. SÁNCHEZ. Okay. That being the case, we will proceed as we normally do under our normal hearing schedule. We will allow all the witnesses to testify and then we will begin a round of 5-minute questions from the Members who are present.

I am now pleased and honored to introduce the witnesses for today's hearing. Our first witness is Steven Aitken, who has been the Acting Administrator of OMB's Office of Information and Regulatory Affairs since 2006. Prior to that appointment, Mr. Aitken was deputy general counsel at OMB, and before that he was an assistant general counsel at OMB. In total, he has worked at OMB for 17 years. Mr. Aitken also was a trial attorney in the civil and antitrust divisions of the Department of Justice. Mr. Aitken obtained his bachelor's degree in government from Harvard College, and a law degree from Harvard Law School. We appreciate your participation at today's hearing, Mr. Aitken, and look forward to your testimony.

Our second witness is Sally Katzen. Professor Katzen is presently an adjunct professor and public interest-public service faculty fellow at the University of Michigan Law School. Prior to this assignment, she has been a visiting professor and lecturer at various other educational institutions. Prior to joining academia, Professor

Katzen served nearly 8 years in the Clinton administration, first as the OIRA administrator, then as deputy assistant to the President for economic policy, and deputy director of the National Economic Council in the White House, and finally as the deputy director for management at OMB. Professor Katzen graduated magna cum laude from the University of Michigan Law School. Following graduation from law school, she clerked for Judge J. Skelly Wright of the United States Court of Appeals for the District of Columbia circuit. I should also note that Professor Katzen has testified on several occasions before this Subcommittee, and has contributed her expertise to the Judiciary Committee's ongoing Administrative Law Project, for which we are grateful. Welcome back, Professor Katzen.

Our third witness is Dr. Curtis Copeland, a Specialist in American Government at CRS. Dr. Copeland's expertise, appropriately relevant to today's hearing, is Federal rulemaking and regulatory policy. Dr. Copeland has previously testified before this Subcommittee, and he is one of three CRS experts who are assisting the Subcommittee in the conduct of its Administrative Law Project. His contributions to the project are deeply appreciated. Prior to joining CRS, Dr. Copeland held a variety of positions at the Government Accountability Office over a 23-year period. He received his Ph.D. from the University of North Texas.

Paul Noe is our next witness. Mr. Noe is a partner with C&M Capitolink LLC and also provides legal services to clients as counsel in Crowell & Moring's Environment and Natural Resources Group. He works on the policy, legal, political, and technical aspects of regulatory and legislative issues. Mr. Noe earned his undergraduate degree from Williams College and his law degree from Georgetown in 1990.

Our final witness is Professor Peter Strauss. Professor Strauss is the Betts Professor of Law at Columbia University School of Law. A renowned scholar of administrative law, Professor Strauss has taught that subject at Columbia Law School for the past 36 years. After obtaining his undergraduate degree from Harvard College, Professor Strauss received his law degree from Yale Law School. He thereafter clerked for Associate Justice William Brennan and Chief Judge David Bazelon of the United States Court of Appeals for the District of Columbia. It is an honor to have you with us, Professor Strauss.

At this point, I would like to extend to each of the witnesses my warm regards and appreciation for your willingness to participate at today's hearing. Without objection, your written statements will be placed into the record. Since you have submitted written statements that will be included in the hearing record, I request that you all limit your oral remarks to 5 minutes. You will note that we have a lighting system that starts with a green light. After 4 minutes it turns to a yellow light, and then after a minute longer it turns to a red light. If you could please finish your testimony by the time the red light turns on, I would appreciate that.

After the witnesses have presented their testimony, the Subcommittee Members will be permitted to ask one round of questions, subject to the 5-minute limit.

Mr. Aitken, you are invited to now begin your testimony.

**TESTIMONY OF STEVEN D. AITKEN, ACTING ADMINISTRATOR,
OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OF-
FICE OF MANAGEMENT AND BUDGET**

Mr. AITKEN. Chairman Sánchez, Ranking Member Cannon, Chairman Conyers, and distinguished Members of the Subcommittee, thank you for giving me the opportunity to testify before you today on the recently-issued Executive Order 13422.

A few weeks ago, the OMB Director issued a bulletin for agency good guidance practices. On that same day, the President issued Executive Order 13422, which amended Executive Order 12866. The bulletin and Executive Order share a common good government goal: to improve the way that the Federal Government does business by increasing the quality, accountability, and transparency of agency guidance documents, including providing the public an opportunity to review and comment on guidance.

OMB recognizes the enormous value of the guidance documents that Federal agencies issue, but as Congress, the Courts, and others have recognized, guidance documents can sometimes have far-reaching effects, but they are not always developed, issued, and used in a transparent and accountable manner that includes an opportunity for the public to comment on the guidance.

In order to improve the transparency, public participation, and accountability of guidance documents, OMB in 2005 issued for public comment a draft bulletin that identified good guidance practices. These practices were based on those already being used by the Food and Drug Administration. OMB recently issued the final version of that bulletin.

The good government improvements that are made by the bulletin are reinforced by the recent Executive Order which provides for a relatively informal process whereby some, but by no means all, of the significant guidance documents that are developed by Federal agencies will be submitted to OMB for interagency review.

The recent Executive Order makes several additional Good Government improvements. There has been some confusion in the press and elsewhere about these changes, and I would like to address that. First, concerns have been raised about the Order's provisions regarding regulatory policy officers. First, these officers are not new. When President Clinton issued Executive Order 12866 in 1993, he directed each agency head to designate a regulatory policy officer.

Second, while the recent Executive Order specifies that these regulatory policy officers will be presidential appointees, the case is that for most departments and agencies, the regulatory policy officers already are presidential appointees, subject to Senate confirmation. In addition, concerns have been raised that the recent Executive Order may require each agency to establish a new regulatory policy office that would be headed by the agency's regulatory policy officer. This reference to an office was a typographical error. The reference should have been to an officer. The Executive Order will be implemented accordingly.

In addition, the recent Executive Order increases the transparency of Executive Order 12866 regarding that Order's discussion of market failure. Before explaining what this amendment does do, I would like to explain first what it does not do.

First, the concept of market failure is not new to Executive Order 12866, but instead has been an integral part of that Order since President Clinton issued it in 1993, when he not once, but twice, referred in the Order to the “failures of private markets” as a justification for regulatory action.

Second, the recent Executive Order does not make a market failure the only basis on which a Federal agency can justify regulatory action. To the contrary, the recent Order expressly allows agencies to identify as a justification for regulatory action any “other significant problem it intends to address.” That is what the Executive Order does not do.

What it does do is to include in the text of Executive Order 12866 three classic examples of what is a market failure. These examples are not new to the implementation of Executive Order 12866. In fact, in 1996, the OIRA Administrator issued best practice guidelines for agency use in implementing Executive Order 12866. The 1996 guidelines included a separate discussion of market failure and the 1996 guidelines discuss the three classic examples of market failure that are referenced in the recent Executive Order.

Some have expressed concern that the recent Order could prevent agencies from issuing regulations to protect public health and safety, but this is not correct. Many of the most significant regulations that agencies issue are, in fact, responses to market failures. For example, environmental pollution is the classic textbook example of the market failure of externality. In response to this type of market failure, this Administration issued the Clean Air Interstate Rule, the CAIR rule, which will have major environmental benefits by reducing pollution.

Ms. SÁNCHEZ. Mr. Aitken, you hit your time, but if you could just summarize briefly.

Mr. AITKEN. Another type of market failure stems from lack of information. In response to this kind of market failure, the Food and Drug Administration recently issued regulations that require packaged foods to include in their nutritional labeling the amount of trans fats that are in the food. This addresses another type of market failure.

This concludes my opening statement. I would welcome any questions the Subcommittee has.

[The prepared statement of Mr. Aitken follows:]

PREPARED STATEMENT OF STEVEN D. AITKEN

**STATEMENT OF STEVEN D. AITKEN
ACTING ADMINISTRATOR
OFFICE OF INFORMATION AND REGULATORY AFFAIRS
OFFICE OF MANAGEMENT AND BUDGET
BEFORE THE
SUBCOMMITTEE ON COMMERCIAL AND ADMINISTRATIVE LAW
OF THE
COMMITTEE ON THE JUDICIARY
UNITED STATES HOUSE OF REPRESENTATIVES**

February 13, 2007

Chairman Sanchez, Ranking Member Cannon, and distinguished Members of this Subcommittee, thank you for inviting me to this hearing and for giving me the opportunity to testify before you today on the recently issued Executive Order 13422 and the related OMB Bulletin on Agency Good Guidance Practices.

I am Steven D. Aitken, the Acting Administrator of the Office of Information and Regulatory Affairs (OIRA), an office within the Office of Management and Budget (OMB). I have worked at OMB for nearly 18 years. Except for the past eight months when I have served as OIRA's Acting Administrator, I have served in the Office of General Counsel at OMB, first as an Assistant General Counsel and then as Deputy General Counsel.

A few weeks ago, on January 18th, the President issued Executive Order 13422, which made several amendments to Executive Order 12866 on "Regulatory Planning and Review." The most important of these amendments relate, not to the regulations that Federal agencies develop, but rather to the guidance that Federal agencies develop and provide to the public. In addition, also on January 18th, the OMB Director issued the OMB Bulletin for Agency Good

Guidance Practices. This is the final version of the bulletin that OMB issued in proposed form for public comment in November 2005.¹

As I will go on to explain, the Bulletin and the recent Executive Order share a common goal: namely, the good-government objective of improving the way that the Federal government does business – by increasing the quality, public participation, and accountability of agency guidance documents and their development and use. Moreover, as I will further explain, the Bulletin and the new Executive Order will operate in a complementary fashion to improve agency guidance documents. For this reason, in order to explain the Executive Order’s guidance provision, it is first necessary to explain the common background for both the Bulletin and the Executive Order and then to explain how the Bulletin is designed to improve the way that agency guidance documents are developed, issued and used. I will then provide a description and explanation of the Executive Order’s guidance provision.

Following that, I will discuss the recent Executive Order’s other non-guidance provisions. The first four that I will discuss are (1) its requirement that the already-existing Regulatory Policy Officer in each agency be designated by the agency head from among the agency’s Presidential appointees (most of the agencies’ Regulatory Policy Officers were already Presidential appointees, and also subject to Senate confirmation), and its typographical-error reference to a Regulatory Policy “Office” rather than “Officer”; (2) its requirement that an agency’s commencement of a rulemaking either be authorized by the agency head or be approved by the agency’s Regulatory Policy Officer (which will mean in practice that, in most if

¹ Executive Order 13422 and the Final Bulletin are published in the Federal Register at, respectively, 72 FR 2763 (January 23, 2007), and 72 FR 3432 (January 25, 2007). OMB requested public comment on the proposed bulletin at 70 FR 71866 (November 30, 2005), and extended the comment period at 70 FR 76333 (December 23, 2005). These documents, along with the public comments that OMB received on the proposal and the OMB Director’s memorandum issuing the Bulletin (Memorandum M-07-07), are available on OMB’s website. The original version of Executive Order 12866, issued in 1993, was published in the Federal Register at 58 FR 51735 (October 4, 1993).

not all cases, an agency's commencement of a rulemaking will be authorized or approved by an agency official who is subject to Senate confirmation); (3) requirement that each agency aggregate the costs and benefits of the individual rules in the agency's section of the annual Regulatory Plan (Executive Order 12866 already required the agencies to include in the Regulatory Plan the estimated costs and benefits for each rule, and thus the only new feature is that the agency – rather than the public – will do the summing-up of the already-reported costs and benefits); and (4) its encouragement of agencies to consider using the Administrative Procedure Act's formal (rather than informal) rulemaking procedures for the agency's resolution of complex determinations.

Finally, I will discuss the recent Executive Order's amendment regarding "market failure," and I will seek to correct the misunderstandings that have arisen regarding this amendment. In sum, as I will explain further, the recent Executive Order does *not* introduce the concept of a market failure into Executive Order 12866; that concept has been a prominent feature of Executive Order 12866 since it was originally issued by President Clinton in 1993. In addition, the recent Executive Order does *not* make the identification of a market failure the only basis on which a Federal agency can justify regulatory action. Rather, the recent Executive Order expressly states that an agency can justify a regulation by reference to an "other specific problem that [the agency] intends to address." Moreover, the recent Executive Order leaves untouched the provision in Executive Order 12866 that expressly directs Federal agencies to "promulgate . . . such regulations as are required by law, [or] are necessary to interpret the law." In many cases, when a Federal agency is issuing a regulation, the agency is doing so for just

Executive Order 12866 was previously amended once, in 2002, by Executive Order 13258, which was published in the Federal Register at 67 FR 9385 (February 26, 2002).

those law-based reasons, and this will continue to be the case; nothing in Executive Order 13422 changes this.

Having explained what the new “market failure” language does *not* do, I will then explain what it actually *does* do, which is two modest things.

First, Executive Order 13422 states that the agency “shall identify *in writing*” the problem -- whether it is a market failure “or other specific problem” -- that the agency “intends to address” through regulatory action. Stating explicitly that Federal agencies shall identify “in writing” the problem that the agency is seeking to remedy through regulatory action does *not* impose a new requirement on rulemaking agencies. Even if an agency did not identify in writing the precise nature of the problem that the agency is seeking to remedy through regulatory action (in order to assist the agency in *its own analysis* of whether regulatory action is warranted and, if so, which regulatory alternatives would best accomplish the agency’s intended result), the agency should be doing so in the preamble to the proposed rule (to assist the public in understanding the agency’s proposal and in offering their comments on it) and in the preamble to the final rule (to persuade the public, Congress, and the courts that the agency has exercised its regulatory authority in a reasonable and well-considered manner).

Second, in order to increase the transparency of Executive Order 12866, the recent Executive Order incorporates into Executive Order 12866 a reference to three classic examples of what constitutes a “market failure” -- namely, externalities (which justify, e.g., the regulation of pollution), market power (which justify, e.g., the regulation of natural monopolies), and lack of information (which justify, e.g., the nutritional labeling of packaged foods). These three examples are *not* new to the implementation of Executive Order 12866. These examples were found in the discussion of “market failure” that was contained in the 1996 “Economic Analysis

of Federal Regulations under Executive Order No. 12866” document that former OIRA Administrator Sally Katzen (working with the former Chairman of the Council of Economic Advisers, Joseph Stiglitz) issued to Federal agencies three years after President Clinton issued Executive Order 12866. Moreover, these three examples were contained in the draft Circular on regulatory cost-benefit analysis that OMB issued for public comment in 2003 and are contained in the final Circular A-4 that OMB issued later that year (and which remains in effect).

Background on the Good Guidance Provisions of the Bulletin and Executive Order:

As OMB has previously stated, agency guidance documents can have “enormous value.”² As OMB explained in 2002: “As the scope and complexity of regulation and the problems it addresses have grown, so too has the need for government agencies to inform the public and provide direction to their staffs. To meet these challenges, agencies have relied increasingly on issuing guidance documents.”³ Guidance documents are issued by agencies throughout the Federal Government, and they address the wide range of societal activities that are affected, in one way or the other, by the Federal Government and its programs. Thus, it is not surprising that, depending on the situation, agency guidance can be addressed to individuals, businesses (both small and large), organizations, State, local, and tribal governments, and others.

For instance, guidance can take the form of an agency explaining to members of the public how they can participate in a Federal program. An example of this kind of guidance is the *Medicare and You* handbook that the Centers for Medicare and Medicaid Services (CMS) distribute to Medicare beneficiaries annually.

² Office of Management and Budget, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Federal Regulations* (2002), p. 72.

³ Office of Management and Budget, *Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations*, 67 FR 15014, 15034 (March 28, 2002).

Guidance can also take the form of an agency providing advice and assistance to members of the public about recommended actions to ensure that they are in compliance with Federal laws and regulations. One element of this guidance can be explaining to the regulated community how the agency interprets or intends to enforce certain laws and regulations. In addition to providing advice and assistance to the regulated community on how to comply with the agency's regulations, such guidance also furthers consistency and fairness in an agency's enforcement of its regulations.⁴ Depending on the context, the audience for this guidance can include individuals, small entities (such as small businesses and organizations, as well as local governments), large corporations, and/or State governments.

Examples of this type of guidance are the compliance-assistance guides that Federal agencies prepare and make available to small businesses. Congress has required Federal agencies to prepare and issue such guidance in the Small Business Regulatory Enforcement Fairness Act of 1996.⁵ In addition, Congress in the Small Business Paperwork Relief Act of 2002⁶ assigned to OMB the responsibility, which is carried out by OIRA, of publishing annually in the *Federal Register* a notice that refers to small business the internet site where they can locate the compliance assistance resources that Federal agencies have prepared for their use. OIRA published the 2006 notice last summer,⁷ where OIRA explained that small businesses can go to one Internet address (www.business.gov/sbpra) and find the compliance-assistance resources that are available from the 15 Cabinet Departments and 25 other Federal agencies.

⁴ "Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency by simplifying and expediting agency enforcement efforts, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties." Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, *id.*, 67 FR at 15034.

⁵ P.L. 104-121, Title II, Subtitle A; 5 U.S.C. § 601 note.

⁶ P.L. 107-198, Section 2(a); 44 U.S.C. § 3504(c)(6).

⁷ 71 FR 39691 (July 13, 2006).

In sum, agency guidance documents are intended to -- and do -- have an impact on society. Depending on the situation, this impact can be relatively small or can be very substantial. As a result, while it is the case that guidance documents (unlike regulations) are not legally binding on the public, agency guidance documents nevertheless can potentially have an impact on society that is of comparable magnitude to the impact that regulations have on society.

In recognition of the impact that its guidance has on society, the Food and Drug Administration (FDA) in February 1997 issued a “Good Guidance Practices” document to govern how the FDA develops, issues, and uses its own guidance documents.⁸ Later that year, and building on this FDA policy, Congress in the Food and Drug Administration Modernization Act of 1997⁹ directed the FDA to follow several procedures in its development, issuance, and use of its guidance documents.

One of the principal congressional requirements in the 1997 Act is that FDA “develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means.”¹⁰ To this end, Congress directed FDA to provide the public with an opportunity to comment on its guidance, either *before* or *after*

⁸ 62 FR 8961 (February 27, 1997).

⁹ P.L. 105-115, § 405; 21 U.S.C. § 371(h).

¹⁰ 21 U.S.C. § 371(h)(1)(A). This direction was consistent with prior recommendations by the Administrative Conference of the United States and the American Bar Association that agencies provide the public with an opportunity to comment on guidance documents. See Administrative Conference of the United States, Rec. 92-2, 1 C.F.R. 305.92-2 (1992) (agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); American Bar Association, Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting, August 10-11, 1993, Vol. 118, No. 2, at 57 (“the American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.”).

its issuance, depending on the level of significance of the particular guidance document.¹¹ “For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, [FDA] shall ensure public participation prior to implementation of guidance documents, unless [FDA] determines that such prior public participation is not feasible or appropriate. In such cases, [FDA] shall provide for public comment upon implementation and take such comment into account.”¹² By contrast, “[f]or guidance documents that set forth existing practices or minor changes in policy, [FDA] shall provide for public comment upon implementation.”¹³

Congress also directed FDA to follow several additional requirements. For example, FDA “shall ensure . . . uniform internal procedures for approval of [guidance] documents”¹⁴ and “shall ensure that employees of [FDA] do not deviate from [FDA’s] guidance without appropriate justification and supervisory concurrence.”¹⁵ In addition, FDA “shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents,” and “[a]ll such documents shall be made available to the public.”¹⁶

Finally, Congress directed FDA, following the agency’s review of the effectiveness of its previously-issued Good Guidance Practices document, to promulgate a regulation in 2000 “consistent with [the statute] specifying the policies and procedures of the [FDA] for the

¹¹ For the legislative history of this provision, see “Food and Drug Administration Modernization and Accountability Act of 1997,” S. Rep. No. 105-43, at 26 (1997) (raising concerns about public knowledge of, and access to, FDA guidance documents, lack of a systematic process for adoption of guidance documents and for allowing public input, and inconsistency in the use of guidance documents).

¹² 21 U.S.C. § 371(h)(1)(C).

¹³ *Id.* § 371(h)(1)(D).

¹⁴ *Id.* § 371(h)(2).

¹⁵ *Id.* § 371(h)(1)(B).

¹⁶ *Id.* § 371(h)(3).

development, issuance, and use of guidance documents.”¹⁷ Following this directive, FDA in early 2000 issued for public comment a proposed rule on Good Guidance Practices.¹⁸ After it reviewed and considered the public comments, FDA finalized the rule later that year.¹⁹

The FDA’s Good Guidance Practices regulation is found at 21 C.F.R. § 10.115. Following the congressional direction in the 1997 Act, the FDA regulation provides that FDA, among other things –

- shall seek public comment on its guidance documents, either before or after their issuance (depending on their level of significance) and consider the comments;²⁰
- shall make its guidance documents easily available to the public by posting it on the Internet;²¹
- “must not include [in its guidance documents] mandatory language such as ‘shall,’ ‘must,’ ‘required,’ or ‘requirement,’ unless FDA is using these words to describe a statutory or regulatory requirement”;²²
- “must have written procedures” in each FDA center and office “for the approval of guidance documents,” which procedures “must ensure that issuance of all documents is approved by appropriate senior FDA officials”;²³ and

¹⁷ *Id.*, § 371(h)(5).

¹⁸ 65 FR 7321 (February 14, 2000) (proposed rule).

¹⁹ 65 FR 56468 (September 19, 2000) (final rule).

²⁰ 21 C.F.R. § 10.115(g).

²¹ *Id.* This direction is consistent with the 2001 recommendation by the American Bar Association. 3 American Bar Association, “Recommendation on Federal Agency Web Pages” (August 2001) (agencies should maximize the availability and searchability of existing law and policy on their websites and include their governing statutes, rules and regulations, and all important policies, interpretations, and other like matters on which members of the public are likely to request).

²² *Id.*, § 10.115(i)(2).

²³ *Id.*, § 10.115(j).

- must provide members of the public with an opportunity to submit and seek resolution of a complaint “that someone at FDA did not follow the requirements in [the regulation] or . . . treated a guidance document as a binding requirement.”²⁴

These FDA regulations went into effect in October 2000, and therefore have now been in operation for six years.

In sum, as I have just outlined, the Congress and the FDA both recognized that, because of the impact that FDA’s guidance can have on society, it was important that FDA’s guidance be subject to public comment (before or after its issuance); be readily available to the public; be developed through agency procedures that ensure the review and approval of appropriate agency officials before it is issued; be followed in practice by agency employees; and avoid the inclusion of language that would suggest to the public that the document is mandatory rather than what it actually is – namely, guidance.²⁵ It should also be noted that these requirements, in particular the requirements for internal-agency review and approval and for public comment, help to ensure that guidance documents are of high quality.

The FDA Good Guidance Practices regulation also addresses concerns that courts have raised about the improper development and use of agency guidance documents. In its 2000 decision in the Appalachian Power case, the United States Court of Appeals for the District of Columbia Circuit discussed these concerns:

“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

²⁴ Id. § 10.115(o).

²⁵ Congressional interest in, and concern about, agency guidance documents is also reflected in House Committee on Government Reform, “Non-Binding Legal Effect of Agency Guidance Documents,” H. Rep. No. 106-1009 (106th Cong., 2d Sess. 2000) (criticizing “back-door” regulation), and the Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong., § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents).

agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance 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.”

Appalachian Power Co. v. EPA, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment). See also Gen. Elec. Co. v. EPA, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as legislative rule requiring notice and comment); Chamber of Commerce v. Dep’t of Labor, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as legislative rule requiring notice and comment).

OMB’s Issuance of the Proposed and Final Bulletin:

OMB believes that Federal agency guidance should be developed, issued and used through an agency’s adherence to procedures that ensure quality, transparency, public participation, coordination, and accountability. For this reason, OMB developed (in consultation with Federal agencies) a draft OMB Bulletin that would establish as government-wide policy a set of “best practices” for achieving these goals.

As I earlier noted, OMB then sought public comment on this draft bulletin by issuing it in November 2005 as a proposal for public comment.²⁶ OMB received 31 public comments on the proposal, and these comments are available on OMB’s website. As evidence of the diverse nature of Federal guidance documents, and of the groups in American society that are affected by them, below are examples of some of the associations that submitted comments (as noted below,

²⁶ 70 FR 71866 (November 30, 2005).

these listed associations supported OMB's development of a bulletin on Good Guidance

Practices, while also providing their suggestions for how OMB could improve the bulletin):

-- **the Association of American Medical Colleges**, representing all 125 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 94 academic and scientific societies ("The AAMC commends the OMB for its proposal to establish consistent and appropriate standards for developing good guidance practices within federal agencies.");

-- **the National Association of Home Builders**, representing more than 220,000 members involved in home building, remodeling, multifamily construction, property management, subcontracting, design, housing finance, building product manufacturing and other aspects of residential and light commercial construction ("The National Association of Home Builders (NAHB) would like to thank the Office of Management and Budget (OMB) for proposing a process to bring transparency and consistency to Executive Branch activities that affect the public directly, but do not qualify as rules under the Administrative Procedure Act (APA).");

-- **the American Society of Safety Engineers**, representing 30,000 members ("ASSE commends OMB/OIRA for taking a proactive stance to ensure that agencies can readily provide interpretation and guidance of regulations, but still do so in a manner that affords due process to the regulated community and that is in accordance with the requisites of the Administrative Procedure Act, 5 USC 551 et seq.");

-- **the National Funeral Directors Association**, representing more than 11,000 funeral homes in all 50 states ("NFDA supports the Office of Management and Budget (OMB) proposal to establish standards to increase the quality and transparency of agency guidance practices and the guidance documents produced through them.");

-- **the Association of Metropolitan Planning Organizations** ("In general, AMPO strongly supports the Proposed Bulletin's intent and reliance on the guidance practices adopted by the Food & Drug Administration ('FDA') at 21 C.F.R. 5 10.115.");

-- **the Ornithological Council**, which consists of eleven leading scientific ornithological societies - the American Ornithologists' Union, Association of Field Ornithologists, CIPAMEX, Cooper Ornithological Society, Neotropical Ornithological Society, Pacific Seabird Group, Raptor Research Foundation, Society of Canadian Ornithologists/La Société des Ornithologistes du Canada, Society for Caribbean Ornithology, Waterbird Society, and Wilson Ornithological Society - that together have a membership of nearly 6,500 ornithologists ("we would like to express our gratitude to OIRA for its efforts to improve agency guidance practices");

-- **the Aircraft Owners and Pilots Association**, representing over 407,000 members (“AOPA shares OMB’s concern that agency guidance practices should be more transparent, consistent and accountable. We also agree with OMB that the absence of procedural review mechanisms undermines the lawfulness, quality, fairness and accountability of agency policymaking.”);

-- **the National Leased Housing Association**, which represents the interests of housing agencies, developers, lenders, housing managers and others in providing federally assisted rental housing, and whose members are primarily involved in the Section 8 housing programs and are involved with the operation of rental housing for over three million families (“we commend OMB for its efforts”);

-- **the American Road and Transportation Builders Association**, whose membership includes public agencies and private firms and organizations that own, plan, design, supply and construct transportation projects throughout the country (“Once again, ARTBA is extremely supportive of the GGP and feels that it represents a significant step forward in the regulatory process. It will engender fairness and improved dialogue between agencies and those that have a vital stake in the guidance they issue. ARTBA and our members are eager to take advantage of the new opportunities for involvement in the guidance process offered by the GGP and help OMB make the GGP standard agency practice.”); and

-- **the Associated Equipment Distributors**, representing 1,200 construction equipment distributors, manufacturers and industry-service firms (“ Our association thanks the Office of Management and Budget (OMB) for recognizing the impact that guidance material issued by federal regulatory agencies has on the regulated community. We agree with the OMB that transparency in the guidance drafting process is critical, as guidance should not be used for rulemaking.”).

As I have indicated, the comment letters from these associations can be found on OMB’s website, along with the other comment letters on the proposed bulletin.²⁷

On January 18th of this year, after considering the public comments and after further consultation with Federal agencies, the OMB Director issued the Final Bulletin on Agency Good

²⁷ OMB also received comments, some supporting and others opposing the proposed bulletin, from the following (in alphabetical order): the Aeronautical Repair Station Association, the American Bar Association, the American Chemistry Council, the American Composites Manufacturers Association, the American Petroleum Institute, AMGEN, C. Blake McDowell (Professor of Law), Citizens for Sensible Safeguards (OMB Watch), Coalition for Effective Environmental Information, Consumer Specialty Products Association, General Electric Company, Keller and Heckman LLP, McKenna Long & Aldridge LLP, Mercatus Center, National Mining Association, Natural Resources Defense Council, PIMA County (AZ) Wastewater Management Department, Regulatory Checkbook, Sanofi-aventis, Stuart Shapiro Ph.D. (Edward J. Bloustein School of Planning and Public Policy, Rutgers University), U.S. Chamber of Commerce.

Guidance Practices.²⁸ The final version of the Bulletin is very similar to the proposal in its overall framework, but – as OMB explained in the preamble to the final Bulletin -- OMB made a number of improvements to the Bulletin in response to comments that we received from the public and during the interagency review process.

The following are a few of the noteworthy provisions of the Bulletin, which reflect the requirements of the FDA's Good Guidance Practices regulation and are designed to improve the quality, transparency, public participation, and accountability of agency guidance documents:

- Each agency will ensure (as agencies should be doing anyway, as a matter of good internal management) that appropriate officials within the agency have reviewed and approved the agency's issuance of "significant" guidance documents;
- Agencies will maintain on their websites current lists of their "significant" guidance documents that are in effect, so that the public can know what guidance applies to them;
- Agencies will provide the public with access to and the opportunity to provide feedback on their "significant" guidance documents. Agencies will advertise on their websites a means for the public to submit comments electronically on these guidance documents; and
- For those guidance documents that are "economically significant" (e.g., a guidance document that "may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more"), agencies will publish drafts of the documents in the Federal Register, invite public comment on them, and prepare responses to the comments before finalizing the guidance.

²⁸ OMB Memorandum M-07-07 (January 18, 2007), which is found on OMB's website. The final Bulletin is published in the Federal Register at 72 FR 3432 (January 25, 2007).

In recognition of the potentially broad range of guidance documents that are issued by Federal agencies, the Bulletin also (1) includes certain express exclusions from the definition of “significant” and “economically significant” guidance document; (2) authorizes OMB to exempt “economically significant documents” (singly or by category) from the requirement for *prior* public comment before issuance; and (3) includes an express exception from the Bulletin’s requirements for “emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow.”

In light of concerns that have been raised about the final Bulletin and the Executive Order, this last point bears emphasis. The Bulletin does *not* stand in the way of a Federal agency responding appropriately to an emergency situation. In addition, the Bulletin does *not* override a Federal agency’s obligation to comply with applicable laws.

Executive Order 13422

The Executive Order’s Guidance Provision

In the furtherance of its goal to improve the guidance documents that Federal agencies develop and issue, the Bulletin is reinforced by the principal provision in Executive Order 13422, which the President issued, also on January 18th. Through an amendment to Executive Order 12866, which President Clinton issued in 1993, the recent executive order provides for a relatively informal process whereby *some* – but by *no* means all – of the “significant guidance documents” that are developed by Federal agencies will be submitted to OMB for interagency review.

It is important to underscore the point that this amendment provides for an *opportunity* for interagency review, and therefore that guidance documents are *not* treated the same as regulations. When he issued Executive Order 12866 in 1993, President Clinton directed

agencies to submit the drafts of all of their “significant” regulations to OIRA for review (subject to certain limited exceptions). By contract, agencies are *not* required under the recent amendments to submit all of their “significant” guidance documents to OMB for review. Instead, the recent executive order requires agencies to *inform* OMB of upcoming significant guidance documents, which thereby provides an *opportunity* for interagency review to occur.

In this regard, just as the new Bulletin directs agencies to follow good guidance practices that, to a greater or lesser extent, are probably being followed by many agencies for many of their guidance documents (e.g., posting them on the agency’s website), the recent Executive Order -- in recognizing the desirability of ensuring an *opportunity* for interagency review -- also reflects a practice that already happens in a number of situations.

In other words, interagency review of important guidance documents is *not* new. And, one reason why such review is desirable, and already happens, is because the programs and activities of one Federal agency often overlap or have implications for the programs and activities of one or more other Federal agencies. For example, in June of last year, the Department of Health and Human Services (HHS) issued a State Medicaid Director letter that provides guidance on the implementation of the provision in the Deficit Reduction Act of 2005 that requires individuals claiming U.S. citizenship to provide – when initially applying for Medicaid or upon the first redetermination – satisfactory documentary evidence of citizenship or nationality. Before HHS finalized and issued this guidance, OMB ensured that HHS consulted first with affected and interested agencies – the Departments of State and Homeland Security, and the Social Security Administration. This interagency consultation, which took place in a two-week period, ensured that HHS had the benefit of the expertise and experience of these other

agencies and that the HHS guidance took into account the interests and programs of these agencies.

This *interagency* coordination, then, had the effect of improving the quality of the HHS guidance in the same way that the quality of guidance can be improved through *public participation* and *internal-agency review and approval*.²⁹ Thus, by ensuring that there is an *opportunity* for interagency review, this amendment made by Executive Order 13422 serves as a complement to the requirements in the OMB Bulletin for public participation and internal-agency review and approval.

In addition, as OMB explained in March 2002, interagency review of a guidance document is also justified because “interagency review can ensure that agency action is consistent with Administration policy and is beneficial from a broader, societal perspective.”³⁰ This type of review during the development of agency *guidance documents* is entirely appropriate, for the same reason that the courts have held that it is appropriate to conduct this same type of review during the development of agency *regulations*. As the United States Court of Appeals for the District of Columbia Circuit explained in 1981 (in an opinion by Judge Wald):

“The court recognizes the basic need of the President and his White House staff to monitor the consistency of executive agency regulations with Administration policy. He and his White House advisers surely must be briefed fully and frequently about rules in the making, and their contributions to policymaking considered. The executive power under our Constitution, after all, is not shared -- it rests exclusively with the President.

* * *

²⁹ OMB made this same general point in March 2002 when OMB asked the public to identify examples of “problematic guidance documents” that would be potential candidates for reform. Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, 67 FR 15014, 15035 (March 28, 2002) (“problematic guidance might be improved by interagency review”).

³⁰ Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, *id.*, 67 FR at 15035.

“The authority of the President to control and supervise executive policymaking is derived from the Constitution; the desirability of such control is demonstrable from the practical realities of administrative rulemaking. Regulations such as those involved here demand a careful weighing of cost, environmental, and energy considerations. They also have broad implications for national economic policy. Our form of government simply could not function effectively or rationally if key executive policymakers were isolated from each other and from the Chief Executive. Single mission agencies do not always have the answers to complex regulatory problems. An overworked administrator exposed on a 24-hour basis to a dedicated but zealous staff needs to know the arguments and ideas of policymakers in other agencies as well as in the White House.”

Sierra Club v. Costle, 657 F.2d 298, 404, 405-06 (D.C. Cir. 1981). In that decision, the D.C.

Circuit upheld the appropriateness of discussions between the White House and the Environmental Protection Agency, regarding a draft Clean Air Act rule. These discussions took place -- and EPA issued the rule -- in 1979, during the Administration of President Carter.

The Executive Order’s Non-Guidance Provisions

In addition to providing an opportunity for interagency review of draft guidance documents, the recent Executive Order makes several (non-guidance related) process improvements. As is the case with the guidance amendments in the Executive Order and the new Bulletin, these process improvements are designed to encourage good-government practices. Because there has been some confusion in the press and elsewhere as to the meaning and impact of these changes, let me briefly go through them.

i. Regulatory Policy Officers

Concerns have been raised about the provisions in Executive Order 13422 regarding Regulatory Policy Officers. The initial point that should be made is that such officers are *not* new; when he issued Executive Order 12866 in 1993, President Clinton directed each agency head to designate a Regulatory Policy Officer within the agency. Nor is it new that, under the recent amendment, these Regulatory Policy Officers will be Presidential appointees. While the

original EO 12866 did not require that agency heads choose a Presidential appointee to be the agency's Regulatory Policy Officer, the fact is that, in many departments and major agencies, the Regulatory Policy Officer has been a Presidential appointee.

And, I should note that the term "Presidential appointee" should not be confused with "political appointee." Presidential appointees are appointed by the President, whereas agency heads appoint "political appointees" who are in the non-career Senior Executive Service or are under Schedule C; these agency-head appointees are *not* Presidential appointees. Moreover, neither the President nor an agency head can create a Presidentially-appointed position in an agency. Rather, only Congress can do so. And, when Congress does create a Presidentially-appointed position in an agency, Congress usually provides that this appointee shall be subject to Senate confirmation (a PAS official). Thus, by requiring that agency heads designate a Regulatory Policy Officer from among the agency's Presidential appointees, the President is actually ensuring that, in most cases, the Regulatory Policy Officer will be a PAS official.

In addition, concerns have been raised that Executive Order 13422 may require each agency to establish a new "Regulatory Policy Office" that would be headed by the agency's Regulatory Policy Officer. I would like to allay such concerns by explaining that this reference to a Regulatory Policy "Office" was a typographical error. The reference should have been to a Regulatory Policy "Officer" rather than "Office"; the Executive Order will be implemented accordingly.

ii. Commencement of a Rulemaking

Executive Order 13422 amends Executive Order 12866 to require that an agency's commencement of a rulemaking either be authorized by the agency head or be approved by the agency's Regulatory Policy Officer. As explained above, most if not all of the Regulatory Policy

Officers will be -- as they generally have been over the years -- Presidential appointees who are subject to Senate confirmation. In practice, then, this will mean that, in most if not all cases, an agency's commencement of a rulemaking will be authorized or approved by an agency official who is appointed by the President and subject to Senate confirmation.

iii. Aggregation of annual costs and benefits in the Regulatory Plan

Section 4 of President Clinton's Executive Order 12866 established a "Planning Mechanism" that includes an annual *Regulatory Plan* that reports the most significant regulatory actions anticipated in the coming year and thereafter, along with the agency's estimate of each rule's anticipated benefits and costs. Executive Order 13422 amends this section to ask agencies, in addition, to aggregate the estimated costs and benefits of the individual regulations. While the interested public could always sum-up for themselves the cost and benefit estimates for each of the individual rules, this amendment enhances the transparency of the annual *Regulatory Plan* by requiring the agencies to do the aggregation.

iv. The Encouragement of Agencies to Consider Formal Rulemaking

Another of the amendments in Executive Order 13422 encourages rulemaking agencies to consider using the Administrative Procedure Act's formal -- rather than informal -- rulemaking procedures for the agency's resolution of complex determinations. Agencies already had the option of using the APAs' formal rulemaking procedures, and this amendment simply encourages them to consider the use of a tool that has been -- and remains -- available to them.

v. Market Failure

Executive Order 13422 amended Section I(b)(1) of Executive Order 12866, which was -- and remains -- the first of that Order's "Principles of Regulation." As recently amended, Section I(b)(1) now states that: "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.” Before explaining what this amendment *does* do, I would like to explain first what it does *not* do.

First, the concept of market failure is *not* new to this amendment, but instead has been an integral part of Executive Order 12866 since President Clinton issued it in 1993. Indeed, the overarching “Statement of Regulatory Philosophy,” in Section 1(a) of the original Executive Order 12866 (*unchanged* by EO 13422), states that “Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as *material failures of private markets* to protect or improve the health and safety of the public, the environment, or the well-being of the American people” (*italics added*). Furthermore, the first “Principle of Regulation” that was articulated in Section 1(b) of the original Executive Order 12866 reiterated the requirement that each agency “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” (*italics added*).

Second, the recent Executive Order does *not* make the identification of a market failure the only basis on which a Federal agency can justify regulatory action. The revised section also encourages agencies to identify any “other significant problem it intends to address.” For example, recent regulations to provide disaster assistance to victims of Hurricane Katrina provide important social benefits, but do not address a market failure, *per se*. Moreover, the recent Executive Order leaves untouched the provision in Executive Order 12866 that expressly directs Federal agencies to “promulgate . . . such regulations as are required by law, [or] are

necessary to interpret the law.” In many cases, when a Federal agency is issuing a regulation, the agency is doing so for just those law-based reasons, and this will continue to be the case; nothing in Executive Order 13422 changes this.

Having explained what the revised “market failure” language does *not* do, I would like to now explain what it actually *does* do, which is two relatively modest things.

First, Executive Order 13422 states that the agency “shall identify *in writing*” the problem -- whether it is a market failure “or other specific problem” -- that the agency “intends to address” through regulatory action. Stating explicitly that Federal agencies shall identify “in writing” the problem that the agency is seeking to remedy through regulatory action does *not* impose a new requirement on rulemaking agencies. As an initial matter, an agency should already have been identifying in writing the precise nature of the problem that the agency is seeking to remedy through regulatory action, *in order to assist the agency in its own analysis of whether regulatory action is warranted and, if so, which of the available regulatory alternatives would best accomplish the agency’s intended result.*

Thus, in order to comply with the original version of Section 1(b)(1) of Executive Order 12866, agencies as a practical matter would have had to make (or at least should have made) this identification in writing. However, even if an agency did not do so, the agency should still have identified the problem that it was seeking to remedy through regulatory action in the preamble to the proposed rule (to assist the public in understanding the agency’s proposal and in offering their comments on it) as well in the preamble to the final rule (to persuade the public, Congress, and the courts that the agency has exercised its regulatory authority in a reasonable and well-considered manner). In sum, the requirement that agencies identify the need for the regulation in writing is a good-government measure. It encourages greater transparency in rulemaking, by

helping the public and others understand the problem the regulation is intended to address, enabling more informed comment on whether the proposed rule will likely meet its objectives and whether there are other, better alternatives to address the identified problem.

Second, in order to increase the transparency of Executive Order 12866, Executive Order 13422 incorporates into Executive Order 12866 a reference to three classic textbook examples of what constitutes a “market failure” – namely, externalities (which justify, e.g., the regulation of pollution), market power (which justify, e.g., the regulation of the rates charged by natural monopolies, such as local gas and electricity distribution services), and lack of information (which justify, e.g., the nutritional labeling requirements for packaged foods). These three examples of market failure are *not* new to the Executive Branch’s implementation of Executive Order 12866. To the contrary, three years after President Clinton issued Executive Order 12866 in 1993, these examples were included in the discussion of “market failure” that was contained in the 1996 “Economic Analysis of Federal Regulations under Executive Order No. 12866” document that former OIRA Administrator Sally Katzen (working with former CEA Chairman Joseph Stiglitz) issued to Federal agencies for their use in meeting the analytical requirements of Executive Order 12866 (as well as those of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act).³¹

In its Part I on “Statement of Need for the Proposed Action,” the 1996 “Economic Analysis” document had a Section A on “Market Failure,” which provided separate descriptions of “Externality,” “Natural Monopoly,” “Market Power,” and “Inadequate or Asymmetric

³¹ Memorandum for Members of the Regulatory Working Group from OIRA Administrator Katzen, “Economic Analysis of Federal Regulations under Executive Order 12866 (January 11, 1996), available on OMB’s website at <http://www.whitehouse.gov/omb/memoranda/rwgmemo.html>. As Administrator Katzen stated in her transmittal memorandum, the “Economic Analysis” document “represents the results of an exhaustive two-year effort” by an interagency working group chaired by Joseph Stiglitz of the Council of Economic Advisers and Steve Kaplan, the then General Counsel of the Department of Transportation.

Information.” The 1996 “Economic Analysis document also included the following introductory discussion:

“I. STATEMENT OF NEED FOR THE PROPOSED ACTION

“In order to establish the need for the proposed action, the analysis should discuss whether the problem constitutes a significant market failure. If the problem does not constitute a market failure, the analysis should provide an alternative demonstration of compelling public need, such as improving governmental processes or addressing distributional concerns. If the proposed action is a result of a statutory or judicial directive, that should be so stated.

“A. Market Failure

“The analysis should determine whether there exists a market failure that is likely to be significant. In particular, the analysis should distinguish actual market failures from potential market failures that can be resolved at relatively low cost by market participants. Examples of the latter include spillover effects that affected parties can effectively internalize by negotiation, and problems resulting from information asymmetries that can be effectively resolved by the affected parties through vertical integration. Once a significant market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specified market failure.”

Moreover, the three examples of market failure that are now referenced in the amended Executive Order 12866 (i.e., externality, market power, and lack of information) were contained in the draft Circular on regulatory cost-benefit analysis that OMB issued for public comment and peer review in 2003, and they are contained in the final Circular A-4 that OMB issued later that same year (and which remains in effect).³²

And, thus, the use of these three market failure examples in the implementation of Executive Order 12866 is *not* new. Moreover, Executive Order 13422 did *not* substantively change the first “Principle of Regulation” in Executive Order 12866 or how this Principle is implemented by the Executive Branch. Instead, all that happened as a result of Executive Order

13422, with respect to these three examples of market failure, is that they are now mentioned in Executive Order 12866 itself (rather than only in the implementation documents). In other words, the recent amendment has simply increased the transparency of Executive Order 12866.

Some have expressed concern that this amendment to Executive Order 12866 could prevent agencies from issuing regulations to protect public health and safety, but this is not correct. Many of the most significant regulations that agencies issue are, in fact, driven by – and are in response to – market failures. As the 1996 OMB “Economic Analysis” document noted, “[e]nvironmental problems are a classic case of externality,” and this Administration has issued a number of significant environmental regulations aimed at addressing environmental externalities, including EPA’s Clean Air Interstate Rule (CAIR) and its Non-road Diesel Engines Rule. Similarly, regulations to protect homeland security, such as FDA’s recent regulations under the Public Health Security and Bioterrorism Preparedness and Response Act, respond to inadequate private market incentives to respond to potential terror threats.

Another type of market failure that is mentioned in the amendment made by Executive Order 13422 stems from lack of information. An example of a regulation that is justified by the “lack of information” market failure was the Food and Drug Administration’s recent regulation that requires the nutritional labels on packaged foods to display the amount of trans-fats in them. This labeling requirement is estimated to have considerable public health benefits, by providing consumers important information with which they can make purchasing decisions. Moreover,

³² Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, 68 FR 5492, 5514-15 (February 3, 2003); *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulation* (2003), at pages 121-122 (available on OMB’s website).

this rule was the subject of a “prompt letter” that former OIRA Administrator John Graham sent to HHS in 2001 encouraging the agency to issue a rule to require the labeling of trans-fats.³³

Finally, in both the CAIR and trans-fats rules, identification of a market failure, rather than a specific directive from statute, was the driving force behind the issuance of regulations that are expected to have significant public health and quality of life benefits.

Moreover, as noted above, nothing in this amendment to EO 12866 precludes agencies from justifying regulations on grounds other than the failure of private markets. Nor does it preclude agencies from justifying regulations on the ground that Congress has required the agency to promulgate regulations to address a particular situation, on the grounds that the regulations are necessary to interpret the law, or are made necessary by other compelling public need.

* * *

Thank you again for this opportunity to testify. I would welcome any questions that the Subcommittee has.

³³ Letter from OIRA Administrator Graham to the Department of Health and Human Services regarding trans fatty acids (September 18, 2001) (available on OMB’s website).

Ms. SÁNCHEZ. I thank the gentleman.
 Ms. Katzen, you are now up. You may proceed with your testimony.

**TESTIMONY OF SALLY KATZEN, PROFESSOR,
 UNIVERSITY OF MICHIGAN LAW SCHOOL**

Ms. KATZEN. Thank you.

Madame Chairman, Mr. Cannon, Mr. Conyers, other distinguished Members, I appreciate very much the opportunity to testify today.

Mr. CONYERS. Mr. Aitken, have you turned your microphone off?

Ms. KATZEN. Is my time going?

Ms. SÁNCHEZ. We will reset your time.

Ms. KATZEN. As you mentioned in your introduction, I served as the administrator of OIRA for over 5 years during the Clinton administration, and was involved in the drafting and implementation of Executive Order 12866. I am a strong proponent of centralized review of agency rulemaking, and have often spoken and written in defense and support of OIRA.

I am also a strong proponent of regulations, believing that if properly crafted they can improve the quality of our lives, the performance of our economy, and the Nation's well-being.

Why, then, am I so critical of this new Executive Order? I have prepared written testimony that provides extensive background and explanatory information, and would like to use my 5 minutes to emphasize the most important points.

First, during the last 6 years, the Bush administration has taken many discrete steps to tighten incrementally, but nonetheless tighten OMB control over the agencies: the information data quality guidelines, the peer review guidelines, Circular A-4 for regulatory analyses, the risk assessment bulletin, and now the bulletin on good guidance practices. Each step, standing on its own, can be justified and none standing on its own is really as bad as the critics of the Administration have charged. At the same time, the cumulative effect of all of these is overwhelming the agencies, and there is a dramatically different dynamic between the agencies and the White House than there was at the end of the Clinton administration.

In Executive Order 12866, President Clinton continued the practice of centralized review of rulemaking by OIRA, but at the same time, he reaffirmed the primacy of the Federal agencies which are the repositories of significant experience and expertise, and are the entities to which Congress has delegated the authority to issue rules with the force and effect of law. Today, those agencies have at least one arm tied behind their backs, two 10-pound bricks tied to their ankles, and they are set on an obstacle course to navigate before they can issue any regulations. Forgive me for mangling my metaphors, but the combination of all of the multiple mandates that OMB has imposed on the agencies makes it so much more difficult for them to do their jobs. More mandates and no more resources. In fact, the agencies have been straight-lined or decreased.

Presidential oversight is one thing, but burdening the agencies to slow them down or destroy their morale is something else.

Now, I read Mr. Aitken's written testimony and listened to him just now, and it is really very curious. He has not identified any problems that they were experiencing under the original Executive Order that needed to be fixed. Instead, he has said, again and again, that there is nothing new in the Executive Order, that the agencies are doing it already. What they are doing is not significant. It is no big deal. By the same token then, why did they do it? If it wasn't intended to accomplish anything, why use the prestige of the President and the status of an Executive Order for a non-event?

Let me also be clear to the extent he says that this is just continuing the logical progression from the Clinton administration, that simply is not true. One example is that he cited the 1996 document that I co-authored with Joe Stiglitz that uses the terms "market failure" and "externality," *et cetera*. But that was a document that was called "Best Practices," not guidance, not bulletin, not circular, not Executive Order, and that is a very big difference.

Finally, if you argue that this is simply to increase transparency and good government, then look at the way it was done, without any consultation or explanation. Look at the effect on the agencies, coming on the heels of all of the other things that OMB has done. And look at the message it sends: Regulations to protect the environment and to promote the health and safety of the American people are disfavored—let the market, not the Government, do it.

Now, Executive Order 12866 as originally drafted was neutral as to process, even though President Clinton was highly supportive of regulations as part of the solution to serious problems plaguing our society. The Executive Order was not skewed to achieve a pro-regulatory result. It was not a codification of a pro-regulatory philosophy or ideology. It was, on its face and by intent, a charter for good government without any predetermination of outcomes.

In light of the actions taken over the last 6 years, that is no longer the case with Executive Order 12866 as amended.

As I noted at the outset, there have been—a lot of these steps have been taken. Each one of them has been a thumb on the scale. I think by now we have a whole fist influencing the outcome of regulatory decisions.

Thank you very much for holding this hearing. It is very important, I believe, for Congress to let the Executive know that it takes these matters seriously and is concerned about the integrity of the Administrative process.

[The prepared statement of Ms. Katzen follows:]

PREPARED STATEMENT OF SALLY KATZEN

Chairman Sanchez and Members of the Subcommittee. Thank you for inviting me to testify today on a subject that is vitally important to the American people. During the last six years, there has been a slow but steady change in the process by which regulations are developed and issued—specifically, in the balance of authority between the Federal regulatory agencies and the Office of Management and Budget. With its most recent actions, the Bush Administration has again restricted agency discretion and made it more difficult for them to do the job that Congress has delegated to the Federal agencies. It is therefore important that this Subcommittee consider the reasons for these changes and the implications of these changes for administrative law and regulatory practice.

I served as the Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) for the first five years of the Clinton Administration, then as the Deputy Assistant to the President for Eco-

nomic Policy and Deputy Director of the National Economic Council, and then as the Deputy Director for Management of OMB. I am a proponent of centralized review of agency rulemaking, and I was personally involved in the drafting and implementation of Executive Order 12866. I have remained active in the area of administrative law generally and rulemaking in particular. Since leaving government service in January 2001, I have taught Administrative Law and related subjects at the University of Michigan Law School, George Mason University Law School, and the University of Pennsylvania Law School, and I have also taught American Government seminars to undergraduates at Smith College, Johns Hopkins University, and the University of Michigan in Washington Program. I frequently speak and have written articles for scholarly publications on these issues.

On January 18, 2007, the Bush Administration released two documents. One was expected; the other was not. I can understand why OMB issued a "Final Bulletin for Good Guidance Practices." While I disagree with several of the choices made, I recognize that a case can be made that there is a need for such a Bulletin. On the other hand, there is no apparent need for Executive Order 13422, further amending Executive Order 12866. Regrettably, none of the plausible explanations for its issuance is at all convincing. As I will discuss below, there are at least three aspects of the new Executive Order that warrant attention: 1) the way it was done—without any consultation or explanation; 2) the context in which it was done—coming on the heels of OMB's imposing multiple mandates/requirements on the agencies when they are developing regulations; and 3) the effect it will have and the message it sends to the agencies—it will be even more difficult for agencies to do their jobs because regulations are disfavored in this Administration.

To put the most recent Executive Order in perspective, a little history may be helpful. The first steps towards centralized review of rulemaking were taken in the 1970's by Presidents Nixon, Ford and Carter, each of whom had an ad hoc process for selectively reviewing agency rulemakings: President Nixon's was called the Quality of Life Review; President Ford's was focused on the agency's Inflationary Impact Analysis that accompanied the proposed regulation; and President Carter's was through the Regulatory Analysis Review Group. Those rulemakings that were considered significant were reviewed by an inter-agency group, which then contributed their critiques (often strongly influenced by economists) to the rulemaking record.

In 1981, President Reagan took a significant additional step in issuing Executive Order 12291. That Order formalized a process that called for the review of all Executive Branch agency rulemakings—at the initial and the final stages—under specified standards for approval. The Office that President Reagan chose to conduct the review was the Office of Information and Regulatory Affairs (OIRA), established by the Congress for other purposes under the Paperwork Reduction Act of 1980. Unless OIRA approved the draft notice of proposed rulemaking and the draft final rule, the agency could not issue its regulation.

Executive Order 12291 was highly controversial, provoking three principal complaints. One was that the Executive Order was unabashedly intended to bring about regulatory *relief*—not reform—relief for the business community from the burdens of regulation. Second, the Order placed enormous reliance on (and reflected unequivocal faith in) cost/benefit analysis, with an emphasis on the cost side of the equation. Third, the process was, by design, not transparent; indeed, the mantra was "leave no fingerprints," with the result that disfavored regulations were sent to OMB and disappeared into a big black hole. The critics of Executive Order 12291, including Members of Congress, expressed serious and deep concerns about the Executive Order, raising separation of powers arguments, the perceived bias against regulations, and the lack of openness and accountability of the process.

When President Clinton took office and I was confirmed by the Senate as the Administrator of OIRA, my first assignment was to evaluate Executive Order 12291 in light of the 12 years of experience under Presidents Reagan and Bush, and help draft a new Executive Order that would preserve the strengths of the previous Executive Order but correct the flaws that had made the process so controversial. President Clinton would retain centralized review of Executive Branch agency rulemakings, but the *development* and the *tone* of the Executive Order he would sign (Executive order 12866) was to be very different.

I was told that Executive Order 12291 was drafted in the White House (Boyden Gray and Jim Miller take credit for the document) and presented, after President Reagan had signed it, as a fait accompli to the agencies. The protests from the agencies were declared moot. We took a different route, consulting and sharing drafts with the agencies, public interest groups, industry groups, Congressional staffers, and State and local government representatives. When all their comments were considered and changes made to the working draft, we again consulted and shared our new drafts with all the groups, and again took comments. More changes

were made, and where comments were not accepted, we explained the basis for our decisions.

The tenor of Executive Order 12866 was also quite different from Executive Order 12291. As noted above, Executive Order 12866 retained centralized review of rulemakings, but also reaffirmed the primacy of the agencies to which Congress had delegated the authority to regulate. (Preamble) Among other things, Executive Order 12866 limited OIRA review to “significant regulations”—those with a likely substantial effect on the economy, on the environment, on public health or safety, etc. or those raising novel policy issues (Section 6(b)(1))—leaving to the agencies the responsibility for carrying out the principles of the Executive Order on the vast majority (roughly 85%) of their regulations.

Executive Order 12866 continued to require agencies to assess the consequences of their proposals and to quantify and monetize both the costs and the benefits to the extent feasible. (Section 1(a)) But it explicitly recognized that some costs and some benefits cannot be quantified or monetized but are “nevertheless essential to consider.” (Section 1(a)) I believe it was Einstein who had a sign in his office at Princeton to the effect that “not everything that can be counted counts, and not everything that counts can be counted.”

While Executive Order 12292 required agencies to set their regulatory priorities “taking into account the conditions of the particular industries affected by the regulations [and] the condition of the national economy” (Section 2 (e)), Executive Order 12866 instructed agencies to consider “the degree and nature of the risks posed by various substances and activities within its jurisdiction” (Section 1(b)(4)), and it added to the list of relevant considerations for determining if a proposed regulation qualified as “significant” not only an adverse effect on the economy or a sector of the economy, but also “productivity, competition, jobs, the environment, public health or safety or State, local, or tribal governments or communities.” (Section 3(f))

There were other significant differences between Executive Order 12291 and Executive Order 12866, including those relating to the timeliness of review and the transparency of the process, but for present purposes, the key to the difference was that President Clinton was focused on a process for better decision-making and hence better decisions and not a codification of a regulatory philosophy or ideology. Centralized review was seen as a valid exercise of presidential authority, facilitating political accountability (the President takes the credit and gets the blame for what his agencies decide) and to enhance regulatory efficacy (that is, decisions that take into account the multitude of disciplines and the multitude of perspectives that can and should be brought to bear in solving problems in our complex and interdependent society). But whatever one’s view of centralized review of agency rulemakings, Executive Order 12866 was—on its face and by intent—a charter for good government, without any predetermination of outcomes.

The neutrality of the process was essential. President Clinton viewed regulations as perhaps the “single most critical . . . vehicle to achieve his domestic policy goals” (Kagan, 114 Harv. L. Rev 2245, 2281–82 ((2001)), and he spoke often of the salutary effects of regulations on the Nation’s quality of life and how regulations were part of the solution to perceived problems. But the Executive Order was not skewed to achieve a pro-regulatory result. The regulations would be debated on their merits, not preordained by the process through which they were developed and issued.

When George W. Bush became President in January 2001, his philosophy was decidedly anti-regulatory. I know that his advisors considered whether to change Executive Order 12866 and they concluded that it was not necessary to accomplish their agenda. Indeed, President Bush’s OMB Director instructed the agencies to scrupulously adhere to the principles and procedures of Executive Order 12866 and its implementing guidelines. (OMB M–01–23, June 19, 2001) The only changes to the Executive Order came two years into President Bush’s first term, and the changes were limited to transferring the roles assigned to the Vice President to the Chief of Staff or the OMB Director. (Executive Order 13258)

Almost five years later, President Bush signed Executive Order 13422, further amending Executive Order 12866. So far as I am aware, there was no consultation and no explanation of the problems under the existing Executive Order that prompted these amendments, or whether the amendments would have a salutary effect on whatever problems existed, or whether the amendments would have unintended consequences that should be considered. Press statements issued after the fact do not make for good government.

Second, the new Executive Order comes in the course of a steady and unwavering effort to consolidate authority in OMB and further restrict agency autonomy and discretion. On February 22, 2002, OMB issued its Information Quality Act (IQA) Guidelines. (67 *Fed. Reg.* 8452). The IQA itself was three paragraphs attached to a more than 700-page Treasury and General Government Appropriations Act for

Fiscal Year 2001, with no hearings, no floor debate and no committee reports. Its objective was “to ensure the quality, objectivity, utility and integrity of information disseminated to the public.” OMB took up the assignment with a vigor and determination that was remarkable. OMB’s government-wide guidelines created a new construct: now, there would be “information” and “influential information” and different (more stringent standards) would apply to the higher tiers. OMB also required the agencies to issue their own guidelines (subject to OMB approval); establish administrative mechanisms allowing people or entities to seek the correction of information they believe does not comply with these guidelines; and report periodically to OMB on the number and nature of these complaints. The U.S. Chamber of Commerce thought this “would have a revolutionary impact on the regulatory process”—keeping the agencies from relying on data that industry thought was questionable.

Then came OMB’s Proposed Draft Peer Review Standards for Regulatory Science (August 29, 2003), in which OMB attempted to establish uniform government-wide standards for peer review of scientific information used in the regulatory process. Peer review is generally considered the gold standard for scientists. Yet leading scientific organizations were highly critical of what OMB was trying to do and how it was doing it, and they were joined by citizen advocacy groups and former government officials. They argued that the proposed standards were unduly prescriptive, unbalanced (in favor of industry), and introduced a new layer of OMB review of scientific or technical studies used in developing regulations. The reaction was so strong and so adverse that OMB substantially revised its draft Bulletin to make it appreciably less prescriptive and restrictive, and in fact OMB resubmitted it in draft form for further comments before finalizing the revised Bulletin.

On March 2, 2004, OMB replaced a 1996 “best practices” memorandum with Circular A-4, setting forth instructions for the Federal agencies to follow in developing the regulatory analyses that accompany significant draft notices of proposed rule-making and draft final rules. The Circular, almost 50-pages single spaced, includes a detailed discussion of the dos and don’ts of virtually every aspect of the documentation that is needed to justify a regulatory proposal. While the term “guidance” is used, agencies that depart from the terms of the Circular do so at their peril (or more precisely, at the peril of their regulatory proposal).

Then came the OMB Proposed Risk Assessment Bulletin (January 9, 2006), providing technical guidance for risk assessments produced by the Federal government. There were six standards specified for all risk assessments and a seventh standard, consisting of five parts, for risk assessments related to regulatory analysis. In addition, using the terminology from the IQA Guidance, OMB laid out special standards for “Influential Risk Assessments” relating to reproducibility, comparisons with other results, presentation of numerical estimates, characterizing uncertainty, characterizing results, characterizing variability, characterizing human health effects, discussing scientific literature and addressing significant comments. Agency comments raised a number of very specific problems and such general concerns as that OMB was inappropriately intervening into the scientific underpinnings of regulatory proposals. OMB asked the National Academies of Scientists (NAS) to comment on the draft Bulletin. The NAS panel (on which I served) found the Bulletin “fundamentally flawed” and recommended that it be withdrawn.

Then, on January 18, 2007, OMB issued its final Bulletin on “Agency Good Guidance Practices.” Agencies are increasingly using guidance documents to inform the public and to provide direction to their staff regarding agency policy on the interpretation or enforcement of their regulations. While guidance documents—by definition—do not have the force and effect of law, this trend has sparked concern by commentators, including scholars and the courts. In response, the Bulletin sets forth the policies and procedures agencies must follow for the “development, issuance, and use” of such documents. It calls for internal agency review and increased public participation—all to the good. In addition, however, the Bulletin also imposes specified “standard elements” for significant guidance documents; provides instructions as to the organization of agency websites containing significant guidance documents; requires agencies to develop procedures (and designate an agency official/office) so that the public can complain about significant guidance documents and seek their modification or rescission; and extends OIRA review to include significant guidance documents. I do not believe it is an overstatement to say that the effect of the Bulletin is to convert significant guidance documents into legislative rules, subject to all the requirements of Section 553 of the Administrative Procedure Act, even though the terms of that Section explicitly exempt guidance documents from its scope. To the extent that the Bulletin makes the issuance of guidance documents much more burdensome and time consuming for the agencies, it will undoubtedly result in a decrease of their use. That may well have unintended unfortunate con-

sequences, because regulated entities often ask for and appreciate receiving clarification of their responsibilities under the law, as well as protection from haphazard enforcement of the law, by agency staff.

This is quite a record. While each step can be justified as helping to produce better regulatory decisions, the cumulative effect is overwhelming. Requirements are piled on requirements, which are piled on requirements that the agencies must satisfy before they can issue regulations (and now, significant guidance documents) that Congress authorized (indeed, often instructed) them to issue. And OMB has not requested, nor has the Congress in recent years appropriated, additional resources for the agencies to carry out OMB's ever increasing demands. As agencies must do more with less, the result is that fewer regulations can be issued—which is exactly what the business community has been calling on this Administration to do.

It is in this context that Executive Order 13422, further amending Executive Order 12866, is released. Until the Bulletin on guidance documents, OIRA extended its influence throughout the Executive Branch without any amendments to Executive Order 12866. As discussed above, OMB issued Circulars and Bulletins covering a wide variety of subjects, virtually all of which were quite prescriptive (and often quite burdensome) in nature. OMB Circulars and Bulletins do not have the same status as an Executive Order, but they are treated as if they did by the Federal agencies. Why then did OMB draft and the President sign Executive Order 13422?

One indication of a possible answer is that while Executive Order 13422 in effect codifies the Bulletin on guidance documents, it does not pick up and codify the earlier pronouncements on data quality, peer review, regulatory impact analyses, or even risk assessment principles. It may be that it was thought necessary to amend Executive Order 12866 for guidance documents because Executive Order 12866 was written to apply only where the agencies undertook regulatory actions that had the force and effect of law. But it is unlikely that the agencies would balk at submitting significant guidance documents to OIRA if there were an OMB Bulletin instructing them to do so, and since neither Executive Orders nor Circulars or Bulletins are judicially reviewable, it is also unlikely that anyone could successfully challenge in court an agency's decision to submit a significant guidance document to OIRA.

Perhaps more revealing of the reason(s) for Executive Order 13422 is that it is not limited to guidance documents. Consider the other amendments included in the new Executive Order. First, Executive Order 12866 had established as the first principle of regulation that:

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

Executive Order 13422 amends Executive Order 12866 to state instead:

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.*

By giving special emphasis to market failures as the source of a problem warranting a new regulation, the Administration is saying that not all problems are equally deserving of attention; those caused by market failures are in a favored class and possibly the only class warranting new regulations. This could be read as a throw back to the “market-can-cure-almost-anything” approach, which is the litany of opponents of regulation; in fact, history has proven them wrong—there are many areas of our society where there are serious social or economic problems—e.g., civil rights—that are not caused by market failures and that can be ameliorated by regulation.

Second, the new Executive Order amends Section 4 of Executive Order 12866, which relates to the regulatory planning process and specifically references the Unified Regulatory Agenda prepared annually to inform the public about the various proposals under consideration at the agencies. The original Executive Order instructed each agency to also prepare a Regulatory Plan that identifies the most important regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year. Section 4, unlike the rest of the Executive Order, applies not only to Executive Branch agencies, but also to independent regulatory commissions, such as the Securities and Exchange Commission, the Federal Communications Commission, the Federal Trade Commission, and the Federal Reserve Board. It is not without significance that the new Executive Order uses Section 4 to impose an additional restraint on the agencies:

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 . . .

This language should be read in conjunction with an amendment to Section 6(a)(2) that specifies that the agency's Regulatory Policy Officer must be "one of the agency's Presidential Appointees." Executive Order 12866 had provided that the agency head was to designate the agency's Regulatory Policy Officer, with the only condition that the designee was to report to the agency head. The original Executive Order further provided that the Regulatory Policy Officer was to "be involved at every stage of the regulatory process . . ."—in other words, a hands-on job. Now, there is an explicit politicalization of the process; a "sign-off," not a hands-on, assignment; and, most significantly, no accountability. The newly appointed officer is not required to be subject to Senate confirmation, nor is the person required to report to a Senate-confirmed appointee.

The other changes to Section 4 are also troubling. As amended, the agencies must now include with the Regulatory Plan the:

agency's best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year . . .

Very few would dispute that the Regulatory Plan has been notoriously unreliable as an indicator of what an agency is likely to accomplish in any given time frame; it is not unusual for regulations that are not included in the Plan to be issued should circumstances warrant, nor is it unusual for regulations included in the Plan with specific dates for various milestones to languish year after year without getting any closer to final form.

In any event, the requirement to aggregate the costs and benefits of all the regulations included in the Plan for that year is very curious. We know that costs and benefits can be estimated (at least within a range) at the notice stage because the agency will have settled on one or more options for its proposal. But to try to estimate either costs or benefits at the notice of inquiry stage or before the agency has made even tentative decisions is like trying to price a new house before there is even an option on the land and before there are any architect's plans. The numbers may be interesting, but hardly realistic, and to aggregate such numbers would likely do little to inform the public but could do much to inflame the opponents of regulation. This would not be the first time that large numbers that have virtually no relation to reality have driven the debate on regulation—e.g., the \$1.1 trillion estimate of the annual costs of regulations that is frequently cited by opponents of regulation, even though every objective critique of the study that produced that number concludes that it not only overstates, but in fact grossly distorts, the truth about the costs of regulation. The only other plausible explanation for this amendment to the Executive Order is that it is the first step toward implementing a regulatory budget. In my view, the concept of a regulatory budget is deeply flawed, but it should be debated on the merits and not come in through the back door of an Executive Order designed for other purposes.

There is also a gratuitous poke at the agencies in the amendment to Section 4(C). The original Executive Order instructed the agencies to provide a "summary of the legal basis" for each action in the Regulatory Plan, "including whether any aspect of the action is required by statute or court order." The new amendment adds to the previous language the clause, "and specific citation to such statute, order or other legal authority." It may appear to be trivial to add this requirement, but by the same token, why is it necessary to impose such a requirement?

As noted above, I am not aware of any consultation about either the merits of any of the amendments or the perception that may attach to the cumulative effect of those amendments. Therefore, I do not know whether the agencies have, for example, been proposing regulations based on problems caused by something other than market failure which OMB does not consider an appropriate basis for a regulation; whether senior civil servants at the agencies have been sending proposed regulations to OMB that run contrary to the wishes of the political appointees at those agencies; or whether agencies have been misrepresenting what applicable statutes or court orders require.

If not, then there is little, if any, need for these amendments, other than to send a signal that the bar to issuing regulations is being raised; that OMB is deciding the rules of the road; and that those rules are cast so as to increase the I's that must be dotted and the T's that must be crossed. In other words, the message is that agencies should not be doing the job that Congress has delegated to them. This is not a neutral process. If the Bush Administration does not like some or all agency proposed regulations, they can debate them on the merits. But the Executive Order

should not become a codification of an anti-regulatory manifesto. This is not good government.

Ms. SÁNCHEZ. Thank you for your testimony, Professor Katzen. Now we move to Dr. Copeland.

TESTIMONY OF CURTIS W. COPELAND, Ph.D., SPECIALIST IN AMERICAN NATIONAL GOVERNMENT, CONGRESSIONAL RESEARCH SERVICE

Mr. COPELAND. Thank you very much.

Madame Chairman, Members of the Subcommittee, I am pleased to be here today to discuss the changes made by Executive Order 13422. These changes are the most significant to the regulatory review process since 1993, and as you mentioned, can be viewed as part of a broader assertion of presidential authority throughout the Bush administration.

The most consistent attribute of these changes is their lack of clarity. Specifically, it is unclear why the changes were made, their effect on agencies and the public, and their effect on the balance of power between the President and Congress. My bottom line is that because of this lack of clarity, the ultimate effects of these changes are likely to become apparent only through their implementation.

Ironically, although the Executive Order now requires agencies to identify the specific market failure or problem that prompted the issuance of the rules, the Bush administration has not indicated why the changes made by the Order are needed. For example, why did the President conclude that agencies regulatory policy officers now must be presidential appointees? Why do those policy officers no longer report to the agency head, and why was their authority to control agency's regulatory planning and rulemaking activity significantly enhanced? Sound public policy reasons can be envisioned for many of these changes, and enunciation of those reasons might have prevented much of the ensuing controversy.

In some cases, the lack of clarity about the effects of the Executive Order is because of the broad discretion that is provided to both the agencies and OMB. For example, agencies are now required to estimate the aggregate cost and benefits of upcoming rules "to the extent possible" and are required to identify specific market failure or problem before issuing a rule where applicable, but it is unclear who decides what is possible or applicable. Is it the agencies or OMB?

In other cases, the effects of the changes are unclear because, at least on the surface, they don't appear to change existing practices. For example, as Mr. Aitken just mentioned, regulatory officers are already presidential appointees in most agencies—most major agencies. Therefore, the Order seems to require what is already being done. However, if OMB or the President requires agencies to designate different presidential appointees to this position, then this mandate could become much more significant, particularly when coupled with the newly enhanced authority of those officers to control agencies' regulatory planning and output.

Similarly, one might think that agencies could satisfy the requirement that they estimate the aggregate cost and benefits of their plan rules simply by adding up the rules individual estimates;

however, agencies' regulatory plans rarely contain quantitative estimates of cost and benefit, in many cases because the rules are still under development and a year away from publication. Therefore, if agencies are held strictly to this requirement, developing aggregate cost and benefit estimates could be proved difficult for the agencies and of questionable validity.

Other requirements in the Order seem to have broad or unclear scope. For example, it requires agencies to notify OMB about significant guidance documents, and defines a guidance document in such a way that it may cover even oral statements by agency staff. Also, as many others have pointed out, it is not clear how a non-binding guidance document can be expected to have the kinds of significant effects described in the Order; that is, \$100 million impact on the economy. As a result, agencies may conclude that none of their guidance documents meet the Executive Order's requirements for OMB notification. On the other hand, because OMB is also given the authority to determine which documents are significant, the scope and impact of this requirement may be as broad as OMB determines it needs to be.

It is also unclear whether the time limits and transparency requirements applicable to rules will apply to guidance documents. For example, will OMB have to complete its review of guidance documents within 90 days? Will agencies have to disclose the changes made to their guidance documents at the suggestion and recommendation of OMB?

Finally, it is unclear what impact the changes brought about by the Executive Order will have on the balance of power between the President and Congress. As I mentioned earlier, the Order requires agency regulatory policy officers to be presidential appointees, but does not indicate whether they should be subject to Senate confirmation. One could argue that it is the role of Congress to prescribe in law whether the regulatory policy officer position should be subject to Senate confirmation. Even if an agency had designated a person in a Senate-confirmed position as an agency's regulatory policy officer, one could argue that this person would have to undergo another confirmation process because the scope of the person's responsibilities had changed significantly.

Also, it is not clear whether the Orders and requirements regarding policy officers now applies to independent regulatory agencies that had previously been exempt from this requirement, and that Congress establish more—and that Congress established to be more removed from presidential influence. If so, this would represent a clear departure from previous practice.

That concludes my prepared statement. I would be happy to answer any questions.

[The prepared statement of Dr. Copeland follows:]

PREPARED STATEMENT OF CURTIS W. COPELAND

Madam Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the changes made to the Office of Management and Budget's (OMB) regulatory review process as a result of Executive

Order 13422, issued by President George W. Bush on January 18, 2007.¹ The executive order amended the review process that was established by Executive Order 12866 and is implemented by OMB's Office of Information and Regulatory Affairs (OIRA).² The changes are the most significant changes to that process since it was established in 1993. The changes are also controversial, with some characterizing the new executive order as a "power grab" by the White House that undermines public protections and lessens congressional authority,³ and others describing it as "a paragon of common sense and good government."⁴ However, both supporters and critics of the new order agree that it represents an expansion of presidential authority over rulemaking agencies. In that regard, Executive Order 13422 can be viewed as part of a broader statement of presidential authority that has been presented throughout the Bush Administration.

The most important changes made by the executive order appear to fall into five general categories: (1) a requirement that covered agencies identify in writing the specific "market failure" or "problem" that warrants the issuance of a new regulation, (2) a requirement that each agency head designate a presidential appointee within the agency as a "regulatory policy officer" who can largely control upcoming rulemaking activity in that agency, (3) a requirement that agencies provide their best estimates of the aggregate regulatory costs and benefits of rules they expect to publish in the coming year, (4) an expansion of OIRA review to include agencies' significant guidance documents, and (5) a provision permitting agencies to consider whether to use more formal rulemaking procedures in certain cases.

I have provided the Subcommittee with copies of a recent CRS report that describes each of these changes in some detail and notes what observers in the public, private, and nonprofit sectors have said about them.⁵ Rather than reiterate what is in that report, my testimony today focuses on what is unknown or unclear about changes brought about by Executive Order 13422—specifically, (1) why the changes were made, (2) the effect of the changes on federal rulemaking agencies and the public, and (3) the effect of the changes on the balance of power between the President and Congress with regard to regulatory agencies. OMB recently indicated that it planned to issue clarifying "implementation assistance" to the agencies, which may answer many, if not all, of these questions.⁶

WHY THE CHANGES WERE MADE

Executive Order 13422 does not indicate, and the Bush Administration has not explained (except in very general terms), why changes to Executive Order 12866 were needed at this time. For example, it is not clear why the President believed that federal agencies' regulatory policy officers should be required to be presidential appointees, why those policy officers should no longer report to the agency head,⁷ or why their authority to control their agencies' regulatory planning and rulemaking activities should be significantly enhanced.⁸ Likewise, the Administration has not explained why the new executive order requires agencies to provide aggregate estimates of regulatory costs and benefits for all of the agencies' upcoming regulations. The rationale behind the expansion of OIRA's regulatory review to include agencies' significant guidance documents can be inferred, at least to some extent, by reading OMB's "Final Bulletin for Agency Good Guidance Practices" that was issued the

¹ Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review," 72 *Federal Register* 2763, Jan. 23, 2007. Five years earlier, E.O. 13258 re-assigned certain responsibilities from the Vice President to the President's chief of staff, but otherwise did not change the OIRA review process. See Executive Order 13258, "Amending Executive Order 12866 on Regulatory Planning and Review," 67 *Federal Register* 9385, Feb. 28, 2002.

² Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, Oct. 4, 1993.

³ Public Citizen, "New Executive Order Is Latest White House Power Grab," available at <http://www.citizen.org/pressroom/release.cfm?ID=2361>.

⁴ Attributed to William Kovacs, Vice President of Environment, Energy, and Regulatory Affairs, U.S. Chamber of Commerce, in John Sullivan, "White House Sets Out New Requirements for Agencies Developing Rules, Guidance," *Daily Report for Executives*, Jan. 19, 2007, p. A-31.

⁵ CRS Report RL33862, *Changes to the OMB Regulatory Review Process by Executive Order 13422*, by Curtis W. Copeland.

⁶ Personal conversation with OMB staff, Feb. 8, 2007.

⁷ As originally written, Executive Order 12866 required the regulatory policy officers to report to the agency heads; Executive Order 13422 eliminated that language when it required that the officers be presidential appointees.

⁸ Unless specifically authorized by the agency head, the presidential policy officer must approve the listing of all significant forthcoming regulatory actions in the regulatory plan and approve the initiation of all rulemaking actions. Previously, only the agency head could approve the regulatory plan, and there was no language in the order prohibiting rulemaking in the absence of the regulatory policy officer's approval.

same day as the executive order.⁹ Nevertheless, it is not clear why the Administration believed that both the OMB bulletin and the changes to the executive order were necessary.

Neither the President nor OMB is required to explain why executive orders are issued, or why existing OIRA review processes are changed. And sound public policy rationales can be envisioned concerning why the changes were made. Nevertheless, it is notable that, while OMB has required agencies to provide the “specific market failure” or the “specific problem” that led to the development of draft regulations, the Administration has not provided similarly specific reasons why these five changes to the review process for all significant rules and guidance documents were made. Providing those rationales might have gone a long way toward quieting some of the concerns that have been voiced regarding the changes.

EFFECT OF THE CHANGES ON AGENCIES AND THE PUBLIC

Also unclear is the ultimate effect of the changes brought about by Executive Order 13422 in terms of the burden that they may impose on federal rulemaking agencies, the rules that emerge from the rulemaking process, and the transparency of that process to the public. In some cases, this lack of clarity is because of the discretion given to agencies or OIRA in the review process. For example, the requirement in the new executive order that agencies estimate the aggregate costs and benefits of upcoming rules listed in their regulatory plans is required “to the extent possible.” It is not clear whether agencies or OIRA will ultimately determine what is “possible.”

Similarly, the requirement in the “Principles of Regulation” section of the new executive order that each covered agency identify in writing the “specific market failure” or the “specific problem” that it intends to address through a draft regulation is preceded by language indicating that this principle should be followed “to the extent permitted by law and where applicable.” It is unclear whether OIRA will permit agencies to decide when the requirement is “applicable,” or whether OIRA will make that determination for them. Also unclear is how strictly OIRA will enforce this principle. For example, will OIRA consider a statutory requirement that an agency develop a final rule by a particular date a “specific problem” that permits rulemaking to go forward? Finally, although the new executive order requires agencies to make this “market failure” or “problem” determination in writing, it does not indicate whether this written determination should be made public. Conceivably, therefore, agencies could satisfy this requirement by preparing a written determination of the need for a rule without showing it to anyone outside government.

In other cases, the effect of the changes made by Executive Order 13422 are unclear because they do not appear (at least on the surface) to change existing practices. For example, although Executive Order 12866 previously required agency heads to designate regulatory policy officers who reported to them, the new executive order requires each agency head to designate one of the agency’s presidential appointees to that position—a requirement that has stirred considerable controversy.¹⁰ However, available evidence indicates that most agency regulatory policy officers are already presidential appointees (e.g., agency general counsels), so it appears that the order simply requires what most agencies are already doing. Likewise, the new executive order states 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.” However, agencies have always been able to use formal rulemaking procedures, although they almost always elect not to do so because those formal, trial-like processes are generally considered more time-consuming, cumbersome, and expensive than informal “notice and comment” rulemaking. Therefore, the new order seems to provide discretion where discretion is already allowed (but generally not used).

These provisions, however, may be more substantive than they initially appear. For example, the new executive order says agencies may consider whether to use

⁹ Office of Management and Budget, “Final Bulletin for Agency Good Guidance Practices,” 72 *Federal Register* 3432, Jan. 25, 2007. To view a copy of this bulletin, see <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.

¹⁰ For example, see David McNaughton, “Reverse Regulation: With Another Nonsense Order, President Bush Quashes Legitimate Rule-making by Inserting Political Overseer,” *Atlanta Journal-Constitution*, Feb. 2, 2007, p. A10, which cited Emory University Law Professor William Buzbee as saying that this provision “makes it even more likely that regulatory decisions will be made by someone more sympathetic to political pressure and ideology than to the federal agency’s legal duty.” On the other hand, see Jim Wooten, “Vouchers, Transit Alert, Sen. Obama,” *Atlanta Journal-Constitution*, Feb. 2, 2007, p. A11, which approved of this provision and said “There’s nothing radical about applying cost-benefit analysis to proposed laws and regulations.”

formal rulemaking procedures “in consultation with OIRA.” If OIRA is able to persuade agencies during those consultations to use formal procedures more frequently, then the impact of this provision on the agencies may, in fact, be considerable. Also, use of formal rulemaking procedures would not permit the same type of public participation that are the hallmark of informal “notice and comment” rulemaking. By the same measure, if OIRA or the President requires agencies to designate *new* or *different* presidential appointees within the agencies as regulatory policy officers, then this provision—particularly when coupled with the newly enhanced authority of regulatory policy officers to control regulatory output—could become much more important.

The potential effects of other requirements in the new executive order are unclear because of the way existing procedures operate. For example, as originally issued in 1993, Executive Order 12866 required covered agencies, as part of the regulatory planning process, to provide preliminary estimates of the anticipated costs and benefits of each planned significant regulatory action. The new executive order adds the requirement that each agency provide its best estimate of the “combined aggregate costs and benefits of all its regulations planned for that calendar year.” At first impression, an agency could satisfy this requirement by simply tallying up the estimates for each forthcoming rule listed in the agency’s plan. However, agencies’ regulatory plans rarely contain quantitative estimates for forthcoming rules (especially for forthcoming proposed rules that may not be issued for as much as a year), instead either narratively describing in general terms the expected results of the regulatory action or simply indicating that such estimates are “to be determined.” Also, agencies’ regulatory plans are supposed to reflect rules that are expected to be issued during the upcoming fiscal year, so the requirement that agencies develop estimates of aggregate costs and benefits on a calendar year basis seems inconsistent with existing practices.

Other requirements in Executive Order 13422 seem to have an indefinite scope, making their effect on agencies and the benefits they may provide to the public difficult to determine. For example, the new order requires agencies to provide OIRA with “advance notification of any significant guidance documents.” The order (particularly when amplified by the OMB final bulletin on good guidance practices) defines a “guidance document” in such a way that it covers not only written material, but also video tapes, web-based software, and even oral statements by agency staff if they are of “general applicability and future effect.” The order defines a “significant” guidance document as one that, among other things, “may reasonably be anticipated” to, among other things, “lead to an annual effect of \$100 million or more” or “materially alter the budgetary impact” of entitlements, grants, loans, and user fees. However, by definition, guidance documents cannot have a binding effect on the public (if they did, they would have to be rules subject to “notice and comment” and other requirements), so it is not clear how guidance can be expected to have the effects delineated in the definition. As a result, agencies may conclude that none of their guidance documents meet the executive order’s requirements for OIRA notification. On the other hand, because OIRA is given the authority to determine which documents are “significant,” the scope and impact of this requirement may be as broad as OIRA determines that it needs to be.

Supporters of the expansion of presidential review to significant guidance documents have said the change will standardize and make more transparent the process by which federal agencies develop, issue, and use guidance documents.¹¹ Executive Order 12866 contains provisions that provide a measure of transparency to the rulemaking process, requiring (among other things) that agencies disclose to the public the changes made to their rules at the suggestion or recommendation of OIRA, and that OIRA disclose the rules that are under review at OIRA. The executive order also requires that OIRA complete its reviews of draft rules within 90 days. However, it is unclear whether these transparency and time-limit provisions will apply to agency guidance documents, because Executive Order 13422 did not change those sections of Executive Order 12866. If these provisions do not apply, then agencies may submit guidance to OIRA for review and the public may never know that OIRA is reviewing them, for how long, or what changes were made at OIRA’s direction. If the provisions are deemed applicable to guidance documents, then the goals of improved transparency and standardization would appear to be supported.

¹¹John Sullivan, “White House Sets Out New Requirements for Agencies Developing Rules, Guidance,” citing Paul Noe, partner at C&M Capitolink, who was a counselor to former OIRA Administrator John Graham.

EFFECT ON BALANCE OF POWER

Finally, in a larger, constitutional sense, it is unclear what impact the changes brought about by Executive Order 13422 will have on the balance of power between the President and Congress in this area. Congress has a vested interest in the regulations that emerge from the rulemaking process. Congress created each regulatory agency and enacted the legislation underpinning each proposed and final rule. Congress may also establish the criteria under which federal agencies can issue rules. For example, some statutes direct agencies to establish regulations based solely on what is required to protect human health, and may require agencies to regulate with a margin of safety.¹² Therefore, presidentially initiated changes that may affect these congressional directives, such as the requirement that each agency identify a specific “market failure” or “problem” before issuing a rule, are naturally of potential interest to Congress.

Another area of potential congressional interest involves the requirement that agency regulatory policy officers be presidential appointees. Executive Order 13422 does not indicate whether these appointees should be subject to Senate confirmation. Senate confirmation of presidential appointees is generally considered a way to strengthen congressional influence over agency decision making, because (among other things) nominees often agree during the confirmation process to appear subsequently before relevant congressional committees. The most recent “Plum Book” indicates that virtually all presidential appointees in regulatory agencies are subject to Senate confirmation.¹³ In some agencies (such as the Environmental Protection Agency, the Department of Transportation, and the Department of Labor), all presidential appointee positions are Senate confirmed (unless one counts noncareer senior executives, who are appointed by agency heads subject to White House approval). Therefore, it appears that most officials designated as regulatory policy officers will be (or will already have been) subject to Senate confirmation.

In those agencies with presidential appointees who are not Senate confirmed, one could argue that it is the role of Congress to prescribe, in law, whether the regulatory policy officer position should be subject to Senate confirmation. To take this argument further, even if an agency head designated a person in a Senate-confirmed position as the agency’s regulatory policy officer, one could argue that this person would have to undergo another confirmation process because the scope of the person’s responsibilities had changed significantly.

One other element of this process is also unclear, and may represent a change in the scope of presidential influence in rulemaking. The requirement that each agency head appoint one of the agency’s presidential appointees as the regulatory policy officer does not apply to independent regulatory agencies. However, as originally issued, Executive Order 12866 requires independent regulatory agencies to develop regulatory plans, and the requirement in Executive Order 13422 that the “Regulatory Policy Office” approve items included in the plan and the commencement of all rulemaking amends that section of Executive Order 12866. Therefore, this provision could arguably be read to require that independent regulatory agencies have presidential appointees as regulatory policy officers, thereby extending the reach of the President and presidential review into agencies that had not previously been subject to such scrutiny (and commensurately lessening the agencies’ relationships with Congress, which created them to be more independent of the President).

Madam Chairman, that concludes my prepared statement. I would be happy to answer any questions that you or other Members of the Subcommittee might have.

¹²For example, Section 109(b)(1) of the Clean Air Act (42 U.S.C. §7409(b)(1)) instructs the Environmental Protection Agency to set primary ambient air quality standards “the attainment and maintenance of which . . . are requisite to protect the public health” with “an adequate margin of safety.”

¹³U.S. Congress, House Committee on Government Reform, *United States Government Policy and Supporting Positions*, Nov. 22, 2004. For example, the Department of Transportation had 32 positions subject to presidential appointment with Senate confirmation (PAS positions) in 2004, but none without Senate confirmation (PA positions). The Environmental Protection Agency had 14 PAS positions, but no PA positions; the Department of Labor had 19 PAS positions, but no PA positions. On the other hand, the Department of Homeland Security had 18 PAS positions, but also had six PA positions.

CRS Report for Congress

Changes to the OMB Regulatory Review Process by Executive Order 13422

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Congressional
Research
Service

Prepared for Members and
Committees of Congress

Changes to the OMB Regulatory Review Process by Executive Order 13422

Summary

Executive Order (E.O.) 12866 on "Regulatory Planning and Review," issued in September 1993, describes the principles and procedures by which the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) reviews hundreds of significant proposed and final agency regulations on behalf of the President before they are published in the *Federal Register*. On January 18, 2007, President George W. Bush issued E.O. 13422, making the most significant amendments to E.O. 12866 since it was published. The changes made by this new executive order are controversial, characterized by some as a "power grab" by the White House that undermines public protections and lessens congressional authority, and by others as "a paragon of common sense and good government."

The most important changes made to E.O. 12866 by E.O. 13422 fall into five general categories: (1) a requirement that agencies identify in writing the specific market failure or problem that warrants a new regulation, (2) a requirement that each agency head designate a presidential appointee within the agency as a "regulatory policy officer" who can control upcoming rulemaking activity in that agency, (3) a requirement that agencies provide their best estimates of the cumulative regulatory costs and benefits of rules they expect to publish in the coming year, (4) an expansion of OIRA review to include significant guidance documents, and (5) a provision permitting agencies to consider whether to use more formal rulemaking procedures in certain cases.

This report discusses each of these changes, noting areas that are unclear and the potential implications of the changes, and provides background information on presidential review of rules. It concludes by noting that the significance of the changes made to the review process by E.O. 13422 may become clear only through their implementation, and notes some areas of potential congressional interest. The changes made by this executive order represent a clear expansion of presidential authority over rulemaking agencies. In that regard, E.O. 13422 can be viewed as part of a broader statement of presidential authority presented throughout the Bush Administration.

The report will be updated as necessary to reflect legislative or executive branch actions relevant to the implementation of the executive order.

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Changes to the OMB Regulatory Review Process by Executive Order 13422

Executive Order (E.O.) 12866 on “Regulatory Planning and Review,” issued by President William Clinton in September 1993, describes the principles and procedures by which the Office of Management and Budget’s (OMB’s) Office of Information and Regulatory Affairs (OIRA) reviews hundreds of significant proposed and final agency regulations on behalf of the President before they are published in the *Federal Register*.¹ As a result of these reviews, OIRA can have a significant — if not determinative — role in the development of a broad array of public policies, from the homeland security rules governing boarding of passenger aircraft to the amount of arsenic allowed in public water systems.²

On January 18, 2007, President George W. Bush issued E.O. 13422, making the most significant amendments to E.O. 12866 since it was published.³ The changes made by this new executive order are controversial, characterized by some as a “power grab” by the White House that undermines public protections and lessens congressional authority,⁴ and by others as “a paragon of common sense and good government.”⁵ This report describes the changes made to the regulatory planning and review process by the new order, noting the potential impact of those changes and areas that are unclear. First, though, the report provides a brief background

¹ Executive Order 12866, “Regulatory Planning and Review,” 58 *Federal Register* 51735, Oct. 4, 1993.

² U.S. General Accounting Office, *Rulemaking: OMB’s Role in Reviews of Agencies’ Draft Rules and the Transparency of Those Reviews*, GAO-03-929, Sept. 22, 2003, p. 3, available at [<http://www.gao.gov/new.items/d03929.pdf>]. See also CRS Report RL32397, *Federal Rulemaking: The Role of the Office of Information and Regulatory Affairs*, by Curtis W. Copeland; and CRS Report RL32855, *Presidential Review of Agency Rulemaking*, by T.J. Halstead.

³ Executive Order 13422, “Further Amendment to Executive Order 12866 on Regulatory Planning and Review,” 72 *Federal Register* 2763, Jan. 23, 2007. Five years earlier, E.O. 13258 reassigned certain responsibilities from the Vice President to the President’s chief of staff, but otherwise did not change the OIRA review process. See Executive Order 13258, “Amending Executive Order 12866 on Regulatory Planning and Review,” 67 *Federal Register* 9385, Feb. 28, 2002.

⁴ Public Citizen, “New Executive Order Is Latest White House Power Grab,” available at [<http://www.citizen.org/pressroom/release.cfm?ID=2361>].

⁵ Attributed to William Kovacs, Vice President of Environment, Energy, and Regulatory Affairs, U.S. Chamber of Commerce, in John Sullivan, “White House Sets Out New Requirements for Agencies Developing Rules, Guidance,” *Daily Report for Executives*, Jan. 19, 2007, p. A-31.

section on the regulatory planning and review procedures established by E.O. 12866 and its predecessors. The report ends by offering some concluding observations.

Regulatory Planning and Review Under E.O. 12866

Centralized review of agencies' regulations within the Executive Office of the President has been an important part of the federal rulemaking process for more than 35 years. Although each of his three predecessors had some type of review process, the most significant development in the evolution of presidential review of rulemaking occurred in 1981, when President Ronald Reagan issued E.O. 12291.⁶ The executive order established a set of general requirements for rulemaking, and required federal agencies (other than independent regulatory agencies) to send a copy of each draft proposed and final rule to OMB before publication in the *Federal Register*.⁷ It also required covered agencies to prepare a cost-benefit analysis for each "major" rule (e.g., those with at least a \$100 million impact on the economy). As a result of this order, OIRA became the central clearinghouse for covered agencies' substantive rulemaking, reviewing between 2,000 and 3,000 rules per year. In 1985, President Reagan expanded OIRA's influence further by issuing E.O. 12498, which required each covered agency to submit a regulatory plan to OMB for review each year that covered all of their significant regulatory actions underway or planned.⁸ Regulatory reviews under these executive orders were highly controversial, with complaints about the lack of transparency of the review process, unlimited delays in the completion of the reviews, OIRA serving as a conduit for influence by regulated parties, and executive branch displacements of congressional delegations of rulemaking authority.⁹

On September 30, 1993, President Clinton issued E.O. 12866, which revoked E.O. 12291 and E.O. 12498 and established a new process for OIRA review of rules. The order limited OIRA's reviews to actions identified by the rulemaking agency or OIRA as "significant" regulatory actions, defined as those that were "economically significant" (e.g., those with at least a \$100 million impact on the economy) or that (1) were inconsistent or interfered with an action taken or planned by another agency; (2) materially altered the budgetary impact of entitlements, grants, user fees, or loan programs; or (3) raised novel legal or policy issues. As a result of this change, the number of rules that OIRA reviewed dropped from between 2,000 and 3,000 per year to between 500 and 700 per year. For each significant draft rule, the executive order

⁶ Executive Order 12291, "Federal Regulation," 46 *Federal Register* 13193, Feb. 19, 1981.

⁷ Independent regulatory agencies include the Federal Communications Commission, the Nuclear Regulatory Commission, and the Securities and Exchange Commission, and are created by Congress to be more independent of the President than other agencies (e.g., commission members may generally be removed by the President only for cause).

⁸ Executive Order 12498, "Regulatory Planning Process," 50 *Federal Register* 1036, Jan. 8, 1985.

⁹ See, for example, Morton Rosenberg, "Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12291," *Michigan Law Review*, vol. 80 (1981), pp. 193-247.

requires the issuing agency to provide to OIRA the text of the draft rule, a description of why the rule is needed, and a general assessment of the rule's costs and benefits. For draft rules that are "economically significant," the executive order requires a detailed cost-benefit analysis, including an assessment of the costs and benefits of "potentially effective and reasonably feasible alternatives to the planned regulation."

E.O. 12866 also differs from its predecessors in other respects. For example, the order requires that OIRA generally complete its reviews of proposed and final rules within 90 calendar days. It also requires both the rulemaking agencies and OIRA to disclose certain information about how the regulatory reviews were conducted. For example, agencies are to identify for the public (1) the substantive changes made to rules between the draft submitted to OIRA for review and the action subsequently announced, and (2) changes made at the suggestion or recommendation of OIRA. OIRA is required to, among other things, provide agencies with a copy of all communications between OIRA personnel and parties outside the executive branch, and to maintain a public log of all regulatory actions under review and of all the documents provided to the agencies. Finally, E.O. 12866 required all agencies (including independent regulatory agencies) to prepare a regulatory plan listing the most important regulatory actions that the agency expects to issue in the next fiscal year. Agency heads were required to approve this plan personally.

Changes Made by E.O. 13422

The most important changes made to E.O. 12866 by E.O. 13422 fall into five general categories: (1) a requirement that agencies identify in writing the specific market failure or problem that warrants a new regulation, (2) a requirement that every agency head designate a presidential appointee within the agency as a "regulatory policy officer" who can control upcoming rulemaking activity in that agency, (3) a requirement that agencies provide their best estimates of the cumulative regulatory costs and benefits of rules they expect to publish in the coming year, (4) an expansion of OIRA review to include significant guidance documents, and (5) a provision permitting agencies to consider whether to use more formal rulemaking procedures in certain cases. Each of these changes is described more fully in the following sections.

Identification of Market Failure

E.O. 12866 begins with a statement of regulatory philosophy and principles that sets the tone for agency rulemaking covered by the order. The principles say that, "to the extent permitted by law and where applicable," agencies should (among other things) assess alternatives to direct regulation, design regulations in the most cost-effective manner possible, and base regulations on the best information available. As originally written, the first such principle was that "[e]ach 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."

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E.O. 13422 changes that language somewhat, stating the following:

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.

The new language appears to (1) elevate “market failure” to greater prominence as a rulemaking rationale (removing the “where applicable” caveat and placing it before and on par with the more general statement of problem identification); (2) more clearly define what constitutes a market failure (e.g., “externalities, market power, lack of information”);¹⁰ (3) require a more precise delineation of why the agency is issuing the rule (the “specific” market failure or the “specific” problem); (4) require that the delineation be in writing; and (5) make clear that the purpose of this requirement is to facilitate a determination of whether the rule is needed.

The general principle that a covered agency describe the need for a new regulation is procedurally established in Section 6 of E.O. 12866. For rules that are significant, but not economically significant (e.g., do not have a \$100 million impact on the economy), agencies are required only to provide a “reasonably detailed description of the need for the regulatory action.” For economically significant rules, however, more detailed cost-benefit analyses are required. OMB Circular A-4 (which describes how those studies should be done) says agencies “should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy.”¹¹ Therefore, the “market failure” language in E.O. 13422 can arguably be read to apply to all rules that had previously applied only to economically significant rules.

Also, although the order requires agencies to make this determination in writing, E.O. 13422 does not indicate where this written determination should appear (e.g., in the *Federal Register* notice for the proposed or final rule), or, additionally, whether it should be made available to the public in the rulemaking docket. Conceivably, therefore, agencies could satisfy the requirements of the order by preparing a written determination of the need for a rule without providing it to anyone outside government.

¹⁰ According to OMB Circular A-4, an “externality occurs when one party’s actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods.” It says “[f]irms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices,” such as when a monopoly exists. Inadequate information can occur when the public is unaware of the dangers associated with the use of a product. To view a copy of this circular, see [<http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>].

¹¹ To view a copy of this circular, see [<http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>].

Some commentators have criticized this provision in E.O. 13422 as an attempt to bypass Congress by establishing standards for regulatory initiation that are not consistent with statutory requirements. For example, Public Citizen said the requirement “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.”¹² For example, some statutes (e.g., the Clean Air Act) require agencies to establish regulations based solely on what is required to protect human health. These critics contend that requiring agencies to identify a “specific market failure” or a “specific problem” constitutes a new standard for regulatory initiation. Supporters of this provision may contend, though, that the requirement to identify a “problem” is sufficiently broad to cover all statutory bases, and therefore is not inconsistent with them.

Public Citizen has also criticized this provision as “yet another layer added to the agency analysis” that “places yet another hurdle for agencies to issue regulations in pursuit of protecting the public.” Similarly, Gary Bass, executive director of OMB Watch, said that President Bush, by requiring agencies to show a market failure, “has created another hurdle for agencies to clear before they can issue rules protecting public health and safety.”¹³ On the other hand, supporters of this provision may contend that requiring agencies to identify the specific problem being addressed in a regulation is not onerous, and can help ensure the effectiveness of the resultant rules.

Finally, although stated in terms of a requirement (“[e]ach agency shall”), this and other principles of regulation in the executive order are preceded by more permissive language, stating that agencies “should” adhere to the principles “to the extent permitted by law and where applicable.” Given this language, concerns about the usurpation of congressional standards for rulemaking and unnecessary delay may be exaggerated. Ultimately, though, the extent to which these changes are significant may be revealed only through how they are implemented by OIRA and the agencies.

Regulatory Policy Officers as Presidential Appointees

As originally written, E.O. 12866 required the head of each covered agency (other than independent regulatory agencies) to designate a regulatory policy officer who reported to the agency head.¹⁴ The policy officer is required 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 set forth in this Executive order.” According to agency officials, these regulatory policy

¹² Public Citizen, “New Executive Order Is Latest White House Power Grab.”

¹³ Robert Pear, “Bush Directive Increases Sway on Regulation,” *New York Times*, Jan. 30, 2007, p. A1.

¹⁴ Although the regulatory planning sections apply more broadly, the executive order generally defines an “agency” as “any authority of the United States that is an ‘agency’ under 44 U.S.C. 3502 (1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502 (10).” The order does not define “agency head,” but agency policy officers in Cabinet departments have typically been designated by the secretary.

officers were most commonly each agency's general counsel (which are usually presidential appointees with Senate confirmation) or some other presidential appointee within the agencies.

E.O. 13422 retains the above general statement of the policy officer's duties, but also requires each agency head to "designate one of the agency's Presidential Appointees" to be that officer, to do so within 60 days of the date of the executive order (i.e., by March 19, 2007), to advise OMB of the designation, and to "annually update OMB on the status of this designation." Although the agency head is still permitted (within the parameters of White House and OMB control) to select the individual for this position, the requirement that the individual be a presidential appointee limits the agency head's discretion (compared to the unlimited authority that agency heads enjoyed before this amendment) and strengthens the relationship of the agency policy officers with the President. However, if most of the regulatory policy officers are already presidential appointees, it is not clear how this requirement will affect the current set of regulatory policy officers.

E.O. 13422 also appears to significantly enhance the role of the agency regulatory policy officer as part of the regulatory planning process. Specifically, the order states that "[u]nless 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." Notably, this provision speaks in terms of a regulatory policy "office" as opposed to a regulatory policy "officer," suggesting (but not requiring) that agencies may provide staff to assist the policy officers in their duties within the agencies. In any event, this change appears to represent an elevation in the duties and responsibilities of the agency policy officer when compared to the role previously ascribed to that officer (i.e., to "be involved" in the regulatory process, to "foster the development" of sound rules, and to "further" the order's principles). Unless specifically authorized by the agency head, the presidential policy officer must approve the listing of all significant forthcoming regulatory actions in the regulatory plan and approve the initiation of all rulemaking actions. (Previously, only the agency head could approve the regulatory plan, and there was no language in the order prohibiting rulemaking in the absence of the regulatory policy officer's approval.) As characterized in the *New York Times*, "[t]he White House will thus have a gatekeeper in each agency to analyze the costs and the benefits of new rules and to make sure the agencies carry out the president's priorities."¹⁵

¹⁵ Robert Pear, "Bush Directive Increases Sway on Regulation." Newspaper editorial writers have offered various opinions regarding this issue. For example, see David McNaughton, "Reverse Regulation: With Another Nonsense Order, President Bush Quashes Legitimate Rule-making by Inserting Political Overseer," *The Atlanta Journal-Constitution*, Feb. 2, 2007, p. A10, which cited Emory University Law Professor William Buzbee as saying that this provision "makes it even more likely that regulatory decisions will be made by someone more sympathetic to political pressure and ideology than to the federal agency's legal duty." Also, see Jim Wooten, "Vouchers, Transit Alert, Sen. Obama," *The Atlanta Journal-Constitution*, Feb. 2, 2007, p. A11, which approved of this provision and said "[t]here's nothing radical about applying cost-benefit analysis to proposed laws and regulations."

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The executive order's use of the word "designate" suggests that agency heads must select regulatory policy officers from among current presidential appointees within the agencies. (Neither the President nor agency heads are authorized to create presidential appointee positions; only Congress can do so.) The order is silent as to whether the designated presidential appointee would be subject to Senate confirmation. Senate confirmation of presidential appointees is generally considered a way to strengthen congressional influence over agency decision making, because (among other things) nominees often agree during the confirmation process to appear subsequently before relevant congressional committees. According to the most recent listing of "Policy and Supporting Positions" (known as the "Plum Book"), most major regulatory departments and agencies have few (and in some cases, no) presidential appointees who are not Senate confirmed.¹⁶ Therefore, in most cases, agency heads must select presidential appointees who are subject to Senate confirmation.

Even in agencies with a number of presidential appointees not subject to Senate confirmation, one could argue that it is up to Congress to decide whether the position of regulatory policy officer should be occupied by an appointee who is Senate confirmed. The Supreme Court has held that "any appointee exercising significant authority pursuant to the laws of the United States is an 'Officer of the United States,' and must, therefore, be appointed in the manner prescribed" in the Constitution.¹⁷ Given the enhanced power and authority of the policy officer to control day-to-day rulemaking activities within federal agencies ("no rulemaking shall commence"), the policy officer could be considered an officer of the United States under the appointments clause of the Constitution. Article II, Section 2, clause 2 of the Constitution states the following:

[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

¹⁶ U.S. Congress, House Committee on Government Reform, *United States Government Policy and Supporting Positions*, Nov. 22, 2004. For example, the Department of Transportation had 32 positions subject to presidential appointment with Senate confirmation (PAS positions) in 2004, but none without Senate confirmation (PA positions). The Environmental Protection Agency had 14 PAS positions, but no PA positions; the Department of Labor had 19 PAS positions, but no PA positions. On the other hand, the Department of Homeland Security had 18 PAS positions, but also had six PA positions. This CRS report did not consider noncareer ("general") Senior Executive Service positions to be "presidential appointee" positions. However, some have argued that, because some type of White House approval for their appointment is required, these noncareer SES positions could be considered a type of "presidential appointee" positions. If so, then the agency heads would have a wider range of "presidential appointee" positions from which to designate regulatory policy officers.

¹⁷ *Buckley v. Valeo*, 424 U.S. 1, 126 (1976).

Therefore, one could argue that it is the role of Congress to prescribe, in law, whether the regulatory policy officer position should be subject to Senate confirmation. In fact, to take this argument further, even if the agency head designated a person in a Senate-confirmed position for this new position, one could argue that this person would have to undergo another confirmation process because the scope of the person's responsibilities had been changed significantly.

One other element of this process is also unclear, and may represent a change in the scope of presidential influence in rulemaking. As noted previously, the requirement that each agency head appoint one of the agency's presidential appointees as the regulatory policy officer does not apply to independent regulatory agencies. However, E.O. 12866 requires independent regulatory agencies to develop regulatory plans, and the requirement in E.O. 13422 that the "Regulatory Policy Office" approve items included in the plan and the commencement of all rulemaking amends that section of E.O. 12866. Therefore, this provision could arguably be read to require that independent regulatory agencies have presidential appointees as regulatory policy officers, thereby extending the reach of the President and presidential review into agencies that had not previously been subject to such scrutiny (and commensurately lessening the agencies' relationships with Congress, which created them).

Estimate of Aggregate Regulatory Costs and Benefits

As part of the above-mentioned regulatory planning process, agencies have been required to provide 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." E.O. 13422 adds to this provision the requirement that each agency provide its "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."

At first impression, the changes established by this provision appear relatively straightforward, simply requiring agencies to tally up the costs and benefits of the individual rules listed in the regulatory plan. However, upon closer examination, some aspects of this provision appear unclear. For example, the regulatory plans that agencies develop are supposed to be published at the start of each fiscal year in October, and are required to reflect the most significant proposed and final rules that they expect to publish "in that fiscal year or thereafter." Therefore, the requirement in E.O. 13422 that agencies develop estimates of aggregate costs and benefits for regulations planned "for that calendar year" seems inconsistent with the previous focus on fiscal years.

More substantively, some critics of the order have suggested that this provision is intended to elevate the role of cost-benefit analysis in the development of regulatory priorities. They argue that cost-benefit analysis is inherently biased against regulation, particularly with regard to such issues as global warming and long-term exposure to carcinogens, so the effect of this provision would be to reduce

regulatory activity.¹⁸ Other critics have said this provision is a prelude to the development of a regulatory budget in which the costs associated with an agency's rules could be capped and no new rules could be issued unless other costs were reduced or eliminated.¹⁹ Proponents of this provision, on the other hand, may argue that such aggregate estimates are needed to reveal the cumulative impacts of rulemaking. Individually, regulations on a particular industry may not be significant, but the aggregation of the impact of multiple rules may reveal cumulative effects that are not otherwise apparent.

Also, agencies' regulatory plans are published as part of the *Unified Agenda of Federal Regulatory and Deregulatory Actions*, and contain information about the most significant regulatory actions that agencies expect to undertake in the coming year.²⁰ The listed items include both proposed and final rules that the agency expects to issue during that period. For forthcoming proposed rules, agencies often have not developed cost or benefit estimates because the specifics of the proposed rules have often not been developed. Even for forthcoming final rules, agencies frequently provide only general information about expected costs or benefits. Also, some items that are listed in agencies' regulatory plans are never issued as final rules, and some agency rules never appear in agencies' regulatory plans. Therefore, the requirement in the executive order that agencies provide aggregate cost and benefit information may prove difficult to implement in a meaningful fashion. However, as noted previously, agencies are required to do so only "to the extent possible."

OIRA Review of Significant Guidance Documents

Another controversial provision in E.O. 13422 has been the expansion of OIRA review from agencies' draft regulations to also include significant agency guidance documents.²¹ Specifically, the new executive order adds the following to E.O. 12866:

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

¹⁸ Public Citizen, "New Executive Order Is Latest White House Power Grab."

¹⁹ OMB Watch, "Undermining Public Protections: Preliminary Analysis of the Amendments to Executive Order 12866 on Regulatory Planning and Review," available at [<http://www.ombwatch.org/article/articleview/3685/1/132?TopicID=3>].

²⁰ To view the most recent regulatory plan (published in December 2006), see [http://fwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2006_unified_agenda_&docid=fua061002.pdf].

²¹ On the same day that E.O. 13422 was issued, OMB also issued a "Final Bulletin for Agency Good Guidance Practices" that mirrored, in many respects, the provisions in this section of the executive order. Unlike the order, however, the bulletin requires agencies to include certain standard elements in their significant guidance documents, to list those documents on the agencies' websites, and to publish a notice in the *Federal Register* soliciting public comments on economically significant documents. To view a copy of this bulletin, see [<http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>], and Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," 72 *Federal Register* 3432, Jan. 25, 2007.

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.

E.O. 13422 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." It says a "significant" guidance document is one that is

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.

These categories are essentially the same as those used in E.O. 12866 to define significant rules, the only difference being the use of the prefatory phrase "may reasonably be anticipated to" instead of "is likely to result in a rule that may."

The implications of these amendments to the scope of presidential review of agency actions are potentially significant. Agencies issue thousands of guidance documents each year that are intended to clarify the requirements in related statutes and regulations.²² Therefore, the requirement that agencies provide OIRA with advance notification of significant guidance documents may represent a major expansion of the office's (and, therefore, the President's) influence, particularly when coupled with the ability of OIRA to determine which guidance documents are "significant" and the ability of OIRA to conclude that "additional consultation will be required" before a document is issued. Also, the requirement that presidentially appointed regulatory policy officers ensure compliance with this requirement

²² For example, the Occupational Safety and Health Administration indicated in 2000 that it had issued 3,374 guidance documents since March 1996. See U.S. Congress, House Committee on Government Reform, *Non-Binding Legal Effect of Agency Guidance Documents*, 106th Cong., 2nd sess., H.Rept. 106-1009 (Washington: GPO, 2000), p. 5.

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arguably represents another extension of the President's authority in regulatory agencies.

As is the case with other aspects of E.O. 13422, though, several aspects of these provisions are unclear. For example, although the order refers to guidance "documents," the definition of the term is not limited to written materials. In a related OMB bulletin on agency guidance that was issued the same day as the executive order amendments, OMB said that the bulletin's definition of a guidance document (which is the same as in the executive order)

is not limited only to written guidance materials and should not be so construed. OMB recognizes that agencies are experimenting with offering guidance in new and innovative formats, such as video or audio tapes, or interactive web-based software. The definition of "guidance document" encompasses all guidance materials, regardless of format.²³

Therefore, a wide range of agency communications with the public — even oral statements by agency officials and staff — may be considered guidance "documents," as long as they are statements of "general applicability and future effect."

However, given the definition provided in the executive order, it is unclear what could constitute a "significant" guidance document. Guidance documents, unlike regulations, cannot have a binding effect on the public.²⁴ Therefore, it is not clear how guidance can be expected to have the effects delineated in the definition (e.g., "lead to an annual effect of \$100 million or more" or "materially alter the budgetary impact" of entitlements or grants). Arguably, because no guidance document can, by itself, have such an effect, the requirement that agencies provide OIRA with advance notification of any significant guidance documents could have little or no impact on regulatory agencies. On the other hand, OMB has said that "there are situations in which it may reasonably be anticipated that a guidance document could lead parties to alter their conduct in a manner that would have such an economically significant impact."²⁵ Ultimately, because OIRA is given the authority to determine which documents are "significant," the scope and impact of this section's requirements may be as broad as OIRA determines that it needs to be.

Also unclear is the extent to which certain transparency provisions in E.O. 12866 will apply to guidance documents. For example, will agencies be required to disclose the changes to their significant guidance documents made at the suggestion and recommendation of OIRA (just as they are with regard to rules)? Will OIRA be required to list publicly the significant guidance documents that are under its review,

²³ Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," p. 3434.

²⁴ See, for example, *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000); *Chamber of Commerce v. Department of Labor*, 174 F.3d 206 (D.C. Cir. 1999); Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like — Should Agencies Use Them to Bind the Public?" *Duke Law Journal*, vol. 41 (1992), p. 1311.

²⁵ Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," p. 3435.

and to disclose its meetings with outside entities regarding those documents? Because E.O. 13422 did not change those sections of E.O. 12866, it is reasonable to presume that the transparency provisions applicable to rules are not applicable to agencies' significant guidance documents.

Supporters of the expansion of presidential review to significant guidance documents have said the change will standardize and make more transparent the process by which federal agencies develop, issue, and use guidance documents.²⁶ Critics contend that the potentially broad scope of this provision may result in fewer guidance documents being issued, with the policy officer or OIRA review serving as a "bureaucratic bottleneck that would slow down agencies' ability to give the public information it needs."²⁷ Another possible effect of this requirement, given the number of guidance documents that agencies currently issue, is that OIRA staff may be inundated with such documents to review (on top of the hundreds of significant proposed and final rules and the thousands of paperwork clearances they produce each year) — at least until it is clear to the agencies what is and is not covered.

Use of Formal Rulemaking Procedures

E.O. 13422 also amends Section 6 of E.O. 12866 by adding the following sentence: "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." Virtually all agency regulations are currently issued under informal rulemaking procedures under 5 U.S.C. 553, in which agencies publish proposed rules in the *Federal Register* for public comment, and subsequently publish a final rule reflecting any changes made as a result of those comments. Formal rulemaking, as the name implies, is a much more rigorous, trial-like, on-the-record procedure in which interested persons testify and cross-examine witnesses, and the agency may take depositions and issue subpoenas. It is generally considered a more time-consuming and expensive process than informal rulemaking. Also, according to 5 U.S.C. 556(d)(1), "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof."²⁸ Formal rulemaking was criticized in the 1970s, and has fallen into disuse since then.²⁹ The Administrative Conference of the United States recommended that Congress should not require procedures beyond informal rulemaking, and should never require trial-type procedures for resolving questions of policy or fact.²⁹

²⁶ John Sullivan, "White House Sets Out New Requirements for Agencies Developing Rules, Guidance," citing Paul Noe, partner at C&M Capitolink, who was a counselor to former OIRA administrator John Graham.

²⁷ Public Citizen, "New Executive Order Is Latest White House Power Grab."

²⁸ For a discussion of formal rulemaking, see Jeffrey S. Lubbers, ed., *A Guide to Federal Agency Rulemaking, Fourth Edition* (Chicago: American Bar Association, 2006), pp. 58-59.

²⁹ ACUS Recommendation 72-5, *Procedures for the Adoption of Rules of General Applicability*, 38 *Federal Register* 19782, 1972; Jeffrey S. Lubbers, ed., *A Guide to Federal Agency Rulemaking, Fourth Edition*, pp. 309-310.

The executive order does not indicate, and OIRA has not explained, why this provision was added to E.O. 12866. Agencies have always had the ability to employ formal rulemaking when they conclude that it is in the agencies' best interest to do so. Therefore, the statement that agencies "may also consider whether to utilize formal rulemaking procedures" seems to grant discretion where discretion was already allowed. On the other hand, an agency's "consultation with OIRA" may result in greater use of formal rulemaking if OIRA can convince the agency that it is in their best interest to do so. If that occurs, agency rulemaking could become even more "ossified" than it already is.³⁰

Concluding Notes

The amendments made by E.O. 13422 to E.O. 12866 are the most significant since the latter order was issued in 1993, but the characterizations of the changes by interested parties are dramatically different. Jeffrey Rosen, general counsel at OMB, reportedly characterized the new executive order as "a classic good-government measure that will make federal agencies more open and accountable."³¹ On the other hand, Gary Bass, executive director of OMB Watch said the changes made to the regulatory review process were "had, bad, bad," and predicted that they would hamper the government's ability to respond to regulatory crises such as E.coli outbreaks on fresh vegetables.³² One Member of Congress was quoted as saying that the order "allows the political staff at the White House to dictate decisions on health and safety issues, even if the government's own impartial experts disagree. This is a terrible way to govern, but great news for special interests."³³

However, the ultimate impact of these changes to the regulatory review process is unclear, and will likely depend on how the changes are implemented by OIRA and the agencies. Will, for example, OIRA insist that agencies identify a "specific market failure" before issuing proposed or final rules, or will that provision be interpreted more broadly to require simply a clear statement of the rules' intentions? Will agency heads continue to have discretion in the appointment of regulatory policy officers (albeit less than before since they must now select from current presidential appointees), or will the White House direct the agency heads in those appointments? Will the requirement that agencies provide estimates of aggregate costs and benefits be used as a prelude to greater control and the development of regulatory budgets, or

³⁰ Several observers have commented on the "ossification" of the rulemaking process as a result of numerous statutory and executive order requirements. See, for example, Thomas O. McGarity, "Some Thoughts on 'Deossifying' the Rulemaking Process," *Duke Law Journal*, vol. 41 (June 1992), pp. 1385-1462; Richard J. Pierce, Jr., "Seven Ways to Deossify Agency Rulemaking," 47 *Administrative Law Review*, vol. 47, winter 1995, pp. 59-93; Paul R. Verkuil, "Rulemaking Ossification — A Modest Proposal," *Administrative Law Review*, vol. 47 (summer 1995), pp. 453-459.

³¹ Robert Pear, "Bush Directive Increases Sway on Regulation."

³² John D. McKinnon, "White House Flexes Muscles Over U.S. Regulations," *Wall Street Journal (Europe)*, Feb. 1, 2007, p. 12.

³³ Robert Pear, "Bush Directive Increases Sway on Regulation."

will such estimates be relatively easy to develop and reveal cumulative effects that have heretofore been hidden? Will the requirement that OIRA be notified of forthcoming significant agency guidance documents prove to be a major expansion of presidential influence over regulatory agencies, or will “significant guidance document,” as defined in the order, be a contradiction in terms resulting in virtually no such documents being covered by the order’s requirements? And finally, will OIRA require agencies to enter into more formal rulemaking procedures, or will agencies continue to be allowed to use such procedures in rare circumstances? As noted previously with regard to individual elements, the scope and effect of these changes to E.O. 12866 are likely to become apparent only through their application by OIRA and the agencies.

These uncertainties notwithstanding, the issuance of these amendments to E.O. 12866 are important if for no other reason than that the President deemed them necessary. It is reasonable to conclude that the President had some purpose in mind that led to the issuance of the new executive order. Notably, although E.O. 13422 requires agencies to provide written rationales for why they are issuing regulations, no such rationale was offered in conjunction with this or any of the other new requirements in the order. For example, it is unclear what “market failure” or other specific problem led to the issuance of the requirements that agencies have regulatory policy officers who are presidential appointees, or that agencies submit significant guidance documents to OIRA for review? To date, other than broad statements about openness and accountability, neither the President nor OMB has described why these changes were made to E.O. 12866.³⁴ However, neither the President nor OMB are required by law to offer such an explanation.

The changes made by this executive order represent a clear expansion of presidential authority over rulemaking agencies. In that regard, E.O. 13422 can be viewed as part of a broader statement of presidential authority presented throughout the Bush Administration — from declining to provide access to executive branch documents and information to presidential signing statements indicating that certain statutory provisions will be interpreted consistent with the President’s view of the “unitary executive.”³⁵

³⁴ The closest OMB has come to an explanation for these changes is in a footnote in the final bulletin on agency good guidance practices that was issued the same day as the executive order. In the bulletin, OMB said that “E.O. 13422 addresses the potential need for interagency review of certain significant guidance documents by clarifying OMB’s authority to have advance notice of, and to review, agency guidance documents.” See footnote 12 in the “Final Bulletin for Agency Good Guidance Practices,” available at [<http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>].

³⁵ For a discussion of the Bush Administration’s use of signing statements, see CRS Report RL33667, *Presidential Signing Statements: Constitutional and Institutional Implications*, by T.J. Halstead. More generally, see Adriel Bettelheim, “Executive Authority: A Power Play Challenged,” *CQ Weekly*, Oct. 30, 2006, p. 2858. For a discussion of the unitary executive principle, see Christopher S. Yoo, Steven G. Calabresi, Anthony J. Colangelo, “The Unitary Executive in the Modern Era, 1945-2004,” *90 Iowa L. Rev.* 601 (Jan. 2005); and Robert v. Percival, “Presidential Management of the Administrative State: The Not-So Unitary Executive,” *51 Duke Law Journal* 963 (Dec. 2001).

Some public interest groups and others have suggested that Congress hold hearings on the changes made to the regulatory planning and review process by E.O. 13422.³⁶ If Congress elects to do so, potential topics for review could include the intended purpose of the changes, how OIRA intends to implement them, the scope of their likely effects, and the implications of the changes for the balance of power between Congress and the President in controlling regulatory activity based on statutory authorities.

³⁶ See, for example, [<http://www.citizen.org/pressroom/release.cfm?ID=2361>], in which Public Citizen said that “Congress must immediately arrange hearings to hold the president accountable for this affront to the rule of law.”

Ms. SÁNCHEZ. I appreciate your testimony, Dr. Copeland, and you actually went under the 5 minutes.

Mr. Noe, you are up.

TESTIMONY OF PAUL R. NOE, PARTNER, C&M CAPITOLINK LLC, AND COUNSEL, CROWELL & MORING ENVIRONMENT & NATURAL RESOURCES GROUP

Mr. NOE. Chairman Sánchez, Ranking Member Cannon, Chairman Conyers, distinguished Members of the Subcommittee, my name is Paul Noe. I want to thank you for the honor to testify before you on recent changes to the regulatory review process.

While I am in the private sector now, 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 served on the Senate Governmental Affairs Committee as counsel to Chairman Bill Roth, Ted Stevens, and Fred Thompson on bipartisan regulatory reform efforts. Then until last May, I worked as counselor to Dr. John Graham at OMB's Office of Information and Regulatory Affairs. From my experience in Congress and the Executive Branch, I developed a deep appreciation for the importance of a coordinated interagency regulatory review process. I also know that the public could not expect more talented or dedicated public servants than those I worked closely with at my time at OMB.

I should note that my testimony is my personal opinion, and in my view, the recent changes to Executive Order 12866 and the accompanying OMB bulletin on good guidance practices are important and salutary steps toward good governance.

When President Bush issued the amendments to clarify and strengthen President Clinton's Executive Order 12866, the reactions were remarkable, in my view, compared with the actual language. An attachment to my written statement shows how the main Bush amendments modified President Clinton's Order. I would like to make just a few points now about how the new Order and the OMB bulletin can improve the regulatory process.

First, extending the existing regulatory review process to significant guidance documents is an important improvement. The Clinton Order appropriately sorted significant regulations from the insignificant, but it neglected guidance documents, and there is no doubt that guidance documents can be significant. Concerns have been raised by many quarters that agency guidances should be better coordinated, more consistent, more transparent and accountable, and not be used as legally binding regulations. There is a very strong foundation for these good guidance practices. In fact, Congress required FDA to issue the good guidance regulations that were a model for OMB when it designed its bulletin.

Second, both the Clinton and the Bush Executive Order required the agencies to identify the problem that justifies regulation before proceeding, whether that problem is a market failure, or something else. Although I think the Clinton market failure language was adequate, the Bush Order makes a helpful but modest change by asking the agencies to identify the problem more precisely and in writing to clarify the merits of going forward.

The Bush Orders language on market failure is simply not new, nor is it radical, as some have suggested. In fact, very similar lan-

guage and much greater detail is in the Clinton administration's 1996 guidelines for economic analysis under Executive Order 12866.

I would submit that carefully considering market failures is hardly a subversive way of thinking, and 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 OMB supported EPA adopting this same approach in the Clean Air Interstate Rule that Mr. Aitken mentioned. The CAIR rule will cut power plant emissions dramatically by about 70 percent without the economic disruptions and hardships associated with traditional command and control regulation. In my view, it would be most unfortunate if the concept of market failure and market based approaches that flow from it become politicized at a time when they are critically important tools in the regulatory policy tool kit.

Ms. SANCHEZ. Mr. Noe, you have hit your time, if you could just briefly conclude.

Mr. NOE. Finally, I would like to say that some have alleged the concept of regulatory policy officers is a radical change from the status quo. I respectfully disagree, and I would like to detail that further in question and answer.

In conclusion, regulatory policy is important and often controversial. It is commendable that this Subcommittee is making the effort to view carefully these recent changes and to understand them. In my view, a careful review of the language will allay any concerns.

Thank you.

[The prepared statement of Mr. Noe follows:]

PREPARED STATEMENT OF PAUL R. NOE

Statement of Paul R. Noe¹

Before

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

February 13, 2007

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

¹ Partner, C&M Capitolink, L.L.C.

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 literature² 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

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 Democratic⁹ and Republican¹⁰ Administrations.

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

(continued...)

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

(continued)

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 subject 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 regulator 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 interagency shall commence, nor be included on the Plan, without the approval of the agency's Regulatory Policy Officer.~~

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

Ms. SÁNCHEZ. Thank you, Mr. Noe.
Professor Strauss, please proceed with your testimony.

**TESTIMONY OF PETER L. STRAUSS, PROFESSOR, COLUMBIA
UNIVERSITY SCHOOL OF LAW**

Mr. STRAUSS. Chairman Sánchez, Ranking Member Cannon, Chairman Conyers, distinguished Members, thank you very much for inviting me to testify before you today. Given the time constraints, I hope you won't mind if I launch right into what I have to say and not who I am.

Our Constitution is very clear, in my judgment, in making the President an overseer of all the varied duties that you create for Government agencies to perform. But the Constitution is equally clear in permitting you to assign those duties to them, to the agencies, and not to the President. He is not the decider, but the overseer of decisions by others. When the President fails to honor this admittedly subtle distinction, he fails in his constitutional responsibility to take care that the laws be faithfully executed. The assignment of decisional responsibility to others is a part of the laws to whose faithful execution he is obliged to see.

Executive Order 13422 amends the longstanding Executive Order 12866 in a number of ways that you have heard about. I am going to focus on two aspects of the Order that, in my judgment, threaten this difficult but necessary balance between politicians and experts, between politics and law, that characterizes agency rulemaking.

First, amendments to sections 4 and 6 effect a dramatic increase in the President's asserted control over regulatory outcomes—an increase that, in my judgment, requires congressional authorization that has not occurred.

The second amendment threatens a revival of a discredited, remarkably expensive rulemaking procedure that delivers substantial control over the timing and cost of rulemaking into the hands of private parties, just those whose dangerous activities proposed regulations are generally intended to limit.

So first as to presidential control of rulemaking agendas.

The regulatory plan was first rationalized as an aid to the political heads of administrative agencies, requiring career staff to reveal their priorities and plans for rulemaking to agency leadership in the same way that the annual budget process does. It, I think, is sensible in that respect. It injects the agency's political leadership into the picture before matters get set in concrete. While there have been some hints that it might be used for presidential control over the years, trying to follow that issue I have never heard a whisper of it until this Order.

President Bush's Order purports to confer legal authority on a junior officer in each agency, whose identity has to be coordinated with OIRA, to control the initiation of agency rulemaking and, it seems to be intended, its continued processing in the agency. Conferring this kind of authority is Congress's business, not the President's, and I would urge you not to do it. It diffuses political authority within the agency that you would generally entrust to the agency head.

Congress, as well as the President, has political relationships with the agency head. While the President can cashier an agency

head whose work he doesn't like, that comes at high political cost, including having to get the Senate's concurrence on a successor.

A well-connected friend remarked to me "I have personally watched two agency heads tell the President to pound sand. They wouldn't do what they told and the President knew they had the political capital to win." Junior officers appointed under close White House supervision, knowing that they can be dismissed at any moment—that is what it means to be a presidential appointee—don't have this political capital. There isn't much chance that firing them will have political costs for the White House. They are not ever going to be telling the President or OIRA to pound sand.

There are a number of gaps in the Order that make this problem much worse, in my judgment. First, the Clinton Executive Order provided that the regulatory policy officer "shall report to the agency head." That language has been deleted from the Executive Order. Second, the amended Order doesn't tell us what kind of presidential appointee the regulatory policy officer is to be. You have verbal assurances oh, it will be someone confirmed by the Senate, albeit not for that purpose. Here is a road around constraints that the Constitution insists upon, that people who exercise major authority in Government can do so only with the Senate's blessing, as well as the President's. The consequence is divided Administration within each agency, with real power vested in a shadow officer who answers basically to the President, not to the agency head.

Ms. SÁNCHEZ. Mr. Strauss, you have hit your time. If you could just conclude briefly.

Mr. STRAUSS. Okay.

So let me conclude, if I may, with a suggestion for you. It seems to me that this is a simple affront to two of Congress's responsibilities: to confer organization and authority on elements of Government by enacting statutes, and to approve in the Senate all appointments to high office. You couldn't change it directly, that would encounter a presidential veto, but maybe there are the do not spend riders for appropriations measures that have been used in the past that could be employed to keep the President from paying salary to persons who are doing work that you have not designated for those persons to do.

In my printed remarks, I also address the question of formal rulemaking, and I would be happy to address that in question and answers.

[The prepared statement of Mr. Strauss follows:]

PREPARED STATEMENT OF PETER L. STRAUSS

President Bush's recent amendments to Executive Order 12866 Thank you very much for inviting me to testify before you today. I am a scholar of administrative law, who has had the privilege of teaching that subject at Columbia Law School for the past 36 years and who for two years in the 1970's had the honor of serving as the first General Counsel of the Nuclear Regulatory Commission. I was later Chair of the ABA's Section of Administrative Law and Regulatory Practice, a consultant to the ABA's Coordinating Committee on Regulatory Reform, and long-time chair of the Section's Rulemaking Committee. My 1984 analysis of agency relations with the President won its annual prize for scholarship. I have continued since then to write about separation of powers and, in particular, the President's constitutional relationship to the agencies on which Congress has conferred regulatory authority. At-

tached to this testimony is the current draft of my most recent writing on this subject, an essay to be published this summer by the George Washington Law Review entitled “Overseer or ‘The Decider’—The President in Administrative Law.” This draft will have to be revised in light of the executive order you are hearing about today, but its bottom line will not. Our Constitution is very clear, in my judgment, in making the President an overseer of all the varied duties the Congress creates for government agencies to perform. Yet our Constitution is equally clear in permitting Congress to assign these duties to them and not to the President. He is not “the decider,” but the overseer of decisions by others. When the President fails to honor that admittedly subtle distinction, he fails in his constitutional responsibility to “take Care that the Laws be faithfully executed.” The assignment of decisional responsibility to others is a part of those laws to whose faithful execution he must see.

Our subject is Executive Order 13422, 72 Fed. Reg. 2763 (January 23, 2007), that amends the long standing Executive Order 12866, concerning regulatory planning and review. Others here today may speak to those elements of the order that reach guidance documents, another of its important elements, and that heighten the specificity of the analysis the order requires agencies to perform. I will leave those elements largely to them. Let me say only, as a long-time advocate of the proper use of guidance to help the public deal with agency regulatory standards, that I find the extension of the order to guidance documents possibly troubling only in its details. As a long-time supporter, as well, of the President’s constitutional authority and wisdom in commanding regulatory analyses in connection with important rulemakings, I find that heightened specificity troubling only insofar as it may be administered to require agencies to decide matters on the basis of factors Congress has not authorized them to consider.

In these remarks I want to address two other aspects of the order, that I find particularly troubling—first, enhancements to the existing provisions respecting the regulatory planning office and officer that amended §4(c)(1) of E.O. 12866 by adding

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 Officer,

and §6(a)(2) of EO 12866 by adding

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.

and second, an entirely new idea added to §6(a)(1) of EO, requiring that

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.

Both additions threaten to disturb the difficult but necessary balance between politicians and experts, between politics and law, that characterizes agency rulemaking. The first threatens a dramatic increase in presidential control over regulatory outcomes, to an extent Congress has not authorized and in my judgment must authorize. The second threatens redeployment of a discredited, remarkably expensive rulemaking procedure that delivers substantial controls over the timing and cost of rulemaking into the hands of private parties—notably, I fear, those whose dangerous activities proposed regulations are intended to limit.

I. PRESIDENTIAL CONTROL OF RULEMAKING AGENDAS

When President Reagan elaborated the idea of a regulatory agenda in Executive Order 12498,¹ Christopher DeMuth, who had responsibilities for these issues in his administration, characterized it as essentially an aid to the political heads of administrative agencies—requiring career staff to reveal their priorities and plans for rulemaking to agency leadership, just as the annual dollar budget process does, and consequently injecting the agency’s political leadership into the picture before matters got set in bureaucratic concrete. Seen in this way, the measure supported Congress’s assignments of responsibility—it is, after all, on the agency’s political leadership alone that Congress’s statutes confer the power to adopt rules. To judge by its own actions in measures like the Regulatory Flexibility Act, Congress like the private community was also attracted by the transparency and added opportunities for

¹A predecessor provision may be found in President Carter’s E.O. 12044.

broad public participation early notice of rulemaking efforts would provide. President Clinton's Executive Order 12866 continued and in some ways strengthened this measure, requiring agencies to designate a regulatory policy officer who would coordinate general issues under the Executive Order—in effect be the agency's designated contact person for the OMB Office of Information and Regulatory Affairs (OIRA). While there were hints that it might be used to effect presidential control over agency policy choices, after years of paying fairly close attention to this question in my scholarship and professional associations, I have never heard that that had happened. On specific issues of importance to him, as Dean Elena Kagan of Harvard has detailed, President Clinton through his domestic policy office—not OIRA—would issue directives to particular agencies on particular issues of importance to his program. President Bush's first head of OIRA, John Graham, initiated a practice of occasional "prompt letters" publicly directing agency attention to matters that he concluded might warrant regulation. But a general centralization of actual control over regulatory agendas, so far as I could tell, was never effected. Until this order.

President Bush's order purports to confer authority on a junior officer in each agency, whose identity must be coordinated with OIRA, to control the initiation of agency rulemaking and, it seems to be intended, its continued processing within the agency. I would have thought conferring this kind of authority Congress's business, not something the President is authorized to accomplish on his own say-so. And if Congress were to ask my judgment about such a step I would call it unwise—as a diffusion of political authority within the agency, that Congress generally entrusts to the agency head. While legislation may permit the head to subdelegate some of her authority to persons she trusts and will take responsibility for, it wisely has rarely if ever permitted subdelegation of ultimate control over rulemaking, and it certainly would be unwise to permit that to persons who are controlled by others outside the agency. Congress as well as the President has political relationships with the agency head. While the President has a formal capacity to discipline agency heads whose work displeases him, that capacity is sharply limited by the political costs of doing so—including the necessity of securing senatorial confirmation of a successor. As a well-connected friend of mine recently remarked,

I personally have watched two agency heads tell the President to pound sand—they wouldn't do what they were told and the President knew they had the political capital to win.

Junior officers, given their responsibilities in a process under close White House supervision, knowing as "presidential appointees" that they can be dismissed at any moment, and lacking both this political capital and much prospect that their dismissal would have, in itself, political costs for the White House, are not ever going to be telling the President *or* OIRA to pound sand.

A number of gaps in the order make this problem, in my judgment, a lot worse.

- First, the Clinton executive order reinforced ordinary agency hierarchy by providing in §6(a)(2) that the regulatory policy officer "shall report to the agency head." That language has been omitted. Now it is at least ambiguous to whom the RPO reports. Anyone aware of the change—the agency head, for example—will know that this mandatory relationship has been eliminated.
- Second, the amended order now requires that the "policy officer" be a "presidential appointee," but it doesn't tell us what kind of presidential appointee—one who must also be confirmed by the Senate? One the President can name without need for confirmation? Perhaps a non-career officer in SES, whose appointment occurs only after White House clearance and with a presidentially-signed commission? If it is either of the latter, then the President has found his way around the constraints the Constitution insists upon, that people who exercise major authority in government can do so only with the Senate's blessing as well as his. Then it becomes obvious that the President has created a divided administration within each agency, with real power vested in a shadow officer who essentially answers only to him. As my friend also remarked, this would be "disastrous."

First as a practical matter it takes regulatory power away from the head of the agency where Congress has vested it. Second, it continues the political accretion of power in the bureaucracy of the White House, away from public scrutiny. But, the worst part from my vantage point is that it treats the agency as a conquered province—the career staff is explicitly told it is distrusted and is not to make recommendations to the agency head but to the White House's political officers. That in turn destroys

communication between the staff and the political level of the agency. And, the agency is quite ineffective when that happens.

- Third, it is unclear to what extent the new controls extend to the independent regulatory commissions. Section 4's language, including the requirement that "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 Officer," is explicitly applicable to independent regulatory commissions. Section 6, that defines the regulatory policy officer's appointment, is not. As a legal requirement of agencies Congress has chosen to constitute as independent regulatory commissions, this is truly extraordinary.
- The final gap I want to note for you, one of signal importance in my judgment, concerns political access. Among the elements that have made the Executive Order regime acceptable to Congress, and I might add to much of the academic community, are the commitments it contains to a professionalized, unusually transparent and apolitical administration. Oral contacts with outside interests are limited to OIRA's senate-confirmed Administrator or his particular designee; agencies attend any meetings with outsiders; written communications from outsiders are also logged; and all of this information is publicly disclosed. My understanding is that Congress has properly insisted on these elements of transparency, as a condition of its acceptance of this generally valuable regime. The OIRA website, within a generally closed White House environment, has been a remarkable monument to the worth of this insistence.² The professional qualities, too, of OIRA's staff, and the striking qualities of its leadership over time, have offered reassurance. Notice that none of these constraints are made applicable to the Regulatory Policy Officer or his office.

So the President has attempted to do by executive order something that, in my judgment, can only be done by statute. Moreover, in doing so he threatens excessive politicization of agency rulemaking, the subversion of a public process by back-corridor arrangements, and compromising the lines of authority Congress has created. These officers will, in practice, be answerable only to him, as is underscored by the disappearance of "shall report to the agency head" from § 6(a)(2). Their conversations with him, his lieutenants, and any political friends he may send their way will be invisible to us.

You will likely hear from the other side that the President is, after all, our chief executive, that our Constitution embodies the judgment that we should have a unitary executive, and so even if the result were to convert agency judgments about rulemaking into presidential judgments, that would only be accomplishing what the Constitution commands. This is the subject of the writing I have attached to this testimony. In my judgment it is not only an erroneous argument, but one dangerous to our democracy. The President is commander in chief of the armed forces, but not of domestic government. In domestic government, the Constitution is explicit that Congress may create duties for Heads of Departments—that is, it is in the heads of departments that duties lie, and the President's prerogatives are only to consult with them about their performance of those duties, and to replace them with senatorial approval when their performance of those duties of theirs persuades him that he must do so. This allocation is terribly important to our preservation of the rule of law in this country. The heads of departments the President appoints and the Senate confirms must understand that their responsibility is to decide—after appropriate consultation to be sure—and not simply to obey. We cannot afford to see all the power of government over the many elements of the national economy concentrated in one office.

²This is not the setting to explore the accounts I am beginning to hear of increasing, and in my judgment, regrettable, politicization and transparency violations in OIRA functioning—for example, deliberate holding back the clock on formal submission of agency proposals to OIRA, so that negotiations and "adjustments" can be complete before the transparency provisions of EO 12866 kick in. See United States General Accounting Office, Report to Congressional Requesters, "RULEMAKING, OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews" GAO-03-929, September 2003, pp. 47–48. When evidence of OIRA changes *has* been available, it has been available to assist reviewing courts in determining whether agencies have themselves reached the decisions statutes commit to their responsibility, and done so only on consideration of the statutorily relevant factors. See *Riverkeeper, Inc. v. EPA*, No. 04-6692-ag(L), 2007 U.S. App. LEXIS 1642 (2d Cir. Jan. 25, 2007), where the published documents showed 58 "major" changes having been made "at the suggestion or recommendation" of OIRA at the proposal stage, and 95 "major" changes made "at the suggestion or recommendation" of OIRA in the rule as finally promulgated.

Professor Peter Shane, a highly respected scholar of the presidency and a former lawyer in the Office of Legal Counsel, put the matter this way in a recent discussion of President Bush's use of signing statements, which I know is not our subject today.

The Bush Administration has operated until recently in tandem—can there be a three-part tandem?—with Republican Congresses and a Supreme Court highly deferential to executive power. . . . It has not only insisted, in theory, on a robust constitutional entitlement to operate free of legislative or judicial accountability, but it has largely gotten away with this stance. And that success—the Administration's unusual capacity to resist answering to Congress and the courts—has fed, in turn, its sense of principled entitlement, its theory that the Constitution envisions a Presidency answerable, in large measure, to no one.

Critics of the Administration have not infrequently charged that the Administration's unilateralism is antagonistic to the rule of law. After all, the ideal of a "government of laws, not of men" seems conspicuously at odds with a President's expansive claims of plenary authority. But no sane President claims to be above the law and, indeed, President Bush takes pains repeatedly to defend his controversial actions as legal, including the widespread warrantless electronic surveillance of Americans, the incarceration of U.S. citizens as enemy combatants, and the intense interrogation of detainees in Iraq and Afghanistan. I doubt that President Bush thinks himself antagonistic to the rule of law; he just has a different idea of what the rule of law consists of. But what the Administration seems to believe in is a version of the "rule of law" as formalism. It is the rule of law reduced to "law as rules." Under the Bush Administration's conception of the rule of law, Americans enjoy a "government of laws" so long as executive officials can point to some formal source of legal authority for their acts, even if no institution outside the executive is entitled to test the consistency of those acts with the source of legal authority cited. . . .

The Bush signing statements, like the doctrines they advocate, are a rebuke to the idea of the rule of law as norms or process. They are a testament to the rule of law as law by rules, preferably rules of the President's own imagination.

This executive order is cut from the same cloth.

What might Congress do about this? This looks like a simple affront to two of Congress's responsibilities—to confer organization and authority on elements of government by enacting statutes, and to approve (in the Senate) all appointments to high office (thus creating one of the Constitution's many checks on unilateral authority in any branch). Change here, though, would likely encounter a presidential veto. Can you find a way to avoid that? There remains the power of the purse. While the use of "do not spend" riders in appropriations measures has often been criticized, perhaps this is a setting in which such a rider would be appropriate, attached to a budget the President will find himself compelled to sign. Why should Congress tolerate the expenditure of government funds to pay the salary of one whose powers it has not authorized, and whose functioning can prove destructive of the public institutions it has worked to create?

II. OUTSIDER CONTROL OF RULEMAKING

I can be much briefer in addressing the provision of the executive order that invites agencies to "consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations," "in consultation with OIRA." This is permissively worded, but one must wonder how permissive its implementation will be. And the point to note is that the difference between "formal rulemaking procedures under 5 U.S.C. 556 and 557" and the notice-and-comment procedures agencies generally employ, is that the former put rulemaking under the procedural control of an administrative law judge, a person trained in trials not policy-setting, and confer on participants in the rulemaking the kinds of rights parties to trials have—rights to put on witnesses, engage in cross-examination, and in other ways slow rulemaking down and add to its internal costs. It is, simply, the delivery of the henhouse to the foxes.

Experience with on-the-record rulemaking led to its virtual abandonment decades ago, and for good reason. Those familiar with the process have recognized for 40+ years that it is simply too clumsy to work except in very isolated instances. In its 1973 judgment in *U.S. v. Florida East Coast Rwy*, 410 U.S. 224, the Supreme Court essentially ruled that agencies did not need to use it in the absence of the clearest of statutory instructions. Congress hasn't been giving those instructions, and agencies haven't been using that process ever since, and for good reason. Experience has

taught us that the use of formal rulemaking is cumbersome and out of all proportion to its benefits because trial-type hearings are poorly suited for determinations that turn on policy judgments, and too subject to unwarranted extension and complication by the participant parties. Why, then, revive it now? Just to help one's friends slow things down—throw a good dose of sand into the gears of rulemaking?

Thank you for the opportunity to address you today. I would be happy to answer any questions you might have.

Ms. SÁNCHEZ. Thank you, Professor Strauss.

I want to thank all of the panelists for testifying today, and I want to remind you that your full written statements will be placed into the record.

We are now going to proceed with questions under the 5-minute rule, and I will begin by recognizing myself for 5 minutes.

Mr. Aitken, you noted that Executive Order 13422 encourages rulemaking agencies to consider using the Administrative Procedure Act's formal rather than informal rulemaking procedures for the agency's resolution of complex determinations. Why do you think that that encouragement is necessary?

Mr. AITKEN. Thank you for your question.

The reason that that provision is in the Executive Order is simply to remind agencies that under the Administrative Procedure Act, they have a tool in their tool belt that they can use to resolve complex determinations. As I mentioned in my prepared testimony, that provision has been in the Administrative Procedure Act for decades. Agencies have been able to use that authority for decades, and the Executive Order simply reminds the agencies of this authority and encourages them to consider it.

Ms. SÁNCHEZ. But is there any evidence to the contrary that they don't use the formal rulemaking procedures when appropriate and necessary?

Mr. AITKEN. I don't think the Executive Order is premised on a view that agencies were using it insufficiently; it simply reminds agencies that there is a provision in the APA that is available for their use if they believe it is appropriate.

Ms. SÁNCHEZ. Okay, thank you.

Professor Katzen, what do you believe Congress should do about this Executive Order? Congress, as Professor Strauss suggested, could put a rider on OMB's or an agency's appropriation prohibiting the implementation of the Order, or is there something else that Congress can do?

Ms. KATZEN. As an alum of OMB, I am always somewhat nervous about talking about riders on spending bills.

I think, first and foremost, you have done the right thing by calling a hearing. Oversight by Congress is incredibly important and has not been in vogue for the last several years. Knowing that you will be held accountable and asked why is this section in there, what does that section do, what is the problem, has a very salutary effect. I also believe that Dr. Copeland has put his finger on something with respect to the appointments power and Senate confirmation. I personally believe that if you are going to hold the position of regulatory policy officer as it is described in here and not be reporting directly to the head of the agency, which was the way we had structured the job, then it would be appropriate for the Senate to inquire as to both the competence and the temperament and per-

haps the regulatory philosophy of the person who would hold that job. And so I would use the power of appointment.

Authorizing Committees could also do legislative work. As I said, these are the agencies. These are not free agents. They do what Congress has told them to do, and if Congress says that a factor is to be—is irrelevant or not to be considered, the agencies will follow and the Executive Order as originally structured said “subject to existing law,” that means subject to what you all say. So I would use those routes.

Ms. SÁNCHEZ. I appreciate your answer.

Mr. Noe, will Executive Order 13422, as asserted by *New York Times* columnist Paul Krugman, “make it easier for political appointees to overrule the professionals, tailoring Government regulations to suit the interests of companies,” and if not, please explain.

Mr. NOE. Madame Chair, I think the answer is no because I think that the changes that are made, for example, to the provisions on regulatory policy officer are insignificant, other than creating greater, not less, political accountability.

This position was created by the Clinton Order. There was no constraint on who could serve as a regulatory policy officer. You could have had someone who was non-accountable to the Congress serve in that position. Under the change, the benefit for Congress will be that person will serve in a congressionally created position that is typically subject to Senate confirmation, and typically engages with the Congress in oversight. So I think as far as oversight committees go, this Executive Order is good news.

Ms. SÁNCHEZ. Professor Katzen, I notice that you did not seem to agree. Could you just briefly respond to that?

Ms. KATZEN. Under the Clinton Order, the regulatory policy officer had to report directly to the agency head. That was the accountability within the agency.

Ms. SÁNCHEZ. Okay, thank you.

I would now like to recognize the Ranking Member of my Subcommittee, Mr. Cannon, for 5 minutes.

Mr. CANNON. I think we have identified the problem, and it is not you, Ms. Katzen, it is the mic—the button. We are going to have to get that fixed.

It has been very interesting hearing, a little more animated than I would have guessed at the outset. We have Dr. Copeland, who is very jealous of Congress’s prerogatives and his comments were directed that we have two people that have the view that Government and bureaucracy has a tendency to perpetuate itself and sometimes perpetuate stupidity. We have two people, Professor Katzen and Professor Strauss, who believe that bureaucracy should be a counterweight to the role of the President. And of course, that is, at least in this given presidency, you have some conflict with the stayed problems that this Administration has decided exist within the regulatory context. I personally served in an agency. I had 100 lawyers who worked for me. We developed regulations and I have the greatest respect for civil servants. The problem is civil servants are part of bureaucracy, and bureaucracies don’t change very quickly.

So what we are dealing with here, it seems to me at a higher level, is how we deal with a world that has changed radically

around us and has resulted in a proliferation of Government law in the context where we don't have—we, that is, Congress, does not have the kind of controls that these—Professor Katzen and Professor Strauss and Dr. Copeland are insisting are important here.

Let me just—one example that I had, a political friend came in and told me that I should take the Code of Federal Regulations into my next meeting. I said, do you know how tall that is? And then he raised his arm about six feet high, and I said when was the last time you saw the Code of Federal Regulations? I brought him down here and showed him our library—Majority's library. Our library, I guess, but in their side. He was dumbfounded. He was absolutely dumbfounded because—I don't know what it is, but my guess is that if you stack the Code of Federal Regulations up it would be about 25 or 30 feet, far more than what he had anticipated, and that doesn't include the guidance documents and the informal guidance which never gets in a document. What we have here is a Government that has vastly insinuated itself in the fabric of American life. And Professor Strauss, you mentioned that we are dealing with dangerous people who we have to control. Granted, there are people who will take advantage. We need sometimes to have some control, especially—well, there are some things we need to control and probably some things that we just interfere with and cause pain and suffering by trying to control.

And so what I would hope—we have worked together over a long period of time, many of us, on the APA. Many of these issues are going to be—are issues that we need to look at from the very highest level. In other words, there are differences that are very apparent in this discussion and I think those are legitimate differences, but we need to take a look at how we actually govern ourselves and look back at the APA to get some guidance.

We need to come up with a thoughtful bipartisan new approach to the APA that will allow us to deal with this much more complex world that we are engaged in, because really what we are talking about here—I mean, for people who don't understand this discussion, we are not talking about regulations. We are not talking about law. We are not talking about that law which is passed by Congress and signed by the President. We are talking about guidance when a company or a person has a problem understanding what a regulation means in his evolving business environment or other environment in his life, and he says tell me what this means. And that answer can come from a bureaucrat in a regional office who may not want to be bothered, or it can come through a process that evolves into a directive that has profound influence. And in the world today with oil at 70, 80, 90, maybe at some point in the future \$100 a barrel, that drives issues and creativity and that is just one of the many things that are happening in our society. Communication has evolved rapidly. That drives innovation and we find ourselves regulating in a context of a presumed danger, when at the same time we have great opportunities for a better society.

And so I am—I actually very rarely do this. I have lectured and I apologize, but what I hope comes out of this discussion is that instead of blaming this President—and by the way, Professor Katzen and Professor Strauss, your comments were well-taken and I appreciate them, and you have educated me on the subject. But this

seems to be a canard. It seems to be off the track of what we need to do as a Committee, and Dr. Copeland, from your perspective, we need—and others in the audience, we need to deal with a world that is different, entirely different from the world that we inherited 10 or 20 or 45 years ago, 44 years ago when we passed the APA the first time—

Ms. SÁNCHEZ. The gentleman's time has expired.

Mr. CANNON. I thank the gentlelady for indulging me, and yield back.

Ms. SÁNCHEZ. Thank you.

The gentleman from Michigan is recognized.

Mr. CONYERS. I thank the gentlelady and Chair.

The gentleman from Utah can tell the witnesses that he doesn't lecture very often, but you know, we are on the Committee, Chris. We know a lot better than that. And we enjoy your criticisms and comments.

I would ask unanimous consent to place into the record Paul Krugman's "New York Times" column of February 5, 2007.

Ms. SÁNCHEZ. Without objection, so ordered.

[The information referred to follows:]

PAUL KRUGMAN

The Green-Zoning of America

One of the best of the many recent books about the Iraq debacle is Rajiv Chandrasekaran's "Imperial Life in the Emerald City." The book tells a tale of hopes squandered in the name of politicization and privatization: key jobs in Baghdad's Green Zone were assigned on the basis of loyalty rather than know-how, while key functions were outsourced to private contractors.

Two recent reports in The New York Times serve as a reminder that the Bush administration has brought to the same corruption of governance to the home front. Call it the Green-Zoning of America.

In the first article, The Times reported that a new executive order re-

quired that each agency contain a "regulatory policy office run by a political appointee," a change that strengthens the hand of the White House in shaping rules that have, in the past, often been generated by civil servants and scientific experts.

Yesterday, The Times turned to the rapid growth of federal contracting, fed "by a philosophy that encourages outsourcing almost everything government does."

These are two different pieces of the same story, under the guise of promoting a conservative agenda: the Bush administration has created a supersized version of the 19th-century spoils system.

considered too sensitive to privatize: yesterday's Times article begins with the case of CACI International, a private contractor hired, in spite of the obvious conflict of interest, to process cases of incompetence and fraud by private contractors. A few years earlier, CACI provided interrogators at Abu Ghraib.

The ostensible reason for politicizing and privatizing was to promote the conservative ideal of smaller, more efficient government. But the small-government rhetoric was never sincere: from Day 1, the administration set out to create a vast new patronage machine.

Those political appointees chosen for their loyalty, not their expertise, aren't very good at doing their proper jobs — as all the world learned after Hurricane Katrina struck. But they have been very good at rewarding campaign contributors, from energy companies that benefit from lax regulation of pollution to pharmaceutical companies that got a Medicare program systematically designed to protect their profits.

And the executive order described by The Times will make it even less-

for political appointees to overrule the professionals, tailoring government regulations to suit the interests of companies that support the GOP. — or to give lucrative contracts to people with the right connections.

Meanwhile, never mind the idea that outsourcing of government functions should be used to promote competition and save money. The Times reports that "fewer than half of all 'contract actions' — new contracts and payments against existing contracts — are now subject to full and open competition," down from 79 percent in 2001. And many contractors are paid far more than it would cost to do the job with government employees: those CACI workers protesting claims against other contractors cost the government \$104 an hour.

What's truly amazing is how far back we've slid in such a short time. The modern civil service system dates back more than a century; in just six years the Bush administration has managed to undo many of that system's achievements. And the administration still has two years to go. □

Of conservatism, cronyism and contracting.

effect of reducing the total number of civil servants.

The Bush administration energetically put these recommendations into effect. Political loyalists were installed throughout the government, regardless of qualifications. And the administration outsourced many government functions previously

TimesSelect: Guest Columnist: Think Again Stanley Fish takes issue with the Bush administration's use of signing statements to influence the interpretation of laws. nytimes.com/opinion.
Join the Conversation Readers can send columnists their comments: nytimes.com/timesselect.

NW TIMES - 2/5/07

Mr. CONYERS. And I hate to read the last two sentences, because we may get another lecture before this hearing is over.

“What’s truly amazing is how far back we’ve slid in such a short time. The modern civil service system dates back more than a century; in just six years the Bush administration has managed to undo many of that system’s achievements. And the Administration still has two years to go.”

You know, this brings in the notion of conservatism, contracting, and I need some guidance from some of our witnesses. We have got the appropriations process, passing laws, confirmation proceedings, and any succeeding President can revoke any Executive Order that he or she chooses. Those aren’t a very tasty set of options to me. What do you think, Professor Strauss? Is there—it seems like we are something like in the position of trying to get out of Iraq. We don’t want to cut off the funds. We are—we want to pass non-binding resolutions. We want to voice our opposition.

Mr. STRAUSS. I find a lot of merit in that analogy, unhappily. I think you are stuck. I mean, if you were to take the position which, in my judgment, is the right position, that authorizing someone in Government to act with the force of law, which is what this Executive Order does for the regulatory policy officer, is something that only Congress can do and the President can not do. You are not in the position of being able to undo that by a simple statute unless you can get it past a presidential veto, which as I read the newspapers, my guess is you can not. So then you are left with a series of unpalatable other alternatives. I don’t, myself, like appropriations riders at all. I think they have been misused in the past, but—

Mr. CONYERS. I don’t even think we can sue in court, unless it is a constitutional issue.

Mr. STRAUSS. I don’t know how.

Mr. CONYERS. How did you find this subject matter to start the hearing off on administrative law? I mean, this is more difficult than most of the other issues that we handle. I am wondering—perhaps a very detailed examination of this is going to make it clear to the public. I mean, this may be another case for public sentiment to kick in, because most people of course haven’t the vaguest idea that this has occurred.

Mr. STRAUSS. Newspaper reporters tend to describe stories about process, as one did to me in the work-up of this occasion, as three bowlers. That is to say, the reader’s face will predictably plop in the oatmeal three times before they finish the story. I don’t know that it will be easy to make it into—

Mr. CONYERS. Dr. Copeland, what is your diagnosis here?

Mr. COPELAND. I would refer to a document that was prepared by a colleague of mine at CRS, TJ Halstead, on Executive Orders, and he mentions previous instances where Congress has revoked them, most recently Executive Order 12806, where Congress revoked an Order by President George H.W. Bush to establish a human fetal tissue bank for research purposes. To effectuate this repeal, Congress simply directed that “The provisions of Executive Order 12806 shall not have any legal effect.” While this seems to be the most recent action, there have been numerous similarly revoked Executive Orders.

So there is precedent for Congress revoking Executive Orders.

Ms. SÁNCHEZ. The time of the gentleman has expired.

Mr. CONYERS. Thank you.

Ms. SÁNCHEZ. Thank you.

I now recognize the gentleman from Georgia, Mr. Johnson, for 5 minutes.

Mr. JOHNSON. Thank you. I have got some questions, Mr. Noe.

You were quoted in the Washington Post as saying that the controversy about this new Executive Order is “a tempest in a teapot.” Given that the Order appears to create a cadre of presidentially appointed regulatory police officers who no longer report to the agency heads who designate them, how can this be considered a “tempest in a teapot”? Isn’t it more serious than that, more fundamentally earth-shaking than that?

Mr. NOE. Thank you for your question, Congressman.

The reason I would call it a “tempest in a teapot” is because I think a lot of the concerns that were raised in the initial press reports were not based on a reading of the actual language of the Order, or an understanding of what was already in the existing Executive Order that President Clinton issued. It was not based on an understanding that these regulatory policy officers were not created by President Bush, they were created by President Clinton, and—

Mr. JOHNSON. But this is a fundamental reordering of this Executive Order, is it not?

Mr. NOE. Well, sir, I think that the main change in that part of the Order is to say a regulatory policy officer, who admittedly was appointed by the agency head under the old Order, now actually had to be in a congressionally created position which is going to be more accountable politically and more accountable to congressional oversight, I would submit, than what was previously undefined. And that is what I mean when I say I think that there has been a lot of misunderstanding about these provisions, that when they are actually read closely I don’t think there is less political accountability. I don’t think there is anything new or radical. I actually think this could be used to provide greater accountability to the Congress, and I respect the importance of that, having worked in Congress as a staffer for 7 years.

Mr. JOHNSON. Well, you were also quoted as saying that the Executive Order promotes better informed and more accountable regulatory decisions. Can you explain that a little more?

Mr. NOE. Yes, sir.

I think it is a real improvement over President Clinton’s Order to include guidance documents within the interagency review process, because I have seen many instances where businesses, small businesses especially where people can not keep up with these things, schools, farmers are hurt or affected by these things and they don’t have any idea that they are coming at them. They have no idea of how to access them. And I could tell you, just having heard a number of stories about this, that I think it is very important that that very important component of regulation is brought within the interagency review process. I think that is a big improvement.

Mr. JOHNSON. Professor Katzen, what is your response?

Ms. KATZEN. Well, I find it ironic that on one hand they say it is not doing anything, and on the other hand they say it is doing something. I really don't think they can have it both ways.

On the guidance documents, they do not have the force and effect of law, but they do have an influence, and I am interested in the fact that in Mr. Aitken's testimony he keeps referring back to the FDA guidance process. That process had Congress intimately involved. It was Congress that authorized the FDA to—

Mr. JOHNSON. By the way, Mr. Noe was here before you came in and he made sure to change that microphone.

Ms. KATZEN. I am not paranoid, it just doesn't work.

But Congress was the one that authorized the FDA to issue these guidance documents. Congress was the one that called for public participation. So if you are using the FDA guidance documents as a model, then Congress needs to be involved. Incidentally, Congress did not authorize OMB to review those FDA guidelines that it authorized. What has been done here is like cherry picking, where they take what they like and they add to it what they really like, and they now have got a different kind of an animal.

The bottom line is that Congress has to act. Congress has to become involved, and I think that whether it is looking at the APA generally or looking at the provisions of how the Executive Order is being implemented, Congress has a constitutional obligation and a constitutional role to play, and I encourage you to do it.

Mr. JOHNSON. Professor Strauss, in your testimony—

Ms. SÁNCHEZ. The time of the gentleman has expired.

Mr. JOHNSON. All right, thank you.

Ms. SÁNCHEZ. It is now my pleasure to recognize the gentleman from Massachusetts, Mr. Delahunt, for 5 minutes.

Mr. DELAHUNT. Thank you, Madame Chair. It is very reassuring to serve on this Committee under your leadership.

Professor Katzen, it is good to see you once more.

You know, I look at this in a larger sense. We have had an Administration that has spoken time and time again about this concept of—I think the term is unitary Executive power, which I view as a continuing encroachment on legislative authority. I see this just as another piece of that. Is that a comment that you would like to respond to, Professor Strauss?

Mr. STRAUSS. I think you heard that from Professor Katzen as well. There has been—

Mr. DELAHUNT. I came too late for her testimony.

Mr. STRAUSS. There has been a clear acceleration, and to be fair about it, this is a process that began with President Nixon, and since his Administration, President after President has done more and more to bring the bureaucracy within the political influence over the White House. I think what Mr. Cannon had to say in his statement has an awful lot of merit to it.

The question for me is when you cross the line, you have some wish to have not only politics, but also expertise, and when what one sees is just politics, one gets—

Mr. DELAHUNT. Well, I think maybe, you know, the Ranking Member and I would agree on some of this. I think this is an institutional—this is institutional combat, if you will. And I think we have got to be prepared to go to war. Enough is enough, and with-

out even getting into the merits of this particular Executive Order, because I think it is a statement as to whether this institution, the first branch of Government, has the capacity to retain its constitutional authority. And I would hope that, given the leadership of Congresswoman Sánchez, that there might exist the possibility of a discussion with the Executive Branch to determine what modifications ought to occur from the perspective of Congress as to this Executive Order, and if that just simply is not feasible, if it is not welcome by the Administration, then we ought seriously consider legislative action rescinding the Order.

Mr. CANNON. Would the gentleman—

Mr. DELAHUNT. I yield to my friend from Utah.

Mr. CANNON. Thank you. You know, we live in a very political world and we just lost on the Republican side and were much chastened.

But let me just remind the gentleman that when you suggest we go to war over this issue that America has changed profoundly. Before President Reagan, at the beginning of his Administration, the vast majority, over 60 percent of all people were employed by large corporations of over 5,000 employees. Today, the vast majority are employed by small companies. So what we are doing here, and what I hope this Committee will do over the long term, is create a context where Americans can thrive, and in this battle, we need to remember that this is not us against the President, although Dr. Copeland, as you are aware, I am keenly concerned with the prerogative—

Mr. DELAHUNT. Reclaiming my time.

I am not in disagreement and I clearly am sympathetic to, you know, the small business owner. I think Members of Congress are. That is not the issue here.

The issue is whether this is appropriately within the prerogative of Congress pursuant to our constitutional authority, and if it is, I think that we can demonstrate as much sympathy and support for the small business community. This, to me, is a constitutional issue. It has got nothing to do with the merits of a particular Executive Order. I mean, I am concerned. I mean, the—what was the book, the Imperial City. I mean, we had political appointees there that were running the Stock Exchange who didn't have a degree in economics. You know, is there—I haven't really—I will acknowledge that I haven't read the Executive Order, but the idea of some sort of confirmation process by the Senate just to assure Members of Congress that we are getting people who have an expertise and are not just simply political appointees like we see. We have seen them in Iraq, we saw them in the aftermath of Katrina, and there was much to be revealed.

I don't mean to just beat up on the Bush administration, but they are handy right now.

Ms. SÁNCHEZ. The time of the gentleman has expired.

I would like to thank again all the witnesses for their testimony. Members may have additional written questions for our witnesses which we will forward to you and ask that you answer as promptly as you can so that they can be made part of the record.

Without objection, the hearing record—

Mr. DELAHUNT. Madame Chair?

Ms. SÁNCHEZ. The gentleman is recognized.

Mr. DELAHUNT. If I could ask for unanimous consent for an additional minute.

Ms. SÁNCHEZ. The gentleman—

Mr. DELAHUNT. I would like to congratulate the Chair for conducting her first hearing. You did it with your customary aplomb and professionalism, and I know I speak for Mr. Cannon. We all look forward to working with you.

Ms. SÁNCHEZ. Thank you.

As I was saying before I was so pleasantly interrupted, we will be submitting additional questions in writing. We ask that you respond to those questions so that they can be—as quickly as you can so that they can be made part of the record.

Without objection, the hearing record will remain open until the close of business on Friday for the submission of additional materials.

[The material in the following list was submitted by the Minority for inclusion in the hearing record. The material is not reprinted in this hearing but is on file at the Subcommittee. The information referred to is as follows:]

LIST OF MATERIAL SUBMITTED BY THE MINORITY FOR INCLUSION
IN THE HEARING RECORD

1. Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 371(h)
2. “Food and Drug Administration Modernization and Accountability Act of 1997,” S. Rep. 105–43, at 26 (1997)
3. Executive Order No. 13422, 72 Fed. Reg. 2763 et seq. (Jan. 23, 2007)
4. Executive Order No. 12866, 58 Fed. Reg. 51,735–44 (Oct. 4, 1993)
5. Executive Order No. 13258, 67 Fed. Reg. 9,385–86 (Feb. 28, 2002)
6. Redline-strikeout version of E.O. 12866 as amended by E.O. 13422
7. U.S. Office of Management and Budget Bulletin No. 07–07, “Final Bulletin for Agency Good Guidance Practices,” 72 Fed. Reg. 3,432–40 (Jan. 25, 2007)
8. U.S. Office of Management and Budget, “Proposed Bulletin for Good Guidance Practices,” 70 Fed. Reg. 71866 et seq. (Nov. 30, 2005)
9. U.S. Office of Management and Budget Circular A-4, “Regulatory Analysis,” (Sept. 17, 2003)
10. U.S. Office of Management and Budget, “Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Federal Regulation,” (2002)
11. U.S. Office of Management and Budget, “Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulation,” 69 Fed. Reg. 15014 et seq. (March 28, 2002)
12. U.S. Office of Management and Budget Memorandum, “Economic Analysis of Federal Regulations under Executive Order No. 12866,” (Jan. 11, 1996)
13. U.S. Office of Management and Budget, M-00-08, “Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements,” (March 22, 2000)
14. *Regulatory Program of the United States* (April 1, 1990–March 31, 1991), at pp. 653–54
15. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1019 (D.C. Cir. 2000)
16. 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)
17. Robert A. Anthony, “‘Interpretive’ Rules, ‘Legislative’ Rules and ‘Spurious’ Rules: Lifting the Smog,” 8 Admin. L.J. (Spring 1994).

Ms. SÁNCHEZ. I thank everyone again for their time and patience, and without objection, the hearing of the Subcommittee on Commercial and Administrative Law is adjourned.

[Whereupon, at 3:30 p.m., the Subcommittee was adjourned.]

A P P E N D I X

MATERIAL SUBMITTED FOR THE HEARING RECORD

POST-HEARING QUESTIONS AND RESPONSES FOR STEVEN D. AITKEN, ACTING ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

Response of March 26, 2007 (hearing of February 23, 2007)

QUESTIONS FROM SUBCOMMITTEE CHAIR LINDA SANCHEZ FOR STEVEN AITKEN, ACTING ADMINISTRATOR, OMB OIRA

1. Please explain how Executive Order 13422 was developed.

Who originated the idea to make these changes to Executive Order 12866?

How were the changes agreed upon?

Were regulatory agencies consulted as part of this process? If so, please describe.

A: The Executive Branch has a well-established, long-standing process for the internal-Executive Branch coordination (review and comment) and submission to the White House of draft Executive Orders for the President's consideration. This process is conducted under Executive Order No. 11030, as amended. This process was followed in the development of Executive Order 13422.

Regulatory agencies were consulted as part of the process. The coordination and submission of proposed Executive Orders to the White House involves discussions within and between Executive Branch agencies and offices that are of a predecisional and deliberative nature. The effectiveness of the executive order process depends on maintaining the confidentiality of these predecisional, deliberative discussions and materials. In order to preserve this confidentiality, I cannot indicate who suggested particular changes, or who was consulted during the process, or what those consultations consisted of.

Why were these revisions to Executive Order 12866 deemed to be necessary at this time?

A: The primary purpose for the issuance of Executive Order 13422 was to amend Executive Order 12866 in order to establish an interagency review process for significant guidance documents, which would serve as a complement to OMB's issuance of the Final Bulletin on Agency Good Guidance Practices. As I indicated in my testimony, the Bulletin and Executive Order are aimed at ensuring that significant agency guidance documents are developed through procedures that ensure quality, transparency, public participation, coordination, and accountability.

As it was the case that Executive Order 12866 was being amended to establish the interagency review process for significant guidance documents, this provided an opportunity to make additional (non-guidance) amendments to Executive Order 12866 that reflect good-government practices.

Was any explanation for Executive Order 13422 provided at the time it was issued?

A: When the Executive Order and Bulletin were issued, the Office of Management and Budget briefed the press and congressional offices.

2. Executive Order 13422 requires agencies' regulatory policy officers to be presidential appointees. The executive order requires each "agency head" to "designate" one of the agency's "presidential appointees" to be the agency's regulatory policy officer.

Why was this change made?

A: As background, many of the Regulatory Policy Officers had already been Presidential appointees (and most if not all of these Presidential appointees held Senate-confirmed positions). The chief advantage of having a Presidential appointee serve as the Regulatory Policy Officer is that it ensures accountability with respect to this role.

In the context, what does "agency head" mean? In cabinet departments, is it the secretary or the agency head within the department (e.g., the FAA within DOT)?

A: The agency head is the official who is the head of the agency. In a Cabinet Department, the agency head is the head of the department.

What does "presidential appointees" mean? For example, does it refer only to positions that are subject to Senate confirmation? Could the term also include noncareer Senior Executive Service employees who are appointed by the agency head after approval by the White House?

A: The agency head may designate the agency's Regulatory Policy Officer from among those agency positions whose appointment is vested by law in the President. Congress may establish in statute Presidential appointees who are not Senate-confirmed, but as the Congressional Research Service explained in its report of February 5, 2007, "most major regulatory departments and agencies have few (and in some cases, no) presidential appointees who are not Senate confirmed" (p.7). Such "political appointees" as non-career SES employees and Schedule C employees are appointed by the agency head, not by the President, and thus they are not Presidential appointees and may not be designated as the agency's Regulatory Policy Officer.

How much latitude will agency heads have in the designation of these officials?

A: Executive Order 13422 places no restrictions on an agency head's discretion in choosing which Presidential appointee within the agency to designate as the agency's Regulatory Policy Officer.

Executive Order 13422 deleted the sentence in Executive Order 12866 specifying that regulatory policy officers "shall report to the agency head." If not the agency head, to whom must these officers now report?

A: The inference – that deletion of the "report to the agency head" phrase means that the Regulatory Policy Officer will no longer reports to the agency head – is incorrect. The deletion of this language does not change the fact that the Regulatory Policy Officer reports to the agency head. As before, the agency head continues to be the official who designates which official shall serve as the agency's Regulatory Policy Officer, and that designated official will continue to report to the agency head in performing this role, just as that official reports to the agency head in performing his or her other responsibilities.

Please identify who are the current regulatory policy officers in the agencies. Also, please indicate whether these officers are already political appointees?

A: Below are the Regulatory Policy Officer designations that OIRA has received as of Friday, March 23, 2007, pursuant to and in accordance with Executive Order 13422 (as noted below, all but one of the designated officials are Presidentially-appointed, Senate-confirmed (PAS) positions). We are awaiting additional designations.

Department of Agriculture: General Counsel (PAS)
Department of Commerce: General Counsel (PAS)
Department of Education: General Counsel (PAS)
Department of Energy: General Counsel (PAS)
Department of Health and Human Services: Deputy Secretary (PAS)
Department of Homeland Security: General Counsel (PAS)
Department of Housing and Urban Development: General Counsel (PAS)
Department of the Interior: Deputy Secretary (PAS)
Department of Justice: Assistant Attorney General, Office of Legal Policy (PAS)
Department of Labor: Assistant Secretary for Policy (PAS)
Department of State: Assistant Secretary for Administration (PAS)
Department of Transportation: General Counsel (PAS)
Department of the Treasury: General Counsel (PAS)
Department of Veterans Affairs: Deputy Secretary (PAS)
Environmental Protection Agency: Deputy Administrator (PAS)
Access Board: Chair (PA)
Office of Federal Housing Enterprise Oversight: Director (PAS)
National Archives and Records Administration: Archivist of United States (PAS)

Social Security Administration: Commissioner (PAS)

When Executive Order 13422 was issued, we did not have an up-to-date listing of the Regulatory Policy Officers. However, included among the Regulatory Policy Officers at that time were the following (all of whom continue to be the Regulatory Policy Officers at their agencies):

Department of Commerce: General Counsel (PAS)
Department of Health and Human Services: Deputy Secretary (PAS)
Department of Homeland Security: General Counsel (PAS)
Department of Justice: Assistant Attorney General, Office of Legal Policy (PAS)
Department of Transportation: General Counsel (PAS)

Given that Executive Order 13422 substantively expands the authority of these officers to control regulatory planning and output, should these officials be subject to a new Senate confirmation – even if they had previously been confirmed for another position?

A: I am not sure that I would say that Executive Order 13422 “substantively expands the authority of [the Regulatory Policy Officers] to control regulatory planning and output.” In any event, the designation of officials as Regulatory Policy Officers pursuant to Executive Order 12866, as amended, does not require that these officials (in the case of PAS officials) be subject to a new Senate confirmation. PAS officials periodically are assigned additional responsibilities, either through statute, executive order, or otherwise, and my understanding is that the assignment of these additional responsibilities does not require that the officials be subject to a new Senate confirmation.

3. In your testimony, you note that “in most if not all cases, an agency’s commencement of a rulemaking will be authorized or approved by an agency official who is subject to Senate confirmation.”

Will all current policy officers who are presidential appointees be allowed to continue in those positions, or will some of them be replaced?

A: As noted above, it is within the agency head’s discretion to select the agency’s Regulatory Policy Officer from among the Presidential appointees within the agency. As noted above, a number of the Regulatory Policy Officers that have been designated pursuant to Executive Order 13422 were already the Regulatory Policy Officers for their agencies.

Will presidential appointees who are not Senate confirmed be allowed to be regulatory policy officers?

A: Yes. The amendment made by Executive Order 13422 provides that the Regulatory Policy Officer must be a Presidential appointee. In relatively infrequent instances,

Congress has established in statute positions that are subject to Presidential appointment but not Senate confirmation (PA positions). But many Cabinet Departments have no PA positions, and have only Presidentially-appointed, Senate-confirmed positions (PAS), available for designation as the Regulatory Policy Officer.

4. Executive Order 12866, as originally issued, provided that a regulatory officer's duties were limited (e.g., "be involved" and "foster the development" of rules). Executive Order 13422 now provides that "[u]nless 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 Officer[r]...."

Why were the powers of regulatory policy officers so significantly enhanced?

A: I am not sure that I would say that Executive Order 13422 "significantly enhanced" the "powers" of the Regulatory Policy Officers. In any event, with respect to the inclusion of a rulemaking in the Regulatory Plan, Executive Order 12866 had previously provided that the Plan had to be "personally approved by the agency head." The amendment made by Executive Order 13422 enables the agency head to rely on the agency's Regulatory Policy Officer to approve the Plan. With respect to the commencement of a rulemaking, the requirement that the Regulatory Policy Officer approve its commencement – unless the agency head decides to authorize the rulemaking's commencement – ensures accountability.

Pursuant to Executive Order 13422, may a regulatory policy officer prevent a proposed rule or final rule from being published in the Federal Register?

A: Executive Order 13422 does not address the publication of a proposed rule or final rule in the Federal Register. In addition, with respect to a rulemaking's commencement or inclusion in the Regulatory Plan, the amendment made by Executive Order 13422 makes clear that the agency head may authorize its commencement or its inclusion. I also should note that the senior agency officials who are designated as Regulatory Policy Officers are likely to have additional authority at their agencies, beyond those set forth in Executive Order 13422.

5. Executive Order 13422 amends that part of Executive Order 12866 (requiring independent regulatory agencies to have regulatory plans) to now require the “regulatory policy office[r]” to approve items in the plan and the commencement of all rulemaking.

Does Executive Order 13422 require independent regulatory agencies to have presidential appointees as regulatory policy officers?

A: Agencies that are “independent regulatory agencies” under the Paperwork Reduction Act have not previously been required to have a Regulatory Policy Officer under Executive Order 12866, and the amendments made by Executive Order 13422 do not change this situation. The head of an “independent regulatory agency” may, but is not required to, designate a Regulatory Policy Officer.

Will independent regulatory agencies now have presidential appointees controlling their rulemaking?

A: As noted above, “independent regulatory agencies” under the Paperwork Reduction Act have not previously been – and are not now – required to have Regulatory Policy Officers. Executive Order 12866 had previously required that the agency head of the agencies, including the “independent regulatory agencies,” personally approve the agency’s Regulatory Plan. The amendment made by Executive Order provides the agency heads of the “independent regulatory agencies” with the option of either authorizing the Regulatory Plan (as before) or instead designating a Regulatory Policy Officer who would approve the Regulatory Plan.

6. Section 5 of Executive Order 13422 provides that an agency, in consultation with OIRA, may consider utilizing formal rulemaking procedures under sections 556 and 557 of the Administrative Procedure Act. In your testimony, you noted that Executive Order 13422 “encourages rulemaking agencies to consider using the Administrative Procedure Act’s formal – rather than informal – rulemaking procedures for the agency’s resolution of complex determinations.”

Are not agencies already authorized to use formal rulemaking when they deem it necessary?

A: Yes.

If so, why was this authorization set forth in Executive Order 13422?

A: This amendment to Executive Order 12866 serves to remind agencies of a rulemaking authority that they have possessed, and continue to possess, under the Administrative Procedure Act.

In light of the fact that formal rulemaking procedures – because of their cumbersomeness and cost – are generally not the preferred way to issue rules, why would an agency choose that route? Please provide examples of where formal rulemaking may be appropriate.

A: I do not have an example of when formal rulemaking might be the best approach to rulemaking. In general, as the amendment in Executive Order 13422 indicates, such procedures may be valuable where there are complex determinations for the agency to resolve in the rulemaking. As noted above, this amendment to Executive Order 12866 serves as a reminder to agencies of a rulemaking tool that is available.

7. What does “specific market failure” mean in the context of Executive Order 13422?

A: The market failure referenced in Executive Order 13422 is not a new concept. It is the same concept of market failure that was referenced in Executive Order 12866 as it was issued by President Clinton in 1993; that was discussed in then-OIRA Administrator Katzen’s 1996 “Memorandum re: Economic Analysis of Federal Regulations Under Executive Order No. 12866”; and that was discussed in the 2003 proposed and final versions of OMB Circular A-4 for Regulatory Analysis. The major types of market failure include externality (environmental problems being the classic example), market power, and inadequate or asymmetric information. A fuller discussion of market failure is found in the 1996 OIRA Memorandum and in Circular A-4.

8. With respect to Executive Order 13422’s requirement that an agency identify a “specific problem” to warrant new agency action, how much specificity will agencies have to provide in order to satisfy this requirement. For example, if EPA issues a proposed rule intended to reduce cancer risks in the future, does that explanation satisfy the requirement that the agency identify a “specific problem?”

A: The agencies should provide sufficient specificity so as to inform the public, the Congress, the courts, OMB, and others as to the nature of the problem that the agency is intending to address through the rulemaking. The description of the problem should be specific enough so that others can understand why the agency believes that regulatory action is appropriate to address the problem, as well as evaluate whether the agency’s proposed (or chosen) regulatory alternative is, among other things, an effective and reasonable approach for addressing the problem.

9. Executive Order 13422 requires agencies to provide OIRA with “advance notification” of any “significant guidance document,” which is defined as a document that may reasonably be anticipated to have, among other things, a \$100 million annual effect on the economy, or to “[m]aterially alter the budgetary impact of entitlements, grants, user fees, or loan programs.”

Please explain how a nonbinding guidance document could have either of those effects? If it did, would not such agency action have to be in the form of a rule?

A: Although agency guidance may not be legally binding, there are situations in which it may be reasonably anticipated that a guidance document could lead parties to alter their conduct in a manner that would have such an economically significant impact. Agency guidance documents can potentially have an impact on society that is of comparable magnitude to the impact that regulations have on society.

10. Do the transparency and time limit requirements that apply to agencies' rules now apply to guidance documents? For example, will OMB put on its web site the guidance documents that are under review?

Will OMB review be limited to 90 days?

A: The amendment made by Executive Order 13422 does not specify a time period for review of significant guidance documents. OIRA will remain in close consultation with the agency until the review is completed, and the review will be conducted in as expedited a manner as is possible.

Will agencies have to indicate the changes made at OMB's recommendation?

A: The amendment made by Executive Order 13422 does not require such disclosure.

11. Executive Order 13422's guidance-related requirements and OMB's final bulletin for agency good guidance practices were apparently prompted by the view that some agencies issue guidance documents with binding effects that should perhaps been issued as rules. Why not just require an agency to clearly state at the beginning of any guidance document that the guidance is not binding?

A: The Good Guidance Practices Bulletin does require agency to implement basic standards, such as clearly labeling the document as "guidance" and not including mandatory language such as "shall," "must," "required" or "requirement." However, there are other good-government provisions contained in the Executive Order amendments and the Good Guidance Practices Bulletin – i.e., ensuring appropriate approval procedures are in place within the agency, providing public access and feedback for significant guidance documents, and providing OMB with the opportunity to review selected significant guidance documents (e.g., those with policies implicating more than one agency).

12. Executive Order 13422 provides that “no rulemaking shall commence” without the approval of the regulatory policy officer. This language, however, is in the subsection describing the regulatory plan.

Does this requirement mean that no rulemaking shall be in the plan without the regulatory policy officer’s concurrence, or no rulemaking shall be published in the Federal Register without concurrence?

A: With respect to the inclusion of a rulemaking in the Regulatory Plan, Executive Order 12866 had previously provided that the Plan had to be “personally approved by the agency head.” The amendment made by Executive Order 13422 enables the agency head to rely on the agency’s Regulatory Policy Officer to approve the Plan, but the agency head continues to have the authority to authorize the Plan. Executive Order 13422 does not address the publication of a proposed rule or final rule in the Federal Register. Also, as I noted above, the senior agency officials who are designated as Regulatory Policy Officers are likely to have additional authority at their agencies, beyond those set forth in Executive Order 13422.

Does this requirement mean that every rule has to appear in the plan?

A: No.

13. Some of the provisions in Executive Order 13422 suggest that additional guidance will be forthcoming from OMB.

Will OMB be issuing such guidance?

A: OMB does intend to issue a memorandum to assist agencies with their implementation of the Executive Order amendments and the Good Guidance Practices Bulletin.

If so, when?

A: Soon.

On what topics?

A: We anticipate that the memorandum will address the major elements of the Executive Order amendments and the Bulletin.

14. Professor Katzen, in her prepared statement, notes that requiring agencies to estimate “their costs or benefits at the notice of inquiry stage or before the agency has made even tentative decisions is like trying to price a new house before there is even an option on the land and before there are any architect’s plans.” What is your response to her observation?

A: Including in the Regulatory Plan cost and benefit estimates about individual rulemakings is not new. Agencies have for years provided cost and benefit estimates in the Regulatory Plan when such information was available. The amendments to the Executive Order simply require the agency to add-up the costs and benefits for those rules for which the agency includes in the Regulatory Plan an estimate of their costs and benefits, thereby providing more complete information in a more transparent way.

15. One part of Executive Order 12866 that was not revised was the sentence referring to the “primacy of Federal agencies in the regulatory decision-making process.”

Do you ascribe to this concept, i.e., that federal agencies should be allowed to make the ultimate decision about their rules because they have the expertise and are the ones that must defend the rules to the public and in the courts?

A: As Executive Order 12866 recognizes in its “primacy” language, it is in the rulemaking agencies that Congress has vested the legal authority to promulgate regulations. And, thus, it is the rulemaking agencies which develop and issue proposed and final regulations, and which explain these regulations in the preambles to the Federal Register notices that they publish. Moreover, it is to the reasoning of the rulemaking agency, and to the administrative record that the rulemaking agency has developed, to which the courts look when they review the regulations.

At the same time, as the Supreme Court and the D.C. Circuit have explained (see cases below), the President has the authority to “supervise and guide” agencies in their administration of the laws (including in the exercise of their rulemaking authority), and the agencies may appropriately make regulatory decisions that are informed by the Administration’s policies. The interagency regulatory review process that is set forth in Executive Order 12866 -- and in its predecessor Executive Order 12291 -- has been used by four Presidents for over 25 years now. See *Myers v. United States*, 272 U.S. 52, 135 (1926) (the President “may properly supervise and guide their construction of the statutes under which they act”); *Chevron v. NRDC*, 467 U.S. 837, 865 (1984) (“an agency to which Congress has delegated policymaking responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration’s views of wise policy to inform its judgments”); *Sierra Club v. Costle*, 657 F.2d 298, 405 (D.C. Cir. 1981) (“The court recognizes the basic need of the President and his White House staff to monitor the consistency of executive agency regulations with Administration policy. He and his White House advisers surely must be briefed fully and frequently about rules in the making, and their contributions to policymaking considered.”).

Response of March 26, 2007

**Proposed Follow-Up Questions for Witnesses
House Judiciary Committee Hearing on “Good Governance or
Regulatory Usurpation: Amending Executive Order 12866”
Tuesday, February 13, 2007**

**Questions for Acting Administrator Steven Aitken, OMB Office of Information and
Regulatory Affairs:**

1. At the hearing, you were able to discuss in some measure precisely what problems OMB was trying to fix through Executive Order 13422. Would you like to explain further what those problems were, so that the Subcommittee can have a more complete understanding of the goals OMB was striving to reach?

A: The primary purpose for the issuance of Executive Order 13422 was to amend Executive Order 12866 in order to establish an interagency review process for significant guidance documents, which would serve as a complement to OMB’s issuance of the Final Bulletin on Agency Good Guidance Practices. As I indicated in my testimony, the Bulletin and Executive Order are aimed at ensuring that significant agency guidance documents are developed through procedures that ensure quality, transparency, public participation, coordination, and accountability.

As it was the case that Executive Order 12866 was being amended to establish the interagency review process for significant guidance documents, this provided an opportunity to make additional (non-guidance) amendments to Executive Order 12866 that reflect good-government practices.

2. Executive Order 13422 requires that each agency’s Regulatory Policy Officer (“RPO”) be a Presidential appointee. Your testimony at the hearing clarified that, under the new order, RPOs in most if not all instances will be Senate-confirmed Presidential appointees, and that this simply codifies past practice under Executive Order 12866. What do you think are the chief advantages for the public and Congress of making sure that Regulatory Policy Officers are Senate-confirmed Presidential appointees? Please explain your views in detail, to the extent that detail in addition to that provided by your prior oral and written testimony would help the Subcommittee understand this issue more completely.

A: As background, many of the Regulatory Policy Officers had already been Presidential appointees (and most if not all of these Presidential appointees held Senate-confirmed positions). The chief advantage of having a Presidential appointee serve as the Regulatory Policy Officer is that it ensures accountability with respect to this role.

3. Concern has been expressed over Executive Order 13422's requirement that an agency identify in writing the market failure or other problem that it thinks warrants new agency action. Wasn't that already required, though? Do you think the Amendments materially change anything in this regard? Please explain in detail why, to the extent that detail in addition to that provided by your prior oral and written testimony would help the Subcommittee understand this issue more completely.

A: The requirement that the agency address the market failure or other problem that the regulation seeks to address is not new; in fact, it was a requirement of Executive Order 12866 when it was issued by President Clinton in 1993. The original language of section 1(b)(1) of Executive Order 12866 required each agency to "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." (emphasis added). The recent amendment to section 1(b)(1) updates the requirement to include reference to the classic examples of market failure that were discussed in the guidance that OIRA provided to agencies in 1996 and that is discussed in OMB Circular A-4, which OMB issued in 2003 (after issuing it in draft form for public comment).

Also, the recent Executive Order does *not* make the identification of a market failure the only basis on which a Federal agency can justify regulatory action. The revised section also encourages agencies to identify any "other specific problem that it intends to address." For example, recent regulations to provide disaster assistance to victims of Hurricane Katrina provide important social benefits, but do not address a market failure, per se. Moreover, the recent Executive Order leaves untouched the provision in Executive Order 12866 that expressly directs Federal agencies to "promulgate . . . such regulations as are required by law, [or] are necessary to interpret the law." In many cases, when a Federal agency is issuing a regulation, the agency is doing so for just those law-based reasons, and this will continue to be the case; nothing in Executive Order 13422 changes this.

Finally, stating explicitly that Federal agencies shall identify "in writing" the problem that the agency is seeking to remedy through regulatory action does *not* impose a new requirement on rulemaking agencies. As an initial matter, an agency should already have been identifying in writing the precise nature of the problem that the agency is seeking to remedy through regulatory action, *in order to assist the agency in its own analysis of whether regulatory action is warranted and, if so, which of the available regulatory alternatives would best accomplish the agency's intended result*. Thus, in order to comply with the original version of Section 1(b)(1) of Executive Order 12866, agencies as a practical matter would have had to make (or at least should have made) this identification in writing. However, even if an agency did not do so, the agency should still have identified the problem that it was seeking to remedy through regulatory action in the preamble to the proposed rule (to assist the public in understanding the agency's proposal and in offering their comments on it) as well in the preamble to the final rule (to

persuade the public, Congress, and the courts that the agency has exercised its regulatory authority in a reasonable and well-considered manner).

4. Under Executive Order 13422, is the level of cost-benefit analysis required of regulations now also required of agency guidance? Please explain why or why not, to the extent that detail in addition to that provided by your prior oral and written testimony would help the Subcommittee understand this issue more completely.

A: There is no general requirement, under the amended Executive Order or the Good Guidance Practices Bulletin issued on the same day, for an agency to prepare the kind of cost-benefit analysis that Executive Order 12866 requires agencies to perform for regulations.

Under the as-amended Executive Order 12866, guidance documents are covered under the new Section 9. As such, guidance documents are not governed by Section 6, which addresses the centralized review of regulations. Among other things, this means that guidance documents are not subject to the cost-benefit impact-analysis requirements in Section 6(a)(3)(B)-(C) of the Executive Order.

5. In his oral and written testimony, Prof. Strauss has indicated concern over whether Executive Order 13422 represents an unlawful intrusion of the President into authority delegated to the federal agency heads by Congress. Section 10 of Executive Order 13422, however, specifically provides: "Nothing in this order shall be construed to impair or otherwise affect the authority vested by law in an agency or the head thereof." In your opinion, should this provision temper or put to rest any concerns that Executive Order 13422 might help the President to supplant the authority of agency heads or the rules of the road that Congress has laid down in the statutes that federal agencies implement? Please explain why or not.

A: As the question notes, the recent Executive Order makes clear that it does not impair or otherwise affect the authority vested by law in an agency or the agency head. In addition, the introduction to Executive Order 12866 (which was untouched by Executive Order 13422) affirms the primacy of the rulemaking agency in the regulatory decision-making process. Also, section 1(a) of Executive Order 12866 (again, in language untouched by Executive Order 13422) states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need . . ." Similarly, the introductory language to section 1(b) of Executive Order 12866 (again, in language untouched by Executive Order 13422) provides that agencies should adhere to the Order's *Principles of Regulation* "to the extent permitted by law." Finally, section 10, as noted above, similarly preserves agency authority and the sanctity of the laws.

6. Some concerns have been raised about Executive Order 13422's deletion of the clause in Executive Order 12866 specifying that RPOs should report to agency heads. Please explain further what was the basis and purpose of that aspect of Executive Order 13422.

A: The inference – that deletion of the “report to the agency head” phrase means that the Regulatory Policy Officer will no longer reports to the agency head – is incorrect. The deletion of this language does not change the fact that the Regulatory Policy Officer reports to the agency head. As before, the agency head continues to be the official who designates which official shall serve as the agency's Regulatory Policy Officer, and that designated official will continue to report to the agency head in performing this role, just as that official reports to the agency head in performing his or her other responsibilities. This phrase was deleted (as indicated above, without substantive impact) in the course of amending the provision on the Regulatory Policy Officer to include the requirements that the Regulatory Policy Officer be a Presidential appointee, that the agencies needs to inform OMB of the designations, and that the agencies need to provide OMB with annual updates on the designations.

7. What time constraints do you expect OMB to apply to itself as it goes through the steps of reviewing significant agency guidance under the provisions of Executive Order 13422?

A: The amendment made by Executive Order 13422 does not specify a time period for review of significant guidance documents. OIRA will remain in close consultation with the agency until the review is completed, and the review will be conducted in as expedited a manner as is possible.

8. In your oral testimony at the hearing, you stated that OMB's good guidance bulletin, which was issued contemporaneously with Executive Order 13422, was published in the Federal Register for public comment. Please summarize public sentiment on the guidance. Were public comments generally supportive? Did you address public concerns in the final bulletin?

A: OMB received 31 public comments on the proposed Bulletin, and these comments are available on OMB's website. OMB took these comments (and those from agencies) under consideration while preparing the final Bulletin, and we made some changes as a result, as noted in the final Bulletin itself. For example, in response to comments on the draft bulletin, the final Bulletin -- (i) refines the definitions of “guidance document” and “significant guidance document” to make the terms easier for the agencies and the public to understand and implement; (ii) clarifies what is not a “significant guidance document”; and (iii) requires each agency to designate an office to receive and address complaints by the public that the agency is not following the procedures in the bulletin or is improperly treating a guidance document as a binding requirement.

Many of the commenters expressed support for OMB's issuance of a bulletin on good guidance practices, while at the same time offering suggestions for improving the

bulletin. For example, as I noted in my written testimony, the following diverse organizations expressed general support for OMB's Bulletin:

-- **the Association of American Medical Colleges**, representing all 125 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 94 academic and scientific societies ("The AAMC commends the OMB for its proposal to establish consistent and appropriate standards for developing good guidance practices within federal agencies.");

-- **the National Association of Home Builders**, representing more than 220,000 members involved in home building, remodeling, multifamily construction, property management, subcontracting, design, housing finance, building product manufacturing and other aspects of residential and light commercial construction ("The National Association of Home Builders (NAHB) would like to thank the Office of Management and Budget (OMB) for proposing a process to bring transparency and consistency to Executive Branch activities that affect the public directly, but do not qualify as rules under the Administrative Procedure Act (APA).");

-- **the American Society of Safety Engineers**, representing 30,000 members ("ASSE commends OMB/OIRA for taking a proactive stance to ensure that agencies can readily provide interpretation and guidance of regulations, but still do so in a manner that affords due process to the regulated community and that is in accordance with the requisites of the Administrative Procedure Act, 5 USC 551 et seq.");

-- **the National Funeral Directors Association**, representing more than 11,000 funeral homes in all 50 states ("NFDA supports the Office of Management and Budget (OMB) proposal to establish standards to increase the quality and transparency of agency guidance practices and the guidance documents produced through them.");

-- **the Association of Metropolitan Planning Organizations** ("In general, AMPO strongly supports the Proposed Bulletin's intent and reliance on the guidance practices adopted by the Food & Drug Administration ('FDA') at 21 C.F.R. 5 10.115.");

-- **the Ornithological Council**, which consists of eleven leading scientific ornithological societies - the American Ornithologists' Union, Association of Field Ornithologists, CIPAMEX, Cooper Ornithological Society, Neotropical Ornithological Society, Pacific Seabird Group, Raptor Research Foundation, Society of Canadian Ornithologists/La Société des Ornithologistes du Canada, Society for Caribbean Ornithology, Waterbird Society, and Wilson Ornithological Society - that together have a membership of nearly 6,500 ornithologists ("we would like to express our gratitude to OIRA for its efforts to improve agency guidance practices");

-- **the Aircraft Owners and Pilots Association**, representing over 407,000 members ("AOPA shares OMB's concern that agency guidance practices should be more transparent, consistent and accountable. We also agree with OMB that the absence of procedural review mechanisms undermines the lawfulness, quality, fairness and accountability of agency policymaking.");

-- **the National Leased Housing Association**, which represents the interests of housing agencies, developers, lenders, housing managers and others in providing federally assisted rental housing, and whose members are primarily involved in the Section 8 housing programs and are involved with the operation of rental housing for over three million families ("we commend OMB for its efforts");

-- **the American Road and Transportation Association**, whose membership includes public agencies and private firms and organizations that own, plan, design, supply and construct transportation projects throughout the country ("Once again, ARTBA is extremely supportive of the GGP and feels that it represents a significant step forward in the regulatory process. It will engender fairness and improved dialogue between agencies and those that have a vital stake in the guidance they issue. ARTBA and our members are eager to take advantage of the new opportunities for involvement in the guidance process offered by the GGP and help OMB make the GGP standard agency practice."); and

-- **the Associated Equipment Distributors**, representing 1,200 construction equipment distributors, manufacturers and industry-service firms ("Our association thanks the Office of Management and Budget (OMB) for recognizing the impact that guidance material issued by federal regulatory agencies has on the regulated community. We agree with the OMB that transparency in the guidance drafting process is critical, as guidance should not be used for rulemaking.").

The comment letters from these associations can be found on OMB's website, along with the other comment letters (both supportive and critical) on the proposed Bulletin.

9. Is there anything further that you would like to state with regard to questions that were posed to witnesses at the hearing or that arose from the oral and written testimony given at the hearing? If so, please provide any information regarding those questions that you believe would help the Subcommittee better understand the issues concerned.

A: The issue was raised and discussed at the hearing about whether it was appropriate for OMB to issue the Bulletin in the absence of specific statutory direction or authorization for the Bulletin. In this regard, another witness referred to the 1997 statute that directed the Food and Drug Administration (FDA) to issue its Good Guidance regulations. I would like to note that FDA issued its original Good Guidance Practices document on February 27, 1997 (62 Fed. Reg. 8961), nearly nine months before the enactment on November 21, 1997, of the Food and Drug Modernization Act of 1997 (P.L. 105-115),

which in the amendment made by Section 405 of that Act directed FDA to issue regulations on Good Guidance Practices. In fact, the amendments in Section 405 (which added a new subsection (h) to Section 371 of Title 21, U.S. Code) themselves referenced the Good Guidance Practices document that FDA had issued earlier in the year. Also, when it issued the Good Guidance Practices document in February 1997, FDA explained that it was doing so in response to a petition that FDA had received from a private organization, and that – as part of the process of responding to that petition – FDA had issued a Federal Register notice on March 7, 1996 (61 Fed. Reg. 9181) asking for public comments on how to improve the agency's guidance practices, and also held a public meeting on April 26, 1996, to discuss the issue.

Finally, I would like to take this opportunity to reiterate (as I noted in my answer to the first question above, and in my testimony) that the Bulletin and Executive Order are aimed at ensuring that significant agency guidance documents are developed through procedures that ensure quality, transparency, public participation, coordination, and accountability.

POST-HEARING QUESTIONS AND RESPONSES FOR SALLY KATZEN, PROFESSOR,
UNIVERSITY OF MICHIGAN LAW SCHOOL

**QUESTIONS FROM SUBCOMMITTEE CHAIR LINDA SÁNCHEZ
FOR SALLY KATZEN**

1. Executive Order 12866 required each agency to have a regulatory policy officer.

What was the thinking behind that requirement when the order was issued in 1993?

How does Executive Order 13422 change that?

2. You mentioned in your testimony that one effect of the guidance bulletin is to “convert significant guidance documents into legislative rules.” If agencies are issuing rules as guidance documents, why would that not be an improvement?

3. Does requiring major guidance documents to be published in the Federal Register and commented on blur the line between rules and guidance?

Would a better approach be to make the distinction between rules and guidance clear, such as by requiring guidance to clearly say that it is not binding?

4. Mr. Aitken explains in his prepared statement that the new requirement that agencies aggregate the estimated costs and benefits of individual regulations “enhances the transparency of the annual Regulatory Plan by requiring agencies to do the aggregation.” Likewise, Mr. Noe notes that the process involves the “simple toting up of already required information.”

What is your reaction to these statements?

5. Mr. Noe, in his prepared statement, explains that the new Executive Order simply requires agencies to be more precise in identifying the problem that needs to be addressed by rulemaking.

What is your response?

Questions for Prof. Sally Katzen:

1. Some argue that Executive Order 13422 does not radically alter the framework established in Executive Order 12866, which you helped to author. The further explanation provided by OMB at the hearing was consistent with this view. Based on your consideration of Executive Order 13422's provisions, and in light of the information provided at the hearing, please identify on a line-by-line basis which of Executive Order 13422's changes to the specific text of Executive Order 12866 you believe to be minor or technical, which changes you believe to be moderate, and which changes you believe to be major. Please also identify on a line-by-line basis which of these changes you believe to be positive and why, and which you believe to be negative and why.
2. The inclusion of significant guidance documents within E.O. 12866's framework responds to mounting concern in the courts and the legal community over the improper use of guidance by agencies to regulate. Do you believe that Executive Order 13422's inclusion of significant guidance documents within this framework is a timely and positive development? Please explain why or why not.
3. You have expressed significant concern over the impact of Executive Order 13422. Please explain whether your concerns would exist regardless of which president's administration were in office, and why or why not.
4. You spent several years implementing the provisions of Executive Order 12866 to help OMB oversee the federal agencies. With regard to each provision of Executive Order 13422, please explain whether that provision would have helped or hindered you and OMB in accomplishing that oversight. Please also provide an overall estimate of the degree to which Executive Order 13422 would have helped or hindered you and OMB in that oversight.
5. You have argued that, prior to and at the time of Executive Order 13422's issuance, OMB should have offered the public more information about what it was doing and why. You've now heard more information from OMB as a result of Mr. Aitken's testimony at the hearing. Does that information resolve any of your concerns and speculation about the bases for the order? Please explain why or why not. Also, if that information does resolve a material amount of your concern, please explain whether you believe that Executive Order 13422's provisions should now be given an opportunity to be proven in practice, as were Executive Order 12866's provisions, and why or why not.
6. On p.9 of your written testimony, you conclude that "each step" OMB has taken to improve the regulatory review and development process "can be justified as helping to produce better regulatory decisions." Please explain in detail why each of those steps can be justified, in and of itself, as helping to produce better regulatory decisions. Please also explain whether the accumulation of these steps does or does not detract from each of the specific benefits provided by each of these steps individually, and why or why not.

7. You have argued that it is only the cumulative effect of OMB's improvements to the regulatory review and development process that has been negative. Please identify at what specific point you believe the implementation of OMB's successive and individually meritorious improvements to that process began to be negative, and why.
8. You state on p.5 of your written testimony that President George W. Bush's philosophy has been "decidedly anti-regulatory." You also suggest that the actions discussed above by the Bush administration to improve the regulatory review and development process have been consistent with that philosophy. Please explain whether and how your views can be reconciled with the report by OMB that major regulations issued by the current Bush Administration have had double the benefits at less than half the costs when compared with the historical average (see, e.g., OMB's 2006 Report to Congress on the Costs and Benefits of Federal Regulations, Executive Summary at iii).
9. On page 5 of your testimony, you argue that President Clinton's agenda was pro-regulatory and that President Bush's agenda is "decidedly anti-regulatory." You also state, however, that President Bush's advisors considered changing Executive Order 12866 earlier in the Bush Administration, and "concluded it was not necessary to accomplish their [anti-regulatory] agenda." Please explain how it is possible to take the same language that you crafted to facilitate President Clinton's pro-regulatory agenda and use it to implement an anti-regulatory agenda?
10. You state in your written testimony that "President Bush's OMB Director instructed the agencies to scrupulously adhere to the principles and procedures of Executive Order 12866 and its implementing guidelines." Do you believe that any other instruction would have been appropriate? If so, please explain why. Did the instruction by President Bush's OMB director require a significant change in OMB's and the agencies' actual practices? If so, please explain how that could have been possible, unless OMB and the agencies had not scrupulously adhered to these principles and procedures during your tenure at OMB?
11. You suggest that OMB should have sought Congressional authority for the issuance of Executive Order 13422. The changes in the regulatory process worked by Executive Order 12866, however, were more extensive than those worked by Executive Order 13422. Did OMB seek Congressional authority before issuing Executive Order 12866? If not, why not? If it did not, do you think that was wrong? If OMB did seek such authority, did it obtain it? If it did not, do you think that it was wrong for the Clinton Administration to go ahead and issue Executive Order 12866, rather than to wait for Congress to legislate regulatory reforms such as those contained in Executive Order 12866? Have you ever stated prior views on this? If so, please summarize for the Subcommittee what those views were?
12. You also suggest that Executive Order 13422 was issued "without consultation," such as

you conducted when drafting Executive Order 12866. How common is it for a President to issue a draft Executive Order for public notice and comment? Do you believe that every Executive Order should be issued for public notice and comment?

13. You circulated Executive Order 12866 for comment among select groups, but you did not issue it for public notice and comment by all potentially interested parties, such as through notice and solicitation of comments in the Federal Register. Why did you not opt for full notice and comment, since Executive Order 12866 was a complete rewrite of the principles and procedures for regulatory review?
14. Why do you believe it was inappropriate for OMB to offer less notice and comment on Executive Order 13422 than you did on Executive Order 12866, since the former was only a modest set of changes to the latter, and the only substantive change contained in the former – OMB authority to review significant guidance documents – was a complement to an OMB bulletin that was the subject of public notice and comment?
15. You state on p. 8 of your written testimony, with regard to OMB's Final Bulletin on Good Guidance Practices (the "Good Guidance Bulletin," or the "Bulletin"), that "[you] do not believe it is an overstatement to say that the effect of Bulletin is to convert significant guidance documents into legislative rules, subject to all the requirements of Section 553 of the Administrative Procedure Act." It appears that, under the Bulletin, agencies are not required, for the majority of their guidance (other than the limited economically significant guidance) either: (1) to undergo pre-adoption notice and comment; or (2) to respond to comments. In addition, agencies are not required to comply with other procedures under APA Section 553, such as providing a statement of basis and purpose for the rule. Could you explain in more detail, therefore, the basis for your theory that the Bulletin converts significant guidance into legislative rules?
16. Some might argue that OMB's recent actions at most use selected procedures modeled on some procedures of the APA. Is it your position that APA sec. 553 prohibits the Executive from ever using procedures modeled on those of the APA in other contexts in which they would make sense and would be helpful? If so, please explain why or why not. Is that position shared by others in the legal community? If so, please identify who has advocated that position and list any publications such as law journal articles or learned treatises in which that position has been discussed and advanced or rejected.
17. In the Good Guidance Bulletin, OMB has explicitly instructed agencies not to use mandatory language in guidance. In light of that fact, please explain how it can reasonably be maintained that the Bulletin and Executive Order 13422 convert significant guidance into legislative rules.
18. At the hearing, the use of FDA's good guidance practices as a model for OMB's recent actions was discussed. Are you aware of whether FDA has fallen into converting significant guidance into legislative rules as it has complied over the past several years

with its new good guidance regulations?

19. You are a former Chair of the ABA Administrative Law Section. A 1993 ABA Annual Report cited in OMB's Good Guidance Bulletin (at p.2., n.2) recommended preadoption notice and comment on non-legislative rules with significant impacts when practical, and post-adoption comment otherwise. This goes beyond the measures set forth in the Good Guidance Bulletin. Please clarify whether you oppose or support, or opposed or supported, this ABA recommendation, and why.
20. Administrative Conference of the United States Recommendation 92-2 recommended that agencies should afford the public a fair opportunity to challenge the wisdom or legality of policy statements and to suggest alternative choices. Please clarify whether you oppose or support, or opposed or supported, this ACUS recommendation, and why.
21. Administrative Conference of the United States Recommendation 76-5 recommended, for interpretive rules and general policy statements with a substantial impact on the public, that agencies provide pre-adoption notice and comment, or if that would be impractical, post-adoption comment. Please clarify whether you oppose or support, or opposed or supported, this ACUS recommendation, and why.
22. You suggest that Executive Order 13422 will "become a codification of an anti-regulatory manifesto." At the hearing and in written testimony, OMB clarified that the main provisions of Executive Order 1342 to which you object – those on market failure analysis, regulatory policy officers, and aggregation of already-required cost and benefit information -- are minor tweaks to the pre-existing terms of Executive Order 12866. Please indicate whether you continue to believe that these modest provisions codify an "anti-regulatory manifesto," and, if you do, please explain in detail why.
23. You state that OMB has been anti-regulatory during the administration of President George W. Bush. During that administration, however, OMB has promoted regulations, such as the Environmental Protection Agency's Clean Air Interstate Rule and Nonroad Diesel Rule, the Department of Transportation's CAFÉ rule, and the Food and Drug Administration's Trans Fats rule, that, while costly, can be expected to save thousands of lives. Please explain in more detail why, those actions or others like them notwithstanding, President Bush's OMB should be considered to be "anti-regulatory."
24. Do you believe that OMB's Office of Information and Regulatory Affairs was effective under your watch and Executive Order 12866. If you do, please explain why? If you do, please also reconcile your view with the fact that OMB's cost-benefit analyses over the years show that the current Bush Administration has obtained double the benefits from major rules at less cost than was obtained under your watch?
25. On p.10 of your written testimony, you suggest that the Bush Administration does not believe that all problems are equally deserving of attention, and that market failures are a

avored class -- and possibly the only class -- warranting new regulations. Please explain how you reconcile this criticism with the fact that OMB Guidelines M-00-08, issued by the Clinton Administration in March 2000, appear to elevate market failure higher than Bush Circular A-4 did, by indicating that "the existence of a market failure is not sufficient to justify government intervention," and that agencies should "show that government intervention to correct market failure is likely to do more economic good than harm."

26. Given your criticism of the current Bush Administration's views of the significance of market failures in justifying regulation, please explain the fact that Bush Circular A-4 is far more detailed on additional justifications for regulation, such as protection of civil rights, privacy, personal freedom and other concerns, than were the OMB Best Practices drafted under your watch in 1996?
27. The idea of "market failure" appears to have played a controlling role in a 1996 guidance document that OMB issued under your watch, entitled "Economic Analysis of Federal Regulations under Executive Order 12866" (the "Economic Analysis Guidance"). That document stated that agencies "should determine whether there exists a market failure that is likely to be significant," meaning that not all market failures are important enough to justify federal regulation. Indeed, the document stated that if the problem proposed to be addressed "does not constitute a market failure, the analysis should provide an alternative demonstration of compelling public need" for regulation. Do you now disagree with these views? If so, please explain why you agreed with them in 1996.
28. The Economic Analysis Guidance also stated that agencies' "analysis should distinguish actual market failures from potential market failures that can be resolved at relatively low cost by market participants." Do you now disagree with this view? If you still agree with this view, do you agree that Executive Order 13422 will help spur agencies to make such distinctions?
29. The Economic Analysis Guidance identified four types of market failure: externality, natural monopoly, market power, and inadequate or asymmetric information. Do you no longer believe that these are important examples of market failure? Do you agree that these are largely the same types of market failure that were listed as examples in Executive Order 13422's market failure provision?
30. The Economic Analysis Guidance included market failure analysis among "best practices" in analysis of federal regulations under Executive Order 12866. If market failure analysis is a best practice, do you believe that Executive Order 13422's clarifications of what it is and when it should be considered will help or hinder its use? Please explain why or why not.
31. You have suggested that Executive Order 13422's terms regarding market failure represent "a throw back to the 'market-can-cure-almost-anything' approach?" Isn't it

true, however, that documentation of market failures as required by those terms could help provide proof of the opposite – that markets may not be able to cure everything?

32. In your written testimony, you use the term “regulatory budget.” Please explain what you mean by that term. Some use that term to signify a “budget” setting a “cap” on any new regulatory expenditures unless existing regulatory burdens are cut, thus overriding existing law. If that is the sense in which you use the term, please reconcile your position with the fact that Executive Order 13422 sec. 10 states that “[n]othing in this order shall be construed to impair or otherwise affect the authority vested by law in an agency or the head thereof[.]”
33. OMB has now clarified that, with regard to aggregating regulatory costs and benefits, Executive Order 13422 merely requires the toting up of information already required by Executive Order 12866. Given that fact, do you still believe that Executive Order 13422 is “the first step toward implementing a regulatory budget?” If so, please explain why.

Answers from Sally Katzen to Questions from Subcommittee Chair Linda Sanchez:

1. The concept was that there would be a single person who would report directly to the agency head (no longer required by the Bush Executive Order) held responsible for regulatory matters and who would serve as the point of contact for both OIRA and other agency regulatory policy officers. Among other things, the Administrator of OIRA convened a meeting of all regulatory policy officers monthly (no longer required by the Bush Executive Order) to exchange best practices and to consult one another on matters of mutual interest.
2. Guidance documents do not have the force and effect of law and the courts have not been reluctant to hold that rules issued as guidance documents do not bind either the agency or the regulated entities.
3. Yes to both questions.
4. Agencies traditionally do not provide estimated costs or benefits until there is a notice of proposed rulemaking, reflecting at least tentative decisions about the options the agency is pursuing; until such tentative decisions are made, the numbers are meaningless and the aggregation a useless exercise.
5. There has been no showing -- either before the Executive Order was signed or since -- that agencies were imprecise in identifying the problems they were addressing. Also, the new Executive Order requires precise identification not only of the problem, but also the cause of the problem, which is not always as straightforward as might appear.

Answers from Sally Katzen to Questions 1-33:

1. Making substantive changes in Executive Order 12866 (unlike EO 13258, which substituted either the Chief of Staff or the Director of OMB for the Vice President) is itself major and the combination of the changes sends a very different (and unfortunate) tone than did the original Executive Order. The elevation of economic concerns, reflected in the amendment to Section 1(b)(1) and 4 (b)(1)(B), is major and not positive because other factors may be more pertinent and more important; the changes in the qualifications and duties of the regulatory policy officer (Section 4(b)(1) and 6(a)(2)) are major and not positive because the individual no longer must report to the agency head and cannot be a civil servant even if s/he is the most qualified individual for the position; the inclusion of guidance documents (Sections 1(b)(7), (10), (11) and (12), 2(a) and (b), 3(g), 9) is major and not positive because it will delay and reduce the number of guidance documents issued to assist both agency staff and regulated entities; and encouraging formal rulemaking (Section 6(a)(1)) is major and not positive because that form of rulemaking has long been discredited.
2. No, because providing for OIRA review of documents that do not have the force and effect of law blurs the line between rules and guidance.
3. The message sent by the amendments to the Executive Order is not one that would be sent by a Democratic President.

4. None of the amendments is necessary to improve OMB's oversight of agency rulemakings; the changes with respect to the regulatory policy officer, guidance documents and formal rulemaking may hinder somewhat such oversight.
5. There has been no specification of the problems that might have justified the amendments so there is no way to determine if the amendments solved any such problems without creating unintended adverse consequences.
6. The justification for each step was set forth by OMB in the preamble or text of each of the bulletins, circulars and guidance. I do not agree with every justification provided. As stated in my written testimony, the cumulative effect of all the steps without providing commensurate resources to the agencies necessarily makes it more difficult for the agencies to do the job that Congress delegated to them
7. The individual steps are meritorious only if the agencies have the resources to implement them without impairing their ability to carry out their other responsibilities and obligations. This will vary widely among agencies.
8. The OMB report covers only the monetized costs and benefits of only the rules that were issued after OMB review; it does not take into account costs and benefits that are not monetized (although there are many significant regulations issued that have qualitative benefits and costs that cannot be monetized but are nonetheless essential to consider) and does not include the many rules that the Bush Administration decided not to issue. In any event, the amount of costs and benefits from rules issued in any one year or series of years relative to the amount of costs and benefits from rules issued in another year or series of years is not a measure of pro-regulatory or anti-regulatory philosophy.
9. The language in the original Executive order 129866 was neutral as to outcome; it was neither pro-regulatory nor anti-regulatory.
10. The instruction was appropriate, and no OMB or agency practices were required to be changed because Executive Order 12866 as signed by President Clinton was neutral as to outcome.
11. I did not say, or intend to imply, that congressional authority is either necessary or desirable for the issuance of an executive order. The president has authority to issue executive orders that are not inconsistent with duly enacted law. I invoked congressional involvement with respect to the procedures for adopting guidance documents, because congressional involvement was salutary with respect to FDA guidance practices, which was the model for the OMB Good Guidance Bulletin.
12. Executive Orders are not subject to public notice and comment under either the law or practice; informal consultation with affected entities is another matter.
13. See answer to #12.
14. Consultation might have reduced the adverse reaction to the release of Executive Order 13422 and possibly caused the Administration to rethink or at least rephrase some of the more controversial provisions.
15. The majority of significant guidance documents, like the majority of significant regulations, will be so characterized because they are economically significant guidance documents, and these economically significant guidance documents are now required to have pre-adoption notice and comment and the agencies are required to respond to comments filed (which is the heart of Section 553's

- “statement of basis and purpose for the rule” that is cited in the question).
 Moreover, significant guidance documents can be reviewed by OIRA, just like significant legislative rules.
16. It is not my position that Section 553 of the APA “prohibits the Executive from ever using procedures modeled on those of the APA in other contexts in which they make sense and would be helpful,” and I am not aware of what others in the legal community might think of such a position.
 17. It is the process (and the time and resources) by which legislative rules and guidance documents are issued that is now almost the same, not the effect of such rules or guidance.
 18. I am only aware that FDA is either able or willing to issue fewer guidance documents now than before, which may well be a factor of the increased time and resources needed for such guidance without a commensurate increase in its resources.
 19. I do not have any recollection of the specifics of the ABA recommendation and therefore cannot say how it compares with the OMB Bulletin. Nor do I recall whether I supported or opposed the recommendation, although generally I favor enhanced public participation in agency decision-making subject to the agencies’ having adequate resources to accomplish it.
 20. I do not have any recollection of the specifics of the ACUS recommendation and do not recall whether I supported or opposed the recommendation, although generally I favor enhanced public participation in agency decision-making subject to the agencies’ having adequate resources to accomplish it.
 21. See answer to #20.
 22. The provisions of Executive Order 13422 are not “minor tweaks” to Executive Order 12866 as signed by President Clinton. Taken together, they send a signal that the bar for rulemaking has been raised.
 23. OMB serves the Office of the President, and President Bush campaigned against regulations; one of the first Acts of Congress that he signed eliminated the ergonomics rule, notwithstanding the prevalence of repetitive stress injuries in the workplace; President Bush questioned and proposed rollback of other regulations issued during the Clinton Administration only to later conclude that they were necessary and appropriate (see e.g., arsenic in drinking water); he has acquiesced, if not encouraged, that rules required by Congress be minimalist (see e.g., the tire pressure monitoring rule); his speeches frequently echo industry’s complaints about the burden of regulations; and, his budgets do not provide additional resources for the agencies commensurate with their increased (by OMB) responsibilities.
 24. I believe OIRA “was effective under [my] watch and Executive Order 12866” because during that time we worked with the agencies to fulfill their Congressional mandates in the most effective and efficient manner. See answer to #8.
 25. I disagree with the statement that the Clinton Administration’s OMB Guidance elevated “market failure” higher than Bush Circular A-4 did.

26. Bush Circular A-4 is far more detailed about everything that might appear in a regulatory impact analysis. In any event, Executive Order 13422 raised “market failure” to a new elevated status that takes precedence over an OMB Circular.
27. The statements in the 1996 document are valid. That document was captioned “Best Practices,” was not viewed as binding (unlike an executive order), and the 1996 document was not intended to signal a preferential status to “market failure” as a justification for regulation.
28. The statement in the 1996 document is valid as “Best Practices.” See also answer to #27.
29. The types of market failures identified in the 1996 document are important examples of market failures. See also answer to #27.
30. There has been no allegation, let alone any demonstration, that agencies need clarification of what a market failure is or when it should be considered that would justify an amendment to Executive Order 12866 regarding market failures. See also answer to #27.
31. The concern is that regulation may not be permitted where there is no market failure – that is, so long as markets are working as expected, OMB would conclude that there is no justification for government intervention, even though well functioning markets may not be able to remedy invasions of privacy or discrimination on the basis of race or gender to name just two examples where regulations may be necessary to achieve important and valuable public policy objectives.
32. I understand proponents of a regulatory budget see it as a way to cap the costs of regulations (no consideration being given to benefits) and that once the cap is reached, then new regulations may be issued only if the existing regulatory burdens are decreased in some way. Unless the regulatory budget was adopted by Congress, it could not be used to override existing law.
33. Many agencies do not include in the Regulatory Agenda estimates of costs and benefits for proposed rules at the pre-notice stage and therefore the amendment of Executive Order 12866 does not “merely require[] the toting up of information already required.”

POST-HEARING QUESTIONS AND RESPONSES FOR CURTIS W. COPELAND, PH.D., SPECIALIST IN AMERICAN NATIONAL GOVERNMENT, CONGRESSIONAL RESEARCH SERVICE



Memorandum

March 12, 2007

TO: House Committee on the Judiciary
Subcommittee on Commercial and Administrative Law
Attention: Elias Wolfberg

FROM: Curtis W. Copeland
Specialist in American National Government
Government and Finance Division

SUBJECT: Post-hearing Questions on Executive Order 13422

As you requested, below are my responses to the questions submitted to me after the Subcommittee's February 13, 2007, oversight hearing on "Amending Executive Order 12866: Good Governance or Regulatory Usurpation?". Also, attached are my edits to the transcript of the hearing. If you have any questions, please do not hesitate to call me at (202) 707-0632.

Q1 – Based on the oral and written testimony provided by OMB at the hearing, please explain whether you now consider the questions or issues you identified in your written testimony to be clarified and resolved, and why or why not.

A – I do not believe that OMB's testimony at the hearing clarifies or resolves any of the major issues in Executive Order 13422 that I identified in my testimony as unclear. For example, OMB's testimony does not explain why certain actions taken in the executive order were needed (e.g., to require that regulatory policy officers be presidential appointees who do not report to the agency head, and to give them the power to stop all rulemaking unless the agency head objects); does not identify how potential areas of conflict will be resolved (e.g., whether OMB or the agencies will decide whether it is "possible" for an agency to develop aggregate cost and benefit estimates of upcoming rules); and does not make clear the effect that the order will have on the balance of power between the President and Congress (e.g., whether independent regulatory agencies will now have to have regulatory policy officers who report to the President).

Q2 – With regard to any remaining concerns you have regarding Executive Order 13422, please explain whether those concerns would exist regardless of which president's administration were in office, and why or why not.

A – As written, the effects of the executive order on federal agencies would be unclear regardless of which presidential administration was in office. For example, executive order

language indicating that agencies should take certain actions “where applicable” or “to the extent possible” gives both the agencies and the President issuing the order substantial discretion to interpret those terms. As a result, it is difficult, if not impossible, to know how those areas of discretion will ultimately be exercised. Also, any presidential administration that did not explain why an executive order was issued would be subject to questions as to why the action was needed. Finally, questions about the balance of power between the legislative and executive branches are likely with regard to any President who takes actions that are believed to affect the statutory authorities or independence that Congress has given to regulatory agencies.

POST-HEARING QUESTIONS AND RESPONSES FOR PAUL R. NOE, PARTNER, C&M
CAPITOLINK LLC, AND COUNSEL, CROWELL & MORING ENVIRONMENT & NATURAL
RESOURCES GROUP WITH ATTACHMENTS

**QUESTIONS FROM SUBCOMMITTEE CHAIR LINDA SANCHEZ
FOR PAUL NOE**

1. Was Executive Order 13422 formulated while you were counselor to the previous OIRA Administrator John Graham? If so, what can you tell us how Executive Order 13422 originated? Why was Executive Order 13422 issued at this time? How was Executive Order 13422 revised during its development?

In conjunction with deliberations on the OMB Bulletin on Good Guidance Practices, there were deliberations on the Executive Order during part of the time that I served as Counselor to OIRA Administrator John Graham. However, the deliberations continued beyond the period of my service, and the Executive Order was issued about eight months after I left OMB. I believe that OMB is the appropriate party to address questions about issues such as the timing and revisions to the Executive Order.

2. One part of Executive Order 12866 that was not revised was the sentence referring to the "primacy of Federal agencies in the regulatory decision-making process. "Do you ascribe to this concept, i.e., that federal agencies should be allowed to make the ultimate decision about their rules because they have the expertise and are the ones that must defend the rules to the public and in the courts?

Yes.

3. Will Executive Order 13422, as asserted by New York Times Columnist Paul Krugman, "make it even easier for political appointees to overrule the professionals, tailoring government regulations to suit the interests of companies"? If not, please explain.

I do not believe that the article was an accurate or balanced review of Executive Order 13422. While some have claimed that the concept of Regulatory Policy Officers is a radical change from the status quo, Regulatory Policy Officers actually were established by President Clinton's Executive Order 12866. E.O. 12866 required each agency head to designate a Regulatory Policy Officer, who in turn had to report back to her. The 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 continues that tradition and continues to delegate to the agency head the designation of the Regulatory Policy Officer. The Bush Order further specifies that the Regulatory Policy Officer should be one of the agency's Presidential Appointees. To my knowledge, the provision in President Bush's Order only codifies general 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 structure with oversight over the agency's regulatory agenda and 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.

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.

Finally, regarding the concern of "politicization," it should be noted that 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. If the Regulatory Policy Officer were a civil servant and not a Presidential Appointee, it could be awkward for Congress to expect him to testify on behalf of the President. And Congress could have difficulty obtaining authoritative information on presidential priorities. Accordingly, the amendments by Executive Order 13422 should foster accountability and Congressional oversight, not hinder it.

**QUESTIONS FROM SUBCOMMITTEE RANKING MEMBER CHRIS CANNON
FOR MR. PAUL R. NOE**

1. Critics of Executive Order 13422 suggest that it will politicize the regulatory review process, undercut Congress' prerogatives, and clear the way for politics and economics to trump science and health and safety concerns. Others urge that the order makes the regulatory review process more accountable, by placing more responsibility in the hands of officials accountable to Congress, that the order brings development of significant agency guidance documents into a process framework that long has applied to regulations, and that the order in other respects largely carries forward the principles of Executive Order 12866. Based on your testimony at the hearing and your previously submitted written testimony, you appear to agree with the latter view. In light of the written and oral testimony of other witnesses at the hearing, could you please provide any additional discussion of your views that would help the Subcommittee understand which of these views is accurate and which is not, and why?

As explained in my written testimony, I believe that a careful review of the amendments made by the Bush Order to the provisions in Executive Order 12866 for Regulatory Policy Officers and market failure analysis will show they are minor changes to the existing language in E.O. 12866 and were not a significant change from the status quo. I do believe that the new the provision for OMB review of guidance documents is a significant and beneficial change from the status quo that will promote the transparency, accountability and effectiveness of regulatory programs. As explained in my written statement and in my response to Question 3 below, I believe there is a compelling foundation for interagency review of significant guidance documents.

2. Some contend that Executive Order 13422 represents a "power grab" by the President for authority residing in the federal agencies. Can't the order just reflect the Executive exercising his responsibility and pre-existing authority to lead and direct the Executive Branch? Indeed, under our constitutional system, isn't that his duty?

Yes, and centralized regulatory review has been a tradition with every President, Republicans and Democrats alike, since President Nixon.

3. What have been the chief arguments for bringing significant guidance documents into the Executive Order 12866 framework? Do you believe those arguments to be sound? If so, please explain in detail why, to the extent that detail in addition to that provided by your prior oral and written testimony would help the Subcommittee understand this issue fully.

As OMB explained in the Preamble to its Bulletin on Good Guidance Practices, there is a strong foundation for good guidance practices and interagency review of

significant guidance documents. First, as a general matter, while guidance generally has great value to regulated parties, the government, and the public, concerns have been raised about instances where guidance documents were poorly designed and implemented or improperly used to impose binding requirements on regulated parties. OMB heard about those concerns through several rounds of public comment.

It was eminently reasonable to conclude that significant guidances could benefit from interagency review as provided in Executive Order 13422 and the other good guidance practices established in OMB's Bulletin. The strong foundation for the good guidance practices reflected in President Bush's Executive Order and the OMB Bulletin stems from many sources, including court decisions invalidating spurious rules, recommendations of the former Administrative Conference of the United States, recommendations of the American Bar Association, the work of various administrative law scholars, and the groundbreaking work of the Food and Drug Administration to establish good guidance practices on its own initiative. Ultimately, Congress endorsed what FDA did by requiring FDA to re-issue good guidance practices in the form of a regulation under the Federal Food and Drug Administration Modernization Act of 1997. The same concerns that Congress raised at the time – 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 – apply to other agencies as well.

Regarding this issue, I am submitting for inclusion in the Hearing Record two recommendations of the Administrative Conference of the United States, an excerpt from a Report and Recommendation of the American Bar Association, and two articles from Professor Robert Anthony.

4. Concern has been expressed over Executive Order 13422's requirement that an agency identify in writing the market failure or other problem that it thinks warrants new agency action. Wasn't that already required, though? Do you think the Amendments materially change anything in this regard? Please explain in detail why, to the extent that detail in addition to that provided by your prior oral and written testimony would help the Subcommittee understand this issue fully.

Yes, President Clinton's Executive Order 12866 already required agencies to identify in writing the market failure or other problem that the agency thought warranted regulation. As I explained in my written and oral testimony, I believe that a close review of the actual changes made to the provision for market failure analysis in President Clinton's Executive Order 12866 shows that these are very minor changes.

Moreover, the OMB guidelines issued during the Clinton Administration in many respects provide a stronger endorsement of market failure analysis than the Bush Administration's guidelines.

The primary OMB guidelines for cost-benefit analysis issued by the Clinton Administration stated:

"I. STATEMENT OF NEED FOR THE PROPOSED ACTION

"In order to establish the need for the proposed action, that analysis should discuss whether the problem constitutes a significant market failure. If the problem does not constitute a market failure, the analysis should provide an alternative demonstration of compelling public need, such as improving governmental processes or addressing distributional concerns. If the proposed action is a result of a statutory or judicial directive, that should be so stated.

A. Market Failure

The analysis should determine whether there exists a market failure that is likely to be significant. In particular, the analysis should distinguish actual market failures from potential market failures that can be resolved at relatively low cost by market participants.

Examples of the latter include spillover effects that affected parties can effectively internalize by negotiation, and problems resulting from information asymmetries that can be effectively resolved by the affected parties through vertical integration. Once a significant market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specific market failure.

The major types of market failure include: externality, natural monopoly, market power, and inadequate or asymmetric information.

1. Externality. An externality occurs when one party's actions impose uncompensated benefits or costs on another. Environmental problems are a classic case of externality. Another example is the case of common property resources that may become congested or overused, such as fisheries or the broadcast spectrum. A third example is a "public good," such as defense or basic scientific research, which is distinguished by the fact that it is inefficient, or impossible, to exclude individuals from its benefits.

* * * * *

... Government action may have unintentional harmful effects on the efficiency of market outcomes. For this reason, there should be a presumption against the need for regulatory action that, on conceptual grounds, are not expected to generate net benefits, except in special circumstances. ...

OMB, “Economic Analysis of Federal Regulations Under Executive Order 12866” (Jan. 11, 1996) (discussing in detail the importance of market failure analysis and explaining externality, natural monopoly, market power, and asymmetric information) (Emphasis added).

Another set of OMB guidelines issued during the Clinton Administration stated:

“Since the existence of a market failure analysis is not sufficient to justify government intervention, you should show that government intervention to correct market failure is likely to do more good than harm. If the problem is not a significant market failure, you should provide an alternative demonstration of compelling public need.”

OMB, M-00-08, “Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements (March 22, 2000), at p. 62 (Emphasis added). Regarding this issue, I am submitting for inclusion in the Hearing Record excerpts from several OMB guidelines for economic analysis issued during the Administrations of President George H. W. Bush, Bill Clinton, and George W. Bush.

5. Many believe that considering potential regulations and guidance in the light shed by cost-benefit analysis, market failure analysis, and other types of economic analysis can help us regulate smarter and more efficiently, in those cases where we need to. Do you agree, and can you think of some important examples where that has been proven to be the case? Please explain in detail why, to the extent that detail in addition to that provided by your prior oral and written testimony would help the Subcommittee understand this issue fully.

Yes. Applying careful regulatory analysis was a foundation of the Bush Administration’s “smart regulation agenda,” which led to major regulations that had about twice the annual benefits at almost half the cost compared with the historic average. See OMB 2007 Draft Report to Congress on the Costs and Benefits of Regulation at p. 2. The insights of regulatory analysis were a foundation for many pro-regulation positions of OMB, including regarding EPA’s Clean Air Interstate Rule, OMB’s prompt letter asking FDA to expedite the Trans-Fat Labeling Rule, EPA’s Non-Road Diesel Emission Rule, and DOT’s Corporate Average Fuel Economy Standards. While these rules were very costly, OMB supported them because the benefits far exceeded the costs.

Regarding this issue, I am submitting for inclusion in the Hearing Record an excerpt from OMB's 2007 Draft Report to Congress and an article by former OIRA Administrator Dr. John Graham.

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INTERPRETIVE RULES, POLICY STATEMENTS, GUIDANCES, MANUALS, AND THE LIKE—SHOULD FEDERAL AGENCIES USE THEM TO BIND THE PUBLIC?

ROBERT A. ANTHONY*

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This Article is adapted from a report prepared for the Administrative Conference of the United States, which formed the basis for the Conference's Recommendation 92-2. 57 Fed. Reg. 30,103 (1992) (to be codified at 1 C.F.R. § 305.92-2). The recommendation appears as an appendix to this Article. The views herein are those of the author, and should not be attributed to the Administrative Conference.

I am grateful for the generous support of this work by the Sarah Scaife Foundation and the John M. Olin Foundation.

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INTRODUCTION AND SUMMARY

With one exception, the answer to the question in the title is "no." To use such nonlegislative documents to bind the public violates the Administrative Procedure Act (APA) and dishonors our system of limited government. This is true whether the agency attempts to bind the public as a legal matter or as a practical matter.¹ An agency may not make binding law except in accordance with the authorities and procedures established by Congress. To make binding law through actions in the nature of rulemaking, the agency must use legislative rules, which ordinarily must be made in accordance with the notice-and-comment procedures specified by section 553 of the APA.²

1. An agency rule is "binding" when the agency treats it as dispositive of the issue it addresses. A document that was not issued legislatively, and which therefore cannot be binding *legally*, is nevertheless binding as a *practical matter* if the agency treats it as dispositive of the issue it addresses. See *infra* notes 79-94 and accompanying text.

2. 5 U.S.C. § 553 (1988); see *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-03 (1979); *Batterton v. Marshall*, 648 F.2d 694, 701 (D.C. Cir. 1980) ("Advance notice and public participation are required for those actions that carry the force of law."). An agency may make law through adjudication, as contrasted with rulemaking, without complying with § 553 procedures or otherwise

The sole category of exceptions—where an agency may permissibly attempt to make a substantive nonlegislative rulemaking document binding on private parties—is for interpretive rules.³ These are rules that interpret statutory language which has some tangible meaning, rather than empty or vague language like “fair and equitable” or “in the public interest.”⁴ An agency may nonlegislatively announce or act upon an interpretation that it intends to enforce in a binding way, so long as it stays within the fair intendment of the statute and does not add substantive content of its own.⁵ Because Congress has already acted legislatively, the agency need not exercise its own delegated legislative authority. Its attempts to enforce an interpretation can be viewed as simply implementing existing positive law previously laid down by Congress. As a

observing the requirements for making legislative rules. See *infra* text accompanying notes 33-36 and 41-48. This Article is not concerned with the law made by adjudication. That the two styles of lawmaking are governed by widely different procedural requirements (strict for rules but loose for adjudications) is an anomaly created by Congress when it enacted § 553 and confirmed by the Supreme Court in *SEC v. Cheney Corp.*, 352 U.S. 194 (1947), *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759 (1969), and *NLRB v. Bell Aerospace Co.*, 416 U.S. 267 (1974).

3. Legislative rules made pursuant to specific exemptions in § 553, see *infra* text accompanying notes 51-54, do not supply additional exceptions to the statements in the text about *nonlegislative* documents. The exemptions in § 553 relieve the agency of having to follow that section's notice-and-comment procedures, but they do not relieve the agency of the need, if its rule is to be binding, to satisfy other requirements of legislative rulemaking. See *infra* text accompanying notes 41-48. Even on a subject as to which its *legislative* rules would come within § 553's exemption from notice-and-comment procedure, the agency may not use a *nonlegislative* document to bind the public, unless that document is an interpretive rule.

4. See *infra* text accompanying notes 56-68.

5. See *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045-46 (D.C. Cir. 1987) (differentiating “cases in which an agency is merely explicating Congress’ desires from those cases in which the agency is adding substantive content of its own,” and speaking of a “classic example of an agency rule held not to be interpretative—thus requiring notice and comment as a prerequisite to validity”) and authorities cited therein. “The function of § 553's first exception, that for ‘interpretive rules,’ is to allow agencies to explain ambiguous terms in legislative enactments without having to undertake cumbersome proceedings.” *Id.* at 1045; see also *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991) (“[A]s a general rule, an agency can declare its understanding of what a statute requires without providing notice and comment, but an agency cannot go beyond the text of a statute and exercise its delegated powers without first providing adequate notice and comment.”); *United Technologies Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987) (“[T]hese cases show that what distinguishes interpretative from legislative rules is the legal base upon which the rule rests. If the rule is based on specific statutory provisions, and its validity stands or falls on the correctness of the agency's interpretation of those provisions, it is an interpretative rule. If, however, the rule is based on an agency's power to exercise its judgment as to how best to implement a general statutory mandate, the rule is likely a legislative one.”); *American Postal Workers Union v. United States Postal Serv.*, 707 F.2d 548, 559-60 (D.C. Cir. 1983) (“As an interpretative rule, the new annuity computation formula is exempt from the rulemaking requirements of the APA, and OPM therefore did not act unlawfully in promulgating it without notice and comment proceedings.”), *cert. denied*, 465 U.S. 1100 (1984); see also cases cited *infra* note 366.

It is cliché to observe that these distinctions are sometimes difficult to draw. That makes them none the less indispensable to the analysis needed to identify unauthorized attempts to fasten binding norms upon the public.

practical matter, the agency in this way gives the interpretation a binding effect.⁶ The same is true where the agency interprets its own previously promulgated legislative rules.

By contrast, when it does not merely interpret, but sets forth onto new substantive ground through rules that it will make binding, the agency must observe the legislative processes laid down by Congress.⁷ That is, *when an agency uses rules to set forth new policies that will bind the public, it must promulgate them in the form of legislative rules.* The statutory procedures for developing legislative rules serve values that have deep importance for a fair and effective administrative process and indeed for the maintenance of a democratic system of limited government.⁸

6. By declaring that the given interpretation is the one it will apply, or by basing enforcement action upon it, or by routinely applying it to pass upon applications, the agency binds the affected private parties *as a practical matter*, see *infra* text accompanying notes 79-89 and 366-68, at least until a court disapproves the interpretation. The agency treats the interpretation as dispositive of the question involved, and private parties can ignore it only at their peril. The private parties are thus bound *practically* even though the nonlegislatively promulgated interpretation does not *legally* bind them: An agency interpretation does not bind the courts and does not of its own force bind the public unless it has been embodied in a legislative rule or other action carrying the force of law, as a court is free to arrive at a different interpretation. See *BEOC v. Arabian Am. Oil Co.*, 111 S. Ct. 1227, 1235-36 (1991); *General Elec. Co. v. Gilbert*, 429 U.S. 125, 141 (1976); *Morton v. Ruiz*, 415 U.S. 199 (1974); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944); *Metropolitan School Dist. of Wayne Township v. Davila*, 969 F.2d 483, 493 (7th Cir. 1992); Robert A. Anthony, *Which Agency Interpretations Should Bind Citizens and the Courts?*, 7 *YALE J. ON REG.* 1, 3 n.6, 39 (1990); *infra* note 366.

7. Administrative Procedure Act, § 4, 5 U.S.C. § 553 (1988); *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979); *American Hosp. Ass'n*, 834 F.2d at 1044-46. In addition to those of the APA, other statutory requirements may specify the legislative rulemaking procedures in particular areas. E.g., 15 U.S.C. § 37a (1988) (Federal Trade Commission); 20 U.S.C. § 1232 (1988) (Department of Education).

The APA § 553 requirements, often called "notice-and-comment" procedures, call for publication of notice of the proposed rulemaking (including notice of any public proceedings, of the legal authority under which the rules are proposed, and of the terms of the proposal or the subjects and issues involved); opportunity for all interested persons to comment through submission of written views, with or without opportunity for oral presentation; consideration of the matter presented; and publication of the rules, including a concise statement of their basis and purpose, in the *Federal Register*. 5 U.S.C. § 553(n)(1).

Section 553 provides exemptions from these requirements for "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice," *id.* § 553(b)(A), and when the agency "for good cause" finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," *id.* § 553(b)(B). The exemptions for interpretative rules and policy statements are central topics of this Article.

In their adjudicatory opinions, agencies often announce the propositions of law or policy that formed the basis of their decisions. These propositions are not treated as rules by the APA, and are not governed by the statement in the text. See *infra* text accompanying notes 31-36. Nor are non-substantive rules of agency organization, procedure, or practice governed by the statement in the text. See *infra* text accompanying notes 53-54.

8. See *infra* text accompanying notes 356-58.

Except to the extent that they interpret specific statutory or regulatory language, then, *nonlegislative rules like policy statements, guidances, manuals and memoranda should not be used to bind the public.*⁹ While these nonlegislative rules by definition cannot *legally* bind, agencies often inappropriately issue them with the intent or effect of imposing a *practical* binding norm upon the regulated or benefited public. Such use of nonlegislative policy documents is the capital problem addressed by this Article.

Thus, under the taxonomy of the APA,¹⁰ a rulemaking action that the agency wishes to make binding upon affected persons must be either a legislative rule (which binds legally) or an interpretive rule (which may bind practically). All other substantive rulemaking documents—such as policy statements, guidances, manuals, circulars, memoranda, bulletins, and the like—are in APA terminology “policy statements,”¹¹ which the agency is *not* entitled to make binding, either as a legal matter or as a practical matter. These issuances will sometimes be referred to as “non-legislative policy documents” or “policy documents.”

This Article accordingly will advance the general recommendation, based on the APA, that agencies observe legislative rulemaking procedures for any action in the nature of rulemaking that is intended to impose mandatory obligations or standards upon private parties, or that has that effect. To the extent that agency pronouncements interpret specific statutory or regulatory language, this general recommendation does not apply. But the Article will separately recommend that interpretations that substantially enlarge the jurisdiction exercised by the agency, or substantially change the obligations or entitlements of private parties, should nevertheless be promulgated by legislative rulemaking procedures as a matter of sound agency practice.¹²

9. All documents and actions like these are “rules” within the APA definition, 5 U.S.C. § 551(4) (1988), and also are “policy statements” within the APA’s taxonomy, as explicated below, *infra* text accompanying notes 65-70. “[R]ule’ means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . .” 5 U.S.C. § 551(4). The definition thus includes documents and actions that do not have the force of law (nonlegislative rules) as well as those that do (legislative rules). The “agency process for formulating, amending, or repealing a rule” is defined as “rule making” by the APA. *Id.* § 551(5).

10. See *infra* Part I.

11. See *supra* note 9; *infra* text accompanying notes 65-70.

12. See *infra* text accompanying notes 370-73.

The implementation of these recommendations will doubtless in some circumstances prove inconvenient or costly to the agency. See *infra* text accompanying notes 380-81. In especially difficult circumstances, the agency may rely upon the exemption from rulemaking requirements that applies “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary,

The use of legislative rulemaking procedures is not the only cure to be prescribed for the misuse of nonlegislative documents described herein. An agency has the option of issuing its policies in the form of policy statements that are genuinely nonbinding, thereby bringing them within the "policy statement" exemption from the APA's rulemaking requirements.¹³ When it chooses this course of action the agency should observe an alternate process, by which it can assure that its documents are not binding and therefore will not be invalidated on the ground that they were not promulgated by the use of legislative rulemaking procedures. To achieve these outcomes, the agency should stand ready to entertain challenges to the policy in particular proceedings to which the document may apply, and should observe a disciplined system for maintaining an "open mind" when passing upon such challenges.¹⁴

Finally, the Article recommends procedures through which an agency, whenever it intends a rule to be legislative, should announce that intention and inform the public about the statutory authorities and procedures by which it has acted.

Although the subject is complex and evidence is laborious to assemble, it is manifest that nonobservance of APA rulemaking requirements is widespread. Several agencies rely in major part upon nonlegislative issuances to propagate new and changed elements in their regulatory or benefit programs.¹⁵ This Article examines a number of agency attempts to make nonlegislative policy documents bind the public.¹⁶ Frequently such rules are not challenged in court, because the affected private parties cannot afford the cost or the delay of litigation, or because for other practical

or contrary to the public interest." 5 U.S.C. § 553(b)(3). Also available is the exception from publication requirements "as otherwise provided by the agency for good cause found and published with the rule." *Id.* § 553(d)(3). These "good cause" exceptions supply an adequate safety valve, and unless the agency can invoke them it should follow the recommendations herein. See Arthur E. Bonfield, *Public Participation in Federal Rulemaking Relating to Public Property, Loans, Grants, Benefits, or Contracts*, 118 U. Pa. L. Rev. 540, 588-608 (1970).

13. See 5 U.S.C. § 553(b)(A) (1988); *infra* note 66; see also *infra* Part V.

14. See *infra* text accompanying notes 359-63; see also *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988) ("[A]n agency's open-mindedness in individual proceedings can substitute for a general rulemaking . . ."); *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 39 (D.C. Cir. 1974) ("When the agency states that in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself, then the agency intends to treat the order as a general statement of policy.").

15. Examples are the Health Care Financing Administration with respect to Medicare and Medicaid, the Department of Education with respect to guaranteed student loans, the Federal Energy Regulatory Commission with respect to regulation of pipelines, and the Nuclear Regulatory Commission with respect to reactor safety.

16. See *infra* Parts III and V.

reasons they must accept a needed agency approval or benefit on whatever terms the agency sets.¹⁷

The use of nonlegislative policy documents generally serves the important function of informing staff and the public about agency positions, and in the great majority of instances is proper and indeed very valuable. But the misuse of such documents—to bind, where legislative rules should have been used—carries great costs. Affected members of the public are likely to be confused or misled about the reach and legal quality of the standards the agency has imposed. One consequence of this uncertainty can be that affected persons are unaware that the agency intends to give its nonlegislative issuance binding effect. Probably more often, though, the private parties realize all too clearly that the agency will insist upon strict compliance, but conclude that there is little they can do to resist. In either case, the uncertainty can breed costly waste of effort among private parties trying to puzzle out how far they are bound or otherwise affected by the informal agency document.¹⁸

Doubtless more costly yet is the tendency to overregulate that is nurtured when the practice of making binding law by guidances, manuals, and memoranda is tolerated. If such nonlegislative actions can visit upon the public the same practical effects as legislative actions do, but are far easier to accomplish, agency heads (or, more frequently, subordinate officials) will be enticed into using them. Where an agency can nonlegislatively impose standards and obligations that as a practical matter are mandatory, it eases its work greatly in several undesirable ways. It escapes the delay and the challenge of allowing public participation in the development of its rule.¹⁹ It probably escapes the toil and the discipline of building a strong rulemaking record.²⁰ It escapes the discipline of preparing a statement of the basis and purpose justifying the rule.²¹ It may also escape APA publication requirements²² and Office of Management

17. In at least one case, Congress has expressly precluded judicial review of failure to observe § 553's rulemaking requirements. 42 U.S.C. § 1395ff(b)(3)(B) (1988) (national coverage Medicare determinations by Health and Human Services). *But see* Administrative Conference of the United States, Recommendation No. 87-8, National Coverage Determinations Under the Medicare Program, 1 C.F.R. § 301.87-8(4)(b) (1992) (recommending that Congress consider repealing § 1395ff(b)(3)(B)).

18. In some instances, agencies misstate the nature of their rules. *See, e.g.,* Chamber of Commerce v. OSHA, 636 F.2d 464 (D.C. Cir. 1980); Cerro Metal Prod. v. Marshall, 620 F.2d 964, 975-78, 981 (3d Cir. 1980).

19. *See* 5 U.S.C. § 553(c) (1988).

20. *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983).

21. *See* 5 U.S.C. § 553(c); *State Farm*, 463 U.S. at 42-43, 57.

22. 5 U.S.C. §§ 552(a)(1)(D), 553(b)(c). The requirement to publish in the *Federal Register* "statements of general policy or interpretations of general applicability formulated and adopted by the agency," *id.* § 552(a)(1)(D), is honored far more frequently in the breach than in the observance.

and Budget regulatory review.²³ And if the agency can show that its informal document is not final or ripe, it will escape immediate judicial review.²⁴ Indeed, for practical reasons it may escape judicial review altogether.²⁵

One can readily understand how a governmental instrument so quick, cheap, largely unchecked and low in risk, and yet so effectual, may tempt some agencies to slight the APA's mandates.

A particularly perverse phenomenon arises from some courts' emphasis upon the discretion retained by the agency as an indicator of the nonbinding character of its issuance.²⁶ Under this approach, the more discretion the agency reserves in a document, the better are its chances that a court will hold that legislative rulemaking procedures were not required, even though the public was plainly meant to be bound.²⁷ The theory is that the agency, by reserving discretion, has not bound itself. But the incentives work the wrong way here. The prospect of avoiding legislative procedures encourages the agency to be cagey rather than candid, and to state its rules loosely rather than precisely. A preferable test would consider whether the constraints on private persons amount to a binding of *those persons*. Otherwise, it is perfectly easy for a document to reserve plenty of discretion for the agency to act variantly, even where it makes clear that private parties will be held to strict conformity.²⁸ Any tactical advantage the agency may gain will come at the expense of clarity and fairness to affected private persons.

23. See Exec. Order No. 12,291, 3 C.F.R. 127 (Comp. 1981), reprinted in 5 U.S.C. § 601 note (1988). But see Memorandum from the Vice President to the Heads of Executive Departments and Agencies on the Regulatory Review Process 1 (March 22, 1991): "The Administration has consistently interpreted the Executive Order to include all policy guidance that affects the public. Such policy guidance includes not only regulations that are published for notice and comment, but also strategy statements, guidelines, policy manuals, grant and loan procedures, Advance Notices of Proposed Rule Making, press releases and other documents announcing or implementing regulatory policy that affects the public."

24. See RICHARD J. PIERCE, JR. ET AL., ADMINISTRATIVE LAW AND PROCESS 180-206 (1985).

25. See *National Solid Waste Management Ass'n v. EPA*, 27 Env't Rep. Cas. (BNA) 1566 (D.C. Cir. Oct. 27, 1987). The court denied a petition for review under RCRA of an EPA document because it lacked jurisdiction. The court stated that it has jurisdiction under § 7006 of RCRA only where the document is a "regulation, or requirement." *Id.* at 1567 (citing 42 U.S.C. § 6976(a)(1) (1982)). The court noted further that whether a document is a regulation or requirement depends on several factors including the agency's own characterization of the document. *Id.* at 1566. Where there was no regulation or requirement satisfying this test, there could be no judicial review of an agency action. *Id.* at 1567.

26. See *infra* Part V.

27. See *infra* text accompanying notes 305-08.

28. Consider, for example, the new 1991 EPA disclaimer form, *infra* text accompanying note 307.

To countenance nonlegislative documents that bind is inevitably to expand the agency's discretion in a most undesirable way. Although the public is bound the agency is not bound, as it would be had it used legislative rules.²⁹ It is easier for the agency to deviate from or change positions taken in policy statements, memoranda and the like than it is to deviate from or change those adopted through legislative processes.³⁰ Additionally, it may be observed generally that nonlegislative documents often are less clear and definite than legislative rules, and may enable the agency to operate at a lower level of visibility, with greater discretion and with fewer checks from the public and the courts.

Observance of legislative rulemaking requirements may appear burdensome to some agencies. One can realistically confront and assess the practical difficulties, however, only after pursuing the greatest possible clarity with regard to the concepts and requirements that these things entail. That pursuit must be the first objective of this Article.

I. A SHORT TAXONOMICAL GUIDE TO AGENCY RULEMAKING

To subdue this problem, strong analytical tools are needed. The courts lamentably have muddled critical concepts as to which clarity and precision are essential for solution of the problem at hand. First, we must be able to distinguish legislative from nonlegislative rules. Second, we must be able to distinguish policy statements from interpretive rules. Third, we must be able to identify the circumstances in which agencies should use legislatively promulgated rules instead of nonlegislative rules (which are either interpretive rules or policy statements).

29. See *Service v. Dulles*, 354 U.S. 363, 372 (1957) (sustaining the argument that "regulations validly prescribed by a government administrator are binding upon him as well as the citizen"); *Boska v. Comingora*, 177 U.S. 459, 467-70 (1900); see also *United States v. One 1985 Mercedes*, 917 F.2d 415, 423 (9th Cir. 1990) ("To prevail on his claim that the agency impermissibly departed from its own policy in seizing his property, Glenn must establish that the policy in question had the force and effect of law"); *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 536 (D.C. Cir. 1986) (stating that an agency "need not adhere to mere 'general statement[s] of policy'"); *Doe v. Hampton*, 566 F.2d 265, 278-82 (D.C. Cir. 1977).

30. It is not clear whether the judicially established requirement of a reasoned explanation for a change in policy, see *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983), applies to nonlegislative documents as well as to legislative rules or policies adopted in formal adjudications. Compare *One 1985 Mercedes*, 917 F.2d at 423 ("[I]nterpretive rules, general statements of policy or rules of agency organization, procedure or practice" do not have "the force and effect of law.") with *Telecommunications Research & Action Cir. v. FCC*, 800 F.2d 1181, 1184 (D.C. Cir. 1986) ("When an agency undertakes to change or depart from existing policies, it must set forth and articulate a reasoned explanation for its departure from prior norms."). As a practical matter, because nonlegislative documents are not easily challenged when they may be deemed unripe or not final, judicial discipline over policy changes is minimized. See *Middle South Energy, Inc. v. FERC*, 747 F.2d 763, 772 (D.C. Cir. 1984), cert. dismissed sub nom. *City of New Orleans v. Middle South Energy, Inc.*, 473 U.S. 930 (1985).

All of these distinctions arise under section 553 of the APA, whose taxonomy I shall now briefly describe. This description will supply the means to draw the first two of the distinctions just cited. The third is the chief subject of this study, and will be treated at greater length.

A. *Rules and Rulemaking*

This Article is concerned only with agency actions that fall within the APA's definition of "rule" by constituting "the whole or 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 . . ."³¹ Issuances encompassed by this definition come in a myriad of formats and bear a myriad of labels: legislative rules, interpretive rules, opinion letters, policy statements, policies, program policy letters, Dear Colleague letters, regulatory guidance letters, rule interpretations, guidances, guidelines, staff instructions, manuals, questions-and-answers, bulletins, advisory circulars, models, enforcement policies, action levels, press releases, testimony before Congress, and many others.³²

The agency process for formulating, amending, or repealing any such "rule" is defined as "rulemaking" by the APA.³³ Final agency dispositions in matters that are not rulemakings are "adjudications,"³⁴ which typically determine the entitlements, liabilities, or status of individually named or identifiable parties. Agencies are entitled, without observing the statutory rulemaking procedure, to set forth in their adjudicatory opinions the general propositions of law or policy that formed the basis for the adjudicatory decisions.³⁵ Though such statements may create new agency law, they are not "rules," and are not addressed in this Article.³⁶

31. 5 U.S.C. § 551(4) (1988).

32. See *National Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 701 (D.C. Cir. 1971).

33. 5 U.S.C. § 551(5).

34. *Id.* § 551(6), (7).

35. *NLRB v. Bell Aerospace Co.*, 416 U.S. 267 (1974); *SEC v. Chenery Corp.*, 332 U.S. 194 (1947).

36. The author has previously addressed the problems of fairness and effectiveness that agencies engender when they rely for making their law upon a process of case-by-case adjudication instead of rulemaking. Robert A. Anthony, *Towards Simplicity and Rationality in Comparative Broadcast Licensing Proceedings*, 24 STAN. L. REV. 1, 51-55 (1971); see also *infra* note 272. But nothing in the present Article is intended to suggest that it is improper for an agency to lay down, as the basis of its adjudicatory decisions, general principles to which it expects the public to conform.

B. Legislative and Nonlegislative Rules

Rules are broadly classified as "legislative" and "nonlegislative."³⁷ This classification is vital for the present analysis. The United States Court of Appeals for the District of Columbia Circuit has stated: "The distinction between legislative rules and interpretative rules or policy statements [i.e., the main categories of nonlegislative rules] has been described at various times as 'tenuous,' 'fuzzy,' 'blurred,' and, perhaps most picturesquely, 'enshrined in considerable smog.' As Professor Davis puts it, 'the problem is baffling.'"³⁸

With respect, the distinction is very clear.³⁹ Legislative rules *can* readily be differentiated from those that are nonlegislative. The

37. The courts, unfortunately, sometimes confusingly use the term "substantive rule" to mean "legislative rule." Compare *United Technologies Corp. v. EPA*, 821 F.2d 714, 719 (D.C. Cir. 1987) ("distinguish[] interpretive from legislative rules") and *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) ("whether a given agency action is interpretive or legislative") with *id.* at 1045 ("the spectrum between a clearly interpretive rule and a clearly substantive one is a hazy continuum") and *Cabals v. Egger*, 690 F.2d 234, 237 (D.C. Cir. 1980) ("distinguishing between substantive and interpretative rules"); see also *Barrerton v. Marshall*, 648 F.2d 694, 701 (D.C. Cir. 1980) (equating "legislative" or "substantive" rules); *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-03 (1979). Reasons for the preferred usage, observed in this Article, were well expressed in *Metropolitan School Dist. of Wayne Township v. Davila*, 969 F.2d 483, 488 (7th Cir. 1992): "We find the use of the term 'substantive' in this context misleading; an interpretation which explains the meaning of the statute can be just as 'substantive' as a legislative rule. We prefer the interpretive/legislative terminology because it avoids any potential confusion."

As used in this Article, the term "substantive rule" contrasts with "procedural rule," and has a meaning parallel to the concept of "substantive law"—that is, a rule that creates or affects private rights, duties or obligations. See *BLACK'S LAW DICTIONARY* 1429 (6th ed. 1990). This is correct usage under the APA. See 5 U.S.C. § 553(d) (1988). The term "substantive rule," therefore, embraces legislative rules, interpretive rules, and policy statements other than those concerned with procedure, practice, or agency organization. See *id.* §§ 553(b)(A), 553(d); see also *Joseph v. United States Civil Serv. Comm'n*, 554 F.2d 1140, 1153 n.24 (D.C. Cir. 1977) ("Interpretative rules may be substantive in the sense of addressing a substantive rather than a procedural issue of law . . .").

This Article also follows the widespread modern usage of substituting the word "interpretive" for the statutory term "interpretative." See 5 U.S.C. § 553(b)(A), (d)(2). For brevity, the term "policy statements" is used in place of the statute's "general statements of policy." *Id.*

38. *Community Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (citations omitted).

39. Professor Koch had it right when, speaking of the distinction between interpretive rules and legislative rules, he wrote: "The distinction is not 'fuzzy' but clear: a legislative rule must be promulgated pursuant to a legislative grant of authority. The distinction is troublesome not because it is unclear, but because it is not always easy to determine . . ." Charles H. Koch, Jr., *Public Procedures for the Promulgation of Interpretative Rules and General Statements of Policy*, 64 *Geo. L.J.* 1047, 1049 n.11 (1976); see *infra* text accompanying notes 105-10.

Despite their language, the courts just quoted and the authorities they cited were *not* addressing the distinction between legislative and nonlegislative rules (interpretive rules and policy statements). Rather, they were grappling with the question of whether a rule that *plainly was nonlegislative* should be invalidated or remanded because the agency *should have* promulgated it through legislative rulemaking procedures—that is, whether it *should have been a legislative rule*. That inquiry is a central focus of the present study.

fundamental idea is that a "legislative rule is the product of an exercise of delegated legislative power to make law through rules."⁴⁰

More particularly, a rule qualifies as legislative if all of the following requirements are met: 1) The agency must possess delegated statutory authority to act with respect to the subject matter of the rule.⁴¹ 2) Promulgation of the rule must be an intentional exercise of that delegated authority.⁴² 3) The agency must also possess delegated statutory authority to make rules with the force of law.⁴³ 4) Promulgation of the rule must be an intentional exercise of the authority to make rules with the force of law.⁴⁴ 5) Promulgation of the rule must be an effective exercise of that authority.⁴⁵ 6) The promulgation must observe procedures mandated by the agency's organic statute and by the APA.⁴⁶ Particularly, unless it falls within an exemption in the organic legislation or in the APA, the rule must be developed through public notice-and-comment procedures⁴⁷ and be published in the *Federal Register*.⁴⁸ For purposes of this Article, the most important of the requirements is the sixth.

40. 2 KENNETH C. DAVIS, *ADMINISTRATIVE LAW TREATISE* § 718 (2d ed. 1979); see also *Joseph v. United States Civil Serv. Comm'n*, 534 F.2d 1140, 1153 n.24 (D.C. Cir. 1977).

The relevant distinction between legislative and interpretative or any other nonlegislative rules is not the nature of the questions they address but the authority and intent with which they are issued and the resulting effect on the power of a court to depart from the decision embodied in the rule.

41. *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-03 (1979). In the case of interpretation of a statute that the agency has the primary responsibility to administer, such a delegation as to subject matter may be implied from the silence or ambiguity of the statute on this point in question. *Chvron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984); see Anthony, *supra* note 6, at 31-35. One may speculate that the Supreme Court, when presented with a proper case, is likely to establish a similar presumption for rules that do not involve interpretations.

42. See DAVIS, *supra* note 40, §§ 7:10-7:11.

43. *Chrysler Corp.*, 441 U.S. at 302; *Batterton v. Marshall*, 648 F.2d 694, 701 (D.C. Cir. 1980). A general statutory grant of rulemaking power will ordinarily be sufficient to authorize the agency to issue rules having legislative force. See, e.g., *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975).

44. The agency may possess such authority, but intend to produce only a policy statement, which of course is not legislative. See *Batterton*, 648 F.2d at 702; DAVIS, *supra* note 40, §§ 7:10-7:11.

45. The issuance cannot be a legislative one if it is set forth in some format as to which the agency lacks statutory authority to act with the force of law. See Anthony, *supra* note 6, at 36-40. Also, if the agency retains a great deal of discretion to act at variance with the statement it has issued, the issuance might not represent an effective exercise of the rulemaking authority. See *Guardian Fed. Sav. & Loan Ass'n v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 638, 667-68 (D.C. Cir. 1978). However, if the agency intends that private parties are to be bound, the fact that discretion is retained should not relieve the agency from observing the procedural and other requirements for promulgation of a legislative rule. See *infra* Part V.

46. *Chrysler Corp.*, 441 U.S. at 302-03, 315.

47. 5 U.S.C. § 553 (1988).

48. *Id.* §§ 552(a)(1), 553(b), (d).

An agency's issuance is a valid legislative rule if and only if it meets all six of these requirements. *All substantive rules that do not fit this template are nonlegislative. They are either interpretive rules (if they interpret specific statutory or regulatory language) or policy statements (if they do not).*

The APA requires the use of legislative rulemaking procedures for every rule unless the rule falls within one of the statutory exceptions.⁴⁹ The courts have repeatedly declared that the exceptions are to be narrowly construed and reluctantly recognized, so as not to defeat the salutary purposes behind the notice-and-comment provisions of section 553.⁵⁰ For present purposes we must lay to the side the exceptions pertaining to the subject matter of rules⁵¹ and to the existence of good cause to dispense with the statutory procedures.⁵² These exceptions do not relate to the rules' legal quality. And the exception for rules of agency organization, procedure or practice is also set to the side. It bears only peripherally on the present study,⁵³ which is concerned with agency control or guidance of private conduct—that is, with substantive rather than procedural rules.⁵⁴ The exceptions that are of concern here are those for interpretive rules and policy statements.⁵⁵

C. Interpretive Rules and Policy Statements

Our focus, then, is upon substantive rules, which under the APA may be 1) legislative rules, 2) interpretive rules, or 3) policy statements.⁵⁶ This is the entire universe of substantive rules.

49. *Id.* § 553; see, e.g., *W.C. v. Bowen*, 807 F.2d 1502, 1504 (9th Cir. 1987); *Thomas v. New York*, 802 F.2d 1443, 1446-47 (D.C. Cir. 1986), *cert. denied*, 482 U.S. 919 (1987); *Batterton v. Marshall*, 648 F.2d 694, 700-01, 710 (D.C. Cir. 1980); *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740, 742-43, 745 (3d Cir. 1969).

50. See *United States v. Picciotto*, 875 F.2d 345, 347 (D.C. Cir. 1989); *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044-45 (D.C. Cir. 1987) and cases cited therein. On the benefits and costs of notice-and-comment procedures, see Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 *Duke L.J.* 381, 402-09.

51. 5 U.S.C. § 553(a)(1) (involving military or foreign affairs functions); *id.* § 553(a)(2) (involving agency management, personnel, public property, loans, grants, benefits, or contracts).

52. *Id.* § 553(b)(3).

53. The question of when legislative rulemaking should be used for rules that arguably are procedural was presented in *Air Transp. Ass'n of Am. v. Department of Transp.*, 900 F.2d 369 (D.C. Cir. 1990), *judgment vacated as moot*, 111 S. Ct. 944 (1991), and is the subject of Administrative Conference of the United States, Recommendation No. 92-1, *The Procedural and Practice Rule Exemption from the APA Notice-and-Comment Rulemaking Requirements* (to be codified at 1 C.F.R. § 305.92-1).

54. See *supra* note 37.

55. 5 U.S.C. § 553(b)(A).

56. See *supra* note 37. The label placed upon the rule by the agency, "while relevant, is not dispositive." *General Motors Corp. v. Ruokolaheva*, 742 F.2d 1561, 1565 (D.C. Cir. 1984), *cert. denied*, 471 U.S. 1074 (1985).

At this point, it is useful to envision a simple grid. Norms that interpret can be issued either legislatively or nonlegislatively. Norms that do not interpret can also be issued either legislatively or nonlegislatively. All issued legislatively under the tests stated above⁵⁷ are legislative rules, whether they interpret or not. Those that are not legislative are either interpretive rules or policy statements, depending upon whether they interpret or not.

Because they are both nonlegislative, interpretive rules and policy statements are often usefully discussed together,⁵⁸ as in the subheading just above. But they are critically different for present purposes. The critical difference is that the courts do not treat interpretations as making new law, on the theory that they merely restate or explain the preexisting legislative acts and intentions of Congress.⁵⁹ By contrast policy statements, although within the agency's authority, do not rest upon existing positive legislation that has tangible meaning.⁶⁰ Neither Congress nor the agency, acting legislatively, has already made the law that the policy statements express. Thus these documents are looked upon as creating new policy, albeit not legally binding policy as the documents were not promulgated legislatively.⁶¹

57. See *supra* text accompanying notes 39-43.

58. *E.g.*, *Batterson v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980) (treating both interpretive and policy expressions together under the term "non-binding action"); PETER L. STRAUSS, AN INTRODUCTION TO ADMINISTRATIVE JUSTICE IN THE UNITED STATES 147-58 (1989) (analyzing the impact of "interpretive rules and other like formulations"); Michael Ashnow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 520, 523 (1977) (contrasting "nonlegislative rules"—both interpretive rules and policy statements—with "legislative rules"); Koch, *supra* note 39, at 1049-53.

59. *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) ("agency is merely explicating Congress' desires"); *General Motors*, 742 F.2d at 1565; *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 876 (D.C. Cir. 1979); *Peiskoff v. Secretary of Labor*, 501 F.2d 757, 763 n.12 (D.C. Cir.), *cert. denied*, 419 U.S. 1038 (1974); *American President Lines, Ltd. v. FMC*, 316 F.2d 419, 421-22 (D.C. Cir. 1963); *Gibson Wine Co. v. Snyder*, 194 F.2d 329, 331 (D.C. Cir. 1952).

60. See *United Technologies Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987). The court used the term "legislative rules" to refer to nonlegislatively promulgated rules of the sort herein defined as "policy statements." See *infra* notes 65-69 and accompanying text.

61. "A binding policy is an oxymoron." *Vietnam Veterans of Am. v. Secretary of the Navy*, 843 F.2d 528, 537 (D.C. Cir. 1988); see Anthony, *supra* note 6, at 2-6, 55-58.

An interpretive rule is an agency statement that was not issued legislatively and that interprets language of a statute⁶² (or of an existing legislative rule)⁶³ that has some tangible meaning.⁶⁴

A policy statement is an agency statement of substantive law or policy, of general or particular applicability and future effect,⁶⁵ that was not issued legislatively and is not an interpretive rule.⁶⁶

62. "An interpretative rule is one which does not have the full force and effect of a substantive [legislative] rule but which is in the form of an explanation of particular terms in an Act." *Gibson Wine*, 194 F.2d at 331 (quoting David Reich, *Rulemaking Under the Administrative Procedure Act*, 7 N.Y.U. SCH. L. INTR. PROC. 492, 516 (1947)), quoted in *American Hosp. Ass'n*, 834 F.2d at 1045, in *Batterton*, 648 F.2d at 703, and numerous other cases. "If the rule is based on specific statutory provisions, and its validity stands or falls on the correctness of the agency's interpretation of those provisions, it is an interpretative rule." *United Technologies*, 821 F.2d at 719-20.

A rule that purported to interpret a vacuous statutory term like "just and reasonable" or "public interest, convenience and necessity" would not be interpretive; if it were issued by legislative rulemaking it would be a legislative rule, but if not, such a rule would be a policy statement. See *infra* notes 63-64 and accompanying text. *But see* *Friedrich v. Secretary of Health & Human Servs.*, 894 F.2d 829, 837 (6th Cir.) (articulation of what is "reasonable and necessary" in particular circumstances held to be interpretive), *cert. denied*, 111 S. Ct. 59 (1990).

63. *E.g.*, *Indiana Dep't of Public Welfare v. Sullivan*, 934 F.2d 853, 856 (7th Cir. 1991); *Nason v. Kennebec County CETA*, 646 F.2d 10, 18 (1st Cir. 1981); *National Ass'n of Ins. Agents, Inc. v. Board of Governors, Fed. Reserve Sys.*, 489 F.2d 1268, 1270 (D.C. Cir. 1974).

64. A rule that interprets statutory or regulatory language having specific meaning can be either legislative or interpretive. The fact that it interprets a statute does not reduce a legislative rule to the status of an interpretive rule. A classic case of statutory interpretation by means of a legislative rule is *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). I would hazard the guess that a majority of legislative rules involve interpretation of statutes.

Loose language in many of the cases, however, can be misunderstood to suggest that any rule announcing an interpretation must always be a mere nonlegislative rule, even if the rule had been promulgated legislatively. *E.g.*, *Gibson Wine*, 194 F.2d at 329-31 ("[I]nterpretive rules are statements as to what the administrative officer thinks the statute or regulation means."), quoted in *American Hosp. Ass'n*, 834 F.2d at 1045. The original culprit in this respect may have been the "working definition" offered by the Justice Department: "Interpretative Rules—rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." U.S. DEPT OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 30 n.3 (1947) [hereinafter ATTORNEY GENERAL'S MANUAL].

65. See the APA definition of "rule," *supra* text accompanying note 31.

66. It is said that policy statements are "designed to inform rather than to control." *American Trucking Ass'n v. ICC*, 659 F.2d 452, 462 (3rd Cir. 1981), *cert. denied*, 460 U.S. 1022 (1983). And while policy statements often "advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power," ATTORNEY GENERAL'S MANUAL, *supra* note 64, at 30 n.3, and perhaps always *should* do so, it is obvious that the category cannot be confined to statements of these sorts. For example, a nonlegislative document declaring a policy that purports to control or guide private parties' conduct is a policy statement. Whether it *should* have been issued as a legislative rule instead of as a policy statement is a separate question. A document's classification as a policy statement does not *ipso facto* qualify it for the policy statement exemption from § 553's legislative rulemaking requirements. To be exempt, the statement must be tentative and not intended to be binding. See *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320-21, 1323 (D.C. Cir. 1988); *Community Nutrition Inst. v. Young*, 818 F.2d 943, 945-47, 949 (D.C. Cir. 1987); *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 37-39 (D.C. Cir. 1974); cases cited *infra* notes 274-303; *infra* Part V.

If the document goes beyond a fair interpretation of existing legislation,⁶⁷ it is not an interpretive rule.⁶⁸ Because it was not promulgated legislatively, it cannot be a legislative rule; it therefore is a policy statement. This is not merely the logical classification, but the proper one, as the agency is making policy in an area not specifically governed by the existing law.⁶⁹

All substantive nonlegislative issuances that are not interpretive rules are policy statements—whether they are captioned or issued as policy statements or manuals or guidances or memoranda or circulars or press releases or even as interpretations.

The cases are replete with statements to the effect that policy statements are "designed to inform rather than to control."⁷⁰ But many policy statements—and manuals, guidances memoranda and the like that fall within the category of policy statements—manifestly *are* "designed to control." These are the principal concern of this Article.

I have said that a substantive nonlegislative rule must be either an interpretive rule or a policy statement. Rather surprisingly, this perhaps self-evident proposition has eluded most courts and commentators, at least in the terminology they have chosen.

On the distinctions between interpretive rules and policy statements, and between those forms of nonlegislative rules and legislative rules, see generally 1 CHARLES H. KOCH, JR., ADMINISTRATIVE LAW AND PRACTICE §§ 3.23-3.26 (1985); Asimow, *supra* note 50, at 383-401; Arthur E. Bousfield, *Some Tentative Thoughts on Public Participation in the Making of Interpretive Rules and General Statements of Policy Under the A.P.A.*, 23 ADMIN. L. REV. 101, 108-17 (1971).

67. See *supra* text accompanying notes 3-6. In a leading case, Chief Judge Patricia Wald summarized the D.C. Circuit cases as having "generally sought to distinguish cases in which an agency is merely explicating Congress' desires from those cases in which the agency is adding substantive content of its own." *American Hosp. Ass'n v. Bowes*, 834 F.2d 1037, 1045 (D.C. Cir. 1987).

68. See *United Technologies Corp. v. EPA*, 821 F.2d 714, 719 (D.C. Cir. 1987) ("[R]ules in which the agency sought to fill gaps and inconsistencies left by the statutory scheme . . . plucked up where the statute left off; by no stretch of the imagination could [they] have been derived by mere 'interpretation' of the instructions of Congress.") (quoting *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 879 (D.C. Cir. 1979)); *Cabals v. Egger*, 690 F.2d 234, 239 (D.C. Cir. 1982) ("These rules . . . impose an obligation on the states not found in the statute itself. It cannot reasonably be argued that these rules are merely interpretive."); see also *First Bancorporation v. Board of Governors, Fed. Reserve Sys.*, 728 F.2d 434, 438 (10th Cir. 1984) ("[T]he Board abused its discretion by improperly attempting to propose legislative policy by an adjudicative order. Implicit in our holding is a rejection of the Board's contention that this is an interpretative rule . . .") (citations omitted).

69. Consider, for example, what was said about the documents involved in *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n.*, 874 F.2d 205, 207-08 (4th Cir. 1989) ("more is involved than mere 'interpretation'"); *Cabals*, 690 F.2d at 239 (rules and formulae "impose an obligation on the states not found in the statute itself"); *Chamber of Commerce of the United States v. OSHA*, 636 F.2d 464, 468-69 (D.C. Cir. 1980) (nonlegislatively issued "regulation does not merely explain the statute"); *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 878-79 (D.C. Cir. 1979) (rules "founded on no explicit provisions passed by Congress").

70. *American Trucking*, 659 F.2d at 462.

Although documents were plainly nonlegislative (because they were not promulgated by notice-and-comment procedures), courts nevertheless in many cases have regularly asked whether such documents "are" legislative rules⁷¹ rather than interpretive rules⁷² or policy statements.⁷³ This method of framing the issue begs the real question and seems to me to have bred unending confusion. For precision's sake, we must insist that these documents cannot "be" legislative rules, as they were not issued legislatively. What the courts in these cases plainly were looking for was whether the agency was *trying* to issue a rule that was legislative in nature. Did the agency, for example, attempt to "implement a general statutory mandate"⁷⁴ or "intend[] to create new law, rights or duties"⁷⁵ or "impose an obligation . . . not found in the statute itself"⁷⁶ or "attempt[] . . . to supplement the Act, not simply to construe it"⁷⁷ or "conclusively determine[] the . . . trigger [for] the . . . program allocations"⁷⁸ In short, did the agency's nonlegislative action bind or attempt to bind the affected public?

Thus, the proper question in these cases is not whether the policy document *is* a legislative rule. Rather, the proper question is whether the nonlegislative document *should have been* issued as a legislative rule in the circumstances. The key to that question is, I believe, quite clear, based on analysis of the APA and of the many decided cases: *Did the agency intend the document to bind? Has the agency given it binding effect?* If the answer to either of these questions is "yes," the document should have been issued as a legislative rule.

II. NONLEGISLATIVE RULES WITH BINDING EFFECT

Legislative rules⁷⁹ have the force of law and are legally binding upon the courts, the agency, and the public.⁸⁰ Nonlegislative rules

71. Sometimes called a "substantive rule," see *supra* note 37.

72. *E.g.*, *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1307-08 (D.C. Cir. 1991) (citing *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984), *cert. denied*, 471 U.S. 1074 (1985)); *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045-46 (D.C. Cir. 1987); *United Technologies Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987).

73. *E.g.*, *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320-22 (D.C. Cir. 1988); *Community Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) and cases cited therein; *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 37-38 (D.C. Cir. 1974).

74. *United Technologies*, 821 F.2d at 720.

75. *Fertilizer Inst.*, 935 F.2d at 1307-08 (quoting *General Motors*, 742 F.2d at 1563).

76. *Cabals v. Egger*, 690 F.2d 234, 239 (D.C. Cir. 1982).

77. *Chamber of Commerce of the United States v. OSHA*, 636 F.2d 464, 469 (D.C. Cir. 1980).

78. *Batterton v. Marshall*, 648 F.2d 694, 706 (D.C. Cir. 1980).

79. See *supra* text accompanying notes 41-48.

80. See *Anthony*, *supra* note 6, at 3 n.6, 39. More precisely, rules are binding and have the force of law when a court may not review them freely, but must accept them unless they are contrary to statute or unreasonable. *Id.*

(interpretive rules and policy statements), by definition, are not *legally* binding on the courts, the agency, or the public.

This Article deals with nonlegislative rules that have the purpose or effect of binding the public *as a practical matter*. These are nonlegislative documents that are intended to impose mandatory standards or obligations, or that as a practical matter are given that effect.⁸¹

In general, a nonlegislative document is binding as a practical matter if the agency treats it the same way it treats a legislative rule—that is, as dispositive of the issues that it addresses—or leads the affected public to believe it will treat the document that way. Certain indicia that nonlegislative documents are binding in this practical sense are clearly identifiable.

Obviously, *agency enforcement action* based upon nonobservance of the nonlegislative document, or the threat of such action, bespeaks a clear intent to bind and indeed puts it into execution.⁸² Here the eating is the proof of the pudding.

Similarly, in the setting of agency actions that pass upon applications for approvals, permits, benefits, and the like, *regular application of the standards* set forth in the document evidences both the intent to bind and a practical binding effect.⁸³

A document will have practical binding effect before it is actually applied if the affected private parties are reasonably *led to believe* that failure to conform will bring adverse consequences, such as an enforcement action⁸⁴ or denial of an application.⁸⁵ If the document is couched

81. This understanding, that the binding effects are practical ones and not legal ones, clarifies one of the many terminological inexactitudes that plague this field, the so-called "legal effect" test. Professor Asimow has summarized the usage of some courts and commentators: "The prevailing standard for distinguishing legislative and interpretive rules can be described as the 'legal effect' test. If a rule explaining the meaning of language actually makes 'new law,' as opposed to merely interpreting 'existing law,' it is legislative." Asimow, *supra* note 50, at 394. I suggest that greatly improved clarity will be achieved if it is realized that under this "test" the court is actually looking for *practical* binding effects, *not legally* binding ones. (And of course the rule is not legislative when it was not promulgated legislatively.)

82. *E.g.*, *United States v. Pociotto*, 875 F.2d 345 (D.C. Cir. 1989) (conviction based on violation of nonlegislative Park Service document reversed). Other examples of these categories of practical bindingness are set forth in Part III.

83. *E.g.*, *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988) ("Inter conduct applying it confirms [the] binding character" of the model, also evidenced by mandatory language).

84. *E.g.*, *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 208 (4th Cir. 1989) ("[T]he proposed statement has the clear intent of . . . providing the Commission with power to enforce violations of a new rule.").

85. *E.g.*, *Linox v. Heckler*, 800 F.2d 871 (9th Cir. 1986) (denial of Medicare coverage based on manual).

in mandatory language,⁸⁶ or in terms indicating that it will be regularly applied,⁸⁷ a binding intent is strongly evidenced.⁸⁸ In some circumstances, if the language of the document is such that private parties can rely on it as a norm or safe harbor by which to shape their actions, it can be binding as a practical matter.⁸⁹

It is possible that an agency will use mandatory or rigid language even though it does not intend the document to be regularly applied without further consideration. There is nevertheless a practical binding effect if private parties suffer or reasonably believe they will suffer by noncompliance. This phenomenon can occur especially where the document is issued at headquarters but administered in the field.⁹⁰ Mandatory language in the document may combine with the routinized behavior of the field staff to produce a practical binding effect upon affected private parties. Although the document may not have been intended to be "finally determinative of the issues or rights to which it is addressed,"⁹¹ its practical effect is to bind, and affected persons may not be able to risk noncompliance to test it. Similarly, a document that initially was intended to be nonbinding, or one as to which the intent was unclear, may harden into a fixed rule, with binding effect, by repeated application.⁹²

A further emblem of practical binding effect is the absence of an opportunity for affected private parties to be heard on proposed policy

86. *E.g.*, *Community Nutrition Inst. v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987) ("mandatory, definitive language is a powerful, even potentially dispositive, factor" suggesting that the nonlegislative rules were "presently binding norms").

87. *E.g.*, *American Bus Ass'n v. United States*, 627 F.2d 525, 532 (D.C. Cir. 1980) ("in reality a flat rule of eligibility") (quoting *United States ex rel. Paroo v. Morris*, 426 F. Supp. 976, 984 (E.D. Pa. 1977)).

88. Closely parallel is the concept of expected conformity, which is important in determining whether agency action is final, *FTC v. Standard Oil Co.*, 449 U.S. 232 (1980), or ripe for judicial review, *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967). "Characteristics indicating finality include providing a 'definitive' statement of the agency's position, having a 'direct and immediate' effect on the day-to-day business of the complaining parties, having the 'status of law,' and carrying the expectation of 'immediate compliance with [its] terms.'" *Southern Cal. Aerial Advertisers' Ass'n v. FAA*, 881 F.2d 672, 675 (9th Cir. 1989).

89. *See, e.g.*, *Alaska v. Department of Transp.*, 868 F.2d 441 (D.C. Cir. 1989); *Community Nutrition*, 818 F.2d at 943; *see also Public Citizen, Inc. v. NRC*, 940 F.2d 679 (D.C. Cir. 1991).

90. *See infra* Part VI.

91. *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974).

92. "Where the language and context of a statement are inconclusive, we have turned to the agency's actual applications." *Public Citizen*, 940 F.2d at 682 (Williams, J.) (citing *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317 (D.C. Cir. 1988)); *Community Nutrition*, 818 F.2d at 943; *Batterton v. Marshall*, 648 F.2d 694 (D.C. Cir. 1980); *American Bus Ass'n v. United States*, 627 F.2d 525 (D.C. Cir. 1980); *see also American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1036-37 (D.C. Cir. 1987) ("[W]here the agency's characterization of its action would fit them cleanly into a § 553 exemption, we think it the most prudent course to await the sharpened facts that come from the actual workings of the regulation . . ."); *infra* notes 314-15 and accompanying text.

alternatives, before the policy set forth in the document is concretely applied to them, and to have their proposals considered with an open mind by the agency's policymakers. If the document is to be applied rigidly to private persons without first affording them a realistic chance to challenge its policy, its binding effect is evident. By the same token, if the agency affords such an opportunity and genuinely is open to reconsideration of the policy, the document shows neither the intent to bind nor such an effect.⁹³

All of these practical binding effects will be more severe where the affected private parties, for practical reasons, cannot invoke the aid of the courts to challenge the documents. For example, regulations may require the exhaustion of lengthy intra-agency appeals before the challenged permit can be used, even on the agency's terms.⁹⁴

Applying the above guides to determine when a document has practical binding force may not always be easy. As Chief Judge Patricia Wald has well observed with respect to one aspect of the problem, "[d]etermining whether a given agency action is interpretive or legislative⁹⁵ is an extraordinarily case-specific endeavor."⁹⁶ Similarly, Judge Kenneth Starr, having stated that a "legislative rule is recognizable by virtue of its binding effect,"⁹⁷ declared that "[i]his definitional principle, however, is hardly self-executing,"⁹⁸ and cited a number of "factors" to be examined.⁹⁹ That standards have a mathematical or mechanical quality is not determinative of the agency's intent or use of them to

93. The courts often say that a document is not "legislative" (or not "substantive")—meaning that it need not have been issued legislatively—if the agency has reserved discretion to act at variance with it. This notion, which I believe is flawed, is discussed below. See *infra* Part V.

94. See, e.g., 40 C.F.R. § 124.15, .19 (1991) (EPA).

95. Under the analysis and terminology set forth above, this effort is to distinguish an interpretive rule (as to which legislative rulemaking is not required despite the agency's efforts to bind) from a document that goes beyond interpretation and sets forth new law which the agency intends to be binding. The latter document is not a legislative rule, since it was not promulgated legislatively. It is a policy statement that *should have been* issued as a legislative rule. Thus, properly understood, the distinction is between an interpretive rule and a rule that should have been legislative.

96. *American Hops*, 834 F.2d at 1045.

97. *Alaska v. Department of Transp.*, 868 F.2d 441, 445 (D.C. Cir. 1989).

98. *Id.* at 446.

99. The factors in the *Alaska* case, and in *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987), that reinforced the conclusion that the agency intended the action to have binding effect were: mandatory language, prior grant of "exemptions," publication in the Code of Federal Regulations, limitation upon the agency's discretion, and whether the agency could successfully prosecute persons who had complied with the document. *Alaska*, 868 F.2d at 446-47.

bind.¹⁰⁰ The availability of procedures for waiver of the rule should not change a rule from being one that binds to one that does not.¹⁰¹

If a rule is conclusive on one factor but reserves discretion on the second, it is not "any less of a rule . . . even though it does not purport to answer the second question."¹⁰² Indeed, a single nonlegislative document can imaginably be a layer-cake of elements: restatement of statutory language, interpretation of statute, interpretation of legislative regulations, policy statement declaring policy that is not intended to bind,¹⁰³ and policy statement declaring policy that is intended to bind.¹⁰⁴ The last of these must always be carefully distinguished from the other elements, to consider whether legislative rulemaking requirements should have been observed.

A proper focus upon practical binding effects may enable us to understand why the courts have found the "distinction between legislative rules and interpretative rules or policy statements" to be "enshrouded in considerable smog" and "baffling."¹⁰⁵ I believe there are two principal reasons for the courts' perplexity.

The first is that, properly understood, the distinction calls for a largely factual judgment—to pass upon the agency's intent to bind (or its practice of doing so)—without benefit of the sorts of evidence upon which factual findings are ordinarily based.¹⁰⁶ One needs only to sample the opinions that parse the considerations bearing upon these distinctions¹⁰⁷ to see that the evidence and inferences that can be drawn from the administrative record are limited, making the court's task difficult, though by no means impossible. It would seem quite wrong under the

100. Compare *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740, 744-45 (3d Cir. 1969) (holding that document imposing obligation to pay compound interest on refunds was not an exempt policy statement where agency would not reconsider the basic policy, even though it would entertain waiver petitions) with *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 40 (D.C. Cir. 1974) (holding that document establishing a schedule of priorities for curtailing deliveries of gas was an exempt policy statement where agency afforded opportunity to challenge the basic policy).

101. "In general, a discretionary waiver provision is not sufficient to qualify an otherwise nondiscretionary regulation as a 'general statement of policy' . . ." *Guardian Fed. Sav. & Loan v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 667 n.33 (D.C. Cir. 1978). "In filing a waiver application, an operator is entitled to be confronted only with rules adopted in the procedural manner prescribed by Congress." *Texaco*, 412 F.2d at 746.

102. *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1322 (D.C. Cir. 1988).

103. See *Panhandle Producers & Royalty Owners Ass'n v. Economic Regulatory Admin.*, 822 F.2d 1105, 1110-11 (D.C. Cir. 1987).

104. See *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980).

105. *Community Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (citations omitted). The full quotation appears in the text accompanying note 38 *supra*.

106. Chief Judge Wald has said that cases passing upon whether a rule is interpretive "turn on their precise facts." *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987).

107. E.g., *Alaska v. Department of Transp.*, 868 F.2d 441, 445-47 (D.C. Cir. 1989); *American Hosp.*, 834 F.2d at 1045-47.

Morgan IV doctrine¹⁰⁸ to countenance discovery proceedings or evidentiary hearings in which officials could be interrogated about their motives or their deliberative practices. It is significant that the cases have not in any way suggested that such procedures should be allowed.¹⁰⁹ The necessary determinations can be facilitated by a clear recognition of the issues that bear upon the inquiry into the practical binding purposes or effects of an agency issuance.¹¹⁰

The second reason the courts have found the distinction troubling, I would suggest, is one which has already been described: the reigning confusion in the use of terms and their accompanying concepts. It must be firmly grasped that rules that declare new policy can be either legislative rules or nonlegislative rules, depending upon whether they were promulgated legislatively; that those not issued legislatively cannot ever "be" legislative rules, even if they should have been; and that nonlegislative rules that do not interpret (or that "go beyond the statute" in an attempt at interpretation) are policy statements within the APA's taxonomy and must be so treated when determining whether they should have been issued legislatively.

III. EXAMPLES OF AGENCY USE OF NONLEGISLATIVE RULES TO BIND THE PUBLIC

Our focus now narrows to the category of nonlegislative documents that go beyond a fair interpretation of existing legislation and that the agency makes binding upon the public. Again, these documents are "policy statements" within the APA, rather than interpretive rules.¹¹¹ An agency may use interpretive rules in a manner that makes them

108. The *Morgan IV* doctrine holds that it ordinarily is improper to subject a decisional official to questioning on his or her decision processes, just as a judge may not be subjected to such scrutiny. *United States v. Morgan*, 313 U.S. 409, 422 (1941).

109. See *Public Citizen, Inc. v. NRC*, 940 F.2d 679, 682 (D.C. Cir. 1991). Rather than suggesting discovery proceedings, the court said with regard to how it proceeds in these cases: "Where the language and context of a statement are inconclusive, we have turned to the agency's actual application."

110. The courts have suggested that the burden is on the agency to show that its act is within an exemption to § 553. "The issue here is whether the agency has demonstrated that this case is governed by the exceptions to section 553." *Guardian Fed. Sav. & Loan Ass'n v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 663 (D.C. Cir. 1978). "The exceptions to section 553 will be 'narrowly construed and only reluctantly countenanced.'" *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984), quoted in *American Hosp.*, 834 F.2d at 1045, and numerous other cases.

111. See *supra* text accompanying notes 63-70.

binding as a practical matter,¹¹² but it may not so use policy documents.¹¹³ The examples that follow illustrate agency use of nonlegislative policy documents to bind the public.

Although it is not necessary to do so, the examples are grouped for convenience into the categories of enforcement cases, application-and-approval cases, and benefit and reimbursement cases, with separate attention to cases involving administration by the states. The phenomenon of the regular application of nonlegislative policy documents by field offices of the federal agency and by the states will be discussed at a later point,¹¹⁴ apart from presentation of these examples.

The majority of the examples are drawn from adjudicated cases.¹¹⁵ Because the courts have documented and organized the facts, these examples have been relatively easy to gather and can be summarized in a relatively simple fashion. Other examples, collected from non-case sources, have generally required more extensive presentation and documentation.

A. Use of Nonlegislative Policy Documents in Direct Enforcement

Occasionally agencies rely upon guidances or other nonlegislative policy documents as the law under which to bring or to threaten direct enforcement actions in court or within the agency.

A-1. A demonstrator at Lafayette Park in front of the White House was prosecuted for violating "conditions," issued but not made part of its regulations by the United States Park Service, that restricted the storage of property in the Park.¹¹⁶

A-2. The government sought an injunction and civil penalties in district court for violation of the terms of a memorandum sent by the Environmental Protection Agency's Director of Control Programs to the EPA regional office air program chiefs, imposing stricter requirements

112. See *supra* text accompanying notes 3-6.

113. See *supra* text accompanying notes 7-11; *infra* Part IV.

114. See *infra* Part VI.

115. In the examples drawn from decided cases, unless otherwise stated, the agency's use of the nonlegislative document was in each instance disapproved by the court because the agency had failed to observe legislative rulemaking procedures. "Normally, a judicial determination of procedural defect requires invalidation of the challenged rule." *Batterton v. Marshall*, 648 F.2d 694, 711 (D.C. Cir. 1980). This disposition will therefore not be recited in the individual examples. And rather than appending a footnote to every declarative sentence, this section uses a single citation for each case example in its entirety, unless reason exists to do otherwise.

116. *United States v. Picciotto*, 875 F.2d 345 (D.C. Cir. 1989) (holding document "null and void"; reversing conviction).

(through a new method of computing) than those in the duly-promulgated state implementation plan in question.¹¹⁷

A-3. One alleged violation remained after the Food and Drug Administration (FDA) had inspected the plant of a manufacturer of medical apparatus, and the government pressed suit to enjoin it. The company had fallen short of a sterility standard that had been set forth in draft "inspectional guidelines" circulated by FDA's compliance office to its inspectors.¹¹⁸

A-4. The Administrator of the Occupational Safety and Health Administration (OSHA) spoke at a labor union convention and followed up with a document captioned "interpretive rule and general statement of policy," to the effect that employers would be charged with discrimination unless they paid wages to union representatives who accompanied OSHA personnel conducting inspections of the employers' premises, despite the absence of any such provision in the Occupational Safety and Health Act.¹¹⁹

A-5. The Consumer Products Safety Commission, through a "statement of interpretation," eliminated an exclusion to its Small Parts Rule, violation of which could invoke a range of civil and criminal penalties provided by statute. The court found that the statement did not interpret, but amounted to an attempt to impose new duties having the force of law.¹²⁰

A-6. Through an "order," which it argued was a policy statement within the APA exemption, the Federal Power Commission for the first time directed operators to pay interest on refunds it had ordered.¹²¹

A-7. Acting under statutory provisions outlawing discrimination against the handicapped by institutions receiving federal assistance,¹²² the Secretary of Health and Human Services (HHS) without notice and

117. *United States v. Zimmer Paper Prods., Inc.*, 20 *Env't. L. Rep. (Env't. L. Inst.)* 20,536 (S.D. Ind. 1989) (holding memorandum to be of no effect).

118. *United States v. Bioclinical Sys., Inc.*, 666 F. Supp. 82, 84 (D. Md. 1987) (denying injunction; "At bottom, what the Government is asserting here is that . . . the SAL [sterility assurance level] should be what the Office of Compliance dictates it to be.").

119. *Chamber of Commerce of the United States v. OSHA*, 636 F.2d 464, 470 (D.C. Cir. 1980) (vacating rule; "[M]ost important of all, high-handed agency rulemaking is more than just offensive to our basic notions of democratic government; a failure to seek at least the acquiescence of the governed eliminates a vital ingredient for effective administrative action."); *see also id.* at 472 (Bazelon, J., concurring) ("[A]dvance notice and opportunity for public participation are vital if a semblance of democracy is to survive in this regulatory era.").

120. *Jerrif's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205 (4th Cir. 1989) (setting aside document).

121. *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740 (3d Cir. 1969) (setting aside order).

122. Rehabilitation Act of 1973, § 504, 29 U.S.C. § 794 (1986).

comment issued an immediately effective "interim final regulation" requiring hospitals to post notices that discriminatory denial of food and customary medical care to a handicapped infant is unlawful.¹²³ Because the regulation was "intended, among other things, to change the course of medical decisionmaking,"¹²⁴ it affected substantive rights and was not an interpretation, and therefore was "declared invalid due to the Secretary's failure to follow procedural requirements in its promulgation."¹²⁵

A-8. The FDA's regulations requiring tamper-resistant packaging for certain over-the-counter drug products¹²⁶ were augmented by a 1988 Compliance Policy Guide (CPG),¹²⁷ stating the agency's conclusion that certain packaging technologies (tinted wrappers, and cellophane with overlapping end flaps) were "no longer acceptable."¹²⁸ A CPG such as this one may be an example of an advisory opinion which the FDA states "may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement."¹²⁹ However, if a drug company were wilfully to use tinted wrappers or cellophane in violation of the CPG, it could hardly be doubted that the FDA would initiate some sort of enforcement action.¹³⁰

A-9. Under the amended Motor Vehicle Cost Savings and Information Act, manufacturers were required to meet average fuel economy standards.¹³¹ EPA's responsibilities under the Act included establishing, "by rule," test and calculation procedures,¹³² and conducting the tests and calculating manufacturers' corporate average fuel economy (CAFE) ratings.¹³³ A manufacturer that failed to meet its CAFE standard by as little as 1/10 of a mile per gallon could incur millions of dollars in civil penalties.¹³⁴ EPA was criticized by the Comptroller General for its use

123. 48 Fed. Reg. 9630 (1983) (the "Baby Doe regulation").

124. *American Academy of Pediatrics v. Heckler*, 361 F. Supp. 395, 401 (D.D.C. 1983).

125. *Id.* at 400.

126. 21 C.F.R. § 211.132 (1991).

127. Food and Drug Administration, Compliance Policy Guide No. 7132a.17 (Mar. 1, 1988) reprinted as enclosure to THE PROPRIETARY ASSOCIATION, ACTIVE MEMBER REPORT NO. 32-88.

128. *Id.* at 2.

129. 21 C.F.R. § 10.85(d) (1991).

130. Though one would not expect any regulated company to flout the agency's policy in this particular, this fact does not change the binding effect created by the evident agency intent to require affected parties to obey the CPG's prohibitions. Potential penalties include injunction, 21 U.S.C. § 332 (1988), seizure, *id.* § 334, and criminal prosecution, *id.* § 333.

131. 15 U.S.C. §§ 2001-2012 (1982).

132. *Id.* § 2003(d)(1).

133. *Id.* §§ 2002, 2003.

134. Op. Comptroller Gen. No. B-217744, at 2 (Letter from Milton J. Socolar, for the Comptroller General, to Representative John D. Dingell, Chairman, Subcomm. on Oversight and Investigations, House Comm. on Energy and Commerce (June 3, 1985)).

of advisory circulars to make changes in the tests instead of performing legislative rulemaking.¹³⁵

A-10. Nonlegislative provisions in United States Department of Agriculture (USDA) manuals are legion, and they are enforced. A large number were cited to the author by USDA senior attorneys.¹³⁶ Here are some examples from the manuals of the Animal and Plant Health Inspection Service: a) A Veterinary Services memorandum went beyond the requirements of statute and regulations¹³⁷ to add a requirement that all containers used for exportation of animal embryos or semen (except to Canada) must be marked with a legend stating that they must be cleaned and disinfected before return to the United States.¹³⁸ A person contemplating export could fairly expect that, if the legend were not included, the inspector would forbid the export, or would cite a violation if export were attempted.¹³⁹ b) The gypsy moth regulations specify a list of "regulated articles" subject to quarantine restrictions upon interstate movement.¹⁴⁰ Under the rubric "[i]f the article is one of the following, then it's regulated," the manual adds a substantial and entirely new category, "timber and timber products."¹⁴¹ c) Certain garbage deriving from food is regulated to avert disease; the regulations provide that "regulated garbage" shall be moved and unloaded under the direction of a USDA inspector,¹⁴² but the manual requires that regulated garbage may be transported only by an approved vessel.¹⁴³ d) The same regulations call for sterilization of regulated garbage by cooking and burial of the residue in a landfill, except that burial is not required for materials extracted from the residue in certain cases.¹⁴⁴ The manual calls for burial

135. "[C]hanges should have been made formally [by legislative rulemaking], unless one of the specific limited exceptions applied to a particular change." *Id.* at 1; see also *id.* at 8.

136. Group interview with John Golden, Associate General Counsel, USDA; Ronald Cipolla, Assistant General Counsel, USDA; William Jenson, Senior Counsel, USDA; Thomas Walsh, Assistant General Counsel, USDA; Robert Paul, Deputy Assistant General Counsel, USDA; and Harold Reuben, Deputy Assistant General Counsel, USDA, in Washington, D.C. (July 9, 1991).

137. 9 C.F.R. pt. 98 (1991) (regulations covering "Importation of Certain Animal Embryos and Animal Semen").

138. Animal and Plant Health Inspection Service, USDA, Veterinary Services Memorandum No. 592.111 (Feb. 6, 1991).

139. Interviews with William Jenson, Senior Counsel, USDA, in Washington, D.C. (July 7, 1991 and Sept. 5, 1991).

140. 7 C.F.R. § 301.45-1(x) (1991).

141. ANIMAL AND PLANT HEALTH INSPECTION SERVICE, USDA, GYPSY MOTH PROGRAM MANUAL 9.3 (Oct. 9, 1990).

142. 9 C.F.R. § 94.5(f)(1) (1991).

143. ANIMAL AND PLANT HEALTH INSPECTION SERVICE, USDA, AIRPORT AND MARITIME OPERATIONS MANUAL 3.40a (FDC 11/90-09).

144. 9 C.F.R. § 94.5(h)(2) (1991) (burial not necessary where residue is unsuitable for use as a food or soil additive).

of all sterilized garbage.¹⁴⁵ e) Regulations require that pet birds of U.S. origin that have been outside the United States for more than sixty days must be confined by the owner at the place where the birds are available for inspection for a minimum of thirty days.¹⁴⁶ The manual requires quarantine at the owner's residence.¹⁴⁷

A-11. The Department of Transportation as successor to the Civil Aeronautics Board issued, without recourse to notice-and-comment rulemaking procedures, an "Order Granting Exemption," followed by an "Order Amending Exemption" and an "Order Clarifying Amendment to Exemption."¹⁴⁸ Their upshot was that air travel advertisements may state certain taxes and surcharges separately from the basic fares, without being regarded as "unfair or deceptive practices or unfair methods of competition" within the meaning of the Federal Aviation Act's analog¹⁴⁹ to section 5 of the Federal Trade Commission Act.¹⁵⁰ After several states, at the recommendation of the National Association of Attorneys General, adopted statutes that conflicted with the Federal Aviation Administration (FAA) position, the federal agency responded that "the Federal government has preempted this aspect of state advertising regulation."¹⁵¹ Twenty-seven states successfully sued to have the actions set aside.¹⁵²

As the examples below illustrate, the private party can be placed in a particularly difficult position when the agency can take enforcement action without prior recourse to the courts or even to agency hearing procedures.

A-12. An inmate working in the Federal Prison Industries Program refused to comply with a "program statement" that called for remittance of half of his prison earnings to pay off certain obligations, preferring to send the money to his wife. He was accordingly fired from his prison job. Thus the document was made binding by the sanction of dismissal. Although the program statement was couched in less-than-

145. AIRPORT AND MARITIME OPERATIONS MANUAL, *supra* note 143, at 3.40a.

146. 9 C.F.R. § 92.101(c)(2)(ii)(B)(1) (1991).

147. AIRPORT AND MARITIME OPERATIONS MANUAL, *supra* note 143, at 3.30.

148. *Alaska v. Department of Transp.*, 868 F.2d 441, 442 (D.C. Cir. 1989).

149. 49 U.S.C. § 1381(a) (1988).

150. 15 U.S.C. § 45(a)(1) (1988).

151. *Alaska*, 868 F.2d at 442-43.

152. *Id.* at 445 ("DOT's actions are strikingly similar to (and in all principled respects, the same as) that deemed to constitute a legislative rule in *Community Nutrition Institute v. Young*, 818 F.2d 943 (D.C. Cir. 1987); we therefore conclude that the 1988 Orders are invalid by virtue of the Department's failure to employ notice-and-comment procedures.").

mandatory terms and was argued by the government to be an interpretive rule, it was applied in an absolute manner.¹⁵³

A-13. An assistant regional manager of the FAA sent a letter to Los Angeles area pilots and operators of banner-towing airplanes, declaring that they no longer could fly through a corridor in the Los Angeles terminal control area. Since the directive would be implemented by the FAA's air traffic controllers denying clearances to transit the corridor, the pilots would be put out of business without any judicial action by the FAA. The court held the letter to be a "rule" within the APA and reviewable as final agency action.¹⁵⁴

A-14. In a similar pattern, the FAA sent a letter to aerial sports parachuting operators, stating that parachuting would no longer be permitted in a previously designated jump zone adjacent to and within the San Diego terminal control area. The court again held the letter to be a "rule" and reviewable final action.¹⁵⁵

A-15. An FDA "import alert" required FDA agents at U.S. ports of entry to detain reimported American-made pharmaceuticals unless the importer could document their full chain of custody while abroad. Under this document, FDA ordered an importer's goods to be reexported or destroyed within ninety days, but agreed to a stay during which the importer was able to obtain judicial relief.¹⁵⁶

A-16. USDA meat inspectors base their evaluations on inspection manuals and bulletins to the field, only relatively minor parts of which are promulgated through legislative rulemaking procedures. The inspectors have the power to close down a packing line temporarily for serious violations, until the plant comes into compliance. The immediate economics of the situation tend to compel the packers to comply with the rules thus enforced rather than to endure a shutdown and await relief in court.¹⁵⁷

Statements of enforcement policy are ordinarily issued nonlegislatively. These statements typically set forth the criteria by which the agency will select cases for prosecution or other enforcement action.

153. *Frows v. Department of Justice*, 704 F. Supp. 272, 274-76 (D.D.C. 1988) (holding program statement null and void), *aff'd*, 938 F.2d 274 (D.C. Cir. 1991).

154. *Southern Cal. Aerial Advertisers' Ass'n v. FAA*, 881 F.2d 672, 673-74 (9th Cir. 1989) (holding letter invalid).

155. *San Diego Air Sports Ctr., Inc. v. FAA*, 887 F.2d 966, 967-68 (9th Cir. 1989) (holding letter invalid).

156. *Bellerno Int'l Ltd. v. FDA*, 678 F. Supp. 410, 411-12 (E.D.N.Y. 1988) (holding import alert unlawful).

157. Interview with John Golden, Associate General Counsel, USDA, in Washington, D.C. (Apr. 9, 1991).

Often they are lengthy and detailed, articulating quite specific standards.¹⁵⁸ To the extent they interpret statutory language that has some tangible meaning, these documents pose little problem, as the agency may lawfully attempt to make them bind.¹⁵⁹ Similarly, where the statement provides for the future exercise of discretion in its application, notice and comment are not required.¹⁶⁰

But what of statements setting enforcement policy under broad language like "just and reasonable" or "unfair"? These in themselves constitute vast subjects, lying beyond the scope of this study. But some elements should be touched upon. First is the question whether a given statement interprets sufficiently concrete statutory language to qualify as interpretive.¹⁶¹ If it is concluded that the statement is not interpretive, there remain questions of what it intends substantively and whether it is meant to be binding. Those questions can be hard to answer.¹⁶² There appear to be at least three possibilities: 1) Sometimes the agency is stating a safe-harbor policy, such that private persons may know that if they observe the policy they will not be deemed in violation and will not be prosecuted. But they will not necessarily be deemed in violation, or be prosecuted, if they do not observe the policy. Such a document can create binding norms.¹⁶³ 2) The agency may intend that the document, for

158. See, e.g., the Guides and Practice Rules of the Federal Trade Commission, 16 C.F.R. pts. 17-24, 228-39 (1992).

159. But see the recommendations, *infra* text accompanying notes 364-73. Enforcement policies that set priorities primarily in terms of resource allocation rather than in substantive terms ordinarily will not pose difficulties for present purposes.

160. See *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1012-15 (9th Cir. 1987); *infra* Part V.

161. To the extent the Guides and Practice Rules of the Federal Trade Commission, *supra* note 158, set forth detailed forms of misrepresentation or deception in industry-specific terms, they arguably are interpretive of the statutory term "unfair or deceptive acts or practices." Federal Trade Commission Act, 15 U.S.C. § 45 (1988). These statutory words are broad but nevertheless have some tangible meaning when applied in a "negative" way—that is, to condemn acts which by common usage or general acceptance are "unfair or fraudulent or tricky." *Schochster Poultry Corp. v. United States*, 295 U.S. 495, 553 (1935) (Cardozo, J., concurring). But where the rules use the statutory words in a "positive" way—not merely to require refraining from unfair or deceptive acts but to require affected parties to perform affirmative acts to be safe from prosecution—it would seem hard to say they draw any tangible meaning from the statutory language. To that extent these rules are policy statements, as they are not interpretive. See *supra* text accompanying notes 59-69. It is worth noting that analogous documents issued by the Department of Transportation under its statutory authority over "unfair or deceptive practices or unfair methods of competition in air transportation or the sale thereof," 49 U.S.C. app. § 1381 (1988), were held *not* to be interpretive. *Alaska v. Department of Transp.*, 868 F.2d 441, 445-47 (D.C. Cir. 1989).

162. See *Public Citizen, Inc. v. NRC*, 940 F.2d 679, 680 (D.C. Cir. 1991) (holding that "policy statement" identifying practices that expose the public to radiation in such minute amounts as to be "below regulatory concern" was unripe for review).

163. E.g., *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987). The FDA's policy statement set forth "action levels," informing food producers of the allowable levels of undesirable contaminants. These were safe-harbor rules in the style of definition (1) in the text above.

the purposes of administration and enforcement, will authoritatively define the offense. Then, any nonobservance is subject to enforcement action, while observance comes within a safe harbor. This approach creates norms that have a practical binding effect. 3) The agency may try to have it both ways—that is, to hold affected parties to the standards set in the enforcement policy, but deny the document a role as a safe harbor, thereby reserving the freedom to proceed against persons who conform to it but for other reasons are deemed in violation of the statute. This again can create a practical binding effect.

Affected persons may flout these rules only at their peril. The agencies rarely will declare which of the three approaches they are taking. The usual disclaimers are consistent with all three,¹⁶⁴ leaving affected private parties uncertain as to which approach is intended and as to its practical binding force.¹⁶⁵

B. *Use of Nonlegislative Policy Documents to Pass upon Applications*

Nonlegislative policy documents are often the vehicles by which the agencies establish standards for approving or granting applications submitted by private parties. If the standards are intended to be routinely applied, or if they are regularly applied, they of course have a practical binding effect, even though they are not legally binding. This is true whether the applicant is able to challenge the document in court or not.

Frequently the applicant is under some sort of practical compulsion to seek the agency's approval. Guidances or manuals or other nonlegislative documents that set standards for an approval that the applicant must have as a business necessity, for example, or as the means of sustaining livelihood, acquire a particularly potent mandatory force. Where denial would place the applicant in a position of noncompliance with the risk of penalties, or would deprive him of essential sustenance, the standards as a practical matter amount to immediately enforceable regulatory norms—indeed, self-executing ones, because applicants in these circumstances have little choice but to accept the agency's terms. And because these applicants are typically unable to tolerate the delay or cost that a contest would entail, the documents and the norms they establish will often elude judicial scrutiny.

The combination of "mandatory, definitive language," *id.* at 947, with the agency's "own course of conduct," *id.* at 949, gave the documents a "present, binding effect," *id.*, and led the court to hold the action invalid "to be invalid in that they were issued without the requisite notice-and-comment procedures." *Id.* at 950; see also *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 535-37 (D.C. Cir. 1986).

164. See, e.g., 16 C.F.R. pt. 17 (1991).

165. An example of this problem is the Fish and Wildlife Service's announcement on the northern spotted owl, discussed *infra* Part VI(B).

B-1. The Interstate Commerce Commission (ICC) adopted a "policy statement," concerning applications for operating authority to and from Canada, which had the effect of releasing shippers from legally enforceable duties and constraints.¹⁶⁶ The court found it to be a "flat rule of eligibility"¹⁶⁷ that "purports on its face to notify applicants for certificates precisely what showings the Commission will or will not require of them."¹⁶⁸

B-2. An ICC "Restriction Removal Statement" contained "guidelines" that were prefaced by a declaration that they were not intended to prejudice any individual application. But the court found that "there are sinews of command beneath the velvet words of the subsequent sections of the guidelines," and that the guidelines as a whole were "decorated with words that appear to be carefully chosen to avert classification as rules."¹⁶⁹ The court remarked further that the "manner of dealing with applicants who do not follow what is declared to be the 'normal' course demonstrates graphically that the carrier who does not conform will incur both delay and potentially vast litigation expense."¹⁷⁰ This practical binding effect reinforced the conclusion that "these are not guidelines but normative rules."¹⁷¹

B-3. In another ICC case, the agency published an announcement in the *Federal Register* that it was cancelling all existing "special permission authorities" and that these authorities would no longer be issued.¹⁷²

B-4. The Department of Labor's program handbook for employment of workers holding H-2A visas changed the definition of "prevailing practices," thereby (as charged by the plaintiff farmworkers' advocacy group) relaxing farmworker protection standards to which employers must adhere. The document as amended was published in the

166. *American Bus Ass'n v. United States*, 627 F.2d 525, 533 (D.C. Cir. 1980) (holding statement unlawful).

167. *Id.* at 532 (quoting *United States ex rel. Parco v. Morris*, 426 F. Supp. 976, 984 (E.D. Pa. 1977)).

168. *Id.*

169. *American Trucking Ass'n v. ICC*, 659 F.2d 452, 463 (5th Cir. 1981) (holding guidelines invalid), *cert. denied*, 460 U.S. 1022 (1983).

170. *Id.* at 463-64.

171. *Id.* at 464. The court quoted *Brown Express, Inc. v. United States*, 607 F.2d 695, 701 (5th Cir. 1979) ("An announcement stating a change in the method by which an agency will grant substantive rights is not a 'general statement of policy.'"). Of course, this document was a general statement of policy as defined by the analysis in this Article, *supra* text accompanying notes 65-69, but the court was saying that it *should have been* promulgated as a legislative rule.

172. *American Trucking Ass'n v. United States*, 688 F.2d 1337, 1348 (11th Cir. 1982) (holding document invalid; "[T]he fact that the prospective announcement affects a discretionary function does not deprive it of its rulemaking quality."), *rev'd in part*, 467 U.S. 354 (1984). "Special permission authorities" are findings by the ICC that cause exists to allow trucking rate changes to take effect before the running of the 30-day period required by statute. *Id.* at 1347.

Federal Register as an "informational notice" but no comment was sought. Government counsel conceded that the handbook was "mandatory" and "binding."¹⁷³

B-5. The Chief of the Guaranteed Student Loan Branch of the Department of Education replied by an individual letter¹⁷⁴ to an inquiry from the New York State Higher Education Services Corporation, concerning the eligibility for a new loan of a borrower whose prior loan had been discharged as a result of his total and permanent disability.¹⁷⁵ The letter specified that an otherwise eligible applicant is ineligible for a further loan unless he reaffirms the previously discharged loan and meets certain other conditions, and that a loan made without observing these requirements would not be covered by federal reinsurance.¹⁷⁶ Although the author of the letter spoke of it as an "interpretation," it would seem difficult to point to specific language in the statute¹⁷⁷ that could yield so detailed an interpretation. The threatened sanction compelled compliance by the lending institution and the state-based guarantor organization, although legislative rulemaking was not used.¹⁷⁸ The author of the letter requested that it be circulated to guarantor organizations nationwide through their trade association,¹⁷⁹ thus making its requirements known to those other than its addressee who might be affected.

173. *Comite de Apoyo para los Trabajadores Agrícolas v. Dole*, 731 F. Supp. 341, 348 (D.D.C. 1990) (directing agency to engage in informal notice-and-comment rulemaking with respect to the definition of "prevailing practice").

174. Letter from Saul Moskowitz, Chief, Guaranteed Student Loan Branch, Division of Policy and Development, U.S. Department of Education, to Milton Wright, Vice President, Division of Guaranteed Loan Programs, New York State Higher Education Services Corp. (Sept. 1, 1989) [hereinafter Letter from Moskowitz].

175. The Higher Education Act of 1965 requires the Secretary of Education to discharge liability on the loan of a student borrower who dies or becomes permanently and totally disabled. 20 U.S.C. § 1087(a) (1988).

176. Letter from Moskowitz, *supra* note 174, at 1.

177. 20 U.S.C. § 1087.

178. The letter stated: "We intend to include our policy in this area in an upcoming notice of proposed rulemaking." Letter from Moskowitz, *supra* note 174, at 2. Such provisions were included in the Notice of Proposed Rulemaking, Guaranteed Student Loans, 55 Fed. Reg. 48,324, 48,342, 48,359 (1990) (to be codified at 34 C.F.R. pt. 682) (proposed Nov 20, 1990). These proposed rules have not yet been adopted.

179. Letter from Moskowitz, *supra* note 174, at 2 ("[P]lease understand that the Department's interpretation of an applicable statute or regulation need not be codified in regulation or memorialized in a Dear Colleague letter to be considered an official Department position. The expression of that view by an authorized Department representative is sufficient. Nevertheless, we agree that this Departmental interpretation is of sufficient general interest and importance that all guarantee agencies should be made aware of it. To that end, we are providing a copy of this letter to the National Council of Higher Education Loan Programs, which we have asked to distribute this guidance to its members.")

It should be noted that by statute "any rules, regulations, guidelines, interpretations, orders, or requirements of general applicability prescribed by the [Department of Education]," 20 U.S.C.

B-6. In 1988 the Assistant Secretary of Labor for Mine Safety and Health established a "Directives System" and manual¹⁸⁰ to provide guidance on how the Mine Safety and Health Administration (MSHA) applies the Federal Mine Safety and Health Act of 1977¹⁸¹ and the corresponding regulations.¹⁸² The system is updated by nonlegislatively issued¹⁸³ program policy letters (PPLs), which in many cases establish new requirements going beyond the regulations or impose new penalties or penalty schedules.¹⁸⁴ An example is PPL P89-11-8, which sets forth specific criteria to be met for approval of electrical equipment that incorporates methane monitors.¹⁸⁵ The pertinent regulation governing electrical equipment¹⁸⁶ speaks of rugged construction, sound engineering, and safety for the intended use, but does not specify engineering criteria for particular types of electrical mining equipment. The quite specific requirements of the electrical equipment PPL, which are stated in mandatory terms, arguably amount to an interpretation of the regulation, although the PPL recites that the pertinent part of the regulations "presently does not contain requirements relative to the use of methane monitors on permissible equipment."¹⁸⁷ A manufacturer who does not meet the standards will be denied the certificate of approval needed to market the equipment, and operators using unapproved equipment face citation and enforcement action.

§ 1232(a)(1) (1988), must comply with the rulemaking procedures of 5 U.S.C. § 553 and certain additional special requirements. 20 U.S.C. § 1232 (b)-(g).

180. 2 MSHA ADMINISTRATIVE POLICY AND PROCEDURES MANUAL, ch. 100 (Release II-4, July 17, 1990).

181. 30 U.S.C. §§ 801-962 (1988).

182. 30 C.F.R. pts. 5-104 (1991).

183. *But see* 30 U.S.C. § 811(a) (1988) ("The Secretary shall by rule in accordance with procedures set forth in this section and in accordance with section 553 of title 5, (without regard to any reference in such section to sections 556 and 557 of such title), develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal or other mines.")

184. A 1990 PPL established higher penalties for mine operators or contractors with an "excessive history of violations" (defined for the first time in the PPL). Increased Assessments for Mines with Excessive History of Violations, PPL No. P90-III-4 (effective May 29, 1990). An MSHA administrative law judge held that "notice and comment under the Administrative Procedure Act are necessary before the program policy letter can be effective." *Drummond Co.*, No. SE 90-126, A.C. No. 01-00323-03638, slip op. at 16 (Mar. 6, 1991).

185. Approval of Methane Monitors Incorporated in the Design of Electric Equipment, PPL No. P89-11-8 (effective Aug. 29, 1989).

186. 30 C.F.R. § 18.20 (1991).

187. PPL No. P89-11-8, *supra* note 185, at 1 (The regulations contain requirements for the use of methane monitors generally, but these requirements "cannot be evaluated as a part of the approval" of equipment.).

B-7. The EPA used a nonlegislatively announced "model" to predict, based on "reasonable worst case assumptions,"¹⁸⁸ the "leachate levels" of wastes that applicants petitioned to have removed from the list of hazardous wastes subject to regulation under the Resource Conservation and Recovery Act.¹⁸⁹ EPA argued that the model as a policy statement was exempt from notice-and-comment requirements. In an incisive and highly significant opinion, Judge Stephen Williams observed that the document's mandatory language "suggests the rigor of a rule, not the pliancy of a policy,"¹⁹⁰ and that the agency's "later conduct applying it confirms its binding character."¹⁹¹ "The agency treated the model as conclusively disposing of certain issues On those issues, EPA was simply unready to hear new argument. The model thus created a norm with 'present-day binding effect' on the rights of delisting petitioners."¹⁹²

B-8. A landowner sought to fill portions of its property for building development.¹⁹³ The Clean Water Act prohibits the discharge of any "pollutant" (including dredged or fill material) into "navigable waters" except in compliance with a permit issued by the Department of the Army under the Act.¹⁹⁴ The term "navigable waters" is defined to include "the waters of the United States."¹⁹⁵ The Army Corps of Engineers' regulations claim that jurisdiction over "waters of the United States" includes "[a]ll other waters . . . which could affect interstate or foreign commerce."¹⁹⁶

The Corps' Deputy Director for Public Works issued a memorandum to all district Corps offices listing seven categories having a sufficient connection with interstate commerce to warrant the exercise of jurisdiction over isolated waters, including "[w]aters which are used or could be used as habitat by . . . migratory birds which cross state lines."¹⁹⁷ This memorandum potentially swept into the regulatory regime millions of acres of land for which a permit would be required to fill. The Corps

188. *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1319 (D.C. Cir. 1988) (quoting 50 Fed. Reg. 7882, 7883 (1985) (to be codified at 40 C.F.R. § 261) (proposed Feb. 26, 1985)).

189. *Id.* at 1319.

190. *Id.* at 1320-21.

191. *Id.* at 1321.

192. *Id.*

193. *Tabb Lakes, Ltd. v. United States*, 715 F. Supp. 726 (E.D. Va. 1988), *aff'd without op.*, 885 F.2d 866 (4th Cir. 1989).

194. 33 U.S.C. §§ 1311(a), 1344(a), 1362(6), (12) (1988).

195. *Id.* § 1362(7).

196. 33 C.F.R. § 328.3(a)(3) (1991). Congress intended to confer a broad grant of jurisdiction in the Clean Water Act, extending to any aquatic features within the reach of the Commerce Clause. See *Leslie Salt Co. v. Froehike*, 578 F.2d 742, 754-55 (9th Cir. 1978); *California v. EPA*, 511 F.2d 963, 964 n.1 (9th Cir. 1975), *rev'd on other grounds*, 426 U.S. 200 (1976).

197. Memorandum of Brigadier General Patrick J. Kelly, Deputy Director for Civil Works, U.S. Army Corps of Engineers (Nov. 8, 1985), quoted in *Tabb Lakes*, 715 F. Supp. at 728.

asserted jurisdiction over the land involved in the present case on the ground that the portions of it that were wetlands (though not water) could be used as habitat by "not ducks or geese, but woodpeckers, songbirds, etc."¹⁹⁸ The court held that "the Corps intended the November 8, 1985 Kelly Memorandum [to be] binding and intended that it take effect immediately,"¹⁹⁹ and set it aside for failure to observe APA notice-and-comment requirements.²⁰⁰

B-9. Although the court held the document involved to be a proper policy statement, the well-known *Pacific Gas & Electric* case²⁰¹ nevertheless offers a useful illustration. In view of the diversity of curtailment plans submitted by pipeline companies in response to a gas shortage, the Federal Power Commission promulgated a "Statement of Policy" which "set forth the Commission's view of a proper priority schedule" and "further state[d] the Commission's intent to follow this priority schedule unless a particular pipeline company demonstrates that a different curtailment plan is more in the public interest."²⁰² The provisions of the statement were clear and definite, and were couched largely in mandatory terms, but also stated that "[w]hen applied in specific

198. *Tubb Lakes*, 715 F. Supp. at 728.

199. *Id.* at 729.

200. *Id.* The Kelly Memorandum was arguably an interpretation of the regulation 33 C.F.R. § 328.3(a)(3) (1991). A later similar statement contained in *Federal Register* preambular comments upon the regulation, 51 Fed. Reg. 41,206, 41,217 (1986), was apparently assumed to be interpretive in *Leslie Salt Co. v. United States*, 896 F.2d 354, 359-60 (9th Cir. 1990), *cert. denied*, 111 S. Ct. 1089 (1991). On this view, it would not be improper under the APA for the Corps to employ a memorandum rather than a legislative rule to announce a position it intended to make binding. *See supra* notes 3-6 and accompanying text. The huge and debatable extension of jurisdiction it asserted, however, illustrates the good sense of using notice-and-comment rulemaking procedures for the promulgation of interpretations that substantially enlarge the agency's claim of jurisdiction, as recommended in this Article. *See infra* text accompanying notes 371-73.

The entire field of wetlands regulation has been the focus of enormous ongoing controversy. *See, e.g.*, Senator Johnston's proposed amendment to the Clean Water Act that would deny the use of funds to identify or delineate wetlands under any "manual [that was] not adopted in accordance with the requirements for notice and public comment of the rule-making process of the Administrative Procedure Act." 137 CONG. REC. S9342 (daily ed. July 9, 1991); *see also* Michael Weiskopf, *Wetlands Protection and the Struggle over Environmental Policy*, WASH. POST, Aug. 8, 1991, at A17; *How Wet is a Wetland?*, WASH. POST, Aug. 7, 1991, at A14; *Bush's Swamp Thing*, WALL ST. J., July 25, 1991, at A8. On August 14, 1991, the EPA, Corps of Engineers, Soil Conservation Service, and Fish and Wildlife Service jointly published in the *Federal Register* a proposed revision of the controversial wetlands manual. 56 Fed. Reg. 40,446 (1991). The prefatory material stated:

[T]he proposed Manual on which we are soliciting public comment is a technical guidance document and provides internal procedures for agency field staff for identifying and delineating wetlands. Both versions of the document serve to advise the public prospectively of the manner in which agency personnel will apply the definition of wetlands to particular sites on a case-by-case basis.

Id.

201. *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33 (D.C. Cir. 1974).

202. *Id.* at 36.

cases, opportunity will be afforded interested parties to challenge or support this policy through factual or legal presentation."²⁰³ Largely on the basis of interpreting this and related language favorably to the Commission, the court upheld the document. However, one may suspect that, despite the language declaring its tentative effect, the document would lead affected parties to believe it would be rigorously applied and therefore would bind as a practical matter. Perhaps the court had similar doubts in mind when it cautioned: "We expect the Commission . . . to refrain from treating Order No. 467 as anything more than a general statement of policy."²⁰⁴

Although regarded by some as a champion in the game of "rule by memorandum," EPA has recently shown signs of recognizing its obligation to promulgate legislative rules when it intends to bind the public. Twice in the last year or so it has backed away from actions that manifestly were based upon the premise that nonlegislative policy documents may be enforced or applied in the same binding way as legislative rules are.

B-10. In the preamble to a final rule approving revisions in Kentucky's state implementation plan (SIP) under the Clean Air Act,²⁰⁵ EPA had stated that, in view of the complexity of the subject matter:

It would be administratively impracticable . . . to amend the regulations and SIPs every time EPA . . . issues guidance regarding the proper implementation of the NSR [new source review] program. . . . Rather, action by EPA to approve [revisions to a SIP] has the effect of requiring the State to follow EPA's current and future interpretations of the Act's provisions and regulations, as well as EPA's operating policies and guidance . . .²⁰⁶

This is a rather explicit declaration by EPA of its intent to bind through nonlegislative issuances. Obviously, if EPA interpretations and guidances are binding on the states in their implementation of the clean air laws, they are binding upon private parties who must gain the states' approval of their permit applications. EPA stated further that it may deem inadequate a state-issued permit not reflecting these positions, and "may consider enforcement action . . . to address the permit deficiency."²⁰⁷

203. *Id.* at 30.

204. *Id.* at 43.

205. Notification of Clarification, 54 Fed. Reg. 36,307 (1989).

206. *Id.* at 36,307-08.

207. *Id.* at 36,308.

After protest and commencement of litigation,²⁰⁸ EPA issued a "Notice of Clarification"²⁰⁹ in which it stated that interpretations and guidances do not have "independent status . . . such that mere failure to follow such pronouncements, standing alone, would constitute a violation of the Clean Air Act. . . . [I]n defending against such an enforcement action [i.e., one based on such interpretations or guidances], a party is free to assert that EPA has not reasonably interpreted the underlying statutory and regulatory provisions."²¹⁰ The agency properly receded from the assertion that its informal documents are in themselves binding, and recognized that they are subject to challenge.²¹¹

B-11. In a second example, EPA agreed to use legislative rulemaking to promulgate a policy it had for several years enforced through informal documents. The Clean Air Act²¹² establishes requirements to "prevent significant deterioration" of air quality in "attainment" areas—that is, those regions where national air quality standards are currently satisfied with respect to given pollutants.²¹³ Those seeking to construct a new major emitting facility or a major modification to an existing facility must obtain a permit from the permitting authority (EPA, or the state acting under a delegation or other arrangement with EPA).²¹⁴ The permit must include, among other things, emission limitations based on the "best available control technology" (BACT).²¹⁵ The BACT for any facility is "an emission limitation based on the maximum degree of reduction of each pollutant . . . which the permitting authority, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is achievable for such facility . . ."²¹⁶ New source performance standards (NSPS) and national emission standards for hazardous air pollutants (NESHAP) promulgated by EPA generally serve as the baseline for BACT determinations.²¹⁷

208. *Westvaco v. EPA*, No. 89-3975 (6th Cir. filed Oct. 31, 1989).

209. Notice of Clarification, 55 Fed. Reg. 23,547 (1990).

210. *Id.* at 23,548.

211. To the extent interpretations are involved, those issued nonlegislatively cannot bind the courts and should be reviewed independently (subject only to the court's respectful consideration of the agency's views), rather than by a reasonableness test as suggested by EPA's language. See Anthony, *supra* note 6, at 36-42, 55-60.

212. 42 U.S.C. §§ 7470-7479 (1988).

213. *Id.* § 7470.

214. *Id.* §§ 7475(a)(1), 7479(1); 40 C.F.R. §§ 52.21(f)(1), 52.21(b)(2) (1991).

215. 42 U.S.C. §§ 7475(a)(4), 7479(3).

216. *Id.* § 7479(3). The definition in EPA's regulations is very similar. See 40 C.F.R. § 52.21(b)(12) (1991).

217. 42 U.S.C. § 7479(3).

For a number of years, BACT was determined on a "bottom-up" basis, roughly as follows: Starting with the baseline NSPS and any applicable NESHAP, the permitting authority weighed the statutory considerations to determine whether any higher level of control was "available" and "achievable" in the particular circumstances of the case.²¹⁸ Beginning in 1986 and 1987, units within EPA adopted and imposed on the states a "top-down" approach in place of the bottom-up method. Briefly, in place of case-by-case weighing of factors, "top-down" requires use of the most stringent control technology unless the applicant can show that it is technologically or economically "infeasible." The first comprehensive announcement of the new policy came in a 1987 memorandum from the Assistant Administrator for Air and Radiation to EPA's Regional Administrators.²¹⁹ The Assistant Administrator stated that he had "determined that [the top-down approach] should be adopted across the board," and that a state-issued permit that "fails to reflect adequate consideration of the factors that would have been relevant using a 'top-down' type of analysis shall be considered deficient by EPA."²²⁰ There followed in July 1988 a communication (captioned "Memorandum," but introduced by the words "this guidance") from the Associate Enforcement Counsel for Air and the Director of the Stationary Source Compliance Monitoring Division to various subordinate regional and headquarters officials.²²¹ This document stated that "any one of the following factors will normally be sufficient for EPA to find a [state-granted] permit 'deficient' and consider enforcement action: 1. BACT determination not using the 'top-down' approach."²²² Other documents were issued, stating in various terms the mandatory nature of the top-down requirements, which were applied consistently after 1988.²²³ But these requirements

218. See U.S. ENVIRONMENTAL PROTECTION AGENCY, PREVENTION OF SIGNIFICANT DEGRADATION—WORKSHOP MANUAL, at II-B-1 to B-5 (Oct. 1980).

219. Memorandum from J. Craig Potter, Assistant Administrator for Air and Radiation, to Regional Administrators, Regions I-X (Dec. 1, 1987).

220. *Id.* at 4.

221. Memorandum from Michael S. Alshain, Associate Enforcement Counsel for Air, Office of Enforcement and Compliance Monitoring, and John S. Seltz, Director, Stationary Source Compliance Division, Office of Air Quality Planning and Standards, to various addressees (July 13, 1988).

222. *Id.* at 2.

223. On March 15, 1990, the Source Review Section, Noncriteria Pollutants Program Branch, Air Quality Management Division, Office of Air Quality Planning and Standards of EPA issued a document of some 76 pages plus appendices, captioned "'Top-Down' Best Available Control Technology Guidance Document." The cover and every page were prominently marked "draft." In October 1990, EPA's Office of Air Quality Planning and Standards issued a draft New Source Review Workshop Manual, containing a 75-page chapter, the bulk of which was devoted to a detailed explanation of how the top-down process should be applied. Again, every page was marked "draft." These informal guidance documents were never put into a final form, let alone made the subject of rulemaking.

were never made the subject of rulemaking procedures, or of any sort of public notice, opportunity for public comment or any other form of public participation in their development.

Litigation ensued, challenging EPA's promulgation of this mandatory policy without the use of legislative rulemaking.²²⁴ In July 1991, EPA entered into a settlement agreement with the plaintiffs.²²⁵ Although it conceded no admissions on any issue of law, fact, or liability,²²⁶ EPA agreed to publish in the *Federal Register* "a proposed rule proposing to revise or clarify the regulations defining BACT . . . , and proposing to revise or clarify how BACT determinations should be made," and "to take final action on the proposed rule as expeditiously as practicable."²²⁷ The settlement further recited: "Any EPA BACT policy statement or interpretation is intended only to guide the implementation of BACT under approved state new source review programs and is not intended to create binding legal rights or obligations and does not have the force and effect of law."²²⁸

These actions in the Kentucky SIP matter and the top-down case bespeak some degree of recognition by EPA of an obligation to rely upon legislative rules, rather than informal documents, to establish binding standards and requirements. Interestingly, in the top-down situation EPA might have been able to avoid obligatory rulemaking, even though it intended its top-down precepts to bind private parties, by framing them as interpretive rules. The key elements of the top-down policy arguably can be linked to the language of the statutory definition of BACT.²²⁹ As noted above, an agency is not obliged by the APA to use legislative rulemaking for promulgating documents that interpret specifically worded statutory language, even if it intends to apply the interpretations rigorously to private parties affected by them.²³⁰ On the other hand, I believe the top-down documents are more properly viewed as policy

224. The principal case based on failure to use legislative rulemaking procedures is *American Paper Inst. v. Reilly*, No. 89-2030 (D.D.C. filed July 18, 1989). Related cases are *American Paper Inst. v. Reilly*, No. 89-1428 (D.D.C. filed July 10, 1989); *Alabama Power Co. v. Reilly*, No. 89-1429 (D.D.C. filed July 11, 1991); *American Paper Inst. v. Reilly*, No. 90-1364 (D.D.C. filed July 13, 1990).

225. Settlement Agreement entered with the plaintiffs in the cases cited *supra* note 224 (July 9 and 10, 1991).

226. *Id.* at 5.

227. *Id.* at 2.

228. *Id.* The quoted passage was immediately followed by a citation to the "clarification," *supra* text accompanying notes 209-11, of the language in the preamble to the rule approving Kentucky's revised SIP, *supra* text accompanying notes 205-07.

229. See *supra* text accompanying note 50.

230. See *supra* text and authorities accompanying notes 3-6. Portions of the top-down process might be regarded as rules of procedure or practice, exempt from notice-and-comment rulemaking requirements under 5 U.S.C. § 553(b)(A) (1988).

statements, which may not be used in place of legislative rules when the agency intends them to bind. In its own brief in the litigation challenging EPA's failure to promulgate the top-down policy by legislative rulemaking, the government repeatedly characterized the top-down policies and actions as statements of policy (or administrative adjudications), rather than as interpretive rules.²³¹ On this view, of course, legislative rulemaking would be required to the extent the documents were intended to bind private parties.²³²

If not a separate category, rules governing ratemaking should at least be recognized as a distinct subset of the applications-and-approvals category.

B-12. A Federal Communications Commission (FCC) issuance offers an intricate example-in-point. The Commission in 1985 opened an investigation of rates charged by local telephone companies (LECs) for special access services including high-capacity communications (HiCap) services.²³³ The special access services rate category primarily embraces large-scale private-line services offered by LECs to major interstate carriers such as AT&T and MCI and to large business users. Separately established rules required LECs to refund charges if their rate of return for any segment of their operations (such as special access) exceeded the allowable overall rate of return, even if the latter were within permissible limits.²³⁴ Those rules were struck down by the D.C. Circuit in early 1988.²³⁵ In December 1988, the Commission announced in the special access proceeding a set of specific new "guidelines" for evaluating the lawfulness of HiCap rates.²³⁶ Although some comments were received, somewhat in the fashion of FCC ratemaking, section 553 rulemaking procedures were not employed.²³⁷ These guidelines established issues that differed significantly from the issues and factors announced at the

231. Defendants' Memorandum in Support of Motion to Dismiss, at 12, 33, 35, 36, *American Paper Inst. v. Kelly*, No. 89-2030 (D.D.C. filed July 18, 1989).

232. On the fashion in which federal nonlegislative documents may bind or otherwise affect state and local permitting agencies, and through them private parties, see *infra* Part VI.

233. Order Designating Investigation of Special Access Tariffs of Local Exchange Carriers, CC No. 85-166 (released May 24, 1985) [hereinafter Designation Order].

234. Authorized Rates of Return for Interstate Services of AT&T and Exchange Telephone Carriers, 50 Fed. Reg. 41,350 (1985).

235. *American Tel. & Tel. Co. v. FCC*, 836 F.2d 1386 (D.C. Cir. 1988).

236. *In re Investigation of Special Access Tariffs of Local Exchange Carriers*, 4 F.C.C.R. 4797 (1988).

237. The Commission characterized the proceedings as "Rule Makings of particular applicability." *In re Investigation of Special Access Tariffs of Local Exchange Carriers*, 5 F.C.C.R. 4861, 4861 ¶ 7 (1990) (denying reconsideration).

outset of the proceeding.²³⁸ Among them was one (Guideline No. 1) that largely resuscitated, for HiCap special access rates, the refund rules struck down earlier that year.²³⁹

The accompanying order directed the affected companies to file supplemental cases to justify their rates under the guidelines.²⁴⁰ In a January 1990 action,²⁴¹ the Commission applied the guidelines, found (with one exception) that the companies' HiCap rates in effect at the time satisfied the new guidelines, and therefore ordered no change in those existing rates.²⁴² The Commission also applied the guidelines to HiCap rates during the 1985-1986 and 1987-1988 review periods. On the basis of Guideline No. 1, it ordered twelve companies to refund tens of millions of dollars.²⁴³

The companies did not seek judicial review of the failure to use legislative rulemaking to adopt the guidelines, as they were generally content with the way the guidelines were applied to uphold existing rates, which would continue into the future.²⁴⁴ They have, however, challenged the refund orders on grounds of impermissible retroactivity.²⁴⁵

C. Use of Nonlegislative Policy Documents in Benefit Cases

Nonlegislative policy issuances have been used to deny benefits in federal programs.

238. See *MCI Telecommunications Corp. v. New York Tel. Co.*, 5 F.C.C.R. 707, 708 ¶ 10 (1990) ("The Commission . . . decided not to evaluate the specific . . . rates under investigation using the approach [announced at the outset of the proceeding] but instead established a set of guidelines.")

239. *In re Investigation*, 4 F.C.C.R. at 4803 ¶ 58.

240. *Id.* at 4803 ¶ 78.

241. *In re Investigation of Special Access Tariffs of Local Exchange Carriers*, 5 F.C.C.R. 412 (1990) (the "refund order").

242. *Id.* at 416 ¶ 32.

243. *Id.* at 412-13 ¶¶ 6-12, 416 ¶¶ 34-37.

244. Interview with Alfred Winchall Whittaker, counsel for the Ameritech telephone companies, in Washington, D.C. (Aug. 7, 1991).

245. *Ohio Bell Tel. Co. v. FCC*, No. 90-3146 (6th Cir. filed Feb. 21, 1990).

Even if one took the view that (despite the Commission's own characterization, see *supra* note 237) the proceeding was partly an adjudication because it included an investigation of past rates, the method of promulgating the guidelines probably would remain improper. The 1988 document did not merely address the past, but spoke without limitation to all LECs, for all the future: "[W]e will require that all LECs provide a *de novo* justification of their strategically-priced special access rates in each annual access tariff filing. The justification should consist of a demonstration that the rates proposed will meet the standards [guidelines] set forth herein." *In re Investigation*, 4 F.C.C.R. at 4803 ¶ 37. This is the language of rulemaking. That the guidelines were applied in a partly adjudicatory 1990 decision would not legitimate the failure to use rulemaking in 1988 (though their application in 1990 might be sustainable procedurally on the theory that the guidelines were freshly generated for purposes of the adjudication, see *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 (1969)). Whether application of the guidelines could be sustained over the further objection that it was impermissibly retroactive is, of course, an entirely separate matter.

C-1. The Bureau of Indian Affairs (BIA) denied general assistance benefits to full-blooded unassimilated Indians who lived near but not on their reservation.²⁴⁶ The Bureau had issued its restrictive eligibility policy only through a BIA manual, not a legislative rule.²⁴⁷

C-2. The Department of Housing and Urban Development's *HUD Property Disposition Handbook, One to Four Units* governed the disposition of family residences foreclosed and transferred to HUD under its mortgage insurance programs. Homeless persons and organizations aiding the homeless attacked the document in several particulars, and challenged its validity on the ground that it had not been issued through legislative rulemaking procedures. Language in the document directed HUD's property disposition directors in the field to follow the policies and procedures therein set forth.²⁴⁸

C-3. Plaintiff claimants were denied Medicare Part B reimbursement for certain services on the basis of provisions in the Carrier's Manual, a nonlegislative document "made binding in Part B benefit determinations" by regulations issued by the Secretary of HHS.²⁴⁹

C-4. The Social Security Administration's Appeals Council, relying on a Social Security Ruling that implemented a statutory amendment directing the Secretary of HHS to formulate new policy in the disability benefits program, reversed an administrative law judge's award of benefits.²⁵⁰

246. *Morton v. Ruiz*, 415 U.S. 199 (1974).

247. *Id.* The Supreme Court found the Indians eligible under the statute, but assumed that in view of reduced appropriations the agency could rationally limit eligibility to those actually living on the reservation. However, the Court said that the "conscious choice of the Secretary not to treat this extremely significant eligibility requirement, affecting rights of needy Indians, as a legislative-type rule, render[ed] it ineffective." *Id.* at 236. "The Administrative Procedure Act was adopted to provide, *inter alia*, that administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished *ad hoc* determinations." *Id.* at 232.

248. *Lee v. Kemp*, 731 F. Supp. 1101 (D.D.C. 1989) (remanding for violation of notice-and-comment rulemaking requirements). Although the subject matter was exempt from APA rulemaking requirements as relating to "public property," 5 U.S.C. § 553(a)(2) (1985), HUD had voluntarily subjected itself to substantially the same requirements. 731 F. Supp. at 1112-13. Such a voluntary waiver of the exemption is binding on the agency. *Rodway v. USDA*, 514 F.2d 809 (D.C. Cir. 1975).

249. *Linoz v. Heckler*, 800 F.2d 871, 874 (9th Cir. 1986) (holding document invalid). Although the subject matter was exempt from APA rulemaking requirements as relating to "benefits," 5 U.S.C. § 553(a)(2), HHS in 1971 had waived the exemption. 800 F.2d at 877 n.7. In contrast, *Friedrich v. Secretary of Health and Human Servs.*, 894 F.2d 829 (6th Cir.), *cert. denied*, 111 S. Ct. 59 (1990), held that a "national coverage determination," on the basis of which a Part B Medicare reimbursement claim was denied, was an interpretive rule because it interpreted the statutory term "reasonable and necessary." *Id.* at 837.

250. *W.C. v. Bowen*, 807 F.2d 1502 (9th Cir. 1987) (holding ruling void; reinstating ALJ award of benefits).

C-5. HHS's Medicare Provider Reimbursement Manual and a clarifying memorandum called for paying cost-control bonuses to hospitals at the final settlement stage rather than at the interim payment or tentative settlement stage.²⁵¹

D. *Nonlegislative Policy Documents Affecting Programs Administered by the States*

Standards in nonlegislative federal issuances often control the disbursement of federally reimbursed moneys to or by the states, or the conduct of programs administered by the states. "The manner in which the Secretary regulates the states controls the manner in which the states regulate the facilities and that, in turn, controls the treatment of the residents."²⁵²

D-1. The Department of Labor issued an Unemployment Insurance Program Letter, establishing detailed rules with mathematical formulas for determining individual contributions to pension funds, for the states to include when exercising authority under the Federal Unemployment Tax Act to provide in their respective laws for taking account of pension contributions in computing benefits.²⁵³

D-2. Class action plaintiffs were threatened with reduction in food stamps under USDA interim rules, issued without notice or opportunity for comment, that implemented a statutory change in the definition of "household."²⁵⁴

D-3. The Department of Labor, by notification to regional offices, established a new method of calculating the unemployment statistics by which were triggered the emergency job program allocations to the states under the Comprehensive Employment and Training Act.²⁵⁵

D-4. An amended HHS regulation promulgated without notice and comment was used to deny Ohio's proposed amendment to its Medicaid State Plan, with respect to the ceiling on allocations for the

251. *Mount Diablo Hosp. Dist. v. Bowen*, 860 F.2d 951 (9th Cir. 1988) (holding manual provision and memorandum invalid; policy that provides that bonuses are to be paid at tentative settlement is a change that must be promulgated according to APA § 553).

252. *Estate of Smith v. Bowen*, 675 F. Supp. 586, 589 (D. Colo. 1987).

253. *Cabala v. Egger*, 690 F.2d 234, 239 (D.C. Cir. 1982) (holding that document can be enjoined; "These rules . . . impose an obligation on the states not found in the statute itself. It cannot reasonably be argued that these rules are merely interpretative.")

254. *Levesque v. Block*, 723 F.2d 175 (1st Cir. 1983) (holding interim rule invalid, though later regulations legislatively promulgated were valid).

255. *Batterton v. Marshall*, 648 F.2d 694 (D.C. Cir. 1980) (holding Maryland's claims justiciable only in regard to changes in future methodology; further holding that those changes must be promulgated by APA legislative rulemaking procedures).

maintenance and support of noninstitutionalized spouses of institutionalized Medicaid recipients.²⁵⁶

D-5. Certain forms, standards, methods, and procedures were required to be used by state survey agencies in Medicaid facility certifications. They were required despite the fact that, though they had been set forth for comment as appendices to proposed regulations, they were never included in final regulations.²⁵⁷

D-6. To implement a 1981 amendment to the Trade Act of 1974, the Department of Labor issued a series of interpretive letters directing the states to calculate workers' eligibility for trade adjustment allowances in a certain fashion, and threatened to impose penalties on a state that refused to follow them.²⁵⁸

D-7. The Department of Education employs Dear Colleague letters to direct compliance by state-based guarantor organizations²⁵⁹ and lenders with the Department's policies for the Guaranteed Student Loan Program. The Dear Colleague letters sometimes purport to interpret statutory or regulatory language, but often add wholly new requirements. The Department can withhold the reimbursement of funds to lending institutions and to guarantor organizations that do not exert the efforts to collect defaulted loans stipulated in the letters.²⁶⁰

One such document outlined the conditions under which the agency will reinstate reinsurance coverage after a lending institution has violated the federal due diligence or timely filing regulations.²⁶¹ These conditions include requirements that go beyond the statutory and regulatory language.²⁶² For example, the bulletin's entirely new section on "Cures for

256. *Ohio Dep't of Human Servs. v. Department of Health & Human Servs.*, 862 F.2d 1228 (6th Cir. 1988) (holding rule invalid because of failure to comply with APA rulemaking requirements).

257. *Estate of Smith v. Bowen*, 675 F. Supp. 586 (D. Colo. 1987) (holding HHS Secretary in contempt of prior district court and court of appeals orders to promulgate regulations on the subject).

258. *Tyler v. Department of Labor*, 752 F. Supp. 32 (D. Me. 1990) (holding eligibility policy invalid).

259. State-based guarantor organizations may be agencies of the state, public nonprofit corporations, or private nonprofit corporations. These organizations are ordinarily referred to as "guaranty agencies." The term "agency" is not so used here, to avoid confusion with the federal agency.

260. 34 C.F.R. § 682.406(a)(1), (a)(3); 34 C.F.R. § 682.411 (1991).

261. Letter from C. Ronald Kimberling, Assistant Secretary for Postsecondary Education, and Dewey L. Newman, Deputy Assistant Secretary for Student Financial Assistance, to state guarantor organization directors (Mar. 11, 1988) [hereinafter *Cure Bulletin*].

262. The letter cites 34 C.F.R. § 682.406(a)(3), (a)(5), and 34 C.F.R. § 682.423(b)(1) (1988) as the foundation for requiring the lender to comply with the minimum due diligence procedures and with the timely filing deadlines in order for the guarantor organization to receive reinsurance on the loan. But it is the March 11, 1988 Bulletin that delineates the actual situations that can jeopardize the institutions' right to receive or retain interest benefits and special allowance payments on a loan. *See Cure Bulletin, supra* note 261.

Timely Filing Violations and Certain Due Diligence Violations"²⁶³ adds four additional steps and fifty-five days to the due diligence procedures outlined in the regulations. The bulletin then specifies penalties for non-compliance with the due diligence requirements, including the loss of "reinsurance payments on a loan on which the lender has violated the Federal due diligence or timely filing requirements, even if the lender has followed a cure procedure established by the [guarantor] agency."²⁶⁴ Although the regulations do not provide that the Department may withhold payment of accrued interest as a penalty for a lender's violation,²⁶⁵ the bulletin adds this penalty for due diligence violations occurring on or after May 1, 1988.²⁶⁶ Additionally, the regulation relevant to skip tracing²⁶⁷ has been expanded in the bulletin to require location of the borrower and performance of an additional due diligence stream before a claim is filed.²⁶⁸

IV. THE KEY TESTS: INTENT TO BIND OR BINDING EFFECT

Although they do not express it in just the same language, the illustrative judicial decisions cited in the last section support this simple proposition: *If a document expresses a change in substantive law or policy²⁶⁹ (that is not an interpretation) which the agency intends to make binding, or administers with binding effect, the agency may not rely upon the statutory exemption for policy statements, but must observe the APA's legislative rulemaking procedures.²⁷⁰* The legislative rulemaking process must be utilized if the document is to have the binding effect the agency has in view.

263. Cure Bulletin, *supra* note 261, at 9-10.

264. *Id.* at 2.

265. See 34 C.F.R. § 682.413 (1991).

266. Cure Bulletin, *supra* note 261, at 8.

267. 34 C.F.R. § 682.411(g) (1991).

268. Cure Bulletin, *supra* note 261, at 9-10.

269. Numerous cases identify the class of changes that are subject to legislative rulemaking requirements in terms such as "impose[a] rights and obligations," *Community Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting *American Bus Ass'n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980)); "modifies existing rights, law, or policy," *W.C. v. Bowen*, 807 F.2d 1502, 1504 (9th Cir. 1987); "affect a change in existing law or policy," *Mount Diablo Hosp. Dist. v. Bowen*, 860 F.2d 951, 956 (9th Cir. 1988) (quoting *Linceo v. Hookler*, 800 F.2d 871, 877 (9th Cir. 1986)); "substantially alter the rights or interests of regulated parties," *Air Transp. Ass'n of Am. v. Department of Transp.*, 900 F.2d 369, 376 (D.C. Cir. 1990) (quoting *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1041 (D.C. Cir. 1987)), *judgment vacated as moot*, 111 S. Ct. 944 (1991); see also *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979) (A "substantive rule" or "legislative-type rule" is one "affecting individual rights and obligations.").

270. This proposition does not apply to documents that interpret concrete statutory or regulatory language. See *supra* notes 3-6. The theory is that the agency is not making new law or changing the law but is merely clarifying or explaining preexisting law in the statutes or regulations. See *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1043-46 (D.C. Cir. 1987).

These cases reflect a realization that the agency should not be able to fasten its will upon the affected public through any means it pleases. It may not tell people what they can and cannot do except through procedures that Congress by delegation has empowered them to use for making law.²⁷¹ It may not enforce or apply a nonlegislative policy document in just the same way it may enforce or apply a legislative rule.²⁷² Especially in view of the important values served by legislative rulemaking—enrichment of the agency's information and enhancement of the rule's acceptability, flowing from the public's opportunity to present facts and views—can it credibly be argued that unilaterally issued guidances or memoranda can possess the same force? Congress in the APA has provided that they cannot.²⁷³ In one way or another, almost all of the exemplar cases cited above mention an agency's intent to bind affected parties, or a binding effect as administered, as a ground for disapproving the nonlegislative policy document.

Here are samples from the decisions citing agency *intent to bind*: "We find this evidence persuasive that the Park Service intended the Lafayette Park storage rule as an independent substantive rule."²⁷⁴ "BPA is attempting to impose the Rhoads memo upon Zimmer as a presently binding rule."²⁷⁵ "The fundamental question . . . is whether or not the Compliance Office of the Division of Compliance Programs of the FDA may properly insist upon manufacturers of plated culture media meeting an SAL [sterility assurance level, established by draft inspectional guidelines] of 0.1%. It may not do so."²⁷⁶ "Because [OSHA] possesses legislatively delegated power to make legislative rules and because it is apparent to us that [OSHA] must have intended this regulation to be an exercise of that power, we hold that the walkaround pay regulation is a legislative rule."²⁷⁷ "Moreover, the effect of the new regulation exposes the Administration's true intent. . . . Courts often infer the intent behind an action from the action's foreseeable effects."²⁷⁸ "Here, the language of the statement and related comments establishes that more is involved

271. See Anthony, *supra* note 6, at 34-40.

272. Even principles announced through adjudication, which may have the force of law at least as to the parties, see Anthony, *supra* note 6, at 47-52, should not be treated "precisely as if they were rules." Resolution of American Bar Ass'n House of Delegates (adopted Feb. 1985), reprinted in Richard K. Berg, *Re-Examining Policy Procedures: The Choice Between Rulemaking and Adjudication*, 38 ADMIN. L. REV. 149, 177 (1986).

273. 5 U.S.C. § 553 (1988).

274. *United States v. Picciotto*, 875 F.2d 345, 348 (D.C. Cir. 1989).

275. *United States v. Zimmer Paper Prods., Inc.* 20 *Env't. L. Rep. (Env't. L. Inst.)* 20,556, 20,558 (S.D. Ind. Dec. 5, 1989).

276. *United States v. Bioclinical Sys., Inc.*, 666 F. Supp. 82, 83 (D. Md. 1987).

277. *Chamber of Commerce of the United States v. OSHA*, 636 F.2d 464, 468 (D.C. Cir. 1980).

278. *Id.* at 469 & n.7.

than mere 'interpretation,' because the proposed statement has the clear intent of eliminating a former exemption and of providing the Commission with power to enforce violations of a new rule.²⁷⁹ "[O]rder No. 362 adopts a substantive rule imposing such rights and obligations."²⁸⁰ "The agency's own words strongly suggest that action levels are not musings about what the FDA might do in the future but rather that they set a precise level of aflatoxin contamination that FDA has presently deemed permissible. Action levels inform food producers what this level is; indeed, that is their very purpose."²⁸¹ An agency contention that its guidelines "are not intended to prejudice any individual application" was rejected with the observation that "there are sinews of command beneath the velvet words of the subsequent sections of the guidelines."²⁸² "In short, the essential inquiry is what the agency intends to do, for if it chooses to exercise its legislative rulemaking power, then that is what it has done."²⁸³ "[I]n this case it is clear that Brigadier General Kelly's Memorandum affected a change in Corps policy intended to have the full force and effect of a substantive rule, and that the Corps relied on the memorandum in reaching its jurisdiction determination."²⁸⁴ "When the agency states that in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself, then the agency intends to treat the order as a general statement of policy."²⁸⁵ "The district court found that [the Bellmon Amendment review program] was designed to alter ALJ decisions."²⁸⁶ "[S]ubstantial impact does not make a rule legislative, but whether a rule has a substantial impact may be relevant in construing the intent of the agency in issuing the rule. In this case, there is a great deal of evidence . . . to suggest that the Secretary fully intended this rule to have legislative effect."²⁸⁷ "This legislative and regulatory framework heavily supports the conclusion that the Secretary intended the new regulations to have the force of legislative rules."²⁸⁸ "[T]he legislative and regulatory framework suggests that the Secretary, at the time of their

279. *Jerril's Ceramic Arts v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 208 (4th Cir. 1989).

280. *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740, 744 (3d Cir. 1969).

281. *Community Nutrition Inst. v. Young*, 818 F.2d 943, 948 (D.C. Cir. 1987).

282. *American Trucking Ass'ns v. ICC*, 659 F.2d 452, 463 (5th Cir. 1981), *cert. denied*, 460 U.S. 1022 (1983).

283. *American Trucking Ass'n v. United States*, 688 F.2d 1337, 1344 (11th Cir. 1982), *rev'd*, 467 U.S. 354 (1984).

284. *Tabb Lakes, Ltd. v. United States*, 715 F. Supp. 726, 728 (E.D. Va. 1988), *aff'd without op.*, 885 F.2d 866 (4th Cir. 1989).

285. *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 39 (D.C. Cir. 1974).

286. *W.C. v. Bowen*, 807 F.2d 1502, 1505 (9th Cir. 1987).

287. *Lavesque v. Block*, 723 F.2d 175, 182-83 (1st Cir. 1983).

288. *Id.* at 183.

promulgation, intended the regulations to have legislative effect."²⁸⁹ "The perceived need for 'exemptions' reinforced our understanding that the FDA had intended the action levels to have a binding effect."²⁹⁰

Numerous other opinions, beyond those in cases cited as illustrations above, show the centrality of the agency's intent to bind. Here are a few: "[S]tatements whose language, context and application suggest an intent to bind agency discretion and private party conduct—the sort of statements requiring compliance with § 553—will have that effect if valid; interpretive rules or policy statements will not, *regardless* of their validity. A binding policy is an oxymoron."²⁹¹ "When it added the District to its exemption regulation the Commission clearly intended to exercise that authority and promulgate a rule with the full force of law."²⁹² "[T]o determine the effect of a *Manual* provision, a court must determine the Commission's intent in authoring it."²⁹³ "[I]f by its action the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule."²⁹⁴

In the following cases, drawn from those cited as illustrations above, the court's opinion identified the nonlegislative policy document's *binding effect* as an indicium that legislative rulemaking should have been used: "Our limited holding is that the current action levels are treated as substantive rules by FDA and, as such, can only be permitted if notice-and-comment procedures are employed."²⁹⁵ "Notwithstanding FDA's unsupported protestations to the contrary, it is apparent that Import Alert #66-14 binds not only the agency, but the importers as well."²⁹⁶ "More critically than EPA's language adopting the model, its later conduct applying it confirms its binding character. . . . The agency treated the model as disposing conclusively of certain issues."²⁹⁷ "The rule imposed a ceiling *ex proprio vigore*. The rule was mandatory, not advisory, and the mandate was a new one."²⁹⁸ "Although the Program Statement provides that inmates 'will be expected' to allot 50% of their earnings to

289. *Tyler v. Department of Labor*, 752 F. Supp. 32, 38 (D. Me. 1990) (citing *Leresque*, 723 F.2d at 182 (1st Cir. 1983)).

290. *Alaska v. Department of Transp.*, 868 F.2d 441, 446 (D.C. Cir. 1989) (citing *Community Nutrition Inst. v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987)).

291. *Vietnam Veterans of Am. v. Secretary of the Navy*, 843 F.2d 528, 537 (D.C. Cir. 1988).

292. *Joseph v. Civil Serv. Comm'n*, 554 F.2d 1140, 1153 (D.C. Cir. 1977).

293. *Doe v. Hampton*, 566 F.2d 265, 281 (D.C. Cir. 1977).

294. *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984), *cert. denied*, 471 U.S. 1074 (1985).

295. *Community Nutrition Inst. v. Young*, 818 F.2d 943, 949 (D.C. Cir. 1987).

296. *Bellarino Int'l Ltd. v. FDA*, 678 F. Supp. 410, 414 (E.D.N.Y. 1988).

297. *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988).

298. *Ohio Dep't of Human Servs. v. Department of Health & Human Servs.*, 862 F.2d 1228, 1234 (6th Cir. 1988).

the payment process, this 'expectation' has been given the force of law. . . . [P]rogram Statement 5380.1 has been itself interpreted by the defendants as an absolute rule."²⁹⁹ "These rules limit state discretion in this area and impose an obligation on the states not found in the statute itself."³⁰⁰ "[A]t oral argument, agency counsel stated categorically that the handbook definition is mandatory, binding Department policy, not simply a factor to guide the discretion of regional administrators."³⁰¹ "The critical question is whether the agency action jeopardizes the rights and interest of the parties, for if it does, it must be subject to public comment prior to taking effect."³⁰² "[A] legislative rule is recognizable by virtue of its binding effect."³⁰³

In their words, and yet even more in their holdings, the cases exhibit a virtual unanimity in condemning the use of nonlegislative documents (other than interpretations) that are intended to bind or that do bind in practical terms.³⁰⁴

V. THE ROLE OF AGENCY DISCRETION

As a gauge of whether an agency should have issued a policy document legislatively, the courts have made much of the discretion reserved by the agency. Certainly there is a major role for this element of the analysis. In many cases, however, it should not be determinative.

In his important *McLouth Steel* opinion, Judge Stephen Williams succinctly stated the test that he distilled from numerous D.C. Circuit opinions: "The question for purposes of § 553 is whether a statement is a rule of present binding effect; the answer depends on whether the statement constrains the agency's discretion."³⁰⁵ The point of this approach

299. *Frows v. Department of Justice*, 704 F. Supp. 272, 276 (D.D.C. 1988), *aff'd*, 938 F.2d 274 (D.C. Cir. 1991).

300. *Cabala v. Egger*, 690 F.2d 234, 239 (D.C. Cir. 1982).

301. *Comite de Apoyo para los Trabajadores Agrícolas v. Dole*, 731 F. Supp. 541, 545 (D.D.C. 1990).

302. *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980) (footnote omitted).

303. *Alaska v. Department of Transp.*, 868 F.2d 441, 445 (D.C. Cir. 1989). Despite its language rejecting the argument that an agency's action is legislative whenever it has the effect of creating new duties, *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991) is not contrary to the above cases, since the rule in question there was interpretive.

304. A possible exception is *Friedrich v. Secretary of Health & Human Servs.*, 894 F.2d 829 (6th Cir.), *cert. denied*, 111 S. Ct. 59 (1990). The court recognized the binding character of the Medicare national coverage determination ("The Secretary has chosen to seek uniformity by requiring Part B carriers to abide by all regulations in the Manual." *Id.* at 837), but treated the Secretary's determination as an interpretation of the statutory language "reasonable and necessary," which therefore "creates no new law." *Id.* Certainly, the classification as interpretive is fairly arguable either way.

305. *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320 (D.C. Cir. 1988). The discretion considered here appears to be discretion to act at variance with positions set forth in the document at issue. Perhaps distinct is the discretion as to substance connoted when the Eleventh Circuit

is that, if the agency has acted *tentatively*, and reserves discretion to reconsider and to revise or vary or rescind the policy before concretely applying it, then neither the agency nor an affected private party is bound, either as a legal matter or in a practical sense. On this basis, an agency would not err in announcing its policy through a nonlegislative document.

These conclusions must rest, however, on the assumption that, *before applying the policy concretely to a private party*, the agency either will promulgate it as a legislative rule or will hold its mind open to reconsider the policy and to accord the affected party an opportunity to challenge its wisdom.³⁰⁶

One difficulty is that this assumption is not made explicit in the cases. At bottom, however, the problem is that the assumption will be faulty in particular cases. As in many of the illustrative cases mentioned above, the agency may well have settled firmly upon its policies, with every intent of exacting conformity from those affected. The fact that the policy is announced in a nonlegislative document—and speaks of reserved discretion to act at variance with it—does not change that intent. But under the D.C. Circuit's test, this tactic furnishes the agency with a convenient chance to have things both ways: to impose a practical binding effect upon private parties, but also plausibly to argue to the courts that the informal issuance and reserved discretion prove there was no obligation to proceed legislatively. This strategy may through bureaucratic habit be pursued in the best of faith. But in reviewing the cases one cannot avoid suspecting that the agencies consider it easy to fool the courts on these points, or at least think it is worth arguing, in the face of manifest reality, that their reservation of discretion means that they have not bound the complaining members of the public.

In fact, despite any professed reservation of discretion, a nonlegislative document as a practical matter can quite readily impose binding standards or obligations upon private parties. Their discretion is constrained even if the agency's is not. A test more consistent with the spirit of the APA than one looking to the constraints on an agency's discretion

remarked that "the fact that the prospective announcement affects a discretionary function does not deprive it of its rulemaking quality." *American Trucking Ass'n v. United States*, 688 F.2d 1337, 1348 (11th Cir. 1982), *rev'd*, 467 U.S. 354 (1984).

306. "[A]n agency's open-mindedness in individual proceedings can substitute for a general rulemaking . . ." *McLouth*, 838 F.2d at 1325. The agency may say what it is *thinking of* doing. That is a policy statement. But when it *knows* what it is going to do, it must use legislative rulemaking.

Citing *McLouth*, the same Circuit in a related context spoke of a "presumption of closed-mindedness." *Air Transp. Ass'n of Am. v. Department of Transp.*, 900 F.2d 369, 380 (D.C. Cir. 1990), *judgment vacated as moot*, 111 S. Ct. 944 (1991).

would be one that considered whether the intended or actual constraints on the *private persons' discretion* (that is, upon their freedom of action) amount to binding them in a practical sense. If so, the recitation that discretion is reserved should be of no moment, and the agency's circumvention of legislative rulemaking procedures should be redressed.

These points may be illustrated by the following form of disclaimer, which the EPA prepared in the summer of 1991 for inclusion in guidance and other nonlegislative issuances:

NOTICE: The policies set out in this [document] are not final agency action, but are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this [document] or to act at variance with the guidance, based on an analysis of site-specific circumstances. The Agency also reserves the right to change this guidance at any time without public notice.³⁰⁷

It scarcely needs to be observed that this provision is wholly one-sided. The substantive elements in EPA guidance documents are often couched in specific and facially mandatory terms, by which affected private parties may reasonably believe themselves to be bound in one of the practical senses described above.³⁰⁸ The quoted EPA statement preserves great discretion for the agency. But it yields no flexibility to affected persons, nor does it afford any assurance that they will have a realistic chance to challenge the substantive policy positions set forth in the document.

The literal application of the D.C. Circuit's discretion test would sanction the use of nonlegislative procedures for a document endorsed with this disclaimer. And yet if the document is binding as a practical matter—because it is framed in mandatory terms or is regularly applied or is so structured that in context affected persons cannot disregard it—it would be quite wrong to hold that such a disclaimer excuses the failure to observe notice-and-comment requirements.

To do so in such a case would leave the private party in the worst of possible worlds: The private party is bound but the agency retains full freedom to act at variance with its stated position. The reservation of discretion affords the agency scope for unpredictable behavior, without diminishing the prospective compliance burden on the private party. Alternatively, there is little to deter the agency, despite its reservation of discretion to decide variantly, from relentlessly applying the stated positions as though they had the full force of law.

307. Interview with E. Donald Elliott, General Counsel, and Charles L. Elkins, Associate General Counsel, EPA, in Washington, D.C. (July 10, 1991).

308. See *supra* Part II.

Under the corollary to the D.C. Circuit's position—that the more discretion the agency reserves the less likely it is that the rule will be treated as legislative—the agency is rewarded for stating its rules with less precision and authority than might otherwise be required of it. Yet as a practical matter it still may be able to apply or threaten to apply the rule in a binding way. It is simply bad government to tolerate the notion that the more discretion an agency reserves for itself the more readily it can escape the obligation to promulgate its rules in the manner instructed by Congress.

Only if the agency makes it clear that it retains an open mind on the final terms of the policy should the fact that it retains discretion validate its use of nonlegislative guidance documents. If the agency mind is open, the affected party's opportunity at a later proceeding to contend for an alternative or modified policy, or for abandonment of the tentatively adopted one, is the functional equivalent of the opportunity to comment in a legislative rulemaking proceeding.

Thus, an agency may issue a statement of policy setting forth the standards it expects to apply in granting certain approvals. If the agency genuinely maintains an open mind, so that an applicant has a realistic chance to persuade it to adopt a different position when the applicant's particular case is passed upon, the original policy statement had neither the intent nor the effect of imposing mandatory constraints on the applicant. The agency therefore was not obliged to use legislative rulemaking procedures to issue it.³⁰⁹

Similarly, if an agency administering a vague statute sets forth a guidance as to the kinds of behavior it will take enforcement action against, but persons guilty of that behavior have a real opportunity when proceeded against to persuade the agency that that behavior should not be deemed culpable, then the guidance may be issued without observing legislative rulemaking procedure, as it has neither the intent nor the effect of foreclosing the private party.

309. "When the agency states that in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself, then the agency intends to treat the order [which in FPC parlance can be a rule] as a general statement of policy [within the exemption of APA § 553(b)(A)]." *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 39 (D.C. Cir. 1974).

To be treated as having an open mind, it should not be enough that the agency permits affected persons to seek waivers or exceptions from the stated position. In *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740 (3d Cir. 1969), the Commission "elected to proceed in this case by making a general rule," *id.* at 743 (footnote omitted). The court held that Texaco was "harmed by being faced with such a general rule which it must overcome in any ad hoc waiver proceeding. . . . In filing a waiver application, an operator is entitled to be confronted only with rules adopted in the procedural manner prescribed by Congress." *Id.* at 746 (footnote omitted).

But if the outcome of the later proceeding is a foregone conclusion because the earlier policy statement or guidance was to be mechanically applied, there clearly has been an intent or an effect making it binding on the private parties as a practical matter, and legislative rulemaking should have been used.³¹⁰

The announced position might be mechanically applied because the agency decisionmakers intended all along to apply it that way. But it also might be mechanically applied because staff or administrative law judges or cooperating state officials felt obliged to follow strictly the document that came from headquarters, even if the agency heads had not intended that those officials be obliged to follow it. Thus the agency would be well advised to establish a system to prevent the inadvertent closing of minds it intends be kept open. Elements of such a system for assuring that policies are tentative are proposed in Part VII of this Article.

If the agency genuinely has put its document forth on a tentative basis and with an open mind, it should willingly implement the disciplinary measures needed to assure that its intent is effectuated. But when an agency in practice does not provide realistic opportunities to challenge its purportedly tentative policies, or conceals the availability of such opportunities, or issues documents in a way that leaves ambivalence or confusion about their legal effect, its claim to exemption from the APA's rulemaking requirements is to that extent vitiated. An agency should not be suffered to come into court and plead, as agencies so often have done, that the uncertainties with which it has surrounded the document establish its tentative effect and thereby excuse the failure to obey the rulemaking commands of the APA.

VI. ADMINISTRATION OF POLICIES BY AGENCY STAFF AND BY THE STATES

Two further circumstances must be taken into account where agencies have issued nonlegislative policy documents.

A. *Administration of Nonlegislative Policy Documents by Agency Staff*

General knowledge of normal bureaucratic behavior permits us to postulate a basic general proposition about how nonlegislative guidance documents are administered by the agencies' own staffs, especially in the

310. "Had petitioner seriously attacked the reasoning of the Policy Statement, and had ERA responded merely by saying, in effect, 'That is no longer open to discussion. We resolved it in the Policy Statement,' then the agency's conduct would belie its characterization of the Policy Statement." *Panhandle Producers & Royalty Owners Ass'n v. Economic Regulatory Admin.*, 822 F.2d 1105, 1110 (D.C. Cir. 1987).

field: Staff members acting upon matters to which the guidance documents pertain will routinely and indeed automatically apply those documents, rather than considering their policy afresh before deciding whether to apply them. Staffers generally will not feel free to question the stated policies, and will not in practice do so.

Staff members, including the most conscientious, have every incentive to act in this fashion. To accept the agency guidance as conclusive is the quick and simple thing to do, and leaves staff members relatively invulnerable to criticism. By contrast, to treat the document as tentative, and therefore as subject to reconsideration upon the request of affected parties, would demand more time and effort, and would expose staff members to disapproval for departing from established positions. And treating the matter as a settled part of the operational routine is more comfortable for staff members than having to consider the policy anew each time it is to be applied.

Circumstances of course vary in our complicated government. Some nonlegislative policy documents may be framed in general language that is not capable of regularized application, and some may make it clear that the guidance is tentative only. But otherwise, I suspect that the above observations hold true in the great majority of cases. And I suspect that they hold true whether or not the agency³¹¹ intended its document to bind the staff.³¹² Indeed, although the agency may protest otherwise, it can often be quite clear that its nonlegislative document was intended to control the staff's basis for decision.³¹³ But even if the document was intended merely to guide, the tendencies mentioned are likely

311. Although judicial opinions customarily observe the polite fiction of dealing with a rule as though it had been issued by "the Secretary" or "the Administrator" or "the Commission," in reality (as shown by numerous examples in Part III above) nonlegislative documents often—and I would think usually—emanate from officials below the level of the agency heads. To announce policies nonlegislatively, those officials do not ordinarily need a delegation of authority from the agency heads, as they would if the policies were to be issued legislatively. But there is no reason to think that nonlegislative statements issued by lesser officials are applied by subordinates any less regularly than are nonlegislative issuances from the top.

312. The Administrative Conference's rulemaking manual distinguishes among documents that (by intent or effect) bind 1) lower-level staff, 2) members of the public, and 3) the agency itself, and accurately adds: "Any form of binding effect will take an agency pronouncement out of the policy statement exemption because policy statements are to have prospective and not immediate effect." OFFICE OF THE CHAIRMAN, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, A GUIDE TO FEDERAL AGENCY RULEMAKING 65 (2d ed. 1991).

313. See, e.g., *Morton v. Ruiz*, 415 U.S. 199, 233-35 (1974) (BIA); *Lee v. Kemp*, 731 F. Supp. 1101, 1113-14 (D.D.C. 1989) (HUD); *Tabb Lakes, Ltd. v. United States*, 715 F. Supp. 726, 728-29 (E.D. Va. 1988) (U.S. Army Corps of Engineers), *aff'd without op.*, 885 F.2d 866 (4th Cir. 1989); *United States v. Bioclinical Sys., Inc.*, 666 F. Supp. 82, 83-84 (D. Md. 1987) (FDA); *Fugere v. Derwinski*, 119 Daily Wash. L. Rep. 289, 294 (U.S. Ct. Veterans App. Dec. 27, 1990) (rejecting agency argument that the provision's placement in a "procedural manual for the use of field personnel" prevented it from being a "substantive rule"); Example A-10, *supra* text accompanying notes

to harden it into a rigidly applied rule, with the effect of binding private parties.³¹⁴

B. Administration of Nonlegislative Policy Documents by the States

The ways federal and state administrative actions interplay are many, and the span of fields that their interplay touches is broad. It reaches housing, social security, education, environmental protection, conservation, medicare, transfer programs like food stamps and unemployment compensation, and a myriad of others. The role played by federal guidance documents in so cluttered an arena cannot be comprehensively dealt with here.³¹⁵

136-47 (USDA inspection manuals); Example B-6, *supra* text accompanying notes 180-87 (MSHA inspection manuals).

314. The spokesman to whom I was directed by EPA stated that there are a number of circumstances in which EPA's staff permit writers may depart from guidance documents. The permit writers may not disregard the guidance, but may deem an exception appropriate where the guidance makes no sense in a given application, where its applicability is doubtful, or where the guidance is cast in flexible terms such that the permit writer must decide what a concept (like "best available control technology") means in a given application. But the permit writer cannot change basic policy, for example, by allowing use of a lesser technology in place of the "best" on a nontechnical ground such as saving jobs. Nor can the permit writer ignore a methodology mandated by a guidance, such as use of the "top-down" method for determining best available control technology. See *supra* notes 212-16 and accompanying text. Where the guidance is cast in directive language, the staff will follow it faithfully. There is, however, some flexibility in most EPA guidances. The spokesman noted that many EPA draft permits are subject to public comment, which supplies an opportunity for challenge to relevant guidances and affords a procedure functionally similar to the notice-and-comment procedure of AFA § 553. Telephone interview with Walter Mugdan, Deputy Regional Counsel, Region II, EPA (Aug. 14, 1991). Nothing in the EPA manuals for permit writers requires them to treat guidance documents as tentative or to maintain a willingness to reconsider the policies if challenged. Telephone interview with Charles L. Bikins, Associate General Counsel, EPA (Nov. 25, 1991).

The EPA's Judicial Officer, who hears appeals in the Administrator's stead, has occasionally rejected or departed from the agency's guidances. *Id.* An example is *In re Hoechst Celanese Corp.*, RCRA Appeal No. 87-13 (1989). The Judicial Officer held that the guidance documents were not mandatory and that the EPA regional office must justify its action on its own merits.

315. The most significant pattern of interaction involves federal agency insistence upon observance of the nonlegislative document as a condition of channelling money to the states, or through the states to private parties. See, e.g., *Ohio Dep't of Human Servs. v. Department of Health & Human Servs.*, 862 F.2d 1228 (6th Cir. 1988); *Cabels v. Egger*, 690 F.2d 234, 235-36 (D.C. Cir. 1982) ("Unemployment insurance in this nation is a joint federal-state responsibility. . . . The Department of Labor informs state agencies of the minimum federal requirements they must meet to remain certified primarily by issuing Unemployment Insurance Program Letters."); *Batterton v. Marshall*, 648 F.2d 694 (D.C. Cir. 1980); Food Stamp Program Policy Memo 90-6, *HUD Payments*, issued by Thomas O'Connor, Director, Program Development Division (Feb. 9, 1990); Example D-7, *supra* text accompanying notes 259-68 (guaranteed student loan program); see also *Levesque v. Block*, 723 F.2d 175 (1st Cir. 1983); *Tyler v. Department of Labor*, 752 F. Supp. 32 (D. Ma. 1990); *infra* note 366.

Fletcher v. Housing Auth. of Louisville, 491 F.2d 793 (6th Cir.), *receded sub nom.* *Department of Hous. & Urban Dev. v. Fletcher*, 419 U.S. 812 (1974), offers a sample of this interaction:

But a brief look at one document strikingly illustrates the way in which nonlegislative federal guidelines can be translated into commands to the states and then into commands by the states to private parties.

That document is a typewritten set of guidelines issued by a regional office of the Fish and Wildlife Service (FWS), which administers the Endangered Species Act.³¹⁶ The guidelines³¹⁷ aim at protecting the northern spotted owl by restricting the cutting of timber in the vicinity of its habitat.³¹⁸ This species of owl, which is found only in Washington, Oregon, and California, was listed as a "threatened species" effective July 23, 1990,³¹⁹ and the Guidelines were announced that month by FWS's regional office in Portland, Oregon.

Under the Act, a species is "endangered" when it is "in danger of extinction throughout all or a significant portion of its range,"³²⁰ and is "threatened" when it is "likely to become an endangered species within the foreseeable future."³²¹ It is unlawful to "take" any creature listed as

HUD argues that its Circular merely suggested that local housing agencies consider implementing a rent range scheme. For us to accept this argument as a reason for not reviewing HAL's [Housing Authority of Louisville's] rent range formula would be to blind ourselves to the realities of cooperative federalism in this case. The record is clear that the sole reason for HAL's implementation of HUD Circular No. 7465.12 was the desire to conform to HUD's wishes. HUD's desire may not have taken the form of a formal requirement But it took the form of a demand through HUD's controls over HAL's federal funding. . . .

....

. . . [I]t is clear that HUD's actions made Circular No. 7465.12 a matter of federal policy, not federal suggestion.

Id. at 799.

Other significant categories of federal-state interaction in which federal nonlegislative documents play a role include those where financial conditions are not central to the issue arising under the state's administration of the federal statutory program, e.g., Example B-10, *supra* text accompanying notes 205-11 (Kentucky state implementation plan under Clean Air Act), Example B-11, *supra* text accompanying notes 212-28 (state-granted permits to be invalidated by EPA if state fails to use "top-down" method of determining best available control technology); those in which federal liabilities are placed upon the state as an actor or upon the relevant state officials in their personal capacities, *see* discussion of the restrictions on harvesting of timber near habitats of northern spotted owls, *infra* text accompanying notes 316-47; and those in which the states adopt the federal guidance into their own law, *see infra* text accompanying notes 316-47.

316. Endangered Species Act of 1973, as amended, 16 U.S.C. §§ 1531-1544 (1988).

317. U.S. Fish and Wildlife Service, Region 1, Procedures Leading to Endangered Species Act Compliance for the Northern Spotted Owl (July 1990) [hereinafter Guidelines].

318. The statute provides specifically that "section 553 of title 5 (relating to rulemaking procedures), shall apply to any regulation promulgated to carry out the purposes of this [Act]," with two exceptions requiring more elaborate notice-and-comment procedures for certain actions, including the listing of a species as endangered or threatened. 16 U.S.C. § 1533(b)(4)-(6) (1988). The Guidelines were issued without observing these procedures.

319. 50 C.F.R. § 17.11 (1991).

320. 16 U.S.C. § 1532(6).

321. *Id.* § 1532(20).

an endangered species.³²² In a bold application of the authorizing statute,³²³ the Department of the Interior has provided by regulation that all prohibitions pertaining to endangered species shall apply to all threatened species.³²⁴ Thus, "taking" a threatened species like the spotted owl is subject to the same sanctions as is taking an endangered species. These include civil penalties, criminal fines and imprisonment, and federal and citizen suits for injunctive relief.³²⁵ The listing of the northern spotted owl as a threatened species immediately placed logging companies, acting in the normal course of their business on private lands, at risk of prosecution for injury to an owl or to its habitat.

The extent to which unintentional injury to a bird or disturbance of habitat amounts to a "taking" is highly unclear.³²⁶ The term "take" includes "harm,"³²⁷ which is defined by regulation to "include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering."³²⁸ In the absence of designation of a "critical habitat" pursuant to an elaborate statutory procedure,³²⁹ no other statutory or regulatory provision expressly prohibits habitat modification. Modification that results in impairment of essential behavior

322. *Id.* § 1538(a)(1)(B).

323. "The Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 1538(e)(1) of this title, in the case of fish or wildlife . . ." *Id.* § 1533(d).

324. 50 C.F.R. § 17.31 (1991). There are some exceptions which are not pertinent here. *See id.* § 17.21(e)(5).

325. 16 U.S.C. § 1540(a), (b), (c)(6), (g).

326. The Guidelines use the term "incidental take," which they describe as a "'take' (as defined by the Endangered Species Act) that occurs incidentally to otherwise lawful activities. An obvious example of incidental take would be unknowingly cutting a tree which contained an owl nest with eggs or young." Guidelines, *supra* note 317, at 2. This should be read with the regulatory definition that "[i]ncidental taking means any taking otherwise prohibited, if such taking is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity." 50 C.F.R. § 17.3 (1991). Although the statute provides for a permit to exempt taking that is "incidental to, and not the purpose of, the carrying out of an otherwise lawful activity," 16 U.S.C. § 1539(a)(1)(B), that procedure is slow and cumbersome, entailing submission of a large-area conservation plan; as a result, few such permits have been sought or granted. Here, timber operators were confronted with immediate jeopardy from the moment the spotted owl was designated as threatened. Where there is no permit, the Guidelines treat any incidental take of the owl as prohibited activity unless the restrictions on cutting within the stated areas around owl nests and activity centers have been observed. Guidelines, *supra* note 317, at 9-11. The document states that specific information about well-studied individual owls could be used to justify an exception to the guidelines, but provides no procedure for doing so. *Id.* at 10.

327. "The term 'take' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." 16 U.S.C. § 1532(19).

328. 50 C.F.R. § 17.3.

329. 16 U.S.C. § 1533(a)(3)(A). Such a designation for the northern spotted owl, which would not cover any private lands, is in the proposal stage. *See generally* U.S. Fish & Wildlife Service, Region I, News Release, *Revised Northern Spotted Owl Critical Habitat Proposal of 8.2 Million Acres Announced by Fish and Wildlife Service* (Aug. 5, 1991) [hereinafter News Release].

patterns that could lead to extinction may be treated as "harm," even if the extinction might not occur for several decades.³³⁰ Beyond that, one cannot confidently state the extent to which the prohibition of "take" may require maintenance of habitat necessary for essential behavioral patterns. The owl Guidelines bear upon this uncertain area.

The Guidelines were intended, at least in part, to advise timber operators about what they could safely do.³³¹ The document can be viewed in this aspect as a safe harbor rule.³³² But it also discloses an intent to bind affected parties by authoritatively defining the offense³³³—that is, not only to set safe harbor limits but to treat persons as in violation of the Endangered Species Act if they go beyond those limits.³³⁴ Thus, to be safe from prosecution, operators must refrain from cutting timber, around each owl nest site or activity center, in an area which may be as large as 3,960 acres.³³⁵

330. *Palla v. Hawaii Dep't of Land & Natural Resources*, 649 F. Supp. 1070 (D. Haw. 1986), *aff'd*, 852 F.2d 1106 (9th Cir. 1988).

331. Telephone interview with Russell D. Peterson, Field Supervisor, Fish and Wildlife Service Enhancement Field Office, Portland, Oregon (Aug. 8, 1991). The Guidelines state: "If a person engaged in timber harvest can demonstrate that these guidelines were followed, the Service does not intend to seek prosecution in the unlikely event that incidental take occurs in spite of implementing the guidelines." Guidelines, *supra* note 317, at 9.

332. See *supra* text accompanying note 163 (discussing possibility of employing a safe-harbor policy).

333. See *supra* text accompanying notes 161-63 (discussing possibility that the agency intends authoritatively to define the offense).

334. "The Service gives notice that any incidental take of northern spotted owls that results from activities carried out in a manner inconsistent with the guidelines (and not authorized under the provisions of Section 7 or Section 10 of the Act) will be subject to investigation by the Service pursuant to Section 9 of the Act." Guidelines, *supra* note 317, at 9.

The Guidelines at several points use language suggesting that they are tentative (e.g., "these interim guidelines," *id.*) or constitute merely guidance rather than strict rules (e.g., "The Service offers the following general guidance to address 'incidental' take of northern spotted owls that may occur incidentally to timber harvest or related activities," *id.*). Whether intended to be binding or not, the Guidelines nevertheless have had binding practical effect, in that the affected states and private operators have had to act upon the reasonable belief that the Guidelines rules must be observed. See *supra* text accompanying notes 79-88; see also *infra* notes 337-46 and accompanying text (describing the practical binding nature of a Fish and Wildlife Service August 1991 news release). The Guidelines mention that individual situations will be considered relative, not to changing their policy, but to justifying "an exception to these Guidelines." Guidelines, *supra* note 317, at 9.

335. Guidelines, *supra* note 317, at 10-11. Specifically, the rules call for 1) conducting owl surveys in accordance with FWS protocols; 2) avoiding harvest that results in less than 70 acres of "the best available suitable owl habitat" encompassing the nest site and/or activity center of a pair of spotted owls; 3) avoiding harvest that results in less than 500 acres of "suitable habitat" within a 0.7 mile radius (1,000 acres) of a nest site and/or activity center; and 4) avoiding harvest that results in less than a 40% coverage by "suitable owl habitat" within a circle centered on the nest or activity center, having a radius appropriate for its geographical "province." In Washington, the radius for the Olympic Peninsula is 2.2 miles, which amounts to 9,900 acres, 40% of which is 3,960 acres; for the Cascades, the radius is 1.8 miles, amounting to 6,600 acres, 40% of which is 2,640 acres. For

These rules have excited great controversy and bitter outcry about the loss of jobs and productive opportunities. Part of this has resulted from application of the Guidelines to logging on federal lands.³³⁶ But complaint has focused as well upon the limits the Guidelines have placed upon logging on private lands, *particularly through administration of the Guidelines limits by the states.*

The State of Washington has adopted the Guidelines standards, substantially whole, into the administration of its state forest practices laws.³³⁷ This has resulted in a state requirement that the Guidelines limits be adhered to as a condition of receiving a state permit to cut timber, even on one's own land.³³⁸ Washington has enforced the Guidelines

provinces in Oregon and California, the 40% areas protected against logging are either 1,000 or 1,360 acres in extent. *Id.*

336. With regard to the closely related action of proposing designation of a critical habitat for the spotted owl, mostly on federal lands:

[T]imber industry and labor officials immediately accused the agency of being too generous to the owl at the expense of loggers. American Forest Resources Alliance director Mark Ray said more than 130,000 workers would lose their jobs because of the government's action, which he described as a "land lockup equivalent [to the size] of Massachusetts, Vermont and Connecticut combined."

Margaret E. Kriz, *Owls I, Timber 0*, NAT'L J., May 4, 1991, at 1036, 1059 (alteration in original); see also Margaret E. Kriz, *Jobs v. Owls*, NAT'L J., Nov. 30, 1991, at 2913.

337. See Forest Practices Act, WASH. REV. CODE ANN. §§ 76.09-76.09.935 (West Supp. 1992). Harvesting on lands known to contain a pair or the nest or breeding grounds of any threatened or endangered species is classified as a "Class IV - special" forest practice, for which special application and permit requirements must be observed. WASH. ADMIN. CODE § 222-16-050(1)(b)(i) (1989).

The examples herein will be confined to Washington, but the situation is similar in California. Oregon requires no permit for the harvesting of timber as such. The requirements of the federal Guidelines, of course, apply directly to timber operators there, as they do in Washington and California where, additionally, compliance with the Guidelines' requirements is a condition of receiving state forest practices permits for harvesting timber. See CAL. PENAL CODE § 653p (West 1988) ("The violation of any federal regulations adopted pursuant to the [Endangered Species Act] shall also be deemed a violation of this section and shall be prosecuted by the appropriate state or local officials.").

338. "Based on listing of the northern spotted owl as a federal threatened species and the [Owl Guidelines] provided by the USF&WS, the DNR [Department of Natural Resources] has determined that the following actions and conditioning criteria on forest practices are necessary to prevent material damage to this public resource." Memorandum from Arden Olson, Division Manager, Forest Regulation and Assistance Division, Washington State Department of Natural Resources, to Regional Managers, *Owl Memo #2—Interim Operating Procedures for FPA Conditioning to Protect Northern Spotted Owls 1* (Aug. 27, 1990) (on file with author). For passing upon proposed forest practices activities (such as cutting trees), the document provided criteria that are very similar to, and in important respects substantially identical to, those of the Guidelines. For example:

NO HARVEST WILL BE ALLOWED WITHIN THIS CIRCLE [having a radius of 2.2 or 1.8 miles, as prescribed by the Guidelines] THAT RESULTS IN LESS THAN 40% COVERAGE BY SUITABLE OWL HABITAT: 3972 ACRES ON THE OLYMPIC PENINSULA, 2523 ACRES IN THE CASCADES. If the amount of suitable habitat within this circle is less than the indicated minimum acreage, no harvest of suitable habitat will be permitted.

Id. at 4-5. Similar provision is made for protection of 70 acres of the best habitat, and of 500 acres within a radius of 0.7 miles. *Id.* at 5.

limits by means of stop-work orders and permit denials. The following are two examples.

In December, 1990, the Department of Natural Resources ordered Wind River Logging to "STOP ALL WORK" connected with the violation described in the order, and more specifically ordered:

EFFECTIVE IMMEDIATELY CEASE ALL TIMBER FALLING ON THOSE PORTIONS OF THE APPLICATION WITHIN OWL HABITAT, AS INDICATED ON THE ATTACHED MAP. NO FUTURE TIMBER FALLING WILL BE ALLOWED UNTIL APPROPRIATE SPOTTED OWL SURVEY INFORMATION IS ANALYZED AND ACCEPTED BY THE WASHINGTON DEPARTMENT OF WILDLIFE AS PROOF OF THE ABSENCE OF NORHTHERN [sic] SPOTTED OWLS IN THIS LOCATION.³³⁹

The explanation, after paraphrasing federal definitions of "take" and "harm," stated, in terms reflecting the Guidelines: "THIS OPERATION IS WITHIN (1.8) MILES OF A KNOWN SPOTTED OWL NEST OR BREEDING PAIR AND WILL REDUCE AVAILABLE SUITABLE HABITAT BELOW THE LEVEL NECESSARY FOR THE SURVIVAL OF THE PAIR."³⁴⁰

A permit denial involved Betty F. Orem, whose timberland abutting the Olympic National Forest had been classified as a tree farm.

In May and June of 1989, while carrying out clearcutting operations in the neighboring National Forest, the Forest Service burned and otherwise damaged a number of Mrs. Orem's trees. In considering her subsequent compensation claim, the Forest Service advised Mrs. Orem that she had a duty to mitigate the damage by harvesting and selling the damaged trees for their salvage value. When she sought approval to conduct salvage operations and otherwise to maintain the value of her timber stand by routine thinning, however, Mrs. Orem's application was delayed and then substantially denied due to the presence of a

In some contrast to Owl Memo #2, a successor document, Memorandum from Art Stearns, Supervisor, Washington State Department of Natural Resources, to Regional Managers, *Owl Memo #3—Interim Policy and Procedures for Protecting the Northern Spotted Owl* (Mar. 5, 1991), contains passages that stress the independent regulatory role of the state, *id.* at 1 ("Additional spotted owl protection requirements may be established or imposed as a matter of federal law, over which the DNR has no regulatory authority."), and the flexible nature of the revised rules, *id.* ("These are guidelines only and may be adjusted on a case-by-case basis based on site-specific information and consultation . . ."). In some respects, it has recast the rules in less severely mandatory terms; for example, the provision corresponding to that quoted in the last paragraph now reads: "HARVEST WITHIN THIS CIRCLE RESULTING IN LESS THAN 40 PERCENT COVERAGE BY SUITABLE OWL HABITAT (3,972 ACRES ON THE OLYMPIC PENINSULA AND 2,523 ACRES ELSEWHERE), MAY HAVE A PROBABLE SIGNIFICANT ADVERSE IMPACT TO THE OWLS." *Id.* at 3. But it has retained the basic structure from the Guidelines. *See id.* at 3-4.

339. Forest Practices Order/Notice from the Washington State Department of Natural Resources to Wind River Logging Company (Dec. 14, 1990) (on file with author).

340. *Id.*

spotted owl in the Olympic National Forest, about half a mile from her property.³⁴¹

The FWS in August 1991 "praised the incorporation into state forest practices review processes of Federal guidelines on avoidance of 'incidental taking' of spotted owls on private lands by California and Washington."³⁴² But this action by the states can hardly be viewed as voluntary. They and their relevant employees were placed under a plain threat by the federal agency. States and their officers, employees, agents, departments and instrumentalities are "persons" within the Endangered Species Act's definition,³⁴³ and therefore fall within the Act's prohibition of "take" by "any person."³⁴⁴ Their approval of timber harvesting activities that resulted in "take" under the Guidelines could render them liable on a complicity theory:

Timber harvest on State and private lands may result in the incidental take of northern spotted owls. Because the States authorize private timber harvest, they may be *party to take* on private lands, as well as on State lands. In the absence of an incidental take permit, this take would be a violation of the ESA.³⁴⁵

To avoid liability, the states have had to assure that their review and permitting processes do not allow activities that would violate the Guidelines. In this way, the federal agency has in practical effect bound the states to follow the Guidelines. Further, it has conscripted the states as its regulatory agents, to force the nonlegislatively promulgated Guidelines upon private parties.³⁴⁶

In October 1991 the Fish and Wildlife Service rescinded the Guidelines, and stated that it "will investigate the need for a regulation."³⁴⁷

341. Complaint at 6, *Sweet Home Chapter of Communities for a Great Oregon v. Turner*, No. 91-2218 (D.D.C. filed Aug. 30, 1991).

342. News Release, *supra* note 329, at 2.

343. 16 U.S.C. § 1532(13) (1986).

344. *Id.* § 1538(a)(1).

345. Guidelines, *supra* note 317, at 13 (emphasis added).

346. As was contemporaneously reported:

Agency officials said the guidelines were always meant to be strictly voluntary, but Brian Boyle, Washington state commissioner of public lands, said Wednesday such a claim was "insane" and officials in all three states had used the guidelines to design their own owl protection plans. . . . Boyle said that even if the guidelines were meant to be voluntary or advisory, Fish and Wildlife Service officials had made it clear his office would be held legally responsible if it didn't take steps to guard against the incidental "taking" or killing of owls. "Everyone felt they had a gun to their heads," Boyle said. "Most landowners, including my office, had assumed the guidelines had the effect of law."

Les Blumcathal, *Agency Rescinds Owl Guidelines*, THE OREGONIAN, Oct. 17, 1991, at B1.

347. Memorandum from H. Dale Hall, Assistant Regional Director, U.S. Fish and Wildlife Service, Region 1, to Field Supervisors (Oct. 2, 1991). The body of this document, in its entirety, reads: "The July 1990 document titled 'Procedures Leading to Endangered Species Act Compliance for the Northern Spotted Owl,' is hereby rescinded. We will investigate the need for a regulation." *Id.*

VII. RECOMMENDATIONS

Again, our concern is with substantive agency pronouncements that fit the APA's broad definition of "rule"³⁴⁸ and that as a practical matter are binding because they either are intended to bind or are given that effect. As demonstrated,³⁴⁹ any such pronouncement (other than one that interprets specific statutory or regulatory language) must be promulgated in accordance with the procedures required by the APA for legislative rulemaking.³⁵⁰

Described above,³⁵¹ however, are numerous examples of such policy documents that were not issued legislatively but that should have been so issued because as a practical matter they were binding.³⁵²

In such cases, affected persons and the public generally will not have been accorded a regularized notice of the agencies' actions or an assured opportunity to participate in their development. Citizens or lawyers in Pocatello, or even in Washington, sometimes do not have ready access to the guidances or manuals that agencies are using to bind them. And when they do, they can be confused about the legal import of documents like these, and frustrated at their inability to escape the practical obligations or standards the documents impose. Often, in order to win a needed approval, they must accept the conditions demanded by the non-legislative rule, and thereby as a practical matter surrender the opportunity to obtain court review of the offending conditions. The agencies, for their part, might not have issued these pronouncements so freely if legislative rulemaking procedures had had to be followed.

To induce agency observance of proper rulemaking procedures, it is not efficient to rely upon judicial review, which is uncertain and spasmodic and at best a belated curative. It would seem much more productive to set forth for the agencies a clear and comprehensive statement of the precepts they should obey.

Agencies have available to them two courses of procedural action by which to banish the vexing problems described in this Article. They may issue their new policies in binding form through the use of legislative rulemaking procedures (Recommendations A, C and D below). Or they may issue them nonlegislatively, and take care to treat them as nonbinding (Recommendation B below).

348. For examples, see *supra* text accompanying notes 31-32.

349. See *supra* Parts I, II, and IV.

350. 5 U.S.C. § 553 (1988). Exceptions to the requirements of § 553 are discussed *supra* notes 50-55 and accompanying text.

351. See *supra* Part III.

352. See *supra* Part II. These pronouncements were not *legally* binding, of course, because they had not been issued through the APA's legislative rulemaking procedures.

A. Accordingly, this Article recommends that agencies adhere to section 553's legislative notice-and-comment procedures for any substantive statement of general applicability (other than an interpretive rule) that (a) is intended to establish mandatory standards or to impose obligations upon private parties, or (b) is given that effect by the agency.³⁵³ In the limited circumstances in which such rulemaking may be exempted from notice-and-comment requirements,³⁵⁴ agencies should nevertheless observe the procedures whenever it is feasible and appropriate to do so.³⁵⁵

Values served by the legislative rulemaking procedures are large ones.³⁵⁶ Fairness is furthered by giving notice to those who are to be bound, both when the proposed rule is about to be considered and when the final rule is definitively published. The accuracy and thoroughness of an agency's actions are enhanced by the requirement that it invite and consider the comments of all the world, including those of directly affected persons who are able, often uniquely, to supply pertinent information and analysis. The acceptability and therefore the effectiveness of a final rule are elevated by the openness of the procedures through which it has been deliberated and by the public's sense of useful participation in a process that affects them. Its legitimacy rests upon all of these considerations, as well as upon the foundational fact that the agency has observed the procedures laid down by Congress for establishing rules with the

353. This recommendation does not apply to interpretive rules—that is, statements that interpret language of a statute or of an existing legislative rule that has some tangible content. See *infra* text accompanying notes 364-73.

354. Substantive issuances exempted from the required procedures by 5 U.S.C. § 553(a) (1988) are those involving military or foreign affairs functions, agency management or personnel, public property, loans, benefits or contracts. To the extent agencies have voluntarily waived these exemptions, however, the procedures specified by § 553 apply mandatorily. *Linon v. Heckler*, 800 F.2d 871, 877 n.7 (9th Cir. 1986) (HHS); *Rodway v. Department of Agric.*, 514 F.2d 809 (D.C. Cir. 1975); *Lee v. Kemp*, 731 F. Supp. 1101, 1112-13 (D.D.C. 1989) (HUD). The rulemaking of particular agencies or programs may be exempted from the APA requirements by the agencies' governing statutes.

355. See Administrative Conference of the United States, Recommendation No. 69-8, Elimination of Certain Exemptions from the APA Rulemaking Requirements, 1 C.F.R. § 305.69-8 (1992); Administrative Conference of the United States, Recommendation No. 73-5, Elimination of the "Military or Foreign Affairs Function" Exemption from APA Rulemaking Requirements, 1 C.F.R. § 305.73-5 (1992); Bonfield, *supra* note 12; Arthur E. Bonfield, *Military and Foreign Affairs Function Rulemaking Under the APA*, 71 MICH. L. REV. 221 (1972). In all situations, where the use of notice-and-comment procedures would cause extraordinary difficulties for the agency, it may dispense with those procedures under the "good cause" exception. See 5 U.S.C. § 553(b)(3), (c)(3) (1988); *supra* note 12.

356. An excellent summary and discussion of the benefits and costs of notice-and-comment rulemaking procedures is presented in Asimow, *supra* note 50, at 402-09.

binding force of law. The agency's accountability for its rules is deepened by the court-made requirement of a reasoned explanation based upon a substantial rulemaking record.³⁵⁷

Beyond all of this, the APA rulemaking requirements impose a salutary discipline. That discipline deters casual and sloppy action, and thereby forestalls the confusion and needless litigation that can result from such action. And that discipline reduces tendencies toward overregulation or bureaucratic overreaching, and discourages low-profile attempts to create practically-binding norms that Congress or the Administration would not have approved.³⁵⁸

B. Even where an agency does not plan to observe these APA procedures, but instead contemplates a nonlegislative issuance, there is a way it can preserve its fulfillment of the values just discussed. Indeed, this is the fashion in which an agency must issue any policy statement³⁵⁹—that is, any substantive nonlegislative statement that does not interpret specific statutory or regulatory language.³⁶⁰ The agency must intend that the statement will be genuinely tentative, rather than binding, and assure that it will be so treated.³⁶¹

Accordingly, whenever practicable to do so, agencies should forthrightly declare in their nonlegislative policy documents that the stated policies are tentative, and that before they are applied finally to affected persons those persons will have a chance to challenge the policies (in the manner described below). Additionally, agencies should establish systems to assure that agency staff, counsel, administrative law judges, relevant state officials, and others who may apply policy statements or advise on the basis of such statements, are made aware that the policies set forth in such documents are tentative, and are subject to challenge in the manner described below, before they are applied. The agency similarly should make clear to affected private parties, by specific written advice at the time an application is made or at the commencement of enforcement or other proceedings, that the policies set forth in relevant nonlegislative documents are tentative and are subject to challenge before they are finally applied.³⁶²

357. See *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

358. See *Bethlehem Steel Corp. v. EPA*, 723 F.2d 1303, 1309 (7th Cir. 1983).

359. See *supra* Part V.

360. See *supra* Part I(C).

361. "A general statement of policy is . . . neither a rule nor a precedent but is merely an announcement to the public of the policy which the agency hopes to implement in future rulemakings or adjudications." *Batterton v. Marshall*, 648 F.2d 694, 706 (D.C. Cir. 1980) (quoting *Pacific Gas & Elec. Co. v. Federal Power Comm'n.*, 506 F.2d 33, 38 (D.C. Cir. 1974)).

362. If, as is often said, the purpose of the *Miranda* warning is as much to remind the police officer as it is to advise the suspect, so the agency staff official's duty to advise the private party

Then, before it applies a policy statement as herein defined³⁶³ to a private party in a final action, the agency should afford the affected party a fair opportunity to challenge the legality or wisdom of the statement, or to suggest that a different policy be adopted in its stead, in a forum that assures adequate presentation of the affected person's positions and consideration of those positions by agency officials possessing authority to take or recommend final action upon them. (The opportunity merely to challenge the applicability of the policy, or to request waivers or exceptions from it, would not satisfy this standard.) Those agency officials should reconsider the policy afresh, in the light of the positions so advanced by the private party, with an open mind and without allowing prior publication of the policy statement in any way to foreclose the issue.

C. By contrast, interpretive rules—those that interpret language of a statute or of an existing legislative rule that has some tangible content³⁶⁴—are required by law neither to be promulgated by notice-and-comment rulemaking processes (as are binding noninterpretive rules) nor to be issued tentatively while the agency maintains an open mind (as are policy statements).³⁶⁵ This holds true when the interpretation is issued merely to reduce uncertainty about the meaning of the statute and to afford guidance to staff and to the public. It remains true even when the agency intends, if it can, to make the interpretation bind affected private parties—that is, where the agency intends to act upon the interpretation and relentlessly to compel compliance with it up to the point that a court orders it to do otherwise.³⁶⁶ The agency has the responsibility to administer and enforce the statute, and in order to get on with that job it must

would serve as a valuable reminder of his or her own duty to treat the guidance as tentative and subject to policy challenge.

363. See *supra* text accompanying notes 63-69.

364. See *supra* text accompanying notes 58-64.

365. See *supra* note 5. The Department of Agriculture only rarely issues interpretations through notice-and-comment procedures. Interview with John Golden, Associate General Counsel, USDA, in Washington, D.C. (Aug. 9, 1991). Concern about adequate notice to affected parties is met by publication of "notices" without opportunity for comment. *Id.*

366. See, e.g., *Friedrich v. Secretary of Health & Human Servs.*, 894 F.2d 829, 837 (6th Cir.) (interpretive regulation creating no new law, that Secretary required all carriers to abide by, need not be made through § 553 procedures), *cert. denied*, 111 S. Ct. 59 (1990); *American Trucking Ass'n v. United States*, 688 F.2d 1337, 1344 (11th Cir. 1982), *rev'd*, 467 U.S. 354 (1984); see also *Gray Panthers Advocacy Comm. v. Sullivan*, 936 F.2d 1284, 1291-92 (D.C. Cir. 1991).

Though an agency intends to impose the interpretation bindingly rather than tentatively, and may do so without undergoing notice-and-comment procedures, it might not succeed in fulfilling that intention. If the interpretation is not issued legislatively, it is not binding upon courts under the doctrine of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); the reviewing court must give the agency interpretation respectful attention, but may arrive independently at its own interpretation, even if that of the agency is reasonable. Anthony, *supra* note 6, at 36-40, 35-60. "Such mandatory instructions are not binding on the courts, however, if they merely

be able to take a position as to the meaning of the statute or regulation it is interpreting.³⁶⁷ By its interpretation, the agency (at least in theory) is simply applying existing law and not creating new law.³⁶⁸ This contrasts with an agency attempt to establish binding *noninterpretive* norms, which as an act of legislation creating new law can be accomplished only through the APA's legislative rulemaking processes.³⁶⁹

It would champion the worthy precepts of the APA, however, if in certain circumstances agencies would voluntarily make use of notice-and-comment rulemaking procedures to develop interpretive rules. Implicit in the doctrine that notice-and-comment procedures are not required for interpretations is a notion that affected parties are in some sense continuously on notice of any imaginable interpretation, and that it is their business (or their counsel's) to anticipate and guard against all possibilities. But when substantial interpretive changes are afoot, the values of fair notice and public participation and agency accountability demand something better.³⁷⁰

interpret and implement the statute and do not create new law." *American Trucking Ass'n*, 688 F.2d at 1344. Thus, despite an agency's intent to bind, interpretive rules do not "foreclose alternate courses of action [by the agency] or conclusively affect rights of private parties." *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980). The staff may unconditionally apply the interpretive document within the agency, but a court may set it aside.

367. See *Chevron*, 467 U.S. at 863.

368. See *supra* cases cited in note 59.

369. 5 U.S.C. § 553 (1988). "Rules that 'affect a change in existing law or policy,' are subject to the notice and comment rulemaking requirements of section 553." *Mount Diablo Hosp. Dist. v. Bowen*, 860 F.2d 931, 936 (9th Cir. 1988) (quoting *Linoz v. Heckler*, 800 F.2d 871, 877 (9th Cir. 1986)); see also *supra* Part I(B).

370. The Administrative Conference of the United States in 1976 recommended that issuance, repeal or amendment of an interpretive rule "which is likely to have substantial impact on the public" should normally be developed through the procedures of APA § 553; if this is impracticable, unnecessary, or contrary to the public interest, the agency should so state at the time of promulgation and should ordinarily allow a post-promulgation period for public comment and reconsideration. Administrative Conference of the United States, Recommendation No. 76-3, Interpretive Rules of General Applicability and Statements of General Policy, 1 C.F.R. § 305.76-3 (1992). The consultant's report on which this recommendation was based was published as Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 520 (1977); see also Asimow, *supra* note 50 (generally reaffirming this position). The American Bar Association has adopted a resolution with substantially the same effect. American Bar Association, *Summary of Action of the House of Delegates 25* (Annual Meeting Aug. 8-9, 1989).

The proposition that interpretive rules having "substantial impact" are required by § 553 to observe notice-and-comment procedures has been repeatedly rejected in recent years. See, e.g., *Chemical Waste Management, Inc. v. EPA*, 869 F.2d 1526, 1537 (D.C. Cir. 1989); *American Postal Workers Union v. United States Postal Serv.*, 707 F.2d 548, 560 (D.C. Cir. 1983), cert. denied, 465 U.S. 1100 (1984).

Legislation adopted by Florida in 1991 subjects every "rule" (defined as "each agency statement of general applicability that implements, interprets, or prescribes law or policy," FLA. STAT. ANN. § 120.52(16) (West Supp. 1992)) to a statutory notice-and-comment rulemaking procedure, FLA. STAT. ANN. § 120.54 (West 1982 & Supp. 1992), with no exemption for interpretive rules or policy statements, FLA. STAT. ANN. § 120.535 (West Supp. 1992).

An agency should endeavor to observe notice-and-comment procedures, I believe, whenever it contemplates the adoption of an interpretation that would 1) extend the scope of the jurisdiction the agency in fact exercises;³⁷¹ 2) alter the obligations or liabilities of private parties;³⁷² or 3) modify the terms on which the agency will grant entitlements.³⁷³ Of course, the rulemaking procedures need not be considered unless the

The Administrative Conference has adopted a proposal that certain "significant" categories of rules fitting the APA's exemption for "rules of agency . . . procedure] or practice," 5 U.S.C. § 553(b)(A) (1988), be voluntarily made the subject of notice-and-comment procedures. Administrative Conference of the United States, Recommendation No. 92-1, The Procedural and Practice Rule Exemption from the APA Notice-and-Comment Rulemaking Requirements (to be codified at 1 C.F.R. § 305.92-1).

371. A proposed interpretation may reach beyond the literal terms of the statute in unexpected ways, while arguably remaining within the perimeter of the agency's statutory authority. A vivid example is offered by the memorandum, described *supra* notes 197-200 and accompanying text, by which an officer of the Corps of Engineers declared jurisdiction over millions of acres newly identified as "waters of the United States" connected to interstate commerce on the basis that they were or could be used as habitat by migratory birds. Although the court in the *Tubb Lakes* case held the memorandum was not interpretive and therefore should be set aside for failure to observe § 553 rulemaking procedures, *see supra* notes 199-200, the memorandum could be regarded as an interpretation of the pertinent regulation, as a similar statement was apparently assumed to be in the *Leslie Salt* case. *See supra* note 200. Notice-and-comment procedures are eminently sensible in such cases.

372. *See, e.g.,* Fertilizer Inst. v. EPA, 935 F.2d 1303, 1307-09 (D.C. Cir. 1991) (interpretation declaring that stockpiling of reportable quantities of a hazardous substance is a "release," and setting minimum release levels of radionuclides, was validly issued without notice-and-comment procedures even if it had effect of creating new duties).

To the extent EPA's top-down policy might have been viewed as an interpretation as to which notice-and-comment procedures were not required, *see supra* text accompanying notes 229-32, it strikingly illustrates the sort of imposition of obligations for which the use of notice-and-comment procedures is recommended by this Article.

"[A]lthough [the announcement] serves as an interpretation of existing law, it also effectively enunciates a new requirement heretofore nonexistent for compliance with the law. . . . If left undisturbed by this court, this agency action would wield a significant change in the practices which private employers must follow and in the enforcement steps the agency must take. Under these circumstances, I believe that advance notice and opportunity for public participation are vital if a semblance of democracy is to survive in this regulatory era." Chamber of Commerce of the United States v. OSHA, 636 F.2d 464, 471-72 (D.C. Cir. 1980) (Bazelon, J., concurring).

373. *See, e.g.,* American Postal Workers, 707 F.2d at 548 (changed interpretation of statutory terms reduced retirement annuities of 113,000 prospective retirees).

In 1990 the Department of Agriculture changed its interpretation of an exclusion from the Food Stamp Act's definition of "income," 7 U.S.C. § 2014(d)(11) (1988), to require that certain HUD energy assistance payments to publicly-assisted housing tenants, who pay their utilities separately, be counted as "income." Food Stamp Program Policy Memo 90-6, *supra* note 315. If the HUD payments are made directly to the tenant or to the utility provider, rather than to the landlord, the amounts are included in the tenant's income. *Id.* Because eligibility for food stamps is a function of income, 7 U.S.C. §§ 2014, 2017 (1988), the food stamp allowances of tenants directly receiving the HUD payments are reduced. *See* West v. Bowen, 879 F.2d 1122, 1129-32 (3d Cir. 1989), which rejected a substantially identical earlier position taken by USDA. USDA's Food Stamp Program Policy Memo 90-6, *supra* note 315, stated that its "policy applies in all States except those in the third circuit, i.e. Pennsylvania, Delaware, New Jersey and the Virgin Islands, where there is a court order that HUD utility payments be excluded as energy assistance payments." *Id.* at 1.

change of interpretation is a substantial one, that does not derive in an obvious way from established norms.

D. A final cluster of recommended practices springs from the rather obvious proposition that it should be the agency's responsibility to make the purport of its issuances clear and accessible.³⁷⁴ If the agency intends an issuance to be legislative and therefore to be legally binding, it should say so,³⁷⁵ in order that staff and affected persons will be definitively informed of the agency's intentions. It should also explain specifically how its issuance has gained legislative status. Ordinary citizens or even ordinary lawyers should not have to puzzle out the particulars of the agency's authority or its observance of procedural requirements.³⁷⁶ If the agency expects to apply its document in a binding way, it should be willing to declare that the rule is a legislative one, and to back up that claim with a showing of the specific authority and procedures it has observed.³⁷⁷ If these simple declarations were required, the public and the courts could know that documents issued without them were nonlegislative, and treat them accordingly.

Thus, this Article recommends that, in issuing any legislative rule, the agency publish as a part of the document promulgating the rule (a) a statement that the agency intends the rule to be a legislative rule, with the force of law; (b) a statement of the way in which specific statutory provisions confer upon the agency the authority to issue this particular rule in legislative form,³⁷⁸ and (c) a statement of the specific steps the

374. That is the thrust of the APA's publication and public inspection requirements. 5 U.S.C. § 552(a) (1988).

375. Addressing what he termed "interpretative rules with legislative effect," Professor Saunders proposed: "The agency should elect whether it wishes its interpretative rule to enjoy legislative effect. If the agency so chooses, then it must follow the procedures required of legislative rules." Kevin W. Saunders, *Interpretative Rules with Legislative Effect: An Analysis and a Proposal for Public Participation*, 1986 *Duke L.J.* 346, 373.

376. Assuming the agency has no interest in creating confusion, it can gain nothing by withholding this information, whereas disclosing it can increase the effectiveness of a rule by leading affected persons to realize that the rule has the force of law.

377. As the court observed in *Levesque v. Block*, 723 F.2d 175, 179-80 (1st Cir. 1983) (citations omitted):

Because a rule promulgated pursuant to an agency's legislative authority is entitled to greater deference by the courts than are interpretative rules or policy statements, . . . one runs greater risks in not following legislative rules. It is therefore important to inform the public at the time of promulgation that a rule is legislative

A useful parallel is found in the APA: "Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the *Federal Register* and not so published." 5 U.S.C. § 552(a)(1) (1988).

378. The APA's only mention of a rule's statutory authority requires "reference to the legal authority under which the rule is proposed" to be included in the notice of proposed rulemaking. 5 U.S.C. § 553(b)(2) (1988). Perhaps the requirement in § 553(c), that final rules incorporate "a concise general statement of their basis and purpose," could be read to require mention of statutory

agency has taken to satisfy the elements of rulemaking procedure required by 5 U.S.C. § 553 and by any other applicable statutory provisions.³⁷⁹

Agencies will protest that the procedures called for by these recommendations will prove bothersome and will place pressures upon their time and resources. No doubt this is true. Legislative rulemaking procedures can levy upon limited agency funds, people, and other resources.³⁸⁰ It must be remembered, though, that agencies exist solely to serve the public in accordance with the law. The costs of observing the law and fair procedure are bedrock obligations that cannot legitimately be slighted simply because an agency might lack adequate resources or prefer to direct them elsewhere. At worst, they are a price to be paid for lawfulness and openness and accountability in government. The procedures here recommended are in the greatest part required by the law, which should not be dishonored in the name of a false economy.³⁸¹ The balance of the recommendations—in the spirit of the APA—call for the agencies to forswear coyness and advise the public candidly of the actions they are taking. The recommended procedures will avert the imposition of needless cost and confusion upon the public, and will foster a more uniform and punctilious process of administration within the agencies.

In short, if an agency wants to bind the public, it should do it right. It should not try to do it on the cheap or on the sly. It should observe

authority at that stage. See the rules of the Administrative Committee of the *Federal Register* concerning citations of authority, 1 C.F.R. §§ 21.40-21.53 (1992). Agencies often satisfy these loose requirements by citing the entirety of a statute, or citing a section number followed by "et seq." In no place is the agency called upon to state the specific provision that authorizes a rule like the specific rule at hand to be issued legislatively.

379. The following sample statement illustrates the brevity and simplicity with which the recommendations in the text can be implemented: "This rule is published as a legislative rule and has the force of law. It is authorized to be issued in legislative form by 72 U.S.C. § 1234, which provides that 'the Commission may make such rules and regulations as are necessary to carry out the provisions of this chapter.' Elements of rulemaking procedure required by statute have been complied with in the following way: Notice of proposed rulemaking for this rule, in compliance with 5 U.S.C. § 553(b)(1)-(3), was published in the *Federal Register* on [hypothetically] July 25, 1993, 58 Fed. Reg. 34,567. The Notice invited all interested persons to submit written data, views, arguments and comments on the proposed rule, on or before November 1, 1993. The public hearing required by the Commission's enabling statute, 72 U.S.C. § 1235, was held in Hearing Room 2 in the Commission's offices at 2120 J Street, N.W., Washington, D.C. 20000, on October 1, 1993. The statement of the final rule's basis and purpose, as required by 5 U.S.C. § 553(c), is published herewith."

380. See Thomas O. McGarity, *Some Thoughts on "Deactivating" the Rulemaking Process*, 41 DUKE L.J. 1385 (1992); Michael Asimow, *California Underground Regulations*, 44 ADMIN. L. REV. 43 (1992). The "good cause" exception to notice-and-comment rulemaking procedures is available where the use of those procedures would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3), (c)(3) (1988); see *supra* note 12.

381. If the burdens of lawful rulemaking become so severe that the agency cannot act effectively, it can seek legislation empowering it to make legislative rules in a less burdensome manner.

the authorities and procedures laid down by Congress, and it should make use of some simple procedures to tell the public in a helpful way what it is doing.

APPENDIX A
RECOMMENDATION 92-2: AGENCY POLICY STATEMENTS*
ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

This recommendation addresses use of agency policy statements. Policy statements fall within the category of agency actions that are "rules" within the Administrative Procedure Act's definition because they constitute "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or describe law or policy," 5 U.S.C. § 551(4). "Rules" include (a) legislative rules, which have been promulgated through use of legislative rulemaking procedures, usually including the notice-and-comment procedures of the Administrative Procedure Act, 5 U.S.C. § 553, and (b) nonlegislative rules—that is, interpretive rules and policy statements—which fall within the above definition of "rules" but which are not required to be promulgated through use of legislative rulemaking procedures. Thus, policy statements include all substantive nonlegislative rules to the extent that they are not limited to interpreting existing law. They come with a variety of labels and include guidances, guidelines, manuals, staff instructions, opinion letters, press releases or other informal captions.

Policy statements that inform agency staff and the public regarding agency policy are beneficial to both. While they do not have the force of law (as do legislative rules) and therefore can be challenged within the agency, they nonetheless are important tools for guiding administration and enforcement of agency statutes and for advising the public of agency policy.

The Conference is concerned, however, about situations where agencies issue policy statements which they treat or which are reasonably regarded by the public as binding and dispositive of the issues they address.¹ The issuance of such binding pronouncements as policy statements does not offer the opportunity for public comment which is normally afforded during the notice-and-comment legislative rulemaking process for rules which have the force of law. Courts have frequently

* The Administrative Conference of the United States adopted Recommendation 92-2 on June 18, 1992. This text is reprinted from an advance copy of the recommendation provided to the *Duke Law Journal* by Professor Robert A. Anthony. It will be codified at 1 C.F.R. § 303.92-2. It has been edited only to conform to the *Duke Law Journal's* citation conventions.

1. There are many facets that must be assessed in determining whether a policy statement is operationally a rule that binds affected persons. In general, we apply the concept here to agency statements that are usually issued in permanent form and that are relied upon by an agency and its staff to decide policy whose basis, legality, and soundness cannot be challenged within the agency. Whether a statement is a matter of policy or interpretation, is issued in a permanent form, and is in

overruled agency reliance on policy statements as binding on affected persons.

Where the policy statement is treated by the agency as binding, it operates effectively as a legislative rule but without the notice-and-comment protection of § 553. It may be difficult or impossible for affected persons to challenge the policy statement within the agency's own decisional process; they may be foreclosed from an opportunity to contend that the policy statement is unlawful or unwise, or that an alternative policy should be adopted. Of course, affected persons could undergo the application of the policy to them, exhaust administrative remedies and then seek judicial review of agency denials or enforcement actions, at which time they may find that the policy is given deference by the courts. The practical consequence is that this process may be costly and protracted, and that affected parties have neither the opportunity to participate in the process of policy development nor a realistic opportunity to challenge the policy when applied within the agency or on judicial review. The public is therefore denied the opportunity to comment and the agency is denied the educative value of any facts and arguments the party may have tendered.

The Conference believes this outcome should be avoided, first by requiring that when an agency contemplates an announcement of substantive policy (other than through an adjudicative decision), it should decide whether to issue the policy as a legislative rule, in a form that binds affected persons, or as a nonbinding policy statement.² Second, to prevent policy statements from being treated as binding as a practical matter, the recommendation suggests that agencies establish informal and flexible procedures that allow an opportunity to challenge policy statements. Recognizing that each agency's process differs, the choice of which procedures to change in implementing this recommendation remains in the discretion of each agency. Likewise, actions taken during review of the policy statement would not necessarily be affected by such reconsideration.

fact binding (or to what extent it is binding) are often difficult questions that can only be decided in context.

2. The Conference has already urged agencies to use notice-and-comment procedures, where possible, before promulgating an interpretive rule of general applicability or statement of general policy that is likely to have substantial impact on the public. Agencies were urged to use post-promulgation notice-and-comment procedure if it is not practicable to accept and consider comments before the rule is promulgated. *See* Recommendation 76-3, "Interpretive Rules of General Applicability and Statements of General Policy," 1 C.F.R. § 305.76-3.

RECOMMENDATIONS

The following recommendations applicable to policy statements are intended to ensure that, before an agency promulgates substantive policies which bind³ affected persons, it provides appropriate notice and opportunity for comment on such policies, and makes sure that policy statements are not treated as binding.

I. *Legislative Rulemaking for Binding Policies*

A. Agencies should not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures (normally including notice-and-comment). Specifically, agencies should not attempt to bind affected persons through policy statements.

B. When an agency publishes a legislative rule (e.g., in the Federal Register and in official agency publications), the preamble to the rule should state that it is a legislative rule intended to bind affected persons. The preamble should also cite the specific statutory authority for issuing the rule in binding form as well as the steps that it has taken to comply with procedural requirements.

II. *Policy Statements*

A. *Notice of Nonbinding Nature.* Policy statements of general applicability should make clear that they are not binding. Persons affected by policy statements should be advised that such policy statements may be challenged in the manner described in part B below. Agencies should also ensure, to the extent practicable, that the nonbinding nature of policy statements is communicated to all persons who apply them or advise on the basis of them, including agency staff, counsel, administrative law judges, and relevant state officials.

B. *Procedures for Challenges to Policy Statements.* Agencies that issue policy statements should examine and, where necessary, change their formal and informal procedures, where they already exist, to allow as an additional subject requests for modification or reconsideration of

3. As the term is used here, an agency ruling is "binding" when the agency treats it as a standard where noncompliance may form an independent basis for action in matters that determine the rights and obligations of any person outside the agency. This is true whether or not the rule was promulgated in accordance with § 553. A document that was not issued pursuant to § 553, and therefore cannot be binding *legally*, may nevertheless be binding *as a practical matter* if the agency treats it as dispositive of the issue it addresses. This recommendation is concerned only with substantive, as opposed to procedural, rules. See Recommendation 92-1, "The Procedural and Practice Rule Exemption from the APA Notice-and-Comment Rulemaking Requirements" (to be codified at 1 C.F.R. § 305.92-1).

such statements. Agencies should also consider new procedures separate from the context in which the policy statement is actually applied. The procedures should not merely consist of an opportunity to challenge the applicability of the document or to request waivers or exemption from it; rather, affected persons should be afforded a fair opportunity to challenge the legality or wisdom of the document and to suggest alternative choices in an agency forum that assures adequate consideration by responsible agency officials. The opportunity should take place at or before the time the policy statement is applied to affected persons unless it is inappropriate or impracticable to do so. Agencies should not allow prior publication of the statement to foreclose full consideration of the positions being advanced. When a policy statement is subject to repeated challenges, agencies should consider instituting legislative rulemaking proceedings on the policy.

III. *Instructions to Agency Staff*

This recommendation does not preclude an agency from making a policy statement which is authoritative for staff officials in the interest of administrative uniformity or policy coherence. Indeed, agencies are encouraged to provide guidance to staff in the form of manuals and other management directives as a means to regularize employee action that directly affects the public. However, they should advise staff that while instructive to them, such policy guidance does not constitute a standard where noncompliance may form an independent basis for action in matters that determine the rights and obligations of any person outside the agency. Further, agencies are encouraged to obtain public comment on such guidance. Finally, in any case in which staff officials' adherence to such directives may affect a member of the public, care should be taken to observe the requirements of 5 U.S.C. § 552(a) which imposes a publication requirement independent of any obligation to employ notice-and-comment procedures.

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ABA ADMINISTRATIVE PROCEDURE DATABASE**SITE SPECIFIC DIGITAL TEXTS**

Recommendations of the Administrative
Conference of the United States

CODE OF FEDERAL REGULATIONS**TITLE 1--GENERAL PROVISIONS****CHAPTER III--ADMINISTRATIVE CONFERENCE OF
THE UNITED STATES****PART 305--RECOMMENDATIONS OF THE
ADMINISTRATIVE CONFERENCE OF THE UNITED
STATES****1 C.F.R. s 305.92-2**

s 305.92-2 Agency policy statements (Recommendation No. 92-2).

This recommendation addresses use of agency policy statements. Policy statements fall within the category of agency actions that are "rules" within the Administrative Procedure Act's definition because they constitute "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or describe law or policy," 5 U.S.C. 551(4). "Rules" include (a) legislative rules, which have been promulgated through use of legislative rulemaking procedures, usually including the notice-and-comment procedures of the Administrative Procedure Act, 5 U.S.C. 553, and (b) nonlegislative rules--that is, interpretive rules and policy statements--which fall within the above definition of "rules" but which are not required to be promulgated through use of legislative rulemaking procedures. Thus, policy statements include all

substantive nonlegislative rules to the extent that they are not limited to interpreting existing law. They come with a variety of labels and include guidances, guidelines, manuals, staff instructions, opinion letters, press releases or other informal captions.

Policy statements that inform agency staff and the public regarding agency policy are beneficial to both. While they do not have the force of law (as do legislative rules) and therefore can be challenged within the agency, they nonetheless are important tools for guiding administration and enforcement of agency statutes and for advising the public of agency policy.

The Conference is concerned, however, about situations where agencies issue policy statements which they treat or which are reasonably regarded by the public as binding and dispositive of the issues they address. [FN1] The issuance of such binding pronouncements as policy statements does not offer the opportunity for public comment which is normally afforded during the notice- and-comment legislative rulemaking process for rules which have the force of law. Courts have frequently overruled agency reliance on policy statements as binding on affected persons.

[FN1] There are many facets that must be assessed in determining whether a policy statement is operationally a rule that binds affected persons. In general, we apply the concept here to agency statements that are usually issued in permanent form and that are relied upon by an agency and its staff to decide policy whose basis, legality, and soundness cannot be challenged within the agency. Whether a statement is a matter of policy or interpretation, is issued in a permanent form, and is in fact binding (or to what extent it is binding) are often difficult questions that can only be decided in context.

Where the policy statement is treated by the agency as binding, it operates effectively as a legislative rule but without the notice-and-comment protection of section 553. It may be difficult or impossible for affected persons to challenge the policy statement within the agency's own decisional process; they may be foreclosed from an opportunity to contend that the policy statement is unlawful or unwise, or that an alternative policy should be adopted. Of course, affected persons could undergo the application of the policy to them, exhaust administrative remedies and then seek judicial review of agency denials or enforcement actions, at which time they may find that the policy is given deference by the courts. The practical consequence is that this process may be costly and protracted, and that affected parties have neither the opportunity to participate in the process of policy development nor a realistic opportunity to challenge the policy when applied within the agency or on judicial review. The public is therefore denied the opportunity to comment and the agency is denied the educative value of any facts and arguments the party may have tendered.

The Conference believes this outcome should be avoided, first by requiring that when an agency contemplates an announcement of substantive policy (other than through an adjudicative decision), it should decide whether to issue the policy as a legislative rule, in a form that binds affected persons, or as a nonbinding policy statement. [FN2] Second, to prevent policy statements from being treated as binding as a practical matter, the recommendation suggests that agencies establish informal and flexible procedures that allow an opportunity to challenge policy statements. Recognizing that each agency's process differs, the choice of which procedures to change in implementing this recommendation remains in the discretion of each agency. Likewise, actions taken during review of the policy statement would not necessarily be affected by such reconsideration.

[FN2] The Conference has already urged agencies to use notice-and-comment procedures, where possible, before promulgating an interpretive rule of general applicability or statement of general policy that is likely to have substantial impact on the public. Agencies were urged to use post-promulgation notice-and-comment procedure if it is not practicable to accept and consider comments before the rule is promulgated. See Recommendation 76-5, "Interpretive Rules of General Applicability and Statements of General Policy."

Recommendation

The following recommendations applicable to policy statements are intended to ensure that, before an agency promulgates substantive policies which bind [FN3] affected persons, it provides appropriate notice and opportunity for comment on such policies, and makes sure that policy statements are not treated as binding.

[FN3] As the term is used here, an agency rule is "binding" when the agency treats it as a standard where noncompliance may form an independent basis for action in matters that determine the rights and obligations of any person outside the agency. This is true whether or not the rule was promulgated in accordance with section 553. A document that was not issued pursuant to section 553, and therefore cannot be binding legally, may nevertheless be binding as a practical matter if the agency treats it as dispositive of the issue it addresses. This recommendation is concerned only with substantive, as opposed to procedural, rules. See Recommendation 92-1, "The Procedural and Practice Rule Exemption From the APA Notice-and-Comment Rulemaking Requirements."

I. Legislative Rulemaking for Binding Policies

A. Agencies should not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures (normally including notice-and-comment). Specifically, agencies should not attempt to bind affected persons through policy statements.

B. When an agency publishes a legislative rule (e.g., in the Federal Register and in official agency publications), the preamble to the rule should state that it is a legislative rule intended to bind affected persons. The preamble should also cite the specific statutory authority for issuing the rule in binding form as well as the steps that it has taken to comply with procedural requirements.

II. Policy Statements

A. Notice of nonbinding nature. Policy statements of general applicability should make clear that they are not binding. Persons affected by policy statements should be advised that such policy statements may be challenged in the manner described in part B below. Agencies should also ensure, to the extent practicable, that the nonbinding nature of policy statements is communicated to all persons who apply them or advise on the basis of them, including agency staff, counsel, administrative law judges, and relevant state officials.

B. Procedures for challenges to policy statements. Agencies that issue policy statements should examine and, where necessary, change their formal and informal procedures, where they already exist, to allow as an additional subject requests for modification or reconsideration of such statements. Agencies should also consider new procedures separate from the context in which the policy statement is actually applied. The procedures should not merely consist of an opportunity to challenge the applicability of the document or to request waivers or exemption from it; rather, affected persons should be afforded a fair opportunity to challenge the legality or wisdom of the document and to suggest alternative choices in an agency forum that assures adequate consideration by responsible agency officials. The opportunity should take place at or before the time the policy statement is applied to affected persons unless it is inappropriate or impracticable to do so. Agencies should not allow prior publication of the statement to foreclose full consideration of the positions being advanced. When a policy statement is subject to repeated challenges, agencies should consider instituting legislative rulemaking proceedings on the policy.

III. Instructions to Agency Staff

This recommendation does not preclude an agency from making a policy statement which is authoritative for staff officials in the interest of administrative uniformity or policy coherence. Indeed, agencies are encouraged to provide guidance to staff in the form of manuals and other management directives as a means to regularize employee action that directly affects the public. However, they should advise staff that while instructive to them, such policy guidance does not constitute a standard where noncompliance may form an independent basis for action in matters that determine the rights and obligations of any person outside the agency. Further, agencies are encouraged to obtain public comment on such guidance. Finally, in any case in which staff officials' adherence to such directives may affect a member of the public, care should be taken to observe the requirements of 5 U.S.C. 552(a) which imposes a publication requirement independent of any obligation to employ notice-and-comment procedures.

[57 FR 30103, July 8, 1992]

Authority: 5 U.S.C. 591-596.

SOURCE: 38 FR 19782, July 23, 1973; 57 FR 61760, 61768, Dec. 29, 1992, unless otherwise noted.

[Previous Part] [Next Part]

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ANNUAL REPORT

of the

AMERICAN BAR ASSOCIATION

Including Proceedings of the

FIFTY-EIGHTH ANNUAL MEETING

of the House of Delegates

held at

New York, New York
August 10-11, 1995

Volume 118
Number 2

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MEETING

all be subject to an audit conducted
re frequently than one every (three)

nd Regulatory Practice.⁶² William A.
ion of the Section's first recommen-
e Uniform Code of Military Justice to
United States Court of Military Ap-
that the Board of Governors had rec-
Everett of North Carolina insisted that
: much needed reform in order better
urt, which at times has been under at-
the Department of Defense, and to as-
perform its job of protecting the rights
the resolution would assure that the
als were perceived as real judges and
the Armed Services had previously
court.

igation rose in opposition to the pro-
ese judges currently serve fifteen year
that they would be subject to removal.
He argued that the recommendation
nsure that the judges appointed would
the need of the special status for this

t of Columbia rose in favor of the pro-
urisdiction over life and death and re-
independent of the Executive branch
and the possibility of removal at the
nduct. He insisted that the Congress-
streamlined and had recently proven

Virginia proposed an amendment that
spect to providing life tenure for the
of Military Appeals and would suggest
e 1 judges.

ndment out of order because it intro-
duce all Military Appeals judges are
lges are not judges of the Court of Mil-

23 Association and the Standing Com-
Forces, Admiral Jenkins argued that
or judges of the Court of Military Ap-
Supreme Court Justice Scalis, which
[judge life tenure by operation of law
dge" and reminded delegates that the
posed giving Article III status to the

ad at page 367.

HOUSE OF DELEGATES

57

In closing, Robinson O. Everett argued that in recent times there had
been some special problems and continuing difficulties because of the ab-
sence of life tenure, which have led to a number of refusals at the Court
of Military Appeals.

By a voice vote, the House declined to approve the recommendation.

Edward J. Greiner, Jr. from the District of Columbia withdrew the
Section's second recommendation⁶³ concerning the hiring of adminis-
trative law judges because a paragraph that had been left out of the res-
olution was inadvertently still discussed in the report.

William A. Murane of Colorado moved the Section's third recom-
mendation as revised.⁶⁴ He explained that the revision was made to clar-
ify that the proposal was not intended to apply to private letter rulings of
the Department of Treasury or responses to technical advice requests re-
lating to tax audits, only with the so-called non-legislative rules of ad-
ministrative agencies and departments. The recommendation was
approved by voice vote as follows:

BE IT RESOLVED, That the American Bar Association recom-
mends that:

1. Before an agency adopts a nonlegislative rule that is likely to
have significant impact on the public, the agency provide an op-
portunity for members of the public to comment on the pro-
posed rule and to recommend alternative policies or
interpretations, provided that it is practical to do so; when non-
legislative rules are adopted without prior public participation,
immediately following adoption, the agency afford the public an
opportunity for post-adoption comment and give notice of this
opportunity.
2. When an agency proposes to apply a nonlegislative rule in an
enforcement or other proceeding, it provide affected private
parties an opportunity to challenge the wisdom or legality of the
rule. The agency should not allow the fact that a rule has already
been made available to the public to foreclose consideration of
the positions advanced by the affected private parties.
3. When an agency proposes to act at variance with a policy or in-
terpretation contained in an established nonlegislative rule on
which a private party has reasonably relied:
 - a. the party have an opportunity to request relief, and
 - b. the agency explain why it is departing from its established
policy or interpretation.

Note: Section 552 of the Administrative Procedure Act states cir-
cumstances in which an agency is permitted to apply standards, inter-
pretations, or general statements of policy that adversely affect a
member of the public, even though it has not employed the notice-

Full report of the Section can be found at page 373.
Full report of the Section can be found at page 380.

and-comment procedures of 5 U.S.C. §553 in their adoption. For purposes of this recommendation, the term nonlegislative rule refers to any such document, in whatever format it may have been adopted, that comes within the requirements of section 552 to be indexed and published or made available to the public. The recommendation however, reaches only those agency documents respecting which public reliance or conformity is intended, reasonably to be expected, or derived from the conduct of agency officials and personnel; in particular, enforcement manuals setting internal priorities or procedures rather than standards for conduct by the public are not covered, whether or not they have been in fact published or otherwise made available to the public.

Informational Report of the Board of Governors.⁶⁵ Secretary Palermo presented the Informational Report of the Board of Governors on actions taken since the last meeting of the House. He moved approval of the continuation of various Association entities and of the reconstitution of the Steering Committee on Racial and Ethnic Bias as the Council on Racial and Ethnic Justice, and of the reconstitution of the Working Group on Unmet Legal Needs of Children and Their Families as a Steering Committee. The motion was approved by voice vote and the following Committees and Commissions were continued:

- | | |
|--|---|
| Advertising | Member Benefits for Disabled Lawyers |
| Biethics and the Law | Mental and Physical Disability Law |
| Central and Eastern European Law Initiative | Nonlawyer Legal Practice Opportunities for Minorities in the Profession |
| Coalition for Justice | Partnership Programs |
| College and University Nonprofessional Legal Studies | Permanent Facilities |
| Drug Crisis | Project 2000 |
| Energy Law | Public Understanding About the Law |
| Funding the Justice System | RICO Coordinating Committee |
| Homelessness and Poverty | Solo and Small Firm Practitioners |
| Immigration Law | Standards Relating to Child Abuse |
| Impaired Attorneys | Uniform Franchise and Business Opportunities Act |
| Interest on Lawyer Trust Accounts | Women in the Profession |
| International Activities | Youth Education for Citizenship |
| International Criminal Court | |
| Law and Literacy | |
| Legal Education | |
| Legal Problems of the Elderly | |
| Legal Services and the Public | |
| Medical Professional Liability | |

Standing Committee on Specialization.⁶⁶ Christel E. Marquardt of Kansas, Chair of the Committee, moved adoption of the recommendation.

⁶⁵The Informational Report of the Board of Governors can be found at page 61.
⁶⁶The full report of the Standing Committee can be found at page 269.

Secretary Palermo reported that if the late report was accepted it explained that the organizations seek rigorous procedures that were adopted that the applications for the apply the Association entities. She told the opinion that they had done everything worked and that it was done in an Leslie W. Jacobs, delegate from to defer the recommendation and a Public Contract Law, Public Utilities Law, Litigation, Intellectual supported the motion. He argued Sections needed an opportunity to institutions and the precedent that was insisted that the report identified itly set forth in the standards pre expressed concern about the imparole of the Section itself as the priority's antitrust lawyers.

W. Emmett Marston of Tennessee defer action on the recommendation had the opportunity to comment or cedures and that the states were wai to provide some leadership.
 By a standing vote of 72 to 87, t recommendation was then approve

- BE IT RESOLVED**, That the following designated special:
1. Civil Trial Advocacy pro Advocacy, Boston, MA;
 2. Criminal Trial Advocacy Trial Advocacy, Boston.
 3. Business Bankruptcy pro of America Academy of C cialists, Chicago, IL;
 4. Creditors' Rights program America Academy of Co cialists, Chicago, IL;
 5. Business Bankruptcy pro Board of Certification, W
 6. Consumer Bankruptcy pi Board of Certification, W

Section of Administrative Law a
 Brower of the District of Columb

⁶⁷The full report of the Section can be found

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REPORT NO. 4 OF THE
SECTION OF ADMINISTRATIVE LAW AND
REGULATORY PRACTICE

RECOMMENDATION*

BE IT RESOLVED, That the American Bar Association recommends that:

1. Before an agency adopts a nonlegislative rule that is likely to have significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.
2. When an agency proposes to apply a nonlegislative rule in an enforcement or other proceeding, it provide affected private parties an opportunity to challenge the wisdom or legality of the rule. The agency should not allow the fact that a rule has already been made available to the public to foreclose consideration of the positions advanced by the affected private parties.
3. When an agency proposes to act at variance with a policy or interpretation contained in an established nonlegislative rule on which a private party has reasonably relied:
 - a. the party have an opportunity to request relief, and
 - b. the agency explain why it is departing from its established policy or interpretation.

Note: Section 552 of the Administrative Procedure Act states circumstances in which an agency is permitted to apply standards, interpretations, or general statements of policy that adversely affect a member of the public, even though it has not employed the notice-and-comment procedures of 5 U.S.C. §553 in their adoption. For purposes of this recommendation, the term nonlegislative rule refers to any such document, in whatever format it may have been adopted, that comes with the requirements of section 552 to be indexed and published or made available to the public. The recommendation, however, reaches only those agency documents respecting with public reliance or conformity is intended and reasonably to be expected; in particular, enforcement manuals setting internal priorities or procedures rather than standards for conduct by the public are not covered, whether or not they have been in fact published or otherwise available to the public.
*The recommendation was revised and approved. See page 57.

ADMINISTRATIVE LA

A "rule" under the Administrative Procedure Act (APA) is "the whole or part of any agency statement general or particular applicable and future effect designed to implement, interpret, or describe law policy.¹ The APA requires notice comment rulemaking for "legislative" rules, that is, rules that legally binding on persons subject to them. But these procedures are not followed for the adoptive "interpretative rules" and "general statements of policy," or for administrative staff manuals and instructions to staff, both of which are legally binding on the public.²

An agency can require members of the public "to resort" to the nonlegislative rules, or it can resort to them in ways that "adversely affect[]" members of the public, or if the agency complies with the closure provisions of the APA.³

¹5 U.S.C. § 551(4).
²*Id.* § 553. Such rules are not legally binding on persons subject to them because they are not intended by the adopting agency to implement a grant of delegated legislative power. Because such rules are not legislative, the APA does not require their adoption be preceded by notice and comment rulemaking. Thus, it is inappropriate for an agency to use such rules to impose a practical binding effect on members of the public. Robert A. Anthony, *Interpretative Rules, Policy Statements, Guidelines, Manuals, and Like—Should Federal Agencies Use Them To Bind The Public?*, 1992 Duke L.J. 11 [cited hereinafter as "Interpretive Rules"].
³Because such rules must be made available to the public by publishing them in the *Federal Register*, or making them available by copying, see *infra* note 4 & accompanying text, Peter Strauss describes these rules "publication rules." Peter L. Strauss, *An Introduction to Administrative Justice in the United States* 157 (1989). Although the familiar term of "nonlegislative rules" used in the text, that term is intended to be coextensive with Strauss' concept.

Management and Budget (OMB).⁷ In addition, it is unlikely that a nonlegislative rule will be subject to pre-enforcement review; instead, the rule probably will be challenged only in connection with review of a denial of permission or an enforcement proceeding, if it is ever reviewed at all. If so, an agency avoids the necessity of constructing a rulemaking record at the time it adopts the rule.⁸

Nonlegislative rules have been the "bread and butter" of the administrative process for three additional reasons.⁹ Such rules are not only more easily issued and amended than legislative rules, but they permit agency personnel to fill in the details of a regulatory regime, especially the technical details, without necessarily involving top agency administrators.¹⁰ A third reason that agencies issue interpretive rules is that courts are likely to grant at least some deference to the agency's interpretation.¹¹

⁷Thomas O. McGarity, *Some Thoughts On "Deactivating" The Rulemaking Process*, 41 Duke L.J. 1385, 1441 (1992). OMB did try to plug this loophole, but its effectiveness is uncertain. *Id.* at 1442 n. 271.

⁸*Id.* at 1441.

⁹The output of nonlegislative rules dwarfs the promulgation of rules pursuant to notice and comment rulemaking. Peter L. Strauss, *The Rulemaking Continuum*, 1992 Duke L.J. 1463, 1468.

¹⁰*Id.* at 1477.

¹¹*Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Under *Skidmore*, the agency interpretation

is a substantial input and counts for something, much as legislative history may count. But the authoritative act of interpretation remains with the court. The court considers the agency view, and approves it only if it is deemed correct.

Which Agency Interpretations Should Bind, *supra* note 5, at 13.

Beneficial Purposes

Nonlegislative rules serve two beneficial purposes. First, they are a method to inform the public about agency interpretations or policies in circumstances where the agency chooses not to adopt a legislative rule. For example, because a policy statement signals the position that an agency may take in an enforcement action, it eliminates the surprise that might otherwise result if a person did not anticipate the agency's position. Second, nonlegislative rules permit an agency to issue authoritative guidance to agency employees, thereby ensuring administrative uniformity and policy coherence. Agencies rely on staff manuals, for example, as a means of regularizing employee action that directly affects the public.

Adverse Impact

Nonlegislative rules can also have the following three adverse impacts. First, such rules can be adopted without public input. A person who believes the rule to be unwise or illegal must either comply, or challenge the policy in an enforcement or application proceeding at the agency or in pre-enforcement judicial review.¹² Because of the time and expense of challenging a nonlegislative rule, however, members of the public may simply comply. Moreover, problems of ripeness and finality may prevent pre-enforcement review.¹³ In cases where review is not

¹²*National Automotive Laundry & Cleaning Council v. Schultz*, 443 F.2d 689 (D.C. Cir. 1971).

¹³Richard J. Pierce, Sidney A. Shapiro, & Paul R. Verkuil, *Administrative Law & Process* § 5.7 (1992).

sought or is unavailable, members of the public will have no opportunity to contest the rule, and they were in a position to oppose by lobbying the agency before rule was adopted, and the agency is denied the educative value their facts and arguments.¹⁴

Second, an agency may treat nonlegislative rule as binding members of the public. This can occur because of inadvertence: agency personnel erroneously assume the policy is legally binding—or strategic behavior: agency personnel treat the policy as legally binding in the hope that members of the public will acquiesce in its enforcement, thereby enabling the agency to avoid notice and comment rulemaking. Persons who challenge this behavior are protected as long as a court detects that the agency has imposed a binding obligation.¹⁵ But those who acquiesce are denied the opportunity to comment on legislative rule which is afforded them under the APA.

Finally, because members of the public rely on nonlegislative rule authoritative guidance of an agency's intentions, these persons may be adversely affected by their reliance.¹⁶ This can occur, for example, when an agency asserts in an enforcement proceeding a posi-

¹⁴*Interpretive Rules*, *supra* note 2 at 1217.

¹⁵Richard J. Pierce, Sidney Shapiro, & Paul Verkuil, *supra* note 13, §§ 5.4-5.6; *Interpretive Rules*, *supra* note 2, at 1355-59.

¹⁶Agencies warn individuals not to rely, see, e.g., *infra* note 22 & accompanying text, but such warnings are disregarded for good reasons. For example, the agency may adopt a policy statement for the express purpose of guiding the public. Moreover, there is a reasonable expectation that agency employees will follow staff instructions and manuals.

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Beneficial Purposes

Legislative rules serve two principal purposes. First, they are intended to inform the public about interpretations or policies in instances where the agency chooses not to adopt a legislative rule, because a policy it signals the position that the agency may take in an enforcement. It eliminates the surprise that might otherwise result if the agency did not anticipate the position. Second, nonlegislative rules permit an agency to provide authoritative guidance to employees, thereby ensuring administrative uniformity and coherence. Agencies rely on such rules, for example, as a means of regularizing employee conduct that directly affects the public.

Adverse Impact

Legislative rules can also have an adverse impact. First, such rules can be without public input. A person who believes the rule to be illegal must either challenge the policy in an enforcement proceeding or in pre-enforcement judicial review.¹² The time and expense of such a nonlegislative rule, and the fact that members of the public must comply. Moreover, the lack of ripeness and finality in pre-enforcement review cases where review is not

¹² *Automotive Laundry & Cleaners, Inc. v. Schultz*, 443 F.2d 689 (D.C. Cir. 1971).

¹³ Pierce, Sidney A. Shapiro, & (Eds.), *Administrative Law & Practice* (1992).

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sought or is unavailable, members of the public will have no opportunity to contest the rule, unless they were in a position to oppose it by lobbying the agency before the rule was adopted, and the agency is denied the educative value of their facts and arguments.¹⁴

Second, an agency may treat a nonlegislative rule as binding on members of the public. This can occur because of inadvertence—agency personnel erroneously assume the policy is legally binding—or strategic behavior—agency personnel treat the policy as legally binding in the hope that members of the public will acquiesce in its enforcement, thereby enabling the agency to avoid notice and comment rulemaking. Persons who challenge this behavior are protected as long as a court detects that the agency has imposed a binding obligation.¹⁵ But those who acquiesce are denied the opportunity to comment on legislative rules which is afforded them under the APA.

Finally, because members of the public rely on nonlegislative rules for authoritative guidance of an agency's intentions, these persons may be adversely affected by their reliance.¹⁶ This can occur, for example, when an agency asserts in an enforcement proceeding a posi-

tion different from that adopted in an existing nonlegislative rule on which the defendant reasonably relied. Except for the possibility of an estoppel remedy,¹⁷ an agency can disown a nonlegislative rule without prior notice because it has not been adopted by notice and comment rulemaking.¹⁸

Some agencies, such as the Food and Drug Administration (FDA),¹⁹ have addressed the problem of detrimental reliance by voluntarily committing themselves to abide by their nonlegislative rules, but in *Community Nutrition Institute (CNI) v. Young*, FDA's policy was held to be in violation of the notice and comment requirements of section 553.²⁰ CNI reasoned that notice and comment rulemaking was required because FDA's commitment to abide by its policy statements and interpretative rules

¹⁷ Whether a person will have estoppel remedy in the previous circumstance is doubtful. Although the Supreme Court has stated that an agency must follow its own regulations, *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954), this principle is limited to legislative rules. *Peter Raven-Hansen, Regulatory Estoppel: When Agencies Break Their Own Laws*, 64 *Tex. L. Rev.* 1, 15 (1983); Joshua I. Schwartz, *The Irresistible Force Meets The Immovable Object: Estoppel Remedies For An Agency's Violation of Its Own Regulations Or For Other Misconduct*, 44 *Admin. L. Rev.* 653, 676 (1992). A person's reliance on a nonlegislative rule may justify this remedy. See *Raven-Hansen, supra*, at 27-54 (description of case law); Schwartz, *supra* at 660-93 (same). Moreover, recent commentators disagree when estoppel should be available. Compare *Raven-Hansen, supra* at 73 with Schwartz, *supra*, at 744.

¹⁸ See *supra* note 2 & accompanying text; but see Struss, *supra* note 9, at 1472-73 ("question of what legal effect to give to nonlegislative rules is not settled").

¹⁹ 21 C.F.R. § 10.85(c) (1992) (advisory opinions); *id.* § 10.90(b)(2) (guidelines).

²⁰ 818 F.2d 943 (D.C. Cir. 1987).

meant that the agency had adopted a rule which is *binding on itself* whenever it promulgates a policy statement or interpretative rule. Cases like *CNA* have made agencies reluctant to commit themselves to abide by nonlegislative regulations.²¹ FDA, for example, has proposed a procedure rule that warns:

²¹*CNA* has been followed several times within the D.C. Circuit, but it has been cited only once by another federal appellate court, *New England Tank Indus. of New Hampshire v. United States*, 861 F.2d 685 (Fed. Cir. 1988) (remanding to Armed Service Bd. of Congress Appeals for determinations whether DOD funding regulation was a substantive rule or a policy statement, but noting that the regulation contained mandatory language of the type found dispositive in *CNA*). However, *Guardian Federal Savings and Loan Ass'n. v. FSLIC*, 589 F.2d 658 (D.C. Cir. 1978) held that notice and comment rulemaking is required when an agency promulgates a policy statement or interpretative rule and binds itself to follow that rule. *Guardian Federal* involved FSLIC criteria for measuring the adequacy of audits of savings and loan institutions which were challenged as substantive rules promulgated without notice and comment procedures. The court identified the critical factor as whether the regulations limited the agency's discretion, stating "If it appears that a so-called policy statement is in purpose or likely effect one that narrowly limits administrative discretion, it will be taken for what it is—a binding rule of substantive law." *Id.* at 666-67. Having said that, the court upheld the regulations as policy statements, finding that they preserved the agency's discretion. *Id.* at 666. Although this approach to defining a legislative rule has been criticized because it focuses on whether a rule is binding on an agency, rather than on whether it is binding on private parties, *Interpretive Rules*, *supra* note 2, at 1859-63, *Guardian Federal* has gained wide acceptance on this point in other circuits. See, e.g., *W.C. v. Bowes*, 807 F.2d 1502, 1505 (9th Cir. 1987) (invalidating Bellmon Review Program used by HHS Secretary because it limited agency discretion); *Ryder Truck Lines, Inc. v. United States*, 716 F.2d 1369, 1377 (11th Cir. 1983) (upholding ICC formula used to grant private carrier status as a policy statement

an advisory opinion does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. FDA may, in its discretion, recommend or initiate legal or administrative action against a person or product with respect to an action taken in conformity with an advisory opinion, provided that the legal or administrative action is consistent with applicable statutes and regulations.²²

This reluctance by agencies to abide by nonlegislative rules harms the public as Richard Thomas has perceived:

In short, under those cases following the reasoning of *CNI*[], the more unstructured, variable, and undisciplined the agency's prosecutorial approach, the more shielded an agency's prosecutorial discretion will be from public participation and, ultimately, from judicial review. But, if reg-

analogous to FSLIC regulations in *Guardian Federal*); *Burroughs Wellcome v. Schweiker*, 649 F.2d 221, 224 (4th Cir. 1981) (upholding FDA memo regarding procedure for approving new drug applications as a policy statement allowing agency to exercise discretion); *Farmland Industries Inc. v. United States*, 642 F.2d 208, 210 (7th Cir. 1981) (classifying ICC pronouncement as a policy statement); *Iowa Power and Light Co. v. Burlington Northern, Inc.*, 647 F.2d 796, 811 (8th Cir. 1981) (upholding ICC procedure for enforcement of certain rate contracts on a case-by-case basis as a policy statement); *American Trucking Associations v. ICC*, 659 F.2d 452, 463 n.41 (5th Cir. 1981) (classifying ICC guidelines for determining restriction removal applications as substantive rules, and invalidating them—not as violating the APA, but as unreasonable legislative rules under Motor Carrier Act).
²²7 Fed. Reg. 47314 (Oct. 15, 1992).

ularity of agency enforcement, centralized contragency personnel, and impact of public, agency-wide policy desired—and they are desired most citizens—then a rule essentially penalizes an agency for restricting the discretion of its own personnel would a to be counter-productive.²³

Analysis of the Recommendation

The recommendation has goals. One is to increase the opportunity for public comment on nonlegislative rules, including opportunity to challenge a nonlegislative rule at the time it is proposed to be applied. The other is to reduce the hardship that results when a person or entity is on a nonlegislative rule that the agency decides to change without prior notice.

Opportunity To Comment

Paragraph 1 recommends "[b]efore an agency adopts a legislative rule that is likely to have significant impact on the public, the agency should provide opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so" that "[w]hen nonlegislative rules are adopted without prior public participation, the agency should inform members of the public an

²³Richard M. Thomas, *Prosecutorial Discretion and Agency Self-Regulation*, *C Young and the Aflatoxin Dances*, 84 *Ac L. Rev.* 131, 153 (1992).

visory opinion does not confer any rights, privileges, or benefits for or on any person. FDA may, in its discretion, recommend or initiate administrative action against a person or product with respect to an action taken in conformity with an advisory opinion, provided that the legal effect of the administrative action is consistent with applicable statutes and regulations.²²

Reluctance by agencies to promulgate nonlegislative rules harms the public, as Richard Thomas has written:

Under these cases follow the reasoning of *CNI*, the rule is unstructured, variable, and disciplined the agency's prosecutorial approach, the more an agency's prosecutive action will be from public participation and, ultimately, judicial review. But, if reg-

ulations to FSLIC regulations in *de la Cruz*; *Burroughs Wellcome*, 649 F.2d 221, 224 (4th Cir. 1980) (FDA memo regarding approval of new drug application statement allowing agency discretion); *Farmalind Industries*, 155 F.2d 208, 210 (7th Cir. 1947) (classifying ICC pronouncement statement); *Iowa Power and Light Co. v. Federal Power Commission*, 347 U.S. 200, 204 (1954) (upholding ICC enforcement of certain rules on a case-by-case basis as a violation of the APA, but as legislative rules under Motor Vehicle Act); *Young and Rubicam*, 659 F.2d 452, 453 n.41 (5th Cir. 1981) (classifying ICC guidelines regarding restriction removal application rules, and invalidating them as violating the APA, but as legislative rules under Motor Vehicle Act).

47314 (Oct. 15, 1992).

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ularity of agency enforcement action, centralized control of agency personnel, and imposition of public, agency-wide policy are desired—and they are desired by most citizens—then a rule that essentially penalizes an agency for restricting the discretion of its own personnel would appear to be counter-productive.²³

Analysis of the Recommendation

The recommendation has two goals. One is to increase the opportunity for public comment on nonlegislative rules, including the opportunity to challenge a nonlegislative rule at the time it is proposed to be applied. The other goal is to reduce the hardship that results when a person or entity relies on a nonlegislative rule that an agency decides to change without prior notice.

Opportunity To Comment

Paragraph 1 recommends that "[b]efore an agency adopts a nonlegislative rule that is likely to have significant impact on the public, the agency should provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so" and that "[w]hen nonlegislative rules are adopted without prior public participation, the agency should afford members of the public an op-

portunity for post-adoption comment and give notice of this opportunity." The Administrative Conference²⁴ and the American Bar Association²⁵ have recommended that agencies use notice and comment rulemaking procedures for policy statements and interpretative rules. This recommendation would extend the opportunity to comment to administrative staff manuals and instructions to staff as defined in paragraph 5, which is discussed below.

Paragraph 2 recommends that "[w]hen an agency proposed to apply a nonlegislative rule in an enforcement or other proceeding, it should provide affected private parties an opportunity to challenge the wisdom or legality of the rule, either in the instant proceeding or in a separate proceeding established for that purpose" and that "[i]f the agency should not allow the fact that a rule has already been published or made available to the public to foreclose consideration of the

²²Richard M. Thomas, *Prosecutorial Discretion and Agency Self-Regulation: CNI v. Young and the Aflatoxin Dance*, 44 Admin. L. Rev. 131, 155 (1992).

²³The Administrative Conference has recommended that agencies voluntarily comply with the requirements of section 553 of the APA when issuing policy statements and interpretive rules, 5 U.S.C. § 553 (1988), except in cases where it would be impracticable, unnecessary, or contrary to the public interest. Recommendations 76-5, 1 C.F.R. § 305.76-5 (1992). The Conference recommends that when there has been no pre-promulgation notice and opportunity to comment, the public be notified of an opportunity to submit post-adoption comments. *Id.* The recommendation is based on *Public Participation*, *supra* note 6.

²⁴The AB A endorsed the ACUS recommendation, see *supra* note 24, and recommended that Congress should consider amending the APA to require the use of notice and comment rulemaking for policy statements and interpretative rules if agencies failed to utilize these procedures voluntarily. Recommendation on Nonlegislative Rulemaking, August, 1989.

positions advanced by the affected private parties." The Administrative Conference has adopted a similar recommendation for policy statements.²⁶

These procedures should have several beneficial effects. They would relieve members of the public of their "Hobson's choice" and make it possible for the agency to obtain more input from the public. In addition, the procedures address the situation where an agency treats a nonlegislative rule as binding through inadvertence or design. A person or entity could use the recommended procedures to challenge the agency's action on a procedural (as well as substantive) basis in cases where a court challenge is impracticable.

²⁶Agency Policy Statements, Recommendation 92-2, 57 Fed. Reg. 10103 (1992). Concerning policy statements, ACUS recommends:

Agencies that issue policy statements should examine and, where necessary, change their formal and informal procedures, where they already exist, to allow as an additional subject requests for modification or reconsideration of such statements. Agencies should also consider new procedures separate from the context in which the policy statement is actually applied. The procedures should not merely consist of an opportunity to challenge the applicability of the document or request waivers or exemption from it; rather, affected persons should be afforded a fair opportunity to challenge the legality or wisdom of the document or to suggest alternative choices in an agency officials. The opportunity should take place at or before the time the policy statement is applied to affected persons unless it is inappropriate or impracticable to do so.

Id. Concerning instructions to agency staff, ACUS states: "agencies are encouraged to obtain public comment on such guidance." *Id.*

The recommendation could discourage the use of nonlegislative rules by agencies because of the procedural obligations,²⁷ but since these procedural burdens are relatively minor this result should not be a serious problem. All that is asked of an agency is to obtain input from the public, and recommendation 1, which asks agencies to permit comments before a nonlegislative rule is issued, applies only in instances where the rule is likely to have a significant effect on the public, and only if a comment period prior to issuance of the rule is not impracticable. Moreover, even if an agency is burdened by obtain such input, this result must be weighed against the increased accountability that the recommendation would create. Finally, agencies should not regard these recommendations as a deadweight cost. Agencies can benefit from the procedures because they invite members of the public to inform the agency concerning the wisdom and legality of its rule.

Relief From A Policy Change

Paragraph 3a recommends that "[w]hen an agency proposes, in an enforcement proceeding or otherwise, to act at variance with a policy or interpretation contained in an established nonlegislative rule on which a private party has re-

²⁷*Nonlegislative Rules*, *supra* note 6, 404-08 (economic model of bureaucratic choice suggests that additional procedures discourages use of nonlegislative rules); *Underground Regulations*, *supra* note 6, (elaborate California procedural requirements have discouraged use of nonlegislative rules).

sonably relied, the party have an opportunity to relief." This procedure would permit an agency to correct justice attributable to dependence on unrevoked nonlegislative rules, or any other attributable to the agency in policy.

The recommendation speaks to whether a person seeking relief can obtain judicial review of an agency decision not to grant such relief. If there is judicial review of a decision not to grant relief, and if such a decision is not committed to agency discretion by law, an agency would be required to provide a rational reason for its waiver or exemption was appropriate, such as the waiver is inconsistent with the statutory enforcement obligation. The recommendation respects separation of powers considerations that limit the extent to which courts can estop an agency from

²⁸A balancing test is implicit in the approach because to determine whether an agency's failure to grant a waiver is an abuse of discretion, a court would have to weigh the extent of the detrimental effect on the agency's justifications against the agency's justifications. A waiver would be inappropriate if law and commentators' criticisms of the balancing approach. Raven-Hansen, 17, at 70; Schwartz, *supra* note 17, at 70.

The rationality of refusing to grant a waiver must be considered in light of the agency's authority, if any, to grant a waiver, the relationship between the agency's "wrong" and the rule of law to be estopped, the availability of other remedies, and adequacy of other remedies. The agency "wrong," in the context of estoppel-like relief, is the applicable policy or policies. *Id.*

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tive rules, or any other injustice
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in policy.

The recommendation does not
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ing relief can obtain judicial review
of an agency decision not to grant
such relief. If there is judicial re-
view of a decision not to grant a
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not committed to agency discretion
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priate, such as the waiver was
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statutory enforcement obligations.
The recommendation therefore re-
spects separation of powers con-
siderations that limit the extent to
which courts can estop agencies.²⁹

²⁸A balancing test is implicit in this approach because to determine whether the agency's failure to grant a waiver is an abuse of discretion, a court would compare the extent of the detrimental reliance with the agency's justifications concerning why a waiver would be inappropriate. Current law and commentaries envision such a balancing approach. Raven-Hansen, *supra* note 17, at 70; Schwartz, *supra* note 17, at 659. Professor Schwartz, for example, recom-
mends:

The rationality of refusing to grant a waiver must be considered in light of the agency's authority, if any, to grant a waiver, the relationship between the government's "wrong" and the requirements of law to be stopped, the availability and adequacy of other remedies to redress the agency "wrong," and the impact of estoppel-like relief on the applicable policy or policies.

14.

Obligation to Explain Policy Changes

Paragraph 3b recommends that
"[w]hen an agency proposes, in an
enforcement proceeding or other-
wise, to act at variance with a policy
or interpretation contained in an es-
tablished nonlegislative rule on
which a private party has reasonably
relied, the agency should explain
why it is departing from its estab-
lished policy or interpretation." The
recommendation, which addresses
the problem of detrimental reliance
on established nonlegislative rules, is
a middle ground between giving
agencies complete discretion to
abandon such nonlegislative rules
and asking agencies to bind them-
selves voluntarily to follow such
rules. By asking the agency to de-
fend its change in policy or inter-
pretation, which is an obligation it
might have anyway,³⁰ the recom-
mendation protects persons who
have reasonably relied on the estab-
lished rule from an arbitrary change
policy.³¹

²⁹*Motor Vehicle Mfgs. Assoc. v. State Farm Automobile Ins. Co.*, 463 U.S. 29 (1983).
³⁰Peter Strauss has explained the value of requiring such explanation in terms of "publication rules," which for this purpose can be regarded as coextensive with nonlegislative rules. See *Supra* note 3. Strauss notes:

One may assert in the course of agency adjudication that publication rule is inappropriate on the facts, whereas a legislative rule binds the agency adjudicator as well as a court; and an agency is not permitted to treat departure from the advice of a publication rule as an infraction—it still must take its case in terms of the statute or rule underlying the publication rule. But it does not follow that the agency or its staff are free to disregard validly adopted publication rules on which a private party may have relied absent the demonstration of its inappropriateness. The whole point of the exercise is to structure discretion, to provide

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The recommendation that courts should require an agency to explain a departure from an unrevoked non-legislative rule is not intended to alter the extent to which such rules receive judicial deference. As noted earlier, nonlegislative rules receive a weak form of judicial deference. Although an agency's decision (and justification) is taken into account, a court is expected to make an independent interpretative decision.³¹ Instead, the purpose of requiring an explanation is to require an agency to defend departures from such rules. Thus, an agency could avoid following an unrevoked nonlegislative rule by straightforwardly disapproving the prior precedent in an adjudicatory proceeding, providing it explains what it is doing and why.

a warning and context for efficient interaction between the agency and the affected public.

Strauss, *supra* note 9, at 1486.

³¹*Supra* note 11. Some analysts have urged that courts apply *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), to give actual deference to nonlegislative rules. (E.g., Russell L. Weaver, *Chevron: Martin, Anthony, and Forum Requirements*, 40 Kan. L. Rev. 587 (1992).) In *Martin v. Occupational Safety and Health Review Commission*, 111 S. Ct. 1171, 1179 (1991), however, the Court suggested that interpretations not involving lawmaking power would not qualify for *Chevron*. If a court were to grant *Chevron* deference to a nonlegislative rule, the legal effect on the public would be the same as if the agency had adopted a legislative rule. That is, in cases of statutory ambiguity, the court would be bound to accept the agency's interpretation unless it was "arbitrary, capricious, or manifestly contrary to the statute." 467 U.S. at 844. Thus, Professor Anthony warns that applying *Chevron* would therefore eliminate as a conceptual matter the distinction between legislative rules and nonlegislative rules. *Which Interpretations Should Bind*, *supra* note 5, at 40.

Although this approach offers some protection for those who reasonably rely on a nonlegislative rule, it also preserves substantial flexibility for an agency. As noted in the last paragraph, if an agency wishes to change the policy adopted in a nonlegislative rule, it can simply disapprove of the existing policy in an adjudicatory proceeding as long as it defends its departure from the nonlegislative rule. Or it can issue a new legislative rule. This second option would require the agency to meet the publication and availability requirements imposed by the APA,³² and this recommendation, but, as noted earlier, the recommended procedures should not significantly burden an agency.

Scope of the Recommendation

Paragraph 4 explains the scope of the recommendation:

Section 552 of the Administrative Procedure Act states circumstances in which an agency is permitted to apply standards, interpretations, or general statements of policy that adversely affect a member of the public, even though it has not employed the notice-and-comment procedures of 5 U.S.C. §553 in their adoption. For purposes of this recommendation, the term nonlegislative rule refers to any such document, in whatever format it may have been adopted, that comes within the requirements of section 552 to be indexed and published or made available to the public. The recommendation,

³²*See supra* note 4 & accompanying text.

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however, reaches only agency documents respect which public reliance or community is intended and reason to be expected; in particular, enforcement manuals setting national priorities or procedural standards for action by the public are not covered whether or not they have been fact published or otherwise available to the public.

The recommendation passes administrative staffs and staff instructions, as other nonlegislative rules are made public and give substantial circulation in such that affected persons have and timely notice of the documents, because these documents less than policy statements interpretive rules, can pose the harms identified earlier, conc lack of public input, agency ment of nonlegislative rule binding, and detrimental to by the public.³³ These documents are included for a practical as well. If the recommendation applied only to general statement policy and interpretations central applicability contained

³³The recommendation does not cover nonlegislative rules that do not cover the requirements of section 552 indexed and published or made available to the public for two reasons. First, it can not be required to reason to, adversely affected by, such rules, if an agency complies with Section 552 of publishing such rules or otherwise making them available to the public. 5 U.S.C. § 552(1)-(2). Second, because such rules are not published or otherwise made available to the public, there is little likelihood of adverse reliance if an agency follows such rules.

NOTES

though this approach offers protection for those who reasonably rely on a nonlegislative rule, it also preserves substantial flexibility for an agency. As noted in the last paragraph, if an agency wishes to change the policy adopted by a nonlegislative rule, it can simply disapprove of the existing rule in an adjudicatory proceeding as long as it defends its departure from the nonlegislative rule. The second option would require the agency to meet the publication and availability requirements of the APA³³ and this recommendation, but, as noted earlier, the recommended procedures do not significantly burden an agency.

Scope of the Recommendation

Paragraph 4 explains the scope of the recommendation:

Section 552 of the Administrative Procedure Act states circumstances in which an agency is permitted to apply standards, interpretations, or general statements of policy that adversely affect a member of the public, though it has not employed notice-and-comment procedures of 5 U.S.C. §553 in their formulation. For purposes of this recommendation, the term nonlegislative rule refers to any such statement in whatever format it has been adopted, that falls within the requirements of section 552 to be indexed and published or made available to the public. The recommendation,

see note 4 & accompanying text.

ADMINISTRATIVE LAW AND REGULATORY PRACTICE 389

however, reaches only those agency documents respecting which public reliance or conformity is intended and reasonably to be expected; in particular, enforcement manuals setting internal priorities or procedures rather than standards for conduct by the public are not covered, whether or not they have been in fact published or otherwise made available to the public.

The recommendation encompasses administrative staff manuals and staff instructions, as well as other nonlegislative rules if they are made public and given substantial circulation in such a way that affected persons have actual and timely notice of the documents' terms, because these documents, no less than policy statements or interpretive rules, can pose the problems identified earlier, concerning lack of public input, agency treatment of nonlegislative rules as binding, and detrimental reliance by the public.³⁴ These documents are included for a practical reason as well. If the recommendation applied only to general statements of policy and interpretations of general applicability contained in pol-

³³The recommendation does not extend to nonlegislative rules that do not come within the requirements of section 552 to be indexed and published or made available to the public for two reasons. First, a person can not be required to resort to, or be adversely affected by, such rules, unless an agency complies with Section 552 in terms of publishing such rules or otherwise making them available to the public. 5 U.S.C. §§ 552(1)-(2). Second, because such rules are not published or otherwise made available to the public, there is little likelihood of adverse reliance if an agency does not follow such rules.

icy statements and interpretive rules, agencies could avoid the impact of the recommendation by switching to staff manuals and instructions to adopt such rules.

Agencies could deter reliance by attaching a label to administrative manuals or staff instructions that warn private parties not to rely on any statements of general policy or interpretations of general applicability. This solution, however, is undesirable for three reasons. First, agencies may simply attach such a warning routinely to all staff manuals and instructions to staff. Second, this solution prevents useful interaction between the agency and the public concerning administrative manuals and staff instructions, and forestalls constraining agency discretion for purposes of fairness in cases where the private parties are affected by agency action.³⁴ Finally, there is evidence that agencies have regarded staff manuals and instructions to staff as providing binding rules on private parties.

The recommendation extends only to those agency documents respecting which public reliance or conformity is intended and reasonably to be expected. For example, enforcement manuals setting internal priorities or procedures, rather than standards for conduct by the public, are not covered, whether or not they have been in fact published or otherwise made available to the public. Where no such public reliance or conformity is intended and reasonably to be expected, this problem will not exist. The recommendation is also necessary because members of the public may reasonably rely on nonlegislative

³⁴See Peter Strausz, *supra* note 9, at 1486.

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rules as authoritative guidance of an agency's intentions. Where an agency intends a document to set internal procedures or priorities, rather than standards for conduct by the public, however, such reliance by the public is unwarranted. Finally, applying the recommendation to documents which only establish internal guidance and priorities could turn such guidelines into constraints, and thereby deter the agency from relying on this useful method of managing agency employees.

Respectfully submitted,

PETER STRAUSS
Chair
Section of Administrative
Law and Regulatory Practice

August 1993

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BE IT RESOLVED, the development of conduct for government ties that:

- (a) acknowledge the work for the gov to their tasks;
- (b) demand fidelity; petence, diligence;
- (c) seek moral resou cality, and equit;

BE IT FURTHER R gon endorses the integ government services at Government Standards and Government Ethic approach for the fram

This report is a sur "Keeping Faith: Go Ethics and Government E ulation," a report prepar Committee on Govern dards. At the end is an

*The recommendation was app The Committee on Governme the auspices of the Section of by the Board of Governors an tice, Antitrust Law, Business L lje Contract Law, Taxation, an Administration Division. © 1992 American Bar Associa

January 11, 1996

**Economic Analysis of Federal Regulations
Under Executive Order 12866**

After President Clinton signed Executive Order 12866, "Regulatory Planning and Review," the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget convened an interagency group to review the state of the art for economic analyses of regulatory actions required by the Executive Order. The group was co-chaired by a Member of the Council of Economic Advisers and included representatives of all the major regulatory agencies. This document represents the results of an exhaustive two-year effort by the group to describe "best practices" for preparing the economic analysis of a significant regulatory action called for by the Executive Order.

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**ECONOMIC ANALYSIS OF FEDERAL REGULATIONS
UNDER EXECUTIVE ORDER 12866**

INTRODUCTION

In accordance with the regulatory philosophy and principles provided in Sections 1(a) and (b) and Section 6(a)(3)(C) of Executive Order 12866, an Economic Analysis (EA) of proposed or existing regulations should inform decisionmakers of the consequences of alternative actions. In particular, the EA should provide information allowing decisionmakers to determine that:

There is adequate information indicating the need for and consequences of the proposed action;

The potential benefits to society justify the potential costs, recognizing that not all benefits and costs can be described in monetary or even in quantitative terms, unless a statute requires another regulatory approach;

The proposed action will maximize net benefits to society (including potential economic, environmental, public health and safety, and other advantages; distributional impacts; and equity), unless a statute requires another regulatory approach;

Where a statute requires a specific regulatory approach, the proposed action will be the most cost-effective, including reliance on performance objectives to the extent feasible;

Agency decisions are based on the best reasonably obtainable scientific, technical, economic, and other information.

While most EAs should include these elements, variations consistent with the spirit and intent of the Executive Order may be warranted for some regulatory actions. In particular, regulations establishing terms or conditions of Federal grants, contracts, or financial assistance may call for a different form of regulatory analysis, although a full-blown benefit-cost analysis of the entire program may be appropriate to inform Congress and the President more fully about its desirability.

The EA that the agency prepares should also satisfy the requirements of the "Unfunded Mandates Reform Act of 1995" (P.L. 104-4). Title II of this statute (Section 201) directs agencies "unless otherwise prohibited by law [to] assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector..." Section 202(a) directs agencies to provide a qualitative and quantitative assessment of the anticipated costs and benefits of a Federal mandate resulting in annual expenditures of \$100 million or more, including the costs and benefits to State, local, and tribal governments or the private sector. Section 205(a) requires that for those regulations for which an agency prepares a statement under Section 202, "the agency shall [1] identify and consider a reasonable number of regulatory alternatives and [2] from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the proposed rule." If the agency does not select "the least costly, most cost-effective, or least burdensome option, and if the requirements of Section 205(a) are not "inconsistent with law," Section 205(b) requires that the agency head publish "with the final rule an explanation of why the least costly, most cost-effective, or least burdensome method was not adopted."

The "Regulatory Flexibility Act" (P.L. 96-354) requires Federal agencies to give special consideration to the impact of regulation on small businesses. The Act specifies that a regulatory flexibility analysis must be prepared if a screening analysis indicates that a regulation will have a significant impact on a substantial number of small entities. The EA that the agency prepares should incorporate the regulatory flexibility analysis, as appropriate.

This document is not in the form of a mechanistic blueprint, for a good EA cannot be written according to a formula. Competent professional judgment is indispensable for the preparation of a high-quality analysis. Different regulations may call for very different emphases in analysis. For one proposed regulation, the crucial issue may be the question of whether a market failure exists, and much of the analysis may need to be devoted to that key question. In another case, the existence of a market failure may be obvious from the outset, but extensive analysis might be necessary to estimate the magnitude of benefits to be expected from proposed regulatory alternatives.

Analysis of the risks, benefits, and costs associated with regulation must be guided by the principles of full disclosure and transparency. Data, models, inferences, and assumptions should be identified and evaluated explicitly, together with adequate justifications of choices made, and assessments of the effects of these choices on the analysis. The existence of plausible alternative models or assumptions, and their implications, should be identified. In the absence of adequate valid data, properly identified assumptions are necessary for conducting an assessment.

Analysis of the risks, benefits, and costs associated with regulation inevitably also involves uncertainties and requires informed professional judgments. There should be balance between thoroughness of analysis and practical limits to the agency's capacity to carry out analysis. The amount of analysis (whether scientific, statistical, or economic) that a particular issue requires depends on the need for more thorough analysis because of the importance and complexity of the issue, the need for expedition, the nature of the statutory language and the extent of statutory discretion, and the sensitivity of net benefits to the choice of regulatory alternatives. In particular, a less detailed or intensive analysis of the entire range of regulatory options is needed when regulatory options are limited by statute. Even in these cases, however, agencies should provide some analysis of other regulatory options that satisfy the philosophy and principles of the Executive Order, in order to provide decisionmakers with information for judging the consequences of the statutory constraints. Whenever an agency has questions about such issues as the appropriate analytical techniques to use or the alternatives that should be considered in developing an EA under the Executive Order, it should consult with the Office of Management and Budget as early in the analysis stage as possible.

Preliminary and final Economic Analyses of economically "significant" rules (as defined in Section 3(f)(1) of the Executive Order) should contain three elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an analysis of benefits and costs. These elements are described in Sections I-III below. The same basic analytical principles apply to the review of existing regulations, as called for under Section 5 of the Executive Order. In this case, the regulation under review should be compared to a baseline case of not taking the regulatory action and to reasonable alternatives.

I. STATEMENT OF NEED FOR THE PROPOSED ACTION

In order to establish the need for the proposed action, the analysis should discuss whether the problem constitutes a significant market failure. If the problem does not constitute a market failure, the analysis should provide an alternative demonstration of compelling public need, such as improving governmental processes or addressing distributional concerns. If the proposed action is a result of a statutory or judicial directive, that should be so stated.

A. Market Failure

The analysis should determine whether there exists a market failure that is likely to be significant. In particular, the analysis should distinguish actual market failures from potential market failures that can be resolved at relatively low cost by market participants. Examples of the latter include spillover effects that affected parties can effectively internalize by negotiation, and problems resulting from information asymmetries that can be effectively resolved by the affected parties through vertical integration. Once a significant market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specified market failure.

The major types of market failure include: externality, natural monopoly, market power, and inadequate or asymmetric information.

1. **Externality.** An externality occurs when one party's actions impose uncompensated benefits or costs on another. Environmental problems are a classic case of externality. Another example is the case of common property resources that may become congested or overused, such as fisheries or the broadcast spectrum. A third example is a "public good," such as defense or basic scientific research, which is distinguished by the fact that it is inefficient, or impossible, to exclude individuals from its benefits.
2. **Natural Monopoly.** A natural monopoly exists where a market can be served at lowest cost only if production is limited to a single producer. Local gas and electricity distribution services are examples.
3. **Market Power.** Firms exercise market power when they reduce output below what a competitive industry would sell. They may exercise market power collectively or unilaterally. Government action can be a source of market power, for example if regulatory actions exclude low-cost imports, allowing domestic producers to raise price by reducing output.
4. **Inadequate or Asymmetric Information.** Market failures may also result from inadequate or asymmetric information. The appropriate level of information is not necessarily perfect or full information because information, like other goods, is costly. The market may supply less than the appropriate level of information because it is often infeasible to exclude nonpayers from reaping benefits from the provision of information by others. In markets for goods and services, inadequate information can generate a variety of social costs, including inefficiently low innovation, market power, or inefficient resource allocation resulting from deception of consumers. Markets may also fail to allocate resources efficiently when some economic actors have more information than others.

On the other hand, the market may supply a reasonably adequate level of information. Sellers have an incentive to provide informative advertising to increase sales by highlighting distinctive characteristics of their products. There are also a variety of ways in which "reputation effects" may serve to provide adequate information. Buyers may obtain reasonably adequate information about product characteristics even when the seller does not provide that information, for example, if buyer search costs are low (as when the quality of a good can be determined by inspection at point of sale), if buyers have previously used the product, if sellers offer warranties, or if adequate information is provided by third parties. In addition, insurance markets are important sources of information about risks.

Government action may have unintentional harmful effects on the efficiency of market outcomes. For this reason there should be a presumption against the need for regulatory actions that, on conceptual grounds, are not expected to generate net benefits, except in special circumstances. In light of actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;
- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services, unless they have hidden safety hazards or other defects or involve externalities and the problem cannot be adequately dealt with by voluntary standards or information disclosing the hazard to potential buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

B. Appropriateness of Alternatives to Federal Regulation

Even where a market failure exists, there may be no need for Federal regulatory intervention if other means of dealing with the market failure would resolve the problem adequately or better than the proposed Federal regulation would. These alternatives may include the judicial system, antitrust enforcement, and workers' compensation systems. Other nonregulatory alternatives could include, for example, subsidizing actions to achieve a desired outcome; such subsidies may be more efficient than rigid mandates. Similarly, a fee or charge, such as an effluent discharge fee, may be a preferable alternative to banning or restricting a product or action. Legislative measures that make use of economic incentives, such as changes in insurance provisions, should be considered where feasible. Modifications to existing

M-00-08

March 22, 2000

**“Guidelines to Standardize Measures of Costs and Benefits
and the Format of Accounting Statements”**

Introduction

These Guidelines are designed to help you, our regulatory agencies, do your job more effectively. They also will help us standardize the way we measure the benefits and costs of federal regulatory actions.

Why do we need to do Economic Analysis?

An economic analysis helps you evaluate the consequences of regulatory action. It provides a formal way of organizing the evidence on the key effects -- good and bad -- of the various alternatives you are considering in developing the regulation. This allows you to assess whether the benefits of an action are likely to outweigh the costs. Your evaluation of the consequences of alternative regulatory and non-regulatory actions helps direct resources -- those of society as a whole as well as for your agency -- toward the greatest social good.

Your economic analysis also informs others -- other parts of the Executive Branch of the Federal government, Congress, regulated entities and the public -- of the effects of your action (and assures them of its reasonableness). In order to accomplish this, you should present a “transparent” analysis. This includes:

- Identifying and evaluating reasonable alternatives to the proposed regulatory action,
- Stating the important assumptions and showing the sensitivity of the estimates to these assumptions.

What are the major parts of an Economic Analysis?

Your analysis should contain three basic elements:

- (1) a statement of the need for the proposed action,
- (2) an examination of alternative approaches, and
- (3) an analysis of the benefits and costs of identified alternatives.

SECTION I: GUIDELINES FOR THE ANALYSIS OF BENEFITS AND COSTS
OF MAJOR FINAL RULES

A. GENERAL CONSIDERATIONS

1. **Is There a Need for the Regulatory Action?** President Clinton's Executive Order 12866 states that "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." To establish a need for the proposed action, you should explain whether the problem arises because of a significant market failure or some other compelling public need. If there is a significant market failure, you should describe the nature of this failure in both qualitative and quantitative terms. Since the existence of a market failure is not sufficient to justify government intervention, you should show that government intervention to correct the 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. Such needs may include the improvement of governmental processes or distributional concerns.

If the action is a result of a statutory or judicial directive, you should state so clearly. You should also discuss the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use.

2. **What Alternatives Should I Evaluate?** You should decide on and describe the number and choice of alternatives available to you and discuss the reasons for your choice. Alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For example, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards may offer advantages over standards specifying design, behavior, or manner of compliance.

You should especially consider all appropriate alternatives for the key attributes or provisions of the rule.

What are some alternative regulatory actions I should consider?

- Informational Measures.
- Market-Based Approaches.
- Performance-Based Standards.
- Different Requirements for Different Segments of the Regulated Population.
- Alternative Levels of Stringency.

- Alternative Effective Dates of Compliance.
- Alternative Methods of Ensuring Compliance.

Can you give me more specific examples?

- **Informational Measures** - FDA requires labels showing the levels of nutrients and other ingredients that affect human health, rather than restricting these ingredients.
- **Market-Based Approaches** - EPA's "Acid Rain" program allows firms to trade permits to emit sulfur dioxide. This approach allows firms with high costs of controlling emissions to buy permits from low-cost firms, reducing the costs of the overall program while maintaining aggregate emissions reductions.
- **Performance Standards** - EPA sets automotive tailpipe emission standards in grams per mile traveled rather than requiring specific designs to achieve those ends. The National Highway Traffic Safety Administration (NHTSA) safety standards establish a permissible level of force that may act on occupants in a crash rather than setting specific mandatory vehicle designs.

Where there is a "continuum" of alternatives for a standard (for example, the level of stringency), you should generally analyze at least three options:

- the option serving as a focus for the Agency or program office regulatory initiative;
- a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and
- a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose options that are reasonable alternatives deserving careful consideration. In some cases, the regulatory program will focus on an option that is near or at the limit of technical feasibility or that fully achieves the objectives of the regulation. In these cases, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs.

In some cases, you may decide to analyze a wide array of options. Thus, DOE's 1998 rule setting new energy efficiency standards for refrigerators and freezers analyzed a large number of options and produced a rich amount of information on their relative effects. This analysis – examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers – enabled DOE to select an option that produced \$200 more in net benefits per refrigerator than the least attractive option.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine

provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

Analyzing all possible combinations of provisions in this way is impractical if their number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order No.12866, you should identify these constraints and estimate their opportunity cost.

3. How Do I Choose a Baseline? You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed regulation. The choice of a proper baseline may require consideration of a wide range of potential factors, including:

- evolution of the market,
- changes in external factors affecting benefits and costs,
- changes in regulations promulgated by the agency or other government entities, and the degree of compliance by regulated entities with other regulations.

You may often find it reasonable to forecast that the world absent the regulation will resemble the present. If you do so, however, your baseline should reflect the future effect of current programs and policies. For review of an existing regulation, a baseline assuming "no change" in the regulatory program generally provides an appropriate basis for evaluating reasonable regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in these sensitivity analyses.

EPA's 1998 final PCB disposal rule provides a good example. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA's 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in EPA's implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy -- especially allowing the disposal of automobile "shredder fluff" in municipal landfills -- reduced the cost of the program by more than \$500 million per year.

**REGULATORY PROGRAM
OF THE
UNITED STATES
GOVERNMENT**



APRIL 1, 1990 - MARCH 31, 1991

APPENDIX V

Regulatory Impact Analysis Guidance

A Regulatory Impact Analysis (RIA) should demonstrate that a proposed regulatory action satisfies the requirements of Section 2 of Executive Order No. 12291. To do so, it should show that:

- There is adequate information concerning the need for and consequences of the proposed action;
- The potential benefits to society outweigh the potential costs; and
- Of all the alternative approaches to the given regulatory objective, the proposed action will maximize net benefits to society.

The fundamental test of a satisfactory RIA is whether it enables independent reviewers to make an informed judgment that the objectives of Executive Order No. 12291 are satisfied. An RIA that includes all the elements described below is likely to fulfill this requirement. Although variations consistent with the spirit and intent of the Executive Order may be warranted for some rules, most RIAs should include these elements.

The guidance in this document is not in the form of a mechanistic blueprint, for a good RIA cannot be written according to a formula. Competent professional judgment is indispensable for the preparation of a high-quality analysis. Different regulations may call for very different emphases in analysis. For one proposed regulation, the crucial issue may be the question of whether a market failure exists, and much of the analysis may need to be devoted to that key question. In another case, the existence of a market failure may be obvious from the outset, but extensive analysis might be necessary to estimate the magnitude of benefits to be expected from proposed regulatory alternatives. The amount of analysis (whether scientific, statistical, or economic) that a particular issue requires depends on how crucial that issue is to determine the best alternative and on the complexity of the issue.

Regulatory analysis inevitably involves uncertainties and requires informed professional judgments. Whenever an agency has questions about such issues as the appropriate analytical techniques to use or the alternatives that should be considered, it should consult with the Office of Management and Budget as early in the analysis stage as possible.

This document is written primarily in terms of proposed regulatory changes. However, it is equally applicable to the review of existing regulations. In the latter case, the regulation under review should be

compared to a baseline case of no regulation and to reasonable alternatives.

Elements of a Regulatory Impact Analysis

Preliminary and final Regulatory Impact Analyses of major rules should contain five elements. They are: (1) a statement of the potential need for the proposal, (2) an examination of alternative approaches, (3) an analysis of benefits and costs, (4) the rationale for choosing the proposed regulatory action, and (5) a statement of statutory authority. These elements are explained in Sections I-V below.

I. STATEMENT OF POTENTIAL NEED FOR THE PROPOSAL

In order to establish the potential need for the proposal, the analysis should demonstrate that (a) market failure exists that is (b) not adequately resolved by measures other than Federal regulation.

A. Market Failure

The analysis should determine whether there exists a market failure that is likely to be significant. Once such market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specified market failure. ~~The three major types of market failure are externality, natural monopoly, and inadequate information.~~

1. *Externality.* An externality occurs when one party's actions impose uncompensated benefits or costs on another outside the marketplace. Environmental problems are a classic case of externality. Another example is the case of common property resources that may become congested or overused, such as fisheries or the broadcast spectrum. A third example is a "public good," such as defense or scientific research, whose distinguishing characteristic is that it is inefficient, or impossible, to exclude individuals from its benefits.

2. *Natural monopoly.* Natural monopoly exists where a market can be served at lowest cost only if production is limited to a single producer. Local telephone, gas, and electricity services are examples.

3. *Inadequate information.* The optimum, or ideal, level of information is not necessarily the maximum possible amount, because information, like other goods, should not be produced when the costs of doing so exceed the benefits. The free market does not

necessarily supply an optimal level of information, because information, once generated, can be disseminated at little or no marginal cost, and because it is commonly infeasible to exclude nonpayers from reaping benefits from the provision of information by others. Where market failure due to inadequate information is the rationale for government intervention, a regulatory action to improve the availability of information will ordinarily be the preferred alternative.

The current state of knowledge about the economics of information is not highly developed. Therefore, regulatory intervention to address an information problem should only be undertaken where there is substantial reason to believe that private incentives to provide information are seriously inadequate and that the specific regulatory intervention proposed will provide net benefits for society.

In many circumstances, the availability of information, while perhaps not optimal, is reasonably adequate, so that attempts to regulate information are as likely to make things worse as to make them better. Information about a particular characteristic of a product, for example, would be reasonably adequate if buyers could determine the existence of the characteristic by inspection of the product before purchase or (in the case of a frequently purchased product) by use of the product. Even if the characteristic could not be determined by buyers, government intervention would not be warranted where sellers have incentives to reveal the existence of the characteristic to buyers. Sellers will have substantial incentives to supply information about any characteristic that is important to buyers and valued positively by them, particularly if the level of the characteristic varies between the products of one seller and another. In these circumstances, sellers whose products rank highly in the valued characteristic can increase their sales by informing buyers of the superiority of their products. If the level of the characteristic does not vary between the products of one seller and another, individual sellers have less incentive to inform buyers about the characteristic. Even so, the incentives of individual sellers or of a trade association to supply information may be substantial.

Sellers are least likely to supply adequate information about a particular characteristic of their product where the characteristic is negatively valued by consumers and the level of the characteristic does not vary between the products of one seller and those of another (e.g., cholesterol in eggs). Even in such circumstances, substantial information about the characteristic may be available to buyers. For example, sellers of rival products may supply the information (e.g., while sellers of butter may have no incentive to

tell buyers about cholesterol in butter and its possible consequences, sellers of margarine do have such an incentive). Where the negative characteristic implies a health or safety hazard, the threat of future product liability lawsuits may give sellers adequate incentives to reveal information about the potential hazard. News media, consumer groups, public health agencies, and similar services may supply information not supplied by sellers. In summary, while it is possible to identify situations in which market failure due to inadequate information is more likely to warrant regulatory intervention, each situation must be examined on a case-by-case basis.

There should be a presumption against the use of certain types of regulatory actions, except in special circumstances. A particularly demanding burden of proof is required to demonstrate the potential benefits for any of the following types of regulations:

- Price controls in competitive markets
- Controls on production or sales in competitive markets
- Mandatory uniform quality standards for government services, unless they have hidden safety or health defects and the problem cannot be adequately dealt with by voluntary standards or information disclosing the hazard to potential buyers or users
- Controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal land, and offshore areas).

B. Alternatives to Federal Regulation

Even where a market failure exists, there may be no need for Federal regulatory intervention if other means of dealing with the market failure resolve the problem adequately or better than the proposed Federal regulation would. Among the alternative means that may be applicable are the judicial system (particularly liability cases to deal with health and safety), antitrust enforcement, and workers' compensation systems.

An important alternative that may often be relevant is regulation at the State or local level. In determining whether there exists a potential need for a proposed Federal regulation, the analysis should examine whether regulation at the Federal level is more appropriate than regulation at the State or local level. This analysis may support regulation at the Federal level where rights of national citizenship (such as legal equality among the races) or considerations of interstate commerce are involved. If interstate commerce is involved the analysis should attempt to determine whether the burdens

state commerce arising from different State and regulations are so great that they outweigh the stages of diversity and local political choice. In cases, the nature of the market failure may suggest the most appropriate governmental of regulation. For example, pollution that spills as state lines (such as acid rain whose precursors transported widely in the atmosphere) is probably controlled by Federal regulation, while localized tion (such as garbage truck noise) is probably efficiently handled by local government regula-

general, because demands among localities for rent governmental services differ and because petition among governmental units for taxpayers citizens may encourage efficient regulation, the best unit of government capable of correcting the ket failure should be chosen. This must, however, be balanced against the possibility of higher costs use national firms would be required to comply more than one set of regulations and because entering similar regulations in more than one unit involves some costs of duplication. s, some analysis may be necessary to determine ch level of government can most efficiently regu- a specific market failure.

the analysis does suggest a potential need for a eral action, it should also consider alternatives of regulatory Federal measures. For example, as an alternative to requiring an action or the use of a ticular product, it may be more efficient to subse- it. Similarly, a fee or charge may be a preferable alternative to banning or restricting a product or on. An example would be an effluent discharge which has been recommended as an efficient way limit pollution, because it causes pollution sources h different marginal costs of abatement to control ents in an efficient manner. In addition, legisla- measures that make use of economic incentives, h as changes in insurance provisions or changes in erty rights, should be considered.

AN EXAMINATION OF ALTERNATIVE APPROACHES

The RIA should show that the agency has consid- ed the most important alternative approaches to problem and must provide the agency's reasoning selecting the proposed regulatory change over h alternatives. Ordinarily, it will be possible to nate some alternatives by a preliminary analy- *lowing a manageable* number of alternatives to evaluated by quantitative benefit-cost analysis ording to the principles to be described in Section The number and choice of alternatives to be

selected for detailed benefit-cost analysis is unavoid- sibly a matter of judgment. There must be some balance between thoroughness of analysis and practical limits to the agency's capacity to carry out analysis.

Alternative regulatory actions that should be ex- plored include the following:

1. *More performance-oriented standards for health, safety, and environmental regulations.* Performance standards are generally to be preferred to engineering or design standards because they allow the regulated parties to achieve the regulatory objective in the most cost-effective way. In general, a performance standard should be preferred wherever that performance can be measured or reasonably imputed. Performance standards should also be applied as broadly as possible without creating too much variation in regulatory benefits; for example, by setting emission standards on a plant-wide or firm-wide basis rather than source by source. It is misleading and inappropriate, however, to characterize a standard as a performance standard if it is set so that there is only one feasible way to meet it; as a practical matter, such a standard is a design standard.

2. *Different requirements for different segments of the regulated population.* For example, there might be different requirements for large and small firms. If such a differentiation is made, it should be based on perceptible differences in the costs of compliance or in the benefits to be expected from compliance. For example, some worker safety measures may exhibit economies of scale, that is, lower costs per worker protected in large firms than in small firms. A heavier burden should not be placed on one segment of the regulated population on the grounds that it is better able to afford the higher cost; this is a sure formula for loading disproportionate costs on the most productive sectors of the economy.

3. *Alternative levels of stringency.* In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although costs will eventually increase more rapidly than benefits). It is important to consider alternative levels of stringency to better understand the relationship between stringency and benefits and costs. This approach will increase the information available to the decisionmaker on the option that maximizes net benefits.

4. *Alternative effective dates of compliance.* The timing of a regulation may also have an important effect on its net benefits. For example, costs of a regulation may vary substantially over different compliance dates for an industry that requires a year or more to plan its production runs efficiently. In this instance, a regulation whose requirements provide

sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

5. *Alternative methods of ensuring compliance.* Compliance alternatives include the appropriate entity (local, State, or Federal) enforcing compliance, whether compliance is enforced by on-site inspection or periodic reporting, and structuring compliance penalties so that they provide the most appropriate incentives.

6. *Informational measures.* Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be made mandatory or left voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hot-lines, or public interest broadcast announcements). If intervention is necessary to address a market failure arising from inadequate information, informational remedies will generally be the preferred approaches. As an alternative to a mandatory standard, a regulatory measure to improve the availability of information has the advantage of being a more market-oriented approach. Thus, providing consumers information about concealed characteristics of consumer products gives consumers a greater choice than banning these products (for example, consumers are likely to benefit more from information on energy efficiency than from a prohibition on sale of appliances or automobiles falling below a specified standard of energy efficiency).

Except for prohibiting indisputably false statements (whose banning can be presumed beneficial), specific informational measures must be evaluated in terms of their benefits and costs. Paradoxically, the current state of knowledge does not generally permit the benefits and costs of informational remedies to be measured very accurately. Nonetheless, it is essential to consider carefully the costs and benefits of alternative informational measures, even if they cannot be quantified very precisely. Some effects of informational measures can easily be overlooked. For example, the costs of a mandatory disclosure requirement for a consumer product include not only the obvious cost of gathering and communicating the required information, but also the loss of any net benefits of information displaced by the mandated information, the cost of any inaccurate consumer interpretation of the mandated information, and any inefficiencies arising from the incentive that mandatory disclosure of a particular characteristic gives to producers to overinvest in improving that specific characteristic of their products.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, as will often be the case, the least intrusive alternative, sufficient to accomplish the regulatory objective, should be chosen. For example, it will often be sufficient for government to establish a standardized testing and rating system without mandating its use, because firms that score well according to the system will have ample incentive to publicize the fact.

7. *More market-oriented approaches.* In general, alternatives that provide for more market-oriented approaches, with the use of economic incentives replacing command-and-control requirements, should be explored. Market-oriented alternatives that may be considered include fees, subsidies, penalties, marketable rights or offsets, changes in liabilities or property rights, and required bonds, insurance or warranties (in many instances, implementing these alternatives will require legislation).

III. ANALYSIS OF BENEFITS AND COSTS

A. General Principles

The preliminary analysis called for by Sections I and II should have narrowed the number of alternatives to be considered by quantitative benefit-cost analysis to a workable number. Ordinarily, one of the alternatives will be to promulgate no regulation at all, and this alternative will commonly serve as the base from which increments in benefits and costs are calculated for the other alternatives. Even if alternatives such as no regulation are not permissible statutorily, it is often desirable to evaluate the benefits and costs of such alternatives to determine if statutory change would be desirable. Departments and agencies bear a similar burden when they perform environmental impact statements in which alternatives that lie outside their statutory authority must be considered.

In some cases, the desirability of specific alternatives outside the scope of the agency's regulatory authority may be determined by use of basic economic concepts in light of the principles enumerated in Section I. In other instances, however, only a quantitative benefit-cost analysis can resolve the question, and such alternatives will need to be included in the analysis of this section. In addition, alternative forms of agency regulation will need to be evaluated by quantitative benefit-cost analysis.

1. *Evaluation of Alternatives.* Except where prohibited by law, the primary criterion for choice among alternatives is expected net benefit (benefits minus costs). Other criteria may sometimes produce equivalent results, but they must be used with care to avoid

Circular A-4

September 17, 2003

TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS**Subject: Regulatory Analysis**

This Circular provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order 12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This Circular refines OMB's "best practices" document of 1996 (<http://www.whitehouse.gov/omb/info/reg/riaguide.html>), which was issued as a guidance in 2000 (<http://www.whitehouse.gov/omb/memoranda/m00-08.pdf>), and reaffirmed in 2001 (<http://www.whitehouse.gov/omb/memoranda/m01-23.html>). It replaces both the 1996 "best practices" and the 2000 guidance.

In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review. Peer reviewers included Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; and W. Kip Viscusi, Harvard Law School. Although these individuals submitted comments, OMB is solely responsible for the final content of this Circular.

A. Introduction

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis – called either "regulatory analysis" or "analysis" for brevity – and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

The Need for Analysis of Proposed Regulatory Actions¹

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects –

¹ We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

B. The Need for Federal Regulatory Action

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. If the regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use. Executive Order 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material

failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people ..."

Executive Order 12866 also states that "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." Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy. If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively. You should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values.

Market Failure or Other Social Purpose

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality, common property resource and public good

An externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. If bargaining were costless and all property rights were well defined, people would eliminate externalities through bargaining without the need for government regulation.³ From this perspective, externalities arise from high transactions costs and/or poorly defined property rights that prevent people from reaching efficient outcomes through market transactions.

Resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent common property resources. "Public goods," such as defense or basic scientific research, are goods where provision of the good to some individuals cannot occur without providing the same level of benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices. They may exercise market power collectively or unilaterally. Government action can be a source of market power, such as when regulatory actions exclude low-cost imports. Generally, regulations that increase market power

³ See Coase RH (1960), *Journal of Law and Economics*, 3, 1-44.

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for selected entities should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer – local gas and electricity distribution services, for example – a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and/or production decisions. Nevertheless, you should keep in mind that technological advances often affect economies of scale. This can, in turn, transform what was once considered a natural monopoly into a market where competition can flourish.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. Because information, like other goods, is costly to produce and disseminate, your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information. Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, such as a seller offering a warranty or a third party providing information.

Even when adequate information is available, people can make mistakes by processing it poorly. Poor information-processing often occurs in cases of low probability, high-consequence events, but it is not limited to such situations. For instance, people sometimes rely on mental rules-of-thumb that produce errors. If they have a clear mental image of an incident which makes it cognitively “available,” they might overstate the probability that it will occur. Individuals sometimes process information in a biased manner, by being too optimistic or pessimistic, without taking sufficient account of the fact that the outcome is exceedingly unlikely to occur. When mistakes in information processing occur, markets may overreact. When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met. However, the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In addition, Congress establishes some regulatory programs to redistribute resources to select groups. Such regulations should be examined to ensure that they are both effective and cost-effective. Congress also authorizes some regulations to combat discrimination that conflicts with generally accepted norms within our society. Rulemaking may also be appropriate to protect privacy, permit more personal freedom or promote other democratic aspirations.

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ARTICLE

"INTERPRETIVE" RULES, "LEGISLATIVE" RULES AND "SPURIOUS" RULES: LIFTING THE SMOG

ROBERT A. ANTHONY*

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Federal regulations and other agency rules¹ ordinarily must be promulgated in accordance with the public notice-and-comment procedures specified by the Administrative Procedure Act ("APA").² The APA,

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The author acknowledges with gratitude the support of the Sarah Scaife Foundation and the John M. Olin Foundation. The author was consulted at the petition for rehearing stage by counsel for the private parties in *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993), discussed herein. The views of the author do not necessarily represent the views of any of these persons or organizations.

1. The Administrative Procedure Act defines a "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . ." 5 U.S.C. § 551(4) (1988).

2. 5 U.S.C. § 553 (1988). This Article is concerned with rules that are substantive in nature—that is, those affecting private rights, duties, and obligations—rather than with rules dealing with procedural, remedial, or other adjective subjects. See BLACK'S LAW DICTIONARY 1429 (6th ed. 1990) (defining "substantive"). Thus, excluded from consideration are "rules of agency organization, procedure or practice," which, under the APA, are exempt from the provision requiring public notice-and-

however, provides an exemption from those procedures for "interpretative" rules,³ and it is to that exemption that this Article directs its primary attention.

Courts often are called upon to determine whether an agency rulemaking document qualifies for this exemption, and, if it does not, whether it is invalid as a result of the agency's failure to observe notice-and-comment requirements.

In the title of this Article, the word "interpretive" is set off in quotation marks because it is commonly used in place of the APA's "interpretative."⁴ The word "legislative" is placed in quotation marks for quite a different reason: The term "legislative rules," which does not appear in the APA, is widely used in two contradictory senses.

That contradictory usage is a main source of the utterly needless but seemingly ineradicable confusion that has grown up around the subject at hand. Properly, "legislative rules" are those that have been promulgated pursuant to statutory law-making authority and in accordance with the statutory procedures for making rules that carry the force of law.⁵ When contrasting interpretive rules with other rules, however, courts

comment procedures. 5 U.S.C. § 553(b)(A) (1988).

3. 5 U.S.C. § 553(b)(A) (1988).

4. This conforms to the usage of the Administrative Conference of the United States in its Recommendation 76-5, 1 C.F.R. § 305.76-5 (1993) and Recommendation 92-2, 1 C.F.R. § 305.92.2 (1993). See also Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 520, 522 n.6 (1977) [hereinafter Asimow, *Public Participation*] (stating preference for "interpretive" for stylistic reasons).

5. Legislative rules are typified by agency regulations that are published in proposed form in the Federal Register and, after adoption, published in the Code of Federal Regulations. There are a number of requirements for a rule to be a legislative rule carrying the force of law. See *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-03, 315 (1979) (stating that, to have force of law, rule must be promulgated pursuant to congressionally granted quasi-legislative authority and in accordance with procedural requirements imposed by Congress); 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, 1322-23 (1992) [hereinafter Anthony, *Interpretive Rules, Policy Statements*] (enumerating six requirements for valid legislative rule). Chief among these are the APA's requirements for the observance of public notice-and-comment procedures. *Id.*

Sometimes particular statutes require more extensive procedures. *E.g.*, 15 U.S.C. § 57a (1988) (Federal Trade Commission rules pertaining to unfair and deceptive acts and practice in commerce); 20 U.S.C. § 1232 (1988) (Department of Education rules of general applicability). On the other hand, in some circumstances even notice-and-comment procedures are not required. See *infra* note 20 (describing exceptions provided in APA).

often use the term "legislative rules" in another sense: as a shorthand to denote documents that *are not* in fact legislative rules as just defined—and therefore are *nonlegislative rules*—but that *should have been* promulgated as legislative rules because the agency treated them as binding.⁶ It is this category of documents to which the courts almost invariably are referring when they speak of distinguishing "legislative" from interpretive rules.

The correct distinction, central to this Article, lies entirely within the realm of nonlegislative rules. This distinction differentiates interpretive rules from rules that *should have been* promulgated legislatively.⁷ An understanding of this distinction will contribute to ensuring that day-to-day governmental power is exercised democratically and not autocratically.

Disputes in this field arise from agency efforts to bind affected parties by issuing documents in the nature of rules⁸ without having followed the APA notice-and-comment procedures or other requirements for the promulgation of legislative rules.⁹ Affected private parties typically pro-

6. *E.g.*, *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993); *National Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 239-40 (D.C. Cir. 1992); *Jeri's Ceramic Arts v. Consumer Product Safety Comm'n.*, 874 F.2d 205, 208 (4th Cir. 1989); *Alaska v. DOT*, 868 F.2d 441, 445-47 (D.C. Cir. 1989); *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1320 (D.C. Cir. 1988); *United Technologies v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987); *Community Nutrition Inst. v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987).

Terminological confusion is the worse confounded, even though sound results are reached, by the use in some opinions of the word "substantive" in place of "legislative" in this sense. *See, e.g.*, *United States v. Ficciotto*, 875 F.2d 345, 347-48 (D.C. Cir. 1989); *Mt. Diablo Hosp. Dist. v. Bowen*, 860 F.2d 951, 956 (9th Cir. 1988); *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (using both "legislative" and "substantive"). "We find the use of the term 'substantive' in this context misleading; . . ." *Metropolitan School Dist. of Wayne Township v. Davila*, 969 F.2d 485, 488 (7th Cir. 1992).

7. A third category of nonlegislative rules comprises those that do not interpret and that are not binding. These are the "general statements of policy" that are exempt from APA notice-and-comment requirements. 5 U.S.C. § 553(b)(A) (1988). They are neither interpretive rules nor rules that should have been promulgated legislatively. *See infra* notes 33-36 and accompanying text (distinguishing exempt statements of policy from statements treated as binding).

8. Documents falling within the APA definition of "rule," *supra* note 1, can take many forms, including regulations, policy statements, bulletins, guidances, manuals, circulars, memoranda, and the like.

9. Sometimes these other requirements are more stringent than the APA's notice-and-comment requirements, *supra* note 5, and sometimes they are less stringent. *Infra*

test that these issuances are invalid because the agency treats them as binding and, therefore, should have promulgated them as legislative rules. The agency typically rejoins that the rules interpret existing legislation and are, therefore, valid interpretive rules that do not have to be promulgated legislatively.

The courts seem to have an awkward time of it when they deal with these matters, and occasionally the judges will bemoan the travail of resolving them.¹⁰ But the APA and indeed our constitutional system make the chore of confronting these questions an inescapable one.¹¹ It helps no one for the courts repetitiously to incant clichés about how the distinctions are “fuzzy”¹² or “enshrouded in considerable smog.”¹³

note 20.

10. *Picciotto*, 875 F.2d at 347 (stating that task “is not always an easy one”); *Stoddard Lumber Co. v. Marshall*, 627 F.2d 984, 987 (9th Cir. 1980) (stating that “distinguishing between those types of rules which to be valid must be promulgated pursuant to the procedures of section 553 and others whose validity does not rest on observance of that section’s notice and comment procedures has proved to be quite difficult”); *Chemical Waste Management v. EPA*, 869 F.2d 1526, 1534 (D.C. Cir. 1989) (commenting that “distinction between interpretive (or “interpretative”) and substantive (or “legislative”) rules is admittedly far from crystal-clear”); *Community Nutrition*, 818 F.2d at 946 (quoting statements that distinction is “tenuous,” “fuzzy,” “blurred,” “enshrouded in considerable smog” and “baffling”); *American Mining Congress*, 995 F.2d at 1108-09 (providing similar quotations); *Diamond Shamrock Corp. v. Edwards*, 510 F. Supp. 1376, 1387 (D. Del. 1981) (stating that “the distinction between substantive and interpretive rules is an unclear one”). For examples of judicial use of the term “smog” with regard to this distinction, see *infra* note 13.

11. An agency is little better than an authoritarian rogue if it tries to use its governmental power to compel observance of documents that it did not promulgate in accordance with statutory requirements for documents that are to have the force of law. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1317-19 (discussing costs of improper use of nonlegislative policy documents). The courts will protect the public against this sort of governmental overreaching. *Id.* at 1355-59.

12. *Pacific Gas & Elec. v. Federal Power Comm’n*, 506 F.2d 33, 38 (D.C. Cir. 1974).

13. *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975), *cert. denied*, 423 U.S. 824 (1976). “Smog” has become a catchword for the perplexities that beset the distinctions among nonlegislative rules. The insight that these distinctions are surrounded by smog, first voiced in *Noel*, has become platitudinous by many courts’ quotation of the *Noel* aphorism. *E.g.*, *La Casa del Convaleciente v. Sullivan*, 965 F.2d 1175, 1177 (1st Cir. 1992); *Friedrich v. Secretary of HHS*, 894 F.2d 829, 834 (6th Cir. 1990); *Community Nutrition*, 818 F.2d at 946; *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984); *Story v. Marsh*, 732 F.2d 1375, 1384 (8th Cir. 1984); *Jean v. Nelson*, 711 F.2d 1455, 1480 (11th Cir. 1983), *aff’d*, 472 U.S. 846 (1985); *Assure Competitive Transp., Inc. v. United States*, 635 F.2d 1301, 1307 n.6 (7th Cir. 1980); *Committee for Fairness v. Kemp*, 791 F. Supp. 888, 893 n.19

Clarity in both concept and terminology is ready at hand.

No doubt in specific situations it can be a puzzling task to apply the central distinction, which turns upon the following inquiry: did *this* particular nonlegislative document actually interpret *that* particular statute or legislative rule? This key question, though easy to state, is hard to answer with confidence in many cases. It is this uncertainty in *applying* the law that has generated the difficulties that the courts lament.¹⁴ But the governing concepts themselves are simple and tolerably clear.¹⁵

Large steps toward judicial clarification were recently taken in *American Mining Congress v. Mine Safety and Health Commission*,¹⁶ which endeavored to deal comprehensively with the distinction between interpretive rules and those that should have been issued legislatively. Writing for the court was Judge Stephen Williams, one of the federal judiciary's premier experts on nonlegislative rules, and author of the noteworthy 1988 *McLouth Steel*¹⁷ opinion on the closely related issue of distinguishing legislative rules from general statements of policy.¹⁸ I previously have offered appreciative comment and some criticism of Judge Williams's important *McLouth* opinion,¹⁹ and here I shall do the same with regard to his similarly important *American Mining Congress* opinion.

(D.D.C. 1992); *United States v. Shields*, 733 F. Supp. 776, 781 (D. Vt. 1989); *Bellano Int'l Ltd. v. FDA*, 678 F. Supp. 410, 412 (E.D.N.Y. 1988); *United States ex rel. Parco v. Morris*, 426 F. Supp. 976, 984 (E.D. Pa. 1977).

See also cases cited *supra* note 10 (describing difficulty of distinguishing between interpretive and noninterpretive rules).

14. "Determining whether a given agency action is interpretive or legislative is an extraordinarily case-specific endeavor . . . [A]nalogizing to prior cases is often of limited utility in light of the exceptional degree to which decisions in this doctrinal area turn on their precise facts." *American Hosp. Ass'n*, 834 F.2d at 1045.

15. "The distinction is not 'fuzzy' but clear: a legislative rule must be promulgated pursuant to a legislative grant of authority. The distinction is troublesome not because it is unclear, but because it is not always easy to determine . . ." Charles R. Koch, Jr., *Public Procedures for the Promulgation of Interpretive Rules and General Statements of Policy*, 64 *Geo. L.J.* 1047, 1049 n.11 (1976). Professor Koch was speaking of the broader distinction of legislative versus nonlegislative rules. His comment, however, is equally apt for the narrower distinction between those nonlegislative rules that interpret existing legislation and those that do not.

16. 995 F.2d 1106 (D.C. Cir. 1993).

17. *McLouth Steel*, 838 F.2d at 1317.

18. General statements of policy, more commonly called "policy statements," are exempted from APA legislative rulemaking requirements by the same provision as are interpretive rules. 5 U.S.C. § 553(b)(A) (1988).

19. Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1359-63.

Although the *American Mining Congress* court, in my view, incorrectly applied its own standards in the case at bar, its opinion is fundamentally sound in concept and is valuable for its efforts at clarification. Unfortunately, however, it presents a potentially confusing multiplicity of formulations, using language that may confuse readers who are not privy to the arcana of this corner of the law. This Article aims to distill and consolidate the relevant concepts.

I. THREE BASIC PROPOSITIONS ABOUT NONLEGISLATIVE RULES

The subject of nonlegislative rules breeds bewilderment and frustration. It does so, in my opinion, because of idiosyncratic judicial terminology, because of the interplay of multiple concepts, and because of a certain irreducible difficulty in the particular application of those concepts—but *not* because of any inherent complexity or unintelligibility of the concepts. Some patient restatement and sorting-out may dispel the mysteries.

There are legislative rules and there are nonlegislative rules. The latter, rather obviously, are those that have not been promulgated as legislative rules.²⁰ The distinctions examined by this Article are concerned only with nonlegislative rules. The first distinction is drawn by dividing the universe of nonlegislative rules into those that interpret existing legislation (statutes or legislative rules) and those that do not.²¹

20. In some situations, legislative rules can be issued without observance of the APA notice-and-comment procedures. This can occur, for example, if the rule relates to a military or foreign affairs function of the United States, 5 U.S.C. § 553(a)(1) (1988), or to agency management or personnel, or to public property, loans, grants, benefits, or contracts. *Id.* § 553(a)(2). To be legislative rules, however, such rules must fulfill other requirements, most notably that the agency must possess statutory authority to make rules having the force of law and that promulgation is an intentional and effective exercise of that authority. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1322 (outlining six requirements for legislative rules and arguing that when agencies attempt to bind public with nonlegislative documents, agencies violate APA).

21. To "interpret," as used here, is to derive a proposition from an existing document whose meaning compels or logically justifies the proposition. The substance of the derived proposition must flow fairly from the substance of the existing document.

If the relevant language of the existing document consists of vague or vacuous terms—such as "fair and equitable," "just and reasonable," "in the public interest," and the like—the process of announcing propositions that specify applications of those terms is not ordinarily one of interpretation, because those terms in themselves do not supply substance from which the propositions can be derived. The conclusion might be different if the term as enacted has been accompanied by a detailed prior practice,

A nonlegislative rule that interprets existing legislation is an "interpretive rule."²²

*Proposition One: To the extent that a rulemaking document interprets existing legislation, it may be issued without the use of legislative rulemaking procedures, regardless of whether or not the document is treated by the agency as binding upon private parties.*²³

Remaining to be dealt with are nonlegislative rulemaking documents that do *not* interpret—those that do not purport to interpret legislation, and those that claim to do so but go beyond the fair intendment of existing legislative documents. How are these to be classified? Judicial opinions often cite a dichotomy between interpretive and "legislative" rules, and pose their inquiry in terms of whether the document at issue is an interpretive rule or a legislative rule.²⁴ They thereby impart the

or by clear legislative history or established usage or the like, to supply substance by which the derived proposition can be justified.

22. Interpretive rules are "rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules it administers." U.S. DEP'T OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 30 n.3 (1947). Within the terminology of this Article, a document may be an interpretive rule when it interprets an existing interpretive rule, provided that the second interpretation is fairly traceable to the substance of the original legislative document. On the other hand, an interpretation of a nonlegislative document that does not fairly interpret existing legislation cannot be an interpretive rule, because it has no legislative foundation.

23. See *Metropolitan School Dist. of Wayne Township v. Davila*, 969 F.2d 485, 489-92 (7th Cir. 1992) (holding that rule requiring provision of educational services to disabled children expelled from school was interpretive and did not have to be promulgated by notice-and-comment procedures); *Friedrich v. Secretary of HHS*, 894 F.2d 829, 837 (6th Cir. 1990) (holding that interpretive regulation, which Secretary required all carriers to abide by, created no new law and therefore was not subject to § 553 notice-and-comment requirements), *cert. denied*, 498 U.S. 817 (1990); *American Postal Workers Union v. United States Postal Service*, 707 F.2d 548, 558-60 (D.C. Cir. 1983) (stating that "the substantial impact of the new rule . . . does not translate it into a legislative rule. As an interpretive rule, the new annuity computation formula is exempt from the rulemaking requirements of the APA, and OPM therefore did not act unlawfully in promulgating it without notice and comment proceedings"), *cert. denied*, 465 U.S. 1100 (1984).

On the permissibility of an agency's attempting to make interpretive rules binding, see *infra* text accompanying notes 40-45.

24. *E.g.*, *American Mining Congress v. MSHA*, 995 F.2d 1106, 1110 (D.C. Cir. 1993) (referring to "the legislative or interpretive status of the agency rules"); *Ameri-*

oxymoronic impression that a nonlegislative rule that does not interpret can be a legislative rule. Frequently the courts will even say that the nonlegislative rule *is* a legislative rule.²⁵ It should be obvious, however, that such a nonlegislative rule *cannot* possibly be a legislative rule, because it was not promulgated by use of the rulemaking procedures required for making rules with the force of law.²⁶

These courts really are aiming to identify those nonlegislative rules that *should have been* promulgated through use of the APA's legislative rulemaking procedures, including notice and opportunity for comment. The question they are grappling with is whether the documents at issue should have been so promulgated or are merely "general statements of policy" that are exempt from the APA's notice-and-comment requirements.²⁷

can Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (deciding whether rule was "interpretive or legislative").

25. E.g., National Family Planning and Reproductive Health Ass'n v. Sullivan, 979 F.2d 227, 239 (stating "that the Directives are legislative rules . . ."); Jerri's Ceramic Arts v. CPSC, 874 F.2d 205, 208 (4th Cir. 1989) (finding that "the Commission has made a legislative rule and called it an interpretation"); Alaska v. DOT, 868 F.2d 441, 447 (D.C. Cir. 1989) (holding that "the 1988 Orders constitute legislative rules"); Committee for Fairness v. Kemp, 791 F. Supp. 888, 893 (D.D.C. 1992) (stating "that [the documents] were legislative or substantive rules").

In other cases, courts will consider whether the nonlegislative rule "is" a legislative rule, but reach a negative conclusion because the rule is found to be interpretive. For examples see cases cited *supra* note 23.

26. The most precise terminology is to call all substantive nonlegislative rules that do not interpret "policy statements." "All substantive nonlegislative issuances that are not interpretive rules are policy statements—whether they are captioned or issued as policy statements or manuals or guidances or memoranda or circulars or press releases or even as interpretations." Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1326 (emphasis omitted).

This of course merely categorizes them, and distinguishes them from the other category of nonlegislative rules, interpretive rules. It does not thereby establish that these policy statements are exempt from the notice-and-comment procedural requirements of the APA under 5 U.S.C. § 553(b)(A) (1988). Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1325 n.64 and 1359-63. If they are treated as binding by the agency, they are not exempt, because they should have been made as legislative rules, but they remain policy statements nevertheless. See *infra* notes 29-33 and accompanying text (proposing that such rules be called "spurious rules").

It is not essential to the present analysis that this terminology be accepted. What *is* essential is that the courts stop calling these nonlegislative rules "legislative rules." If agencies have made them binding upon the public, the rules should have been promulgated as legislative rules. But that is a far cry from their *being* legislative rules.

27. 5 U.S.C. § 553(b)(A) (1988). See *supra* notes 18 and 26 (discussing policy

How is that inquiry to be resolved? Although judicial language might occasionally suggest otherwise, the conclusion that a rule does not interpret existing legislation does not in itself determine that it should have been issued as a legislative rule.²⁸ For rules that do not interpret existing legislation, another categorization of nonlegislative rules must be called into play, separating those rules that are treated by the agency as binding upon private parties²⁹ from those that are not.³⁰

statements).

28. See cases cited *infra* note 34 (holding that nonlegislative documents, which set forth tentative agency positions and did not themselves change legal rights and obligations, were not required to be promulgated legislatively).

29. In general, a document has binding effect if the agency treats it as dispositive of the issues that it addresses. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1328 (discussing that nonlegislative documents are binding when agencies treat them in same way that they treat legislative rules). Agencies treat rules as binding upon private parties in two principal ways—by announcing them in a binding way and by applying them in a binding way. *Id.* at 1327-30. The first is accomplished by announcing the rule in such a way as to show that conformity is expected—that is, by making it apparent that the rule will be used as a basis for enforcement action against private parties or that it will be used as the standard for passing upon approvals (such as permits, licenses, grants, and benefits) sought by private parties. The second is accomplished by regularly applying the rule as the basis for enforcement actions or as the standard for passing upon approvals sought by private parties.

It is vital to recognize that an agency may have the practical power to treat a rule as binding in these ways whether the rule was issued legislatively or not. If the rule was not issued legislatively (that is, by use of APA procedures including notice-and-comment), by definition it does not have the force of law and is not legally binding. See *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-303, 315 (1979) (holding nonlegislative rules not to have force of law). But it can have *practical* binding effect. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1328-31 (discussing various indicia of practical binding effect). The term "binding" will be used herein to include rules that have practical binding effect as well as those that have the force of law.

30. *Infra* notes 34-36 and accompanying text.

Proposition Two: To the extent that a rulemaking document that does not interpret existing legislation is treated by the agency as binding upon affected parties, it will be invalid if it was not issued by use of legislative rulemaking procedures.³¹

To facilitate clarity, a name should be given to these nonlegislative rules that should have been made legislatively. I propose calling them "spurious rules." They fit within the APA's definition of "rules"³² but are not legislative rules, because they were not promulgated by use of the APA's legislative rulemaking procedures. They are not exempt interpretive rules, because they do not interpret. And, although they are a subset of policy statements, they are *not exempt* policy statements, because they should have been made legislatively. Such rules have no legal force, but because they are treated as binding by the agency, they are spuriously given the appearance of legal force.³³ It would avoid a great deal of confusion if the courts, when passing upon nonlegislative documents that agencies treat as binding, framed the operative distinction as one between interpretive rules on the one hand and spurious rules on the other.

31. Holdings to this effect include *National Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992); *United States v. Picciotto*, 875 F.2d 345 (D.C. Cir. 1989); *Jeri's Ceramic Arts v. CPSC*, 874 F.2d 205 (4th Cir. 1989); *Alaska v. DOT*, 868 F.2d 441 (D.C. Cir. 1989); *Ohio Dep't of Human Services v. HHS*, 862 F.2d 1228 (6th Cir. 1988); *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987); *Batterton v. Marshall*, 648 F.2d 694 (D.C. Cir. 1980); *Chamber of Commerce of the United States v. OSHA*, 636 F.2d 464 (D.C. Cir. 1980).

Normally, rulemaking that disregards required procedures is void. *Ohio Dep't of Human Services*, 862 F.2d at 1237; *Batterton*, 648 F.2d at 711. In one case, however, the court allowed the agency to continue using the document on the condition that it treat it in the future as "a non-binding policy." *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1324 (D.C. Cir. 1988). See also *Batterton*, 648 F.2d at 711 (finding that while judicial determination of procedural defect usually requires invalidation, posture of appeal at bar allowed rule to be applied in future provided that agency complied with APA notice-and-comment requirements).

32. *Supra* note 1.

33. Such spurious rules can readily be misused by the agency—intentionally or unintentionally—to mislead unsophisticated persons who think themselves legally bound, or to intimidate those who have no practical choice but to conform. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1317 (noting misuse and abuse of nonlegislative rules that agencies treat as binding). Tolerance of these spurious rules encourages excessive regulation. *Id.* at 1317-18.

By no means, however, do agencies treat all of their noninterpretive rulemaking documents as binding. It is commonplace for an agency to issue such a document in a nonbinding tentative form, subject to being reconsidered when it becomes pertinent to a particular case.³⁴ To assure that the document has neither the intent nor the effect of binding private parties, the agency should maintain an "open mind,"³⁵ so that an affected party has a realistic chance to persuade the agency to adopt a different position when the party's particular case is acted upon.³⁶

Proposition Three: To the extent that a rulemaking document that does not interpret existing legislation is not treated by the agency as binding on affected parties, it is a policy statement that is exempt from APA notice-and-comment rulemaking requirements.³⁷

Under the three propositions just stated, a court confronting a nonlegislative rulemaking document must decide whether it is an interpretive rule, a spurious rule, or an exempt policy statement. There are two inquiries: First, does the rulemaking document interpret existing legislation? If so, it is exempt from notice-and-comment requirements, whether it is made binding or not. Second, if the document does not in-

34. See the documents involved in *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533 (D.C. Cir. 1986) (finding that Labor Department's "Enforcement Policy and Guidelines for Independent Contractors" announced agency's tentative intentions for future, not present binding norm); *Noel v. Chapman*, 508 F.2d 1023 (2d Cir. 1975) (holding that INS policy was only guideline, not changing existing rights); *Pacific Gas & Electric Co. v. Federal Power Comm'n*, 506 F.2d 33 (D.C. Cir. 1974) (finding that Federal Power Commission document announced agency's tentative intentions for future and that its validity would be considered in subsequent proceedings), analyzed in *Asimow, Public Participation*, *supra* note 4, at 550.

35. *McLouth Steel*, 838 F.2d at 1323, 1325.

36. Administrative Conference of the United States Recommendation 92-2, 1 C.F.R. § 305.92-2 (1993); *McLouth Steel*, 838 F.2d at 1321-22, 1323-25; *Panhandle Producers & Royalty Owners Ass'n v. Economic Regulatory Admin.*, 822 F.2d 1105, 1110 (D.C. Cir. 1987); *Pacific Gas & Elec.*, 506 F.2d at 39; Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1362-63. The central characteristic of an exempt policy statement has long been understood to be its tentative quality. Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 390-93. Some shadow of uncertainty may have been cast upon this understanding by a gratuitous and muddled dictum in *Lincoln v. Vigil*, 113 S. Ct. 2024, 2034 (1993), at least where the discretionary allocation of unrestricted funds from a lump-sum federal appropriation is concerned.

37. 5 U.S.C. § 553(b)(A) (1988).

terpret, has the agency treated it as binding? If so, the document is an invalid spurious rule because it should have been promulgated through use of legislative procedures, ordinarily including full APA notice-and-comment formalities.³⁸ If the agency has not made the document binding, it is excepted from notice-and-comment requirements as an exempt policy statement.³⁹

II. WHY INTERPRETIVE RULES DIFFER FROM OTHER RULES THAT ARE MEANT TO BIND

Agencies may permissibly attempt to make their interpretive rules binding upon private parties without having issued them through notice-and-comment procedures. But agencies may not attempt to make other kinds of rules binding without observing the notice-and-comment requirements. The justifications for this differentiated treatment can be briefly stated.

A. Interpretive Rules

Because an interpretive rule has not been set forth legislatively, it is not *legally* binding, and a court may set aside an interpretation with which it disagrees as well as one that it deems unreasonable.⁴⁰ But an agency can attempt to make an interpretive document binding upon private parties as a *practical* matter. The agency does this in the course of taking action—typically, initiating an enforcement proceeding or passing upon an application—based upon the interpretive rule it has adopted. For the purposes of that action, the agency treats the docu-

38. Even where notice-and-comment procedures are excused because of a document's subject matter (e.g., military or foreign affairs, or grants, benefits, or contracts), other requirements must be satisfied for the document to be a legislative rule and therefore validly binding. *Supra* note 20.

39. 5 U.S.C. § 553(b)(A) (1988); authorities cited *supra* notes 34-36. Thus, an agency can engage in rulemaking without observing legislative rulemaking procedures if its rule is 1) interpretive or 2) not binding even as a practical matter.

40. Interpretations set forth in *legislative* rules may be set aside if found to be arbitrary and capricious—that is, unreasonable—but not on the ground that the court, viewing the matter as an original proposition, would have arrived at a different interpretation. *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). But “[i]nterpretive rules do not have the force of law and even though courts often defer to an agency’s interpretive rule they are always free to choose otherwise.” *National Latino Media Coalition v. FCC*, 816 F.2d 785, 788 (D.C. Cir. 1988). See also Robert A. Anthony, *Which Agency Interpretations Should Bind Citizens and the Courts?*, 7 YALE J. ON REG. 1, 12-14, 55-56 (1990).

ment as determinative of the interpretive issue in question. In this way, the agency has attempted to make the document binding in a practical sense, since affected private parties must abide by it or get the courts to set it aside.⁴¹

This is a normal use of interpretive rules, and there are important theoretical and practical reasons that interpretive rules so used come within section 553's exemption from notice-and-comment requirements.

Interpretive rules articulate positive law that already exists in the form of statute or legislative rule. The theory is that the agency's interpretive document merely explains, but does not add to, the substantive law that already exists.⁴² Because Congress (or the agency, in a prior legislative rule) has legislated previously, a further act of legislation (through notice-and-comment procedures) is conceptually unnecessary to give legal effect to the interpretive proposition set forth in the document. That proposition, at least in the agency's opinion, already possesses the force of law. It has that effect not because the agency endows it with that effect, but because it represents the meaning of a statute or legislative rule that is already law. The agency, by issuing its document, asserts that existing legislation already has established by implication the position that the agency interpretation now specifies. The interpretation, therefore, does not project new legal effect of its own.

Moreover, the function of the exemption for interpretive rules is "to allow agencies to explain ambiguous terms in legislative enactments without having to undertake cumbersome proceedings."⁴³ Agencies cannot shirk their job of carrying out the legislation for which they are responsible, and in doing that job they often must immediately take positions as to the meaning of the legislation, without waiting for notice-and-comment procedures.

Thus it is proper for an agency, without going through the procedures

41. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1327-30 (discussing various ways in which nonlegislative rules can have practical binding effect).

42. *National Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 237 (D.C. Cir. 1992); *Sentara-Hampton General Hosp. v. Sullivan*, 980 F.2d 749, 759 (D.C. Cir. 1992); *Beazer East, Inc. v. EPA Region III*, 963 F.2d 603, 606 (3d Cir. 1992); *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991); *American Hosp. Ass'n*, 834 F.2d at 1045-46; *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 876, 879 (D.C. Cir. 1979).

43. *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (per Wald, C.J.). The same opinion spoke of § 553 exemptions generally as an attempt by Congress "to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake." *Id.*

required for promulgating legislative rules, to issue documents that interpret legislation, and then to enforce or apply those documents until a court holds the interpretation to be incorrect or unreasonable.⁴⁴

B. Nonlegislative Rules That Do Not Interpret

By contrast, if no existing statute or legislative rule impliedly establishes the precept that an agency wishes to impose in a binding way, the agency must issue a new legislative rule. It cannot lawfully attempt to compel compliance through a mere bulletin or guidance or other nonlegislative document.⁴⁵ It cannot, that is, attempt to give legal effect to a document for which there is no legislative foundation.⁴⁶

Thus, if rules do not interpret legislation already in place, the agency may not attempt to make the rules binding unless it promulgates them legislatively.⁴⁷ A nonlegislative document that has no pre-existing foundation of established law represents an effort to occupy new substantive ground and establish new law or policy. If the agency is careful to issue its document in a tentative manner, so that it does not have even a practical binding effect upon the public, nonlegislative issuance is permissible.⁴⁸ But if the agency treats the new propositions as binding, its attempt to go beyond existing legislation without observing legislative processes is invalid. In such a case, the agency has produced only spurious rules.

Because it rests on an ineffable process of discerning whether one meaning flows from another, the distinction between interpretive rules and spurious rules unavoidably carries a certain air of imprecision. Moreover, when agencies interpret, they often are in some sense making policy rather than merely voicing it;⁴⁹ further, agencies over time may

44. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1313-14 & n.6 (discussing practical binding effect of interpretations of existing legislation).

45. Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1332-59.

46. This is a correct use of the term "legal effect." The term often is used confusingly as the test for whether a rule "is legislative" (meaning, whether it should have been issued legislatively). See *infra* notes 66-69 and accompanying text (discussing "legal effect" label).

47. Legislative promulgation ordinarily requires observance of the notice-and-comment procedures of 5 U.S.C. § 553 (1988). For exceptions see *supra* notes 5 and 20.

48. The document is an exempt policy statement within the APA's exception for "general statements of policy." 5 U.S.C. § 553(b)(A) (1988). For more on such permissible nonlegislative issuances, see cases cited *supra* note 34; Asimow, *Nonlegislative Rulemaking and Regulating Reform*, *supra* note 36, at 390-93; Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1359-63.

49. See Richard J. Pierce, Jr., *Chevron and its Aftermath: Judicial Review of*

change their interpretations of unchanged legislation.⁵⁰

Nevertheless, the distinction between interpretive and spurious rules is sound and indeed is absolutely of the essence in our system of administrative law. Difficult though it may be to apply in given circumstances, there must be a differentiation between those acts of an agency that rest upon the substance of legislation already in force and those that do not. The alternative is to allow agencies autocratically to impose binding rules without doing what Congress says must be done to impose binding rules.

III. THE D.C. CIRCUIT'S RESTATEMENT OF THE DISTINCTION

In *American Mining Congress*, Judge Williams states that "the legislative or interpretive status of the agency rules turns . . . on the prior existence or non-existence of legal duties and rights."⁵¹ This statement captures the essentials of the law: if the duties or rights in question have not previously been legislated, any agency rulemaking effort to bindingly establish those duties or rights must be done legislatively (normally requiring the use of APA notice-and-comment procedures).⁵² But if the duties or rights do have a prior legal existence, as legislated in a statute or legislative rule, the agency may articulate them in detail

Agency Interpretations of Statutory Provisions, 41 VAND. L. REV. 301, 304-06 (1988) (stating that "[m]any instances of statutory interpretation require an agency to resolve policy issues"); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 411 (7th Cir. 1987) (stating that "there is a range of possible meanings; the selection from the range is an act of policymaking"). See also Peter L. Strauss, *One Hundred Fifty Cases Per Year: Some Implications of the Supreme Court's Limited Resources for Judicial Review of Agency Action*, 87 COLUM. L. REV. 1093, 1118-22 (1987) (speaking of interpretation occurring within "range of indeterminacy" left by statute).

50. "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 863-64 (1984). A potentially strong restraint on casual or frequent changes of interpretation is the requirement that a change in policy be accompanied by a reasoned explanation, see *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983) (ruling that agencies must provide explanations for their policy decisions), if that doctrine applies to nonlegislative rules. See Anthony, *Interpretive Rules, Policy Statements*, *supra* note 5, at 1319 n.30 (stating that it is unclear whether reasoned explanation is required for policy changes involving nonlegislative documents).

51. *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1110 (D.C. Cir. 1993).

52. For exceptions to the notice-and-comment requirement, see *supra* note 20.

through an interpretive rule (not requiring notice-and-comment).

This is assuredly the key test, and the *American Mining Congress* opinion is wholly consistent with it. Taking a comprehensive grip on the subject, that opinion valuably reviews prior analyses and elaborates component themes and concepts. Its thoroughness in so doing, however, may somewhat becloud the clarity that it otherwise promotes, and some comment here may make its statement of the law more accessible.

The opinion sets forth or cites, with apparent approval, ten variously formulated tests pertinent to the legislative or interpretive status of agency rules.⁵³ (It also, correctly in my opinion, rejects three others.)⁵⁴

53. These tests are: 1) Interpretive rules advise of "the agency's construction of the statutes and rules which it administers." *American Mining Congress*, 995 F.2d at 1109 (quoting Attorney General's Manual on Administrative Procedure at 30 n.3 (1947)). 2) Legislative history of the APA has been read to suggest a "legal effect test" as "marking the line between substantive and interpretive rules." *Id.* at 1109 (citing Asimow, *Public Participation*, *supra* note 4, at 542 & n.95). 3) The courts inquire whether the disputed rule has the force of law, which a rule has only where the agency intended to exercise legislative power delegated by Congress. *Id.* at 1109. 4) Such "intent to exercise" can be found where, "in the absence of a legislative rule by the agency, the legislative basis for agency enforcement would be inadequate." *American Mining Congress*, 995 F.2d at 1109. 5) "[A]n agency presumably intends a rule to be legislative if it has the rule published in the Code of Federal Regulations." *Id.* at 1109. 6) A rule that repudiates or is irreconcilable with a prior legislative rule is an amendment and must itself be legislative. *Id.* at 1109. 7) The focus should be "on whether the agency needs to exercise legislative power (to provide a basis for enforcement actions or agency decisions conferring benefits)." *Id.* at 1110. 8) This focus on "need" helps explain the distinction between instances where an agency merely declares its understanding of what a statute requires (interpretive) and where an agency goes beyond the text of a statute (legislative), *id.* at 1110 (citing *Fertilizer Institute v. EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991) and *Chamber of Commerce v. OSHA*, 636 F.2d 464, 469 (D.C. Cir. 1980)) because if a rule supplies needed legislative action the rule is legislative while if the rule spells out a pre-existing duty it will be interpretive. *Id.* at 1110. 9) The legislative or interpretive status of rules depends upon the prior existence or non-existence of legal duties and rights. *American Mining Congress*, 995 F.2d at 1110. 10) If an agency chose to invoke its general legislating authority the rule would be treated as an attempted exercise of legislative power. *Id.* at 1110-11.

54. The court rejected three proposed tests as follows: 1) The distinction whereby rules based on specific statutory provisions are treated as interpretive while those based on broad statutory authority to create rights and duties are treated as legislative, *United Technologies Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987), is statistically likely to yield the right outcome, but the status of rules should not turn on the narrowness or breadth of the statutory or regulatory terms in question. *American Mining Congress*, 995 F.2d at 1110. 2) The determination that a rule has "binding effect," in the sense that it does not leave the agency free to exercise discretion, is

Judge Williams summarized his analysis as follows:

Accordingly, insofar as our cases can be reconciled at all, we think it almost exclusively on the basis of whether the purported interpretive rule has "legal effect", which in turn is best ascertained by asking (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a legislative, not an interpretive rule.⁵⁵

This formulation is fundamentally a good one. Indeed, it is the best judicial expression on the subject to date. To be fully serviceable, though, I believe it should be examined in the light of the framework presented in this Article.

At the threshold it must be insisted that, where the answer to any of the four stated questions is affirmative, the document is *not* a "legislative . . . rule," but rather is one that *should have been* a legislative rule—what I have called a "spurious rule."⁵⁶ Putting an end to the solecism of calling spurious rules "legislative rules" is the quickest way to disperse the smog.⁵⁷

The quoted passage essentially restates and embellishes the analysis I have drawn above. The critical first question remains: did the nonlegislative document interpret an existing statute or legislative rule?

The court's inquiry numbered 1, which is the basic one to which the others are peripheral, simply reframes this question. The existence of "an adequate legislative basis for enforcement or other agency action"⁵⁸ means, precisely, the existence of a statute (or other legislative act) upon which the agency could legitimately base the action in question without having first promulgated a new legislative rule.

Where legislation does exist to serve as the substantive basis⁵⁹ for

pertinent to distinguishing policy statements from legislative norms (that is, norms that *should have been* promulgated legislatively), but tells little about whether a rule is interpretive. *Id.* at 1111. 3) Again, the use of mandatory as opposed to permissive language may be useful in drawing a line between policy statements and "legislative rules" (rules that *should have been* promulgated legislatively), but it is not useful to distinguish interpretive rules. *Id.* at 1111.

55. *Id.* at 1112.

56. *Supra* text accompanying notes 26-33.

57. *See supra* note 13 (citing judicial use of "smog" in context of distinguishing nonlegislative rules).

58. *American Mining Congress*, 995 F.2d at 1111.

59. Legislation that supplies substantive norms to serve as the "legislative basis

the action in question, then a document fairly stating that *that* action is covered by *that* legislation is an interpretive rule. The substance of the interpretive rule flows from the meaning of the "adequate legislative basis" already in existence. Finding no "adequate legislative basis" in a particular case is tantamount to finding that there is no legislation whose meaning the document in question can be fairly said to interpret. This also is the sense in which the court speaks of "focus[ing] on whether the agency *needs* to exercise legislative power (to provide a basis for enforcement action or agency decisions conferring benefits) . . .".⁶⁰ if there is no legislation that the putatively interpretive rule fairly flows from, the agency "needs" to exercise its legislative rulemaking power to take action based on that position.

The opinion adverts to cases drawing the distinction between "construing" legislation and "supplementing" it.⁶¹ Though I would not put it just this way, we may assume that this is the same distinction as the one I draw between documents that interpret and those that do not. Judge Williams acutely observes that the "difficulty with the distinction is that almost every rule may seem to do both."⁶² Amen. This is the very source of the perplexities that entoil the courts. But it is unavoidably in the nature of things that it often is hard to tell whether the purported interpretive rule adds to, or merely explains, the existing legislation. I do not think this inquiry is rendered any different, or any easier, when it is reframed by suggesting that "the dividing line is the necessity for agency legislative action."⁶³ In either case it must be determined whether legislative substance justifying the agency's position exists.⁶⁴ These varying formulations call for exactly the same inquiry.

for enforcement or other agency action" should be carefully distinguished from statutes that do not contain substantive norms but merely authorize agencies to promulgate rules. In the latter situation, it is the rules (if any), not the statute, that would serve as the substantive legislative basis for the agency action of which the court speaks.

60. *American Mining Congress*, 995 F.2d at 1110.

61. *Id.* (citing *Fertilizer Inst.*, 935 F.2d at 1308 and *Chamber of Commerce*, 636 F.2d at 469).

62. *American Mining Congress*, 995 F.2d at 1110.

63. *Id.*

64. Judge Williams followed the sentence quoted at note 62 above with this: But if the dividing line is the necessity for agency legislative action, then a rule supplying that action will be legislative no matter how grounded in the agency's 'understanding of what the statute requires,' and an interpretation that spells out the scope of an agency's or regulated entity's pre-existing duty . . . will be interpretive, even if . . . it widens that duty even beyond the scope

It should be added, because it is not explicit in the quoted passage, that even if "in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action,"⁶⁵ the document is not invalid—as what the court calls a "legislative rule" and what I call a "spurious rule"—unless the agency has treated it as binding.⁶⁶ If the agency has pronounced the rule in a nonbinding tentative fashion, it is neither an interpretive rule nor a "spurious" ("legislative") rule, but is a presumably valid policy statement exempt from notice-and-comment requirements.⁶⁷ Transparency on this point should dispel some of the smog.

The court's inquiry numbered 4 is, on analysis, a subset of number 1, and is therefore subject to the same comment. If the purported interpretive rule effectively amends a prior legislative rule, there is by definition no adequate legislative basis for it. This is true even if the new document does not contradict the legislative rule but attempts to add substance. Casting the issue in terms of amendment does not supply an escape route by which to dodge the unavoidable (if sometimes enigmatic) labor of distinguishing documents that add new content from those

allowed the agency under *Chevron U.S.A. v. NRDC*, 467 U.S. 837 (1984). *American Mining Congress*, 995 F.2d at 1110.

The second half of this passage seems accurate, and represents an important perception: as in the case cited by Judge Williams, *Fertilizer Institute v. EPA*, 935 F.2d 1313 (D.C. Cir. 1991), an attempted interpretation that the court finds to be unreasonable or wrong is not for that reason disqualified as an interpretive rule or invalidated for not having been issued by notice-and-comment. But it may be observed (though not an issue here) that reviewing courts should not accord deference under the *Chevron* case to interpretive rules, which instead should be reviewed independently under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). See Anthony, *Which Agency Interpretations Should Bind Citizens and the Courts*, *supra* note 40, at 40-41, 55-58 (analyzing review of interpretive rules in federal courts).

The first half of the quoted passage, on the other hand, seems nugatory. Perhaps it intends to emphasize that the test is an objective one, and that the agency's belief as to the extent that the rule is grounded in the statute is irrelevant. But otherwise, if in a given case there is a "necessity for agency legislative action," it is precisely because the document is not grounded in a statute or other legislation establishing a pre-existing duty or right that can be spelled out by interpretation to justify the agency position. To determine the necessity for agency legislative action, one first must determine whether the agency position interprets existing legislation.

65. *American Mining Congress*, 995 F.2d at 1112.

66. See *supra* text accompanying notes 31-33 (setting out basis for term "spurious").

67. 5 U.S.C. § 553(b)(A) (1988). See *supra* text accompanying notes 34-37 (discussing how nonbinding policy statements need not be promulgated legislatively).

that merely flesh out existing legislative meaning or make it more specific.⁶⁸

By covering all four of its enumerated inquiries with the label "legal effect,"⁶⁹ the court needlessly foments confusion. As used in the *American Mining Congress* opinion, this test adds nothing conceptually, and indeed serves to distract and to complicate the analysis. Its difficulties are largely those of terminology, parallel to those posed by calling certain nonlegislative rules "legislative rules."

The opinion appears to use the term "legal effect" to mean "practical binding effect" rather than a legally binding effect, which a nonlegislatively issued document by definition cannot possess. But in the article cited in the court's initial mention of the concept,⁷⁰ the "legal effect test" is defined as classifying a rule "as legislative or nonlegislative on the basis of whether it alters the legal rights or obligations of members of the public."⁷¹ This is the right idea, provided that it is understood (as clearly intended) to mean that a rule should be promulgated legislatively if it attempts to impose binding obligations or standards not already established by existing legislation.⁷² Determining

68. Judge Williams soundly observed: "A rule does not, in this inquiry, become an amendment merely because it supplies crisper and more detailed lines than the authority being interpreted." *American Mining Congress*, 995 F.2d at 1112.

On the other hand, it seems excessively complaisant toward the agencies to suggest that a new document interprets and cannot amend unless it "repudiates or is irreconcilable with an existing legislative rule." *Id.* at 1113. Substantial new matter added to a rule can amend it even if it does not repudiate it. I believe that is what in fact occurred in the *American Mining Congress* case itself. In my opinion, there was no pre-existing duty to do what the putative interpretive rule (a "Program Policy Letter") required; thus that document added to and amended the existing regulation, even if it did not repudiate it or impose irreconcilable provisions. For the same reason, I believe that the court, under its own analysis, was incorrect in saying that there was "no legislative gap that required the PPL as a predicate to enforcement action." *Id.* at 1112.

69. *Id.* at 1112, at the outset of the long quoted passage indented in the text above.

70. *Id.* at 1109 (citing Asimow, *Public Participation*, *supra* note 4, at 542 & n.95, as "reading legislative history of Administrative Procedure Act as 'suggest[ing] an intent to adopt the legal effect test' as marking the line between substantive and interpretive rules.>").

71. Asimow, *Public Participation*, *supra* note 4, at 531.

72. The author cited by the court stated in a later article: "The prevailing standard for distinguishing legislative and interpretive rules can be described as the 'legal effect' test. If a rule explaining the meaning of language actually makes 'new law,' as opposed to merely interpreting 'existing law,' it is legislative." Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, *supra* note 36, at 394. Obviously,

whether a purported interpretive rule has this kind of "legal effect" thus depends exactly upon the lines of inquiry already identified: does the document interpret existing legislation, or does it try to bind without an existing legislative basis? In the cited usage, "legal effect" has no conceptually independent meaning beyond this, and therefore is superfluous and potentially misleading.

Judge Williams, moreover, apparently has chosen to employ the term "legal effect" to embrace all situations that call for the use of legislatively issued rules rather than exempt interpretive rules, including cases covered by the inquiries numbered 2 and 3 in his summary. I do not wish here to assert that these cases need not be governed by legislative rulemaking requirements. But it should be realized that those categories can include documents that are properly analyzed as having interpreted existing legislation and thus might otherwise be entitled to the interpretive rules exemption. Number 2 would cover interpretive rules that the agency has chosen to publish in the Code of Federal Regulations.⁷³ Number 3 apparently would cover interpretive documents that the agency has explicitly declared to be issued pursuant to its authority to make law, though without observance of legislative rulemaking procedures.

In both categories it is suitable to insist upon legislative rulemaking, despite the interpretive nature of the action, lest the public be misled into believing that these rules have the force of law. It might promote clarity, though, to state the norms governing these interpretive documents separately from the conceptually different norms that ordinarily govern the distinctions between interpretive rules and rules that should be legislative. Comprehending them all under an overall "legal effect" rubric enables all four of these categories to be accorded the same treatment, as rules that should have been issued legislatively. But use of this broad rubric should not be allowed to distract from the inquiries that are central to the analysis of nonlegislative agency rules.

Those central inquiries are these: 1) Does the nonlegislative rulemaking document interpret existing legislation? 2) If it does not do so, has the agency nevertheless made it binding on the public?

When the document does interpret, it is an interpretive rule exempt from APA notice-and-comment requirements. When it does not interpret

when this passage says a rule "is legislative," it means it "should have been legislative." See *supra* notes 23-32 and accompanying text (discussing this distinction). But in substance the test is the same as that presented in this Article.

73. *American Mining Congress*, 995 F.2d at 1109, 1112 (citing *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 553, 539 (D.C. Cir. 1986)).

and has not been made binding, it is a policy statement exempt from APA notice-and-comment requirements. But where the document does not interpret and nevertheless has been made binding (albeit only as a practical matter), it is a spurious rule that should have been promulgated legislatively.

**DRAFT 2007 REPORT TO CONGRESS
ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS**

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EXECUTIVE SUMMARY

This draft Report to Congress on the Costs and Benefits of Federal Regulations (Report) was prepared to implement Section 624 of the Treasury and General Government Appropriations Act of 2001 (Pub. L. No. 106-554, 31 U.S.C. § 1105 note), commonly known as the "Regulatory Right-to-Know Act." The Report will be published in its final form later this year, after revisions to this draft are made based on public comment, external peer review, and interagency review. This is the tenth annual Report since the Office of Management and Budget (OMB) began issuing this Report in 1997.

A key feature of this Report is the estimates of the total costs and benefits of regulations reviewed by OMB. Similar to previous Reports, the Report includes a ten-year look-back of major Federal regulations reviewed by OMB to examine their quantified and monetized benefits and costs:

- The estimated annual benefits of major Federal regulations reviewed by OMB from October 1, 1996 to September 30, 2006 range from \$99 billion to \$484 billion, while the estimated annual costs range from \$40 billion to \$46 billion. These totals are somewhat higher than those reported last year. The difference is largely due to the addition this year of the Environmental Protection Agency's (EPA) Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM).
- During the past year, seven "major" final rules were adopted that had quantified and monetized benefits and costs. These rules added \$6.3 billion to \$44.8 billion in annual benefits compared to \$3.7 billion to \$4.2 billion in annual costs. One rule, EPA's NAAQS for PM, accounts for 60 to 89 percent of these estimated benefits and for 67 to 70 percent of the corresponding costs.
- There were an additional three major final rules that were adopted last year that did not have quantified and monetized estimates of both benefits and costs. One of these three rules implemented an air cargo security program where the benefits of improved security are very difficult to quantify and monetize. The other two implemented migratory bird hunting regulations and estimated only the net benefits of bird hunting activities.

In addition, we report the latest results of our ongoing historical examination of the trends in Federal regulatory activity. As explained in Chapter II of this Report, the data reveal that:

- The average yearly cost of the major regulations issued during the Bush (43) Administration is about 47 percent less than over the previous 20 years.
- The average yearly benefit of the major regulations issued during the Bush (43) Administration is more than double the yearly average for the previous eight years.

- Over the last 26 years, the major regulations reviewed by OMB have added at least \$126.9 billion to the overall yearly costs of regulations on the public.
- The benefits of major regulations issued from 1992 to 2006 exceed the costs by more than three fold.

The draft Report also provides a summary of the analysis of major regulatory activity by the so-called "independent" regulatory agencies over the past ten years.

Chapter III provides an update on agency implementation of the Information Quality Act (IQA) (Section 515 of the Treasury and General Government Appropriations Act, 2001 (Pub. L. No. 106-554, 31 U.S.C. § 3516 note)). The chapter summarizes the current status of correction requests that were received by agencies in FY 2006, and includes an update on the status of requests received in FY 2003, FY 2004, and FY 2005. This year's Report accelerates OMB's presentation of summary information about IQ requests and appeals, thereby increasing the accessibility and transparency of information for the public. The chapter also summarizes agency annual reports for the Information Quality Bulletin for Peer Review. This is the first year for which reports on the implementation of the Bulletin were required.

This Report is being submitted along with the Twelfth Annual Report to Congress on Agency Compliance with the Unfunded Mandates Reform Act (UMRA), (Pub. L. No. 104-4, 2 U.S.C. § 1538). This year, for the first time, we are publishing, as Chapter IV, a draft of the UMRA report with the draft Report to Congress on the Costs and Benefits of Federal Regulations. By doing so, we hope to make available to the public information on the previous fiscal year in a more timely fashion. In this draft, OMB reports on agency compliance with Title II of UMRA, which requires that each agency, before promulgating any proposed or final rule that may result in expenditures of more than \$100 million (adjusted for inflation) in any one year by State, local, and tribal governments, or by the private sector, to conduct a cost-benefit analysis and select the least costly, most cost-effective, or least burdensome alternative. Each agency must also seek input from State, local, and tribal government.



J O I N T C E N T E R
AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

**The Evolving Role of the U.S. Office of Management and Budget in
Regulatory Policy***

John D. Graham[†]

Working Paper 07-04

February 2007

This paper is forthcoming in the *Review of Environmental Economics and Policy*.

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In order to promote public understanding of the impact of regulations on consumers, business, and government, the American Enterprise Institute and the Brookings Institution established the AEI-Brookings Joint Center for Regulatory Studies. The Joint Center's primary purpose is to hold lawmakers and regulators more accountable by providing thoughtful, objective analysis of relevant laws and regulations. Over the past three decades, AEI and Brookings have generated an impressive body of research on regulation. The Joint Center builds on this solid foundation, evaluating the economic impact of laws and regulations and offering constructive suggestions for reforms to enhance productivity and welfare. The views expressed in Joint Center publications are those of the authors and do not necessarily reflect the views of the Joint Center.

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Executive Summary

Since the early Reagan years, critics have argued that benefit-cost analysis is used by the U.S. Office of Management and Budget (OMB) as a one-sided tool of deregulation to advance the interests of business. This article discloses a little-known fact: OMB also plays a powerful pro-regulation role when agency proposals address market failures and are supported by benefit-cost analysis. Drawing on four case studies from the George W. Bush Administration, the author examines how and why OMB encouraged regulatory initiatives while protecting some rulemakings from opposition by forces inside and outside of the executive branch. The case studies address the labeling of foods for trans fat content, control of diesel engine exhaust, improvement of light-truck fuel economy, and control of air pollution from coal-fired power plants. OMB's role in the 2001-2006 period was unusual by historic standards because, rather than await agency drafts, OMB played a pro-active role in both the initiation of rulemakings and the creation of regulatory alternatives for consideration. The benefit-cost framework could be much more powerful if greater investments were made in applied research to expand knowledge on key regulatory issues.

INTRODUCTION

On New Year's Eve of 2001, after the disputed Florida recount, I received a call from the Bush-Cheney transition team. They asked me to consider a senior regulatory post in the Office of Management and Budget (OMB), the largest unit within the Executive Office of the President.

The call was a pleasant surprise since I had not been involved in the Bush-Cheney campaign. In fact, I answered gingerly a question about why I made a financial contribution to Elizabeth Dole's short-lived 2000 presidential campaign.

Having taught benefit-cost analysis for seventeen years at the Harvard School of Public Health, the opportunity to practice what I was preaching was intriguing. And my own scholarship on regulation of health risks had called for a more rigorous approach to selecting regulatory priorities, weighing risks, and devising cost-effective solutions (Graham and Wiener, 1995; Graham, 1997). Thus, I accepted the offer to serve with hopes of advancing the practice of benefit-cost analysis in regulatory policy making.

After going through a meticulous FBI background check, I was nominated in March 2001 to be the President's "regulatory czar" -- the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA).

The Senate confirmation process was my introduction to hardball politics in Washington, DC. A coalition of liberal activists opposed my nomination with provocative rhetoric, but their allegations were effectively countered in the confirmation process (U.S. Congress, 2001). I was both encouraged and humbled when so many of my academic colleagues, both Democrats and Republicans, voiced support for my nomination. In July 2001, I was confirmed by the Senate and went to work leading 50 career policy analysts at OIRA.

OIRA's role in federal regulation has been controversial. Since the early Reagan years, critics have argued that benefit-cost analysis is used by OMB as a one-sided tool of deregulation to advance the interests of business. A variety of regulatory scholars and pro-regulation activists have raised concerns about the role of OIRA, especially as applied to public health, safety and environmental issues (Andrews, 1984; Morrison 1986; Percival, 1991; McGarity, 1998). Some argue that health protection is an absolute right, even though it is difficult to base such a claim on modern philosophical theories (Schroeder, 1986). They also fear a transfer of power from the regulators to OMB, since the civil servants working at the mission-oriented agencies tend to be more zealous about regulation than the policy analysts at OMB (McGarity, 1991; Moe and Wilson, 1994).

As I entered a pro-business Republican administration, I expected that my office would work to stop bad rules and find less costly ways for regulators to achieve worthy public objectives (e.g., environmental protection). And we did so.

My purpose in this article is to disclose a little-known fact: Benefit-cost analysis also caused OIRA to be a pro-regulation advocate in the Bush administration. I support this claim by providing specific examples of how and why OIRA became a voice -- usually an effective one -- for sensible pro-regulation initiatives that addressed risks created by business activity.

I begin with a short description of the federal regulatory process, with an emphasis on the basis for OIRA's participation in agency rulemaking. I then offer four case studies that illustrate how OIRA worked with the Department of Health and Human Services (HHS) on labeling foods for trans fat content, the Department of Transportation (DOT) on improving light-truck fuel economy, and the Environmental Protection Agency (EPA) on controlling diesel engine exhaust and reducing air pollution from coal-fired power plants. I conclude with some suggestions about how science and economics can play a stronger role in federal regulation in the years ahead.

OMB AND THE REGULATORS

Federal regulatory agencies develop rules based on legislative authority that has been delegated to them by the U.S. Congress. Since 1981, the Executive Office of the President has insisted that all major new regulations be supported by a benefit-cost analysis, including an analysis of the potential market failure that motivates the need for rulemaking (Smith, 1984). It is now well accepted that, based on presidential executive order, OMB has authority to oversee the regulatory activities of federal agencies to ensure that presidential policies are followed and that economic analysis is undertaken to inform regulatory policy (Kagan, 2001; West, 2005).

In order to bring discipline to the regulatory approval process, OMB requires agencies to submit any significant rulemaking proposal to OIRA for "clearance" before it is published in the Federal Register (Blumstein, 2001; GAO 2003). The heart of OMB's power, as administered by OIRA, is to "return" a draft rule to an agency for further "consideration" (OMB, 2002). An agency can overrule OIRA only by a successful appeal to the OMB Director (or the President).

OIRA does not enforce a strict, numeric benefit-cost test. Although OIRA tracks the numbers carefully, it also considers qualitative claims about possible benefits and costs as well as a variety of non-efficiency arguments (e.g., matters of fairness). For example, a civil-rights rule may be proposed on philosophic grounds that have nothing to do with economic efficiency. Agencies must explain why benefits "justify" costs but the showing does not have to be fully monetary. Since there is no rigorous analytic tool for weighing qualitative benefits or fairness claims, OIRA review of regulations inevitably entails some policy judgment (OMB, 2002).

The key limitation on OIRA's authority is that OIRA may not compel a regulator to take a position that is inconsistent with the regulator's legislative authority. If OIRA induces an agency to make such a mistake, the resulting rule is flawed and may be overturned by a federal court. Thus, a complex interaction between economic, legal and fairness considerations, coupled with interest-group pressures, defines the negotiations between OIRA and the regulators (McGarity, 1991; Morgenstern, 1997).

In the summer of 2001, my boss, OMB Director Mitch Daniels (now the Governor of Indiana), explained to me his views on why OMB should oversee the regulators. He said that just as no modern President has permitted a Cabinet department to set its own budget without OMB review, no recent President has permitted federal regulators to impose off-budget expenditures – typically "unfunded mandates" on businesses or states – without

review by analysts in the Executive Office of the President. Yet Daniels also stressed that OIRA could do a good job only if it engaged in careful consideration of benefits as well as costs.

In order to demonstrate OIRA's backbone, Daniels urged me to move quickly to return some bad or poorly-reasoned rulemaking proposals to agencies. I signed more than twenty of these official return letters in my first year on the job (OMB, 2002). That is more than the overall number of returns in eight years of the Clinton Administration, but a much lower return rate than in the Reagan years (Power and Schlesinger, 2002). Once the regulators realized that I was willing to exercise this power, it became far less necessary to use it. We were able to work out problems with an agency in advance, without the need for any public rebuke.

To make it easier for regulators to understand OIRA's analytic perspective, we published a formal guidance document ("OMB Circular A-4") that outlines what OIRA expects to see in a regulatory analysis, especially the benefit-cost evaluation. This document, which is available on OMB's web site, was finalized only after OIRA made revisions to a draft document that was subjected to public comment and expert peer review by academics and other scholars on regulatory policy (OMB, 2003). I turn now to the four case studies of OIRA at work with the regulators.

LABELING FOODS FOR TRANS-FAT CONTENT

Soon after taking office, one of my senior career staff who covered HHS brought to my attention a rulemaking that was started in the Clinton Administration but had never been finished. That was hardly a rare situation, but my economics staff insisted that this rulemaking was permissible under existing law and a good idea.

The proposal, which had been drafted by the Food and Drug Administration (FDA), would have compelled food companies to include the trans-fat content on the food label, just as calories and saturated-fat content are disclosed. FDA's economists argued that a variety of informational obstacles were preventing the market from responding to the dangers of trans-fats. They believed that the new label would not only aid consumer choice but also encourage food processors to reduce the trans-fat content of a variety of widely-consumed foods. FDA projected that the annual health benefits of the rule, measured in less heart disease, would far exceed the annual burdens, which included the costs of food-processing modifications and labeling changes (FDA, 2003).

The key scientific premise was that trans-fat consumption is linked to the development of coronary heart disease. To verify this premise, I asked my staff to consult the recent medical literature and reach out to three groups: the Department of Nutrition at the Harvard School of Public Health, the International Life Sciences Institute (a scientific group affiliated with the food industry), and the Center for Science in the Public Interest (a non-profit advocacy group). All of these consultations reinforced our conviction that FDA's scientific premise was sound.

When the OIRA desk officer checked with FDA, we learned that the rulemaking was moving at a snail's pace, in part because a new FDA Commissioner had not yet been nominated. In order to accelerate this rulemaking, we developed a tool which we called the "prompt letter". It was intended to be a polite nudge -- a suggestion that an agency give

priority to a matter, or alternatively, explain to OMB in a public reply letter why it should not be a priority (OMB, 2002).

The lawyers in the White House disliked the idea. They argued that a prompt letter revealed too much about preliminary thinking inside the executive branch and might be seen as compromising OIRA's objectivity in the subsequent review of a rule. However, Director Daniels did not find these objections convincing, and gave us the go ahead.

We issued the first OIRA prompt letter to the FDA in the fall of 2001. FDA responded by finishing the final rule, and trans-fat content is now a standard entry on food labels (FDA, 2003). As a result of this rulemaking, grocery store shelves became filled with foods low in trans fat content and a variety of restaurants and food establishments are also taking new steps to reduce trans-fat content.

From 2001 to 2006, I signed more than a dozen of these prompt letters, which are posted on OMB's web site (www.whitehouse/omb.eop.gov). Prompt letters were praised as an important innovation by some commentators outside the government (Hahn and Sunstein, 2002), even though they are not legally binding on agencies. They were less popular at the regulatory agencies. With some justification, agencies asked why OIRA didn't simply convey its suggestions to them informally.

Indeed, later in my tenure at OIRA, my staff persuaded me that we could often achieve the same result we had achieved on trans-fats by simply scheduling a meeting with a regulator, where the topic might be a draft prompt letter or a draft return letter. Nonetheless, I favor public prompt letters from OIRA because they exemplify the transparency in government that I believe will increase public trust in OIRA (GAO, 2003; Graham, Noe and Branch, 2006). The public nature of the prompt letters also encourages outside groups to suggest promising topics for prompt letters to OIRA and serves as an occasional reminder of the need for OIRA staff to address shortages as well as excesses of regulation.

The development of the prompt letter and its application to FDA's trans-fat rule may be an important event in the history of OIRA, regardless of how many future prompt letters are issued. It reaffirmed in a public way that OIRA's role is to advance the cause of "smart regulation", which sometimes will lead to more rather than less regulation (OMB, 2002). Some scholars have suggested that there should be a presidential executive order to codify OIRA's power to issue prompt letters (Hahn and Sunstein, 2002; Bagley and Revesz, 2006).

CURBING DIESEL ENGINE EXHAUST

In late 2000, the Clinton Administration issued a flood of new regulations, including an ambitious rule under the Clean Air Act to reduce diesel exhaust from heavy-duty trucks operated on roads and highways. The goal was a 90% diesel-exhaust reduction to be accomplished as refineries reduce the sulfur content of diesel fuel and engine suppliers add modern emission control equipment.

When President Bush took office in 2001, some analysts in the conservative think tank community saw in the new Republican administration a potential opportunity to delay, modify or rescind the highway diesel rule (OMB, 2001). And, in fact, the new policy officials at EPA were asked by some industry officials to reconsider the rule.

Deciding Whether to Retain the Highway Diesel Rule

The highway diesel rule was certainly costly, imposing annualized expenses of \$3 to \$5 billion per year on refineries and engine suppliers (OMB, 2002). Those estimates assumed that the industry would experience a steady decline in variable costs over time as refiners learned how to implement desulphurization at a lower cost. The costs were a bitter pill for an industry that had been downsizing for years. In the 1990s, many small refineries struggled to break even.

Despite the significant costs, what impressed me about the rule was the in-depth benefits analysis prepared by EPA. The rule was projected to prevent, each year, 8,300 premature deaths, 5,500 cases of chronic bronchitis and 361,400 asthma attacks. When the benefits were expressed in monetary units, they were roughly 20 times larger than the estimated costs (OMB, 2002). Moreover, EPA scientists indicated that some of the important human health and ecological benefits were not even included in the benefit calculation because of gaps in scientific knowledge or uncertainty about how to express the benefits in monetary units (EPA, 2004).

From an economic perspective, the producers, buyers and users of diesel engines were creating a classic negative externality: the health risks to people breathing diesel exhaust were not fully considered in market transactions.

Much to the dismay of some White House staff, we decided against reopening the highway diesel rule (OMB, 2001). In fact, rather than delay or rescind the rule, in 2002 OIRA began work on a draft prompt letter calling for EPA to undertake a similar rulemaking that reduce exhaust from numerous off-road engines used in construction, agriculture and mining.

Reducing Exhaust from Off-Road Engines

When we met with EPA informally on the draft prompt, they insisted that there was no need for a prompt because the rulemaking was already a priority. They were also pleased to learn about OIRA's pro-regulation perspective. We therefore agreed to undertake an unprecedented EPA-OMB rulemaking "collaboration", which was announced via press releases in June 2002 by both EPA and OMB.

The complex rulemaking, which required a 90% reduction in diesel exhaust from off-road engines, was completed more quickly than is typical of large EPA rules (EPA, 2004). The rule was costly (\$1.3 billion per year) but the estimated ratio of monetary benefit to cost was over 20 to 1.

In the course of this rulemaking, we asked EPA to undertake an analysis of benefits to determine how likely it was that benefits would prove to be large or small. The point of this probability analysis was to account for the key scientific uncertainties in the health and environmental sciences.

Interestingly, the analysis revealed that the benefits of the rule exceeded the costs, even when the most pessimistic assumptions were applied to the benefits assessment. This

result caused us to ask whether the rule should be made even more stringent. However, a consensus emerged that requiring more than 90% sulfur removal raised feasibility concerns and might lead to unintended yet adverse consequences (Graham and Wiener, 1995).

The EPA-OMB collaboration did lead to some controversy. We asked whether trading of emissions-control credits should be permitted between off-road and highway engines, since a broader trading regime might make both rules even more cost-effective. OMB and EPA lawyers agreed that such trading authority might place the entire rule at legal risk, since the Clean Air Act has no express authority for such an expansive trading regime. Disruptive litigation could cause delays in implementation and lack of predictability for firms expected to make large capital investments. So we retreated to a more modest request that trading of credits be permitted among engines of different sizes within the same off-road engine family. EPA agreed to this request.

As this rulemaking was nearing a conclusion in 2004, one of the more satisfying moments for me occurred when EPA officials were briefing skeptical White House staff about why EPA was undertaking a billion-dollar regulation that was not the subject of any statutory deadline from Congress. Meeting participants turned to me: I explained that the rule had an impressive benefit-cost case, and the meeting did not last much longer.

Enforcing Diesel Exhaust Rules

Writing stringent rules is not useful if businesses do not believe they will be enforced. In 1999, EPA and diesel-engine suppliers reached a settlement on an enforcement action that alleged that some suppliers had installed computer software that turns off emission controls when a heavy truck is operated on the highway. As part of the settlement, the suppliers agreed to an accelerated compliance schedule for their new, cleaner engines being developed under the 2000 highway diesel rule.

As the accelerated deadline approached in October 2002, several companies informed EPA that they might need a delay in the effective date; other companies indicated they were ready to go. EPA made a strong case to us that delay was out of the question, and we agreed.

The following question then arose: How large should the noncompliance penalties be for a manufacturer that offers for sale a noncompliant engine? According to the applicable law, the penalty must be set to ensure that no manufacturer gains a competitive advantage from noncompliance. In addition to potential savings in research and development (R+D) and equipment costs from noncompliance, OIRA felt it was critical that any fuel economy gain over the long life of the noncompliant engine be included in the penalty. Thus, OIRA staff worked closely with EPA staff to produce a rule that imposed large penalties for noncompliance, including the proper discounting of future fuel savings (EPA, 2002).

As our policy leaked to the affected companies, the chief of EPA's clean-air office and I were called to a meeting with members of Congress who were concerned about these non-compliance penalties. EPA was asked why the agency was harassing industry with regulatory fines, especially with such little notice. As the meeting progressed, it became apparent that the members intended to make EPA the villain. I listened carefully but, without disclosing our thinking, suggested that there were much better targets than this rule for efforts

to reduce the burdens of bad regulation. Once again, I was gratified that sound economic thinking prevailed, without any changes to the non-compliance penalties.

After the grilling on Capitol Hill, Director Daniels called me into his office for a briefing. I explained that we needed a policy that rewarded rather than punished innovators in the industry. Daniels offered this advice: "Get the rule out as quickly as possible. Undue delay allows lobbyists to bill more hours as they apply political pressure." That proved to be good advice, which we used on various occasions in the future.

PROMOTING MORE FUEL-EFFICIENT VEHICLES

The run-up of fuel prices in 2001 underscored why the Vice President's energy task force, which was devising a national energy policy for the President, was interested in ways to spur conservation of oil. The U.S. was becoming more heavily dependent on foreign sources of oil (EIA, 2005), and the transportation sector was America's biggest source of oil consumption.

The market-failure rationales for oil conservation were a matter of dispute inside the Bush administration. Some analysts argued that the U.S. was such a large consumer of world oil that we could check the "monopoly" pricing power of OPEC through a concerted program to reduce US oil consumption. Others argued that oil consumption was under-priced because world oil prices do not fully reflect national security concerns or the damages from carbon dioxide emissions that are implicated in global climate change. Still others speculated that consumer decisions about vehicle fuel economy reflected irrationally high discount rates on future gasoline expenses. Although there was no universal agreement as to which market imperfections were most important, there was a broad consensus that a national policy aimed at curbing U.S. oil consumption was required.

Recognizing that cars and light trucks accounted for the majority of oil use in the U.S. transportation sector, the Vice President's energy task force made two key recommendations to enhance vehicle fuel economy (White House 2001). First, Congress should offer tax credits to consumers who purchase cars and light trucks with innovative fuel-saving technologies (e.g., hybrid engines). Second, DOT should reexamine the Corporate Average Fuel Economy program (CAFE), which sets mileage rules for new vehicles, to determine whether CAFE should be reformed or replaced with a more market-based approach to oil savings. Some White House economists argued instead for higher fuel taxes or carbon taxes, but tax hikes were considered political suicide in Congress.

The Science and Politics of CAFE

In 2001, the CAFE program was moribund. Although in 1974 Congress had granted DOT authority to set mileage rules for cars and light trucks, in 1996 a bipartisan coalition in Congress began adding "riders" to DOT appropriations bills each year that froze CAFE standards at 27.5 miles per gallon (MPG) for cars and 20.7 MPG for light trucks (SUVs, vans and pick-up trucks). As a result, the combined fuel economy of cars and light trucks was about 25 MPG in model year 2004, unchanged from ten years earlier (EPA, 2006).

The environmentalists in Congress were arguing for large increases in CAFE standards, but they were outnumbered by members of Congress who feared that large CAFE

increases would harm the economy, especially the auto industry. The dispute was less a partisan fight than a regional and interest-group struggle. Leading Democrats such as Carl Levin of Michigan and Dick Gephardt of Missouri opposed large CAFE increases; prominent Republicans such as John McCain of Arizona and Olympia Snowe of Maine favored stricter mileage rules.

A window of opportunity opened in August 2001 when a committee of the National Academy of Sciences released a major study of the CAFE program (NAS, 2001). Chaired by Dr. Paul Portney of Resources for the Future, this committee concluded that reform of the CAFE standards could save more energy, reduce safety risks to motorists and minimize compliance costs. While tighter CAFE standards for cars had saved fuel in the 1980s, NAS found that those same standards had caused adverse safety consequences among motorists due to the downsizing of cars. NAS suggested that size- or weight-based CAFE standards replace the uniform, fleet-wide mileage standards. In order to enhance economic efficiency, NAS also recommended that the separate CAFE programs for domestic cars, imported cars and light trucks be combined into a single program and that permission be granted for manufacturers to trade CAFE compliance credits.

At about the same time, vehicle manufacturers and the United Auto Workers (UAW) union were beginning to realize what they were up against in California, where the state legislature passed a CAFE-like bill aimed at reducing carbon-dioxide emissions from vehicles sold in California. Other states in the northeast began to follow California's lead. The prospect of a proliferation of state CAFE programs was frightening to all elements of the industry. Reluctantly, industry leaders began to realize that a revitalized federal CAFE program was far better than putting California and various states in charge of national auto policy.

Inside the White House, the President's legislative-affairs team was skeptical about whether any CAFE-related proposal could pass the Congress. Despite their reservations, the decision was made to allow DOT to ask Congress to lift the freeze on CAFE standards and provide DOT with new regulatory authority to implement the NAS suggestions.

The DOT proposal to reform CAFE went nowhere in the Congress. There was never even a vote on the House or Senate floor concerning the NAS reforms. Why? All of the stakeholders – the environmentalists, UAW, vehicle manufacturers and consumer groups – were opposed to giving DOT this broad new authority. As one auto lobbyist told me: "The devil you know is better than the devil you don't know." Although Congress would not budge on the NAS reforms, they did lift the freeze on CAFE standards beginning with model year 2004.

Tightening the Mileage Rules

After this legislative debacle, I was asked by the White House to lead an interagency team charged with reforming CAFE administratively. Our charge was to implement as many of the NAS reforms as permitted under existing legal authority. In addition to DOT, the team included OIRA, the Department of Energy (DOE), EPA, the Council of Economic Advisers (CEA), the Council on Environmental Quality, the Vice President's office and the White House policy offices.

We began by tightening mileage standards for light trucks under the existing CAFE framework, while emphasizing the need to reform CAFE in the long run (DOT, 2003). For model years 2005 through 2007, DOT gradually increased light-truck mileage rules from 20.7 MPG to 22.2 MPG. Although the rule was estimated to cost the industry (primarily GM and Ford) more than \$1 billion per year, the benefit-cost analysis showed that the net financial impact on consumers would be beneficial, even assuming that fuel prices stayed around \$1.50 gallon through 2020. Although the extra 1.5 MPG may sound small, it represents a savings of more than 4 billion gallons of fuel over the life of the affected vehicles – even accounting for the fact that some consumers drive more miles when their vehicles become more fuel efficient.

A key assumption in the DOT analysis was that both the private and external benefits of fuel savings should be counted. DOT analysts had learned that there was some low-hanging fruit in the engineering of fuel economy, in part because CAFE standards had been frozen for almost a decade and in part because, they speculated, many consumers apply irrationally large discount rates to future fuel savings. DOT did consider the possibility that tighter mileage standards might reduce new vehicle sales, but this effect was found to be insignificant.

A breakthrough on one of the NAS recommendations occurred in 2003 when the lawyers on the interagency team discovered that DOT already had the authority to adopt size-based CAFE standards for light trucks (but not for cars). This oddity in the way the 1974 CAFE law was written allowed us to develop stricter, size-based standards for the fastest growing and least fuel-efficient segment of the vehicle market: light trucks.

Using this reform authority, DOT gradually tightened MPG targets for light trucks from 2008 through 2011. The long time horizon of the rulemaking provided a degree of regulatory certainty for vehicle makers and the opportunity to consider more innovative compliance technologies (e.g., hybrid engines and advanced diesel engines).

DOT projected that the CAFE rulemakings covering model years 2005 to 2011 will boost overall light-truck fuel economy to 24.0 MPG by 2011, about 16% higher than the level prevailing when President Bush took office (DOT, 2006). DOT also projected that more than ten billion gallons of fuel will be saved. The benefit-cost analysis was favorable (see Table 1), in part because in 2005 the Energy Information Administration raised the long-term fuel-price projection for 2020 from \$1.50 per gallon to \$2.10 per gallon (EIA, 2005). Since private fuel savings are counted in the DOT analysis, a higher projected fuel price causes higher benefit estimates for those technologies that manufacturers do not plan to implement voluntarily.

For the first time in the history of the CAFE program, DOT set the stringency of the CAFE standards at the point where marginal benefits equaled marginal costs. In setting the MPG targets, no consideration was given to the financial condition of Ford and GM compared to Toyota and the other vehicle manufacturers. Thus, the financial-affordability test used previously by DOT was replaced by net-benefit maximization, a reform that resulted in stricter standards than would have resulted if DOT had taken into account the dismal financial condition of GM and Ford.

The Rationale for Size-Based Reform

For model years 2008 through 2011, DOT reformed the CAFE system so that the stringency of a manufacturer's CAFE standard was adjusted based on the size distribution of new vehicles in the company's fleet. Since it is generally easier to achieve good fuel economy in a small rather than a large vehicle, small vehicles were assigned tougher MPG targets than large ones.

The size-based reform had several policy advantages (DOT, 2006). Fortunately, at least one of these advantages appealed to each of the main stakeholders.

First, reform reduced the safety concerns raised by NAS because any vehicle downsizing would cause the vehicle to be assigned a stricter MPG target. Instead of downsizing vehicles, which would save fuel by reducing vehicle weight, manufacturers were encouraged to comply by adopting innovative technology. Since the reform was based on a vehicle's dimensions (called "footprint" in the auto business), not weight per se, innovative light-weight materials remained a viable compliance strategy.

Second, the new size metric created a more level playing field for vehicle manufacturers. This was a critical issue to the UAW, GM and Ford because Toyota and other competitors were beginning to challenge the dominance of Ford and GM in the market for large SUVs and pick-up trucks. And in previous years, Toyota had accumulated large amounts of CAFE credits by competing only in the market for smaller SUVs. In other words, if GM and Ford can survive their near-term financial troubles, there is no reason to believe that the size-based CAFE standards for model years 2008 to 2011 will place them at a long-term competitive disadvantage.

Third, the smallest SUVs were subjected to roughly the same MPG targets as large passenger cars. No longer did the designation "light truck" provide more lenient regulatory treatment than the "car" designation. As a result, there was no perverse regulatory incentive for companies to offer SUVs or mini-vans instead of large sedans or station wagons. And there was no perverse incentive to raise the ground clearance of a vehicle, possibly creating rollover risks, in order to achieve the "light truck" classification.

Finally, reform saved more fuel because all vehicle manufacturers were induced to innovate. Moreover, the scope of the program was expanded to include large passenger SUVs (e.g., the Hummer) that had previously been exempt from MPG standards. DOT considered the possibility that the size-based formula might encourage companies to offer larger vehicles, but this outcome seemed unlikely due to the cost of larger vehicle platforms and the growing consumer interest in car-like SUVs.

An Appeal to the President

In 2005 there was some last-minute second guessing about CAFE reform. As fuel prices ran over \$3.00 per gallon for a brief period and the red ink in Detroit mushroomed, some White House staffers got cold feet about tighter CAFE standards.

The dissenters advocated a return to the CAFE "freeze" of the 1990s based on two arguments. First, "we don't need CAFE anymore", they argued, because high prices at the

pump will spur plenty of conservation. Proponents of CAFE reform responded that long-term market prices will not fully account for concerns about energy and national security, the risks of climate change, and possible irrationalities in how consumers weigh fuel savings in purchasing decisions. Second, dissenters argued that tighter CAFE standards might force GM and Ford into Chapter 11 bankruptcy. Proponents of CAFE reform responded that the stringency of CAFE standards should be set based on net benefits, not the financial fortunes of specific companies, especially since the new sized-based structure provided a level playing field for each manufacturer offering a vehicle of a specific size.

The policy debate was waged in the Oval Office in early 2005. President Bush decided to stay with CAFE reform. Indeed, in his 2007 State of the Union message, President Bush called for even stricter mileage standards for both cars and light trucks over the next ten years under a size-based CAFE program informed by benefit-cost analysis.

A Wedge Between Consumers and Producers?

OIRA and CEA shared a concern that tighter CAFE standards could cause vehicle producers to build vehicles that consumers do not wish to purchase, especially if fuel prices decline more than expected in the years ahead. Since fuel taxes are not likely to be increased, there is a danger that federal regulation will drive a wedge between what consumers want to purchase and what vehicle makers are required to produce under CAFE. The DOT analysis did not account for the utility losses to consumers who might prefer even larger engines, more interior volume, and other fuel-consuming comforts.

As OIRA and DOT were completing the CAFE reform proposal in 2005, Congress finally passed consumer tax credits for fuel-efficient vehicles in the comprehensive energy bill. Scheduled to take effect January 1, 2006, the scope of the credits was expanded at our request to include advanced diesel technology as well as hybrids and fuel cells. Although consumer tax credits are far from a perfect response to the potential "wedge", they may stimulate both consumers and producers to have more interest in fuel-saving innovation than would otherwise be the case.

Thus, the portfolio of policies that OIRA sought is now operating on both the demand and supply side of the market for fuel economy. The recent advances in hybrid engines and advanced diesel technology announced by Honda, Toyota, Ford, GM, Daimler-Chrysler and BMW have been encouraging. As more experience with these policies accumulates, adjustments may need to be made in response to economic realities.

REDUCING AIR POLLUTION FROM COAL PLANTS

One of President Bush's unsuccessful legislative proposals, "The Clear Skies Initiative", was an ambitious program to replace numerous federal and state clean-air programs with a national "cap-and-trade" program covering the electric utility industry. The idea was to place a cap on total industry emissions of sulfur dioxide, nitrogen dioxide and mercury but to allow plants to trade emissions credits in order to keep the cost of the program as low as possible, just as had been done in the successful 1990 program to combat acid rain (Stavins, 1998). OIRA assisted EPA in preparing the benefit-cost analysis for Clear Skies, which called for a 70% reduction in the three pollutants over the next 15 years.

Clear Skies did not move in the Congress because it became embroiled in a political dispute about what should be done about the threat of global warming and the possibility of mercury "hot spots" (Vendantam, 2005). As the prospects for passage of Clear Skies dwindled, the White House asked OIRA to work with EPA on regulations under existing authority to reduce coal-plant air pollution.

As a result, two coordinated rulemakings were issued in 2005: the Clean Air Interstate Rule (CAIR), which places caps on sulfur dioxide and nitrogen dioxide emissions, and the Clean Air Mercury Rule (CAMR), which places caps on mercury emissions. The caps on sulfur and nitrogen emissions were designed to help states and local communities meet health-based air standards for ozone and particulates. Without passage of Clear Skies, those caps could be applied only in states east of the Mississippi, where long-range transport of coal-plant pollution was significant. The 50-state mercury program was grounded in a rarely-used provision of the 1970 Clean Air Act, even though litigation against this creative use of existing authority was expected.

As a package, the two rulemakings were quite costly to businesses and consumers: CAIR was projected to cost almost \$ 2 billion per year, while the controls on mercury were projected to cost an additional \$750 million per year by 2020 (EPA, 2005ab). The cost of both rules was minimized by the creation of trading markets, where plants facing high costs of control could purchase emissions credits from plants facing low costs of control.

Surprisingly, the benefit-cost case is far weaker for CAMR than for CAIR, even though CAIR is far more costly. This is because the evidence of benefits from mercury removal is quite weak. As a result, OIRA exerted a pro-regulation role on CAIR, but worked hard to reduce the unnecessary economic burdens that otherwise might have been imposed by CAMR.

CAIR

In regions of the country that do not meet EPA's health-based air quality standards, it is often impossible to achieve healthy air without greater emissions reductions by sources in upwind states. Using the Clean Air Act's "good neighbor" authority, EPA was empowered to prevent one state from causing air quality problems in a downwind state.

A regional cap-and-trade program for sulfur dioxide and nitrogen dioxide was established for 28 states and the District of Columbia. Under CAIR, overall emissions from power plants in the region were capped to ensure a 50% emission reduction by 2009-2010 and a 65-70% reduction by 2015 (EPA, 2005a).

The public health benefits of CAIR are estimated to be impressive (EPA, 2005a). By 2015, the reductions in particle concentrations (due largely to the sulfur controls) are projected to prevent 17,000 premature deaths, 8,700 cases of chronic bronchitis, 22,000 nonfatal heart attacks, 10,500 hospitalizations, 1.7 million lost work days and 9.9 million days of restricted physical activity. The health benefits from diminished ozone (smog) levels (due to nitrogen controls) are less impressive but still substantial: 2,800 fewer hospital admissions for respiratory illnesses, 280 fewer emergency room visits for asthma, 690,000 fewer days with restricted activity and 510,000 fewer days where children are absent from

school due to illnesses. The number of premature deaths prevented by the nitrogen controls could be as large as 500 per year.

When expressed in monetary units, the total benefits of the overall CAIR rule were estimated to eventually exceed \$150 billion per year. The lion's share of these benefits is attributable to the premature deaths prevented by the sulfur controls. Thus the overall ratio of CAIR's benefits to costs was on the order of 75 to 1.

OIRA was skeptical of some of these figures. In 2002 we asked EPA to perform an alternative analysis with a series of less optimistic assumptions. The results were still encouraging. The alternative benefit estimate was a factor of ten smaller than EPA's preferred estimate, but the benefit-cost ratio of CAIR remained favorable.

OIRA worked with EPA analysts to take a closer look at the incremental benefits and costs of controlling sulfur and nitrogen. That inquiry suggested that sulfur emissions reductions beyond 70% would be defensible on benefit-cost grounds. Indeed, OIRA had made the case – unsuccessfully – that the sulfur cap under Clear Skies should be tighter than what was proposed. The benefit-cost case for additional controls on nitrogen dioxide (beyond a 70% reduction) was far less clear.

The lawyers on the interagency team argued that the 2015 sulfur cap could not be set more stringently than a 70% reduction – even though it made good economic sense to do so – without exposing the rule to legal risk. Reductions larger than 70% could not be easily justified in court because additional reductions were not necessary to assist downwind states in achieving EPA's standard of healthy air. However, as EPA tightens the 24-hour air-quality standard for particulates, a tighter sulfur cap may become legally defensible in the years ahead (Eilperin, 2006).

OIRA also urged EPA to include industrial as well as utility sources of sulfur and nitrogen dioxide in a broader cap-and-trade program, or in a tailored trading market for industrial sources. Although there was substantial interest in this suggestion, the poor financial condition of the manufacturing sector of the U.S. economy proved to be a formidable obstacle.

CAMR

At the same time that OIRA was urging EPA to make CAIR as stringent as possible, OIRA was working hard to make sure that the CAMR rule was not overly stringent. OIRA was also working against those who believed that no federal mercury rule was necessary.

Mercury in the Environment

After mercury is emitted from the stack and deposited (e.g., during periods of rainfall), it is converted into a more toxic form (methyl mercury) and finds its way into water bodies. EPA scientists were concerned that people living near power plants might experience health risks from eating large amounts of (locally-caught) fish contaminated with mercury.

The most sensitive individuals are pregnant women because of the neurotoxic effects of methyl mercury on the rapidly growing brain of the fetus. In the 1990s many states

adopted fish advisories aimed at discouraging pregnant women from ingesting fish that might be contaminated with mercury. Unfortunately, fish advisories are often ignored, sometimes because low-income, subsistence populations rely on locally-caught fish for their daily diet.

About 4% to 8% of pregnant women in the United States have been shown to have mercury levels in their blood that exceed EPA's safe concentration, the reference level set to protect the fetus and small child (EPA, 2005b). Surveys show that these women consume predominantly marine fish. However, there is no evidence that emissions from U.S. power plants are responsible for the elevated mercury levels in marine fish.

The initial thinking at EPA was that strict mercury controls were necessary at every power plant to ensure that pregnant women living near plants were protected. If an 80-90 percent reduction in mercury emissions had been required at each plant, the cost could have been several billion dollars per year (Gayer and Hahn, 2005). Indeed, the engineers from DOE and EPA were disputing whether such reductions were even technically feasible (especially for boilers that burn sub-bituminous and lignite coals). OIRA and EPA looked hard for a more cost-effective policy alternative.

A promising insight arose from the environmental science: The non-elemental forms of mercury (e.g., oxidized and particulate mercury) are most likely to be deposited near plants, while the elemental form – the pure gas -- enters the global pool of mercury and can be deposited virtually anywhere in the world. It is very difficult and expensive to control elemental mercury. Some plant-specific controls may be needed to address non-elemental mercury emissions, but a "cap-and-trade" program is most appropriate for pollutants (such as elemental mercury) that are rapidly dispersed and transported long distances.

Reducing Mercury Emissions

In the course of the rulemaking, EPA and OIRA discovered that CAIR, by itself (i.e., without CAMR), was quite effective in reducing mercury (EPA, 2005b) because the same controls used by utilities to reduce sulfur and nitrogen also reduce (non-elemental) mercury. Without CAIR or CAMR, EPA projected 45 to 47 tons per year of mercury emissions by 2020. CAIR alone was projected to reduce mercury emissions to 34 tons by 2020. Thus, at no extra cost, the CAIR rule was projected to cut overall mercury emissions by 26%. More importantly, emissions of non-elemental mercury, which tend to deposit locally, were projected to decline by 55% (from 22 to 10 tons per year by 2020) due to CAIR alone.

EPA's health risk assessment did not demonstrate any significant health risk from 10 tons per year of non-elemental mercury emissions, even among pregnant women who did not follow fish advisories. It is theoretically possible that some risks remained at a small number of plants with unusual conditions, since the EPA models were regional in coverage and did not have fine precision very close to plants. However, under CAMR, rare instances of localized risk can be addressed by state and local regulators.

EPA and OIRA ultimately agreed that the case for strict controls at every plant was weak, especially after the effects of CAIR were considered. The policy debate then shifted to whether the U.S. should make a significant economic investment, beyond CAIR, to further reduce our nation's contribution to the global pool of mercury.

U.S. power plants contribute to the global mercury pool, but the best estimate is that the contribution in recent years was less than 5% of the global total (EPA, 2005a). Nevertheless, the U.S. has an interest in stimulating the development of new mercury control technologies that might be used worldwide to reduce the global pool. Based on this rationale, which was outside a traditional benefit-cost framework, OIRA supported a national cap-and-trade program to reduce the mercury emissions expected to remain after CAIR. The end result is that in 2020, CAMR sets a cap on national mercury emissions from power plants at 16 tons per year, about a 65% reduction from pre-CAIR levels, and a 53% reduction from post-CAIR levels.

Although the 2020 mercury cap costs about \$750 million per year beyond CAIR, it has several qualitative benefits. It stimulates U.S. industry to develop new mercury-control technologies that can reduce emissions of elemental mercury. As new technologies are commercialized, they can be used throughout the world as well as in the United States. As CAMR reduces further the U.S. contribution to the global mercury pool, other countries may be more readily persuaded that they should reduce their contributions to the global pool. CAMR also makes a contribution to reducing non-elemental mercury emissions (from 10 to 7 tons per year). The combination of CAIR and CAMR reduces non-elemental mercury emissions by 68%, providing an extra measure of assurance that pregnant women living downwind of power plants are protected. Although this benefit could not be quantified, CAMR was considered a precautionary investment with a plausible fairness rationale.

Objections to Emissions Trading

Some commentators object to the idea of allowing power plants to trade mercury allowances (Heinzerling and Steinzor, 2004). They argue that "hot spots" may result near some plants, where owners decide to buy allowances rather than spend capital to control mercury. Of course, this concern is valid only if pregnant women happen to live downwind at points of high deposition where large amounts of locally-caught fish are ingested regularly.

OIRA and EPA economists argued that market forces are likely to reduce rather than increase any "hot spots" that now exist. Economies of scale in pollution control are greatest at the largest plants, those that emit the most mercury and have the most local mercury deposition. If the average plant reduces mercury emissions by 70%, even larger percentage reductions will occur at the large power plants. Moreover, the permission to trade is likely to cause disproportionate reductions in non-elemental mercury, since it is easier and cheaper to control than elemental mercury. If, for some unexpected reason, "hot spots" do occur at some plants, state and local authorities have adequate authority to set more stringent standards for those plants. In fact, some states are already setting standards that are more stringent than CAMR (Adams, 2006).

In the final analysis, the \$750 million annual cost of the CAMR rule was supported by OIRA and EPA on the basis of qualitative benefits that could not be monetized. The rule should certainly be revisited as more is understood about the benefits and costs of controlling mercury. Some analysts believe a more stringent rule may be supportable by new science indicating mercury intake is related to elevated risks of heart attacks among adults (Rice and Hammitt, 2005). The rule may have to be revisited sooner rather than later if it does not survive the barrage of litigation that has been launched against it.

TAKING STOCK OF OIRA'S PRO-REGULATION HISTORY

OIRA's proactive stances on trans fats, diesel-engine exhaust, vehicle fuel economy and coal-plant pollution were unusual by historic standards. The early years of OIRA's history were dominated by efforts to reduce regulatory burdens on industry (Morrison, 1986, Percival, 1991). Yet, OIRA's support of sound rules in the 2001-2006 period was certainly not unprecedented.

In fact, OIRA's role in diesel-exhaust control is reminiscent of the accelerated phase-out of leaded gasoline that occurred early in the Reagan Administration. In that case, industry came to President Reagan's "regulatory relief" task force seeking a delay of the ban on leaded gasoline that President Carter's EPA had issued. Instead the Reagan OIRA was ultimately persuaded to sign on to the opposite course: an acceleration of the lead phase out. The pivotal input was a careful benefit-cost analysis by EPA analysts, including review and support by OIRA (McGarity, 1991; Morgenstern, 1997; Gray et al, 1997).

In the Clinton years, OIRA also made important pro-regulation accomplishments. For example, OIRA effectively resisted a determined effort by DOT to weaken the automobile airbag requirement. In the face of public outcry from libertarians and citizens who feared the explosive device, DOT sought OIRA approval for a modified rule that would have placed a manual on-off switch in every new vehicle produced with an airbag. OIRA blocked this proposal on the grounds that the safety harms from a misused on-off switch might be vastly greater than the benefits. Once drivers and front-seat passengers were informed about the benefits and risks of airbags and safety belts through a massive education effort, public acceptance of the technology improved considerably (Graham, 2001).

What was different about OIRA in the George W. Bush years was OIRA's proactive role in the priority setting process. In addition to serving as an end-of-the-pipeline mechanism for quality control, OIRA became a determined participant in the formulation stage of policy making.

OIRA's pro-regulation accomplishments in the 2001-2006 period also underscore a lesson that has been repeated throughout OIRA's 25-year history: Careful economic analysis sometimes suggests that more federal regulation is a wiser public policy than less federal regulation (Smith, 1984; Mendeloff, 1988; McGarity, 1991; Breyer, 1993; Sunstein 2002). Regardless of whether OIRA is working in a conservative or liberal administration, this is an essential feature of "smart regulation" based on science and economics.

The diesel-exhaust and coal-plant rulemakings also highlight why it is important for OIRA to be capable of scrutinizing claims of benefits as well as costs. In retrospect, one of my best personnel moves at OIRA was to recruit the office's first toxicologist and epidemiologist, in addition to new specialists in engineering and health policy. The new experts joined OIRA's economists and statisticians as the office began to delve more deeply into the technical aspects of regulatory benefit estimates (OMB, 2002). Although we respected the views of agency experts, we began to ask more penetrating questions about how benefits were determined.

In the diesel-exhaust rulemaking, we did not accept at face value the huge benefit estimates prepared by EPA in collaboration with their science advisors. We recognized that

there was considerable imprecision (and possible bias) in the EPA estimates and thus instructed EPA to prepare an alternative benefit analysis based on more pessimistic assumptions. When we learned that even the alternative benefit estimates supported EPA's policy, we became even more determined advocates of EPA's position in the White House.

The benefit story was much more complex for pollution from coal plants. After persistent probing of EPA over several years, we became convinced that tighter controls on sulfur emissions promised much greater benefits than tighter controls on mercury emissions, even though the mass media and some activist groups often portrayed mercury as the worst of all pollutants. The position we advocated needs to be re-evaluated in the years ahead as more scientific knowledge is obtained about both sulfur and mercury emissions from coal plants.

The CAFE rulemaking illustrates why it is important for OIRA analysts to remain engaged on an important issue, even if the "first-best" policy is rejected. In the George W. Bush administration and in the Congress, higher fuel taxes or new carbon taxes were dead on arrival, even though some economists in the administration saw them as the best course for public policy.

Rather than give up on energy conservation, OIRA worked persistently with multiple agencies, including the Council of Economic Advisers, to improve federal fuel economy regulation and create consumer tax credits for purchase of vehicles with innovative fuel-saving technologies. Coupled with the sustained rise of fuel prices, these "second-best" policies appear to be stimulating a market dynamic in favor of more hybrid engines, more advanced diesel technology and more light-weight construction materials. The resulting technological innovations provide a solid foundation for more ambitious national or international policies to promote energy security and slow the pace of climate change.

CONCLUSIONS AND FUTURE DIRECTIONS FOR RESEARCH

Each year OMB publishes agency estimates of regulatory costs and benefits. These data show that during my tenure as OIRA Administrator, the overall net benefits from regulation were larger than was experienced in the 1990s (see Table 1). In part, this occurred because we cut the growth rate of costly major rules by 49% compared to the 1990s (OMB, 2004; 2005; 2007a; 2007b). But we also encouraged rulemakings with impressive benefits, causing average yearly benefits from major rules to increase 108% compared to the 1990s (OMB, 2007a,b).

Table 1
Total Net Benefits from
Major Federal Rules, 1992-2005
(in billions of 2001 dollars)

Year	Benefits	Costs	Net Benefits
1992	81.1	16.3	64.8
1993	7.7	8.1	-0.4
1994	11.4	8.7	2.7
1995	3.1	3.5	-0.4
1996	19.6	2.6	17.0

1997	2.5	2.4	0.1
1998	12.8	5.4	7.4
1999	15.9	8.4	7.5
2000	35.1	17.9	17.2
2001	0.0	-4.8	4.8
2002	4.3	1.9	2.4
2003	3.1	2.5	0.6
2004	52.2	6.8	45.4
2005	74.0	5.6	68.4
2006	26.0	2.5	23.5

Notes: Figures for 1992 and 2000 include rules issued prior to the presidential inauguration in the next year. Based on 134 major federal rules where agencies produced estimates of benefits and costs. All figures are annualized. Sources: OMB 2007a,b.

Overall, the quantified net benefit of major rules from 2001 to 2005 increased by 280% compared to the 1990s (OMB, 2007b). Fewer major rules were issued, but those that were issued had superior benefit-cost justifications. One of the key lessons is that we should judge regulators not by the number of rules they issue, but by their overall contribution to social welfare (Sunstein, 2002; Adler and Posner, 2006).

Reviewing major new rules was a big challenge, but modernizing the sea of existing federal regulations was an even bigger chore (Crain, 2005). Since OMB began to keep records in 1981, an additional 20,000 new federal rules have been adopted (OMB, 2007). For the vast majority of these rules, the regulator has never looked back to determine what the rule accomplished or how expensive it was. Thus, at the same time that OIRA worked to enhance the efficiency of new rules, we also instructed regulators to reexamine and streamline about 100 existing regulations, the first serious "look-back" effort since the early Reagan years (OMB, 2003; 2004; 2007).

What surprised some, however, was how frequently our office made a *pro-regulation* argument to regulators, to White House staff, to the Vice President's office and even to the President himself. Before coming to government, I had discovered that public health regulators suffer from a syndrome of paranoia and neglect: excessive regulation of some risks, inadequate regulation of others (Graham, 1997). Past practice at OIRA had focused on the first part of this problem, but OIRA had not yet begun to tackle the second part, a longstanding concern of progressive regulatory scholars (Breyer, 1993; Sunstein, 2002; Bagley and Revesz, 2006). I am pleased to have begun an effort at OIRA to address this imbalance.

Unfortunately, the benefit-cost framework for regulatory reform is only as powerful as the tools and data available to implement the framework. Based on my five years of experience overseeing federal regulatory agencies, I have become even more convinced than I was previously of the need for our nation to make expanded research investments in regulatory economics, science, and engineering. The information base on which we made multi-billion dollar decisions was often remarkably slim. Hence, I conclude this paper with several examples of the urgent need for research.

First, environmental regulators assume that each statistical life extended by reducing air pollution should be valued at \$6 million (EPA, 2004; 2005a). This figure was a crucial input to the benefit assessments for both the diesel-engine and coal-plant rulemakings. Upon close inspection, the figures used in the benefit assessments were based primarily on the wage premiums that are necessary to attract workers into occupations with elevated risks of traumatic injury (Viscusi and Aldy, 2003). Although environmental economists use the phrase "benefit transfer" to describe this form of extrapolation, it would be more useful if regulatory analysts had some relevant data on the public's economic demand for improved air quality. That is a challenging research question, but one that would be very worthwhile to study directly with innovative research designs and hard data.

Second, the estimated air-quality benefits are based on another crucial assumption: that all fine particles are equally toxic, regardless of their size or chemical composition. Yet there are sound toxicological reasons to suspect that sulfates, nitrates and carbon-containing particles vary considerably in their toxicity at low concentrations. Moreover, the epidemiologic evidence that currently links air pollution and adverse health outcomes has progressed only modestly beyond what Lester Lave and colleagues published in the early 1970s (Lave and Seskin, 1970). Much of the recent literature does not make use of the modern econometric tools that are now considered standard in economics. I would like to see the next generation of environmental epidemiology studies be produced by teams of analysts that include physicians, toxicologists, environmental scientists, statisticians and econometricians. The future stakes in regulatory policy – whether measured in public health or monetary terms – justify new kinds of scientific collaborations.

Finally, we need better economic models of how consumers and producers in the automotive industry will respond to a multiplicity of federal and state regulations, higher fuel prices, tax policies, and a major restructuring of the industry. A key question is what products will arise from a U.S. automotive market with fuel prices below European experience (\$4-5 per gallon) but considerably above the U.S. experience of the 1990s (\$1 - \$2 per gallon). As energy-security and climate-change concerns intensify over the next decade, there will be numerous policy proposals aimed at the world transport sector. Unless our economic models of the global auto industry improve considerably, much of this policymaking will be based on guesswork. I believe our universities, think tanks and government policy shops are capable of producing a stronger analytic foundation for future policy making.

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**QUESTIONS FROM SUBCOMMITTEE CHAIR LINDA SANCHEZ
FOR PETER STRAUSS**

1. Could you please explain why formal rulemaking is rarely used?
2. Could you please explain the so-called "peanut butter" case?

I believe both of these questions can be well answered with the explanation we give for not treating formal rulemaking seriously in our law school teaching materials, **Strauss, Rakoff and Farina, Gellhorn & Byse's Administrative Law – Cases and Comments 486-87 (10thEd. Rev. 2003)**:

As a procedure, formal rulemaking was criticized for being a voracious consumer of agency resources, and giving excessive control over the development of the rule to the parties to the proceeding. For example, an FDA formal rulemaking to determine the percentage of peanuts a substance must contain in order to be labeled "peanut butter" took nine years and twenty weeks of hearings producing 8,000 pages of hearing record, to produce a six-page opinion to justify a decision to require at least 90% peanuts). Robert W. Hamilton, Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking, 60 Calif.L.Rev. 1276, 1312-1313 (1972)) reported more generally:

"It is surprising to discover that most agencies required to conduct formal hearings in connection with rulemaking in fact did not do so during the previous five years.... Thus, the primary impact of these procedural requirements is often not, as one might otherwise have expected, the testing of agency assumptions by cross-examination, or the testing of agency conclusions by courts on the basis of substantial evidence of record. Rather these procedures either cause the abandonment of the program (as in the Department of Labor), the development of techniques to reach the same regulatory goal but without a hearing (as FDA is now trying to do), or the promulgation of noncontroversial regulations by a process of negotiation and compromise (as FDA historically has done and Interior is encouraged to do). In practice, therefore, the principal effect of imposing rulemaking on a record has often been the dilution of the regulatory process rather than the protection of persons from arbitrary action."

In 1973, one year after publication of Hamilton's study, the Supreme Court assured the marginalization of formal rulemaking with its decision in UNITED STATES V. FLORIDA EAST COAST RAILWAY CO., 410 U.S. 224. The ICC had by regulation established "incentive" rates to encourage railroads to send empty freight cars back to their owners. Without such rates, railroads had no particular reason to return the cars, and cars that tended to go full in only one direction – refrigerator cars, say, carrying produce to urban markets – tended to pool there and create artificial and unnecessary shortages. Its statute directed it to act "after hearing" and the ICC had initially contemplated oral trial-type procedures for its regulatory effort. However, after intense congressional pressure to move more quickly, the agency

limited the railroads to written submissions.¹ The Supreme Court upheld the Commission. It held that the simple statutory reference to "hearing" was not enough to activate §553(c)'s reference to cases in which "rules are required by statute to be made on the record after opportunity for an agency hearing." "The District Court[, in reaching the opposite conclusion,] observed that it was 'rather hard to believe that the last sentence of §553(c) was directed only to the few legislative sports where the words 'on the record' or their equivalent had found their way into the statute book.' 318 F.Supp., at 496. This is, however, the language which Congress used, and since there are statutes on the books that do use these very words, see, e.g., the Fulbright Amendment to the Walsh-Healey Act, 41 U.S.C. §43a, and 21 U.S.C. §371(e)(3), the regulations provision of the Food and Drug Act, adherence to that language cannot be said to render the provision nugatory or ineffectual. We recognized in *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742 (1972) that the actual words 'on the record' and 'after ... hearing' used in §553 were not words of art, and that other statutory language having the same meaning could trigger the provisions of §§556 and 557 in rulemaking proceedings. But we adhere to our conclusion, expressed in that case, that the phrase 'after hearing' in §1(14)(a) of the Interstate Commerce Act does not have such an effect." Earlier cases like *ICC v. Louisville & Nashville R. Co.*, above, were distinguished as involving the rates of a single railroad grounded in its individual financial circumstances, not uniform and nationwide incentive payments ordered to be made by all railroads subject to the regulation.

Formal rulemaking was essentially abandoned from this point forward. In 1978, the United States Supreme Court strongly disapproved judicial reasoning looking in the same direction in its famous decision in *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519. (Candor requires acknowledging that, as General Counsel of the US Nuclear Regulatory Commission at the time, I helped to write the government's brief in the case.) The enduring lesson of that decision has been that the conversion of rulemaking into a species of adjudication, subject to the control of private parties through procedural maneuvering, is unwise.

¹ The ICC actually proceeded as if under the special dispensation of §556(d) permitting it to act just on the basis of written submissions, unless a party would be "prejudiced thereby"; as indicated in the text, the Supreme Court simply found that section inapplicable.

Questions for Prof. Peter Strauss:

1. You acknowledge on p. 2 of your written testimony that it is the President's duty to see that the laws are faithfully executed. In your opinion, will the regulatory plans contemplated under Executive Order 13422's amendments to Executive Order 12866 literally help or hinder the President in seeing whether the laws are being faithfully executed by federal agencies?

In my judgment, the regulatory plans in and of themselves, as contemplated by EO 12866 both before and after its amendment, will help the President to determine whether the laws are being faithfully executed; I share Congress' judgment (as in SBREFA) about their importance. The important point, in my judgment, is to preserve the distinction between presidential oversight – entirely appropriate and constitutionally commanded – and presidential decision. Formulation of agency priorities and plans is the statutory responsibility of the agency head, and a part of the President's obligation to see whether the laws are being faithfully executed by federal agencies is to honor and protect that responsibility.

2. In particular, under Executive Order 13422, the President and his appointees will be better able to see plans for significant guidance, and therefore better able to inquire into those plans. In your opinion, will that help or hinder the President from seeing whether statutes and regulations, which are laws, are being faithfully executed in the giving of agency guidance?

I agree that well-formulated and express plans will assist the President in oversight and open opportunities for his guidance. The important point, in my judgment, is to preserve the distinction between presidential oversight – entirely appropriate and constitutionally commanded – and presidential decision. Formulation of agency priorities and plans is the statutory responsibility of the agency head, and a part of the President's obligation to see whether the laws are being faithfully executed by federal agencies is to honor and protect that responsibility.

3. Executive Order 13422 calls for the identification of planned actions and information that will help to prioritize those actions. In your opinion, will that help or hinder the President from seeing whether the laws are being faithfully executed by federal agencies?

I cannot improve on my answer to the preceding questions. The important point, in my judgment, is to preserve the distinction between presidential oversight – entirely appropriate and constitutionally commanded – and presidential decision. Formulation of agency priorities and plans is the statutory responsibility of the agency head, and a part of the President's obligation to see whether the laws are being faithfully executed by federal agencies is to honor and protect that responsibility.

4. You suggest that the Executive Order 13422's terms regarding Regulatory Policy Officers threaten "a dramatic increase in presidential control over regulatory outcomes, to an extent Congress has not authorized and in my judgment must authorize." In your opinion, did Executive Order 12866 similarly threaten to increase presidential control? Please explain why or why not.

Executive Order 12866 marked *some* increase in presidential control over regulatory outcomes. I took a position relatively early in the Clinton administration critical of its apparent tendency, and President Clinton's apparent tendency to take over as his own certain rulemakings *outside* the confines of the Executive Order. In Peter L. Strauss, *Presidential Rulemaking*, 72 Chi-Kent L.Rev. 965 (1997) I worried, as I did in my testimony to your committee, that the result of these developments was to erode the important distinction between oversight and decision and, in doing so, to threaten our rule-of-law culture. "The stakes for the psychology of government," I concluded at p. 986, "for the extent to which civil servants and political appointees imagine themselves as acting within a culture of law, are rather high."

As Professor Katzen testified to your committee, EO 13422 is a distinct increase in the already significant degree of presidential control over regulatory outcomes, beyond that established by EO 12866, which in turn exceeded what had been done in its predecessor executive orders. Each step in a hazardous direction increases the hazard. In particular, by deleting EO 12866's provision that the RPO "shall report to the agency head" and instead making him subject, as a "presidential appointee" to presidential (not agency head) dismissal, EO 13422 takes a decisive step from President as overseer to President as decider. The President is not constitutionally entitled to confer decisional authority on persons outside the White House, and Congress has conferred no such authority on him statutorily; but that, too, is what EO 13422 purports to do.

The important point, in my judgment, is to preserve the distinction between presidential oversight – entirely appropriate and constitutionally commanded – and presidential decision. Formulation of agency priorities is the statutory responsibility of the agency head, and a part of the President's obligation to see whether the laws are being faithfully executed by federal agencies is to honor and protect that responsibility.

5. Section 10 of Executive Order 13422 specifically provides: "Nothing in this order shall be construed to impair or otherwise affect the authority vested by law in an agency or the head thereof." In your opinion, does this provision temper or put to rest any concerns that Executive Order 13422 might help the President to supplant the authority of agency heads or the rules of the road that Congress has laid down in the statutes that federal agencies implement? Please explain why or not.

If I could understand Section 10 as confessing to the legal nullity of the matters I testified about, I might think it tempered or put to rest my concerns.

But I believe the President's lawyers concluded that he actually does have legal authority to make the changes that I discuss in my testimony. While these issues are very unlikely to find their way into litigation, they can profoundly affect the way in which government personnel understand their responsibilities. No agency head or RPO will understand Section 10 to mean that the RPO still "shall report to the agency head," or that the RPO in fact lacks the legal authority that EO 13422 ostensibly confers on him. Thus, my concerns are not tempered.

6. The Office of Management and Budget testified at the hearing that the Regulatory Policy Officers ("RPOs") described in Executive Order 13422 will be Senate-confirmed presidential appointees. In light of that testimony, have your concerns about RPOs subsided? Please explain why or why not.

Testimony to a committee of Congress by an acting head of OIRA is not binding on the President, or even on OIRA. Even if this provision were in the Executive Order, which it is not, it would remain the case that the President had purported to confer legal authority on a person no longer required to "report to the agency head," and dismissible by the President – not the agency head – at will. This internal division of agency authority, unauthorized by Congress, would concern me still.

The important point, in my judgment, is to preserve the distinction between presidential oversight – entirely appropriate and constitutionally commanded – and presidential decision. Formulation of agency priorities is the statutory responsibility of the agency head, and a part of the President's obligation to see whether the laws are being faithfully executed by federal agencies is to honor and protect that responsibility.

7. It appears that Executive Order 13422 merely codifies prior practice related to RPOs under Executive Order 12866. Were you equally concerned about politicization of the process under the uncodified, prior RPO practice? Please explain why or why not.

See my answer to question 4, above. With respect, I find it hard to see these provisions as a mere codification. Every inquiry I had made as a scholar about the uses of RPOs and regulatory plans prior to these amendments – when, as noted above, I did have some concerns – led me to conclude that possibilities for presidential control of regulatory plans implicit in EO 12866 had been put up on the shelf, however they *might* have been used. These included candid conversations with Prof. Katzen and Dr. John Graham, and a number of responsible agency officials who were quite willing to share their experiences with me "off the record." Regulatory plans just weren't being controlled. Now we see a formal mechanism for control, put in the hands of an official divorced from the agency head and subject to direct presidential control – both new, and to me disturbing, developments.

The important point, in my judgment, is to preserve the distinction between

presidential oversight – entirely appropriate and constitutionally commanded – and presidential decision. Formulation of agency priorities is the statutory responsibility of the agency head, and a part of the President's obligation to see whether the laws are being faithfully executed by federal agencies is to honor and protect that responsibility.

8. In your written testimony, you expressed concern that RPOs under Executive Order 13422 might be "junior officers." In your opinion, were junior officers eligible to be designated as RPOs under Executive Order 12866, and did anything in Executive Order 12866 prevent an agency head from delegating the RPO function to a non-Senate-confirmed political official, or even to a junior career agency employee?

Inferior officers could, and to my knowledge did, occupy RPO positions. I am not aware of any limit on the authority of the agency head to designate a person he was willing to entrust with the much more limited authority RPOs held under EO 12866 before its recent amendment.

9. You have taken the position that the transparency provisions of Executive Order 12866 would not apply to RPOs. In your opinion, would RPOs have been subject to the transparency provisions of Executive Order 12866 prior to Executive Order 13422's issuance? Please explain why or why not.

So far as I know, RPOs had no responsibilities under EO 12866 that would have warranted subjecting them to its transparency provisions. OIRA officials coordinating with them were, of course, subject to those provisions.

To the extent EO 12866 embodied a decision process that might have interfered with an agency's internal ordering of its priorities and plans (and, again, as indicated in answer 7, I am unaware despite efforts to determine the question of any indication that in fact this happened), that process would have applied. Now RPOs have decisional authority they never previously possessed, and structures for limiting outside contacts and making them transparent are completely missing.

10. Professor Katzen has testified that she consulted with various experts prior to the issuance of Executive Order 12866, and that she responded to comments. Did Professor Katzen consult with you? If she did, what did you tell her, and how did she defend the heightened role of the Vice President under Executive Order 12866's terms?

Professor Katzen did consult with me. I have no recollection, however, of the details of our conversation. She may.

Note in this respect that EO 12866 merely formalized a process of increasing responsibility for the Vice President in assisting the President in his oversight of domestic policy issues. Recall, for example, Vice President Quayle's role in the Council on Competitiveness, and the central roles played by Boyden Grey, as Counsel to Vice President Bush during the Reagan Administration.

11. In 2002, President Bush revised Executive Order 12866 to remove the provision granting the Vice President that heightened role in the regulatory review process. Did you publicly support that action at that time? Please explain why or why not.

At about that time, I was part of a discussion of the Vice President's role in a national forum of the Federalist Society in Washington DC. It may have a transcript of my remarks; I do not believe I do. My general position, which I believe I would have stated, is that dignifying the Vice President's office by delegating such responsibilities to it is a welcome step – and that EO 12866 considerably improved on the prior administrations' practice by bringing it into the open and placing some legal and transparency constraints around it. Vice President Cheney has seemed more interested in defense and security matters than ordinary public policy – understandable in the wake of 9-11, Afghanistan and Iraq – but if a future Vice President were to agree to such responsibilities, I would welcome that. For me, as above, the real issues are ones of regularity, transparency, and law.

12. In your opinion, will it help or hinder Congress in its oversight of statutory implementation that, under Executive Order 13422, RPOs will be publicly named, so that Congress knows precisely upon whom to call when there is a need for oversight?

Public naming of RPOs is a helpful step, for the reasons stated in the question. Of course it also identifies them for private efforts at influence, see Question 9.

13. Do you believe that the market failure principle embodied in the terms of Executive Order 13422 transgresses on the authority of Congress? If so, is it your opinion that the market failure principle embodied in Executive Order 12866 did the same, and is it also your opinion that the same can be said of each of the other principles of regulation embodied in Section 1(b) of Executive Order 12866, such as the principle that agencies should only adopt regulations with benefits that justify their costs? Please explain why or why not.

This was not a matter about which I testified, and I hope the interlocutor will excuse a summary response. The issues here, in my judgment, are whether the executive order (or any predecessor) in practice results in decisions that turn on factors Congress has not authorized for consideration. To take a prominent example, many scholars (including myself) believe that the Supreme Court's tolerance for the extraordinary authority of the EPA Administrator at issue in *Whitman v. American Trucking Assn*, 531 US 457 (2001) was heavily dependent on its conclusion that Congress had *not* authorized her to consider cost as a factor. The result was to keep her judgment, at least apparently, within the constraints of technological issues and not infect it with political trade-offs of a sort perhaps only the Congress should be authorized to make. The very fact that, as the Court understood the statute, her competence was limited to health questions, made it more acceptable that she should have such authority.

14. With regard to each of the concerns you have expressed in your oral and written testimony regarding Executive Order 13422, please explain whether those concerns would exist regardless of which president's administration were in office, and why or why not.

My concerns are legal, not political. As remarked above, for example in connection with your question 4, I have been critical of actions of President Clinton that seemed to raise similar dangers. Under EO 13422, in my judgment, those dangers are greatly magnified – regardless of who is the President. The important point, in my judgment, is to preserve the distinction between presidential oversight – entirely appropriate and constitutionally commanded – and presidential decision. Formulation of agency priorities is the statutory responsibility of the agency head, and a part of the President's obligation to see whether the laws are being faithfully executed by federal agencies is to honor and protect that responsibility.

