

**SUSAN E. DUDLEY**  
**ADMINISTRATOR,**  
**OFFICE OF INFORMATION AND REGULATORY AFFAIRS**  
**BEFORE THE**  
**COMMITTEE ON THE JUDICIARY**  
**SUBCOMMITTEE ON COMMERCIAL AND ADMINISTRATIVE LAW**  
**UNITED STATES HOUSE OF REPRESENTATIVES**

**May 6, 2008**

Chairwoman Sanchez, Ranking Member Cannon, and distinguished Members of this Subcommittee, thank you for inviting me to testify at today's hearing titled "Rulemaking Process and the Unitary Executive Theory."

As the Administrator of the Office of Information and Regulatory Affairs (OIRA), and as someone who served as a career economist on its staff in the 1980s, I am pleased to be here today to talk with you about OIRA's role in the rulemaking process and also the history of executive oversight of the regulatory process.

**Role of OIRA**

OIRA was created as part of the Office of Management and Budget (OMB) by the Paperwork Reduction Act of 1980, more than twenty-five years ago. In fact, our 27<sup>th</sup> anniversary was at the beginning of last month. Staffed almost exclusively by career civil servants, OIRA has served Administrations, both Democratic and Republican, for decades by providing centralized oversight and interagency coordination of federal information, regulatory, and statistical policy.

While OIRA's current regulatory oversight functions are authorized by Executive Order 12866, issued by President Clinton in 1993, every President since at least the early 1970s has established some form of executive oversight of the regulatory process within the Executive Office of the President. For example, before the formation of OIRA, President Carter issued Executive Order 12044, "Improving Government Regulations," which established general principles for regulating and required regulatory analyses for major regulations. The Council on Wage and Price Stability (CWPS), the Office of Management and Budget, and the Regulatory Analysis

Review Group chaired by the Council of Economic Advisors reviewed the regulatory analyses of major regulations. The Carter Administration helped to institutionalize regulatory review by the Executive Office of the President and the utility of benefit-cost analysis for regulatory decision makers.

President Reagan formalized the process in 1981 when he issued Executive Order 12291 that gave the newly created OIRA the mandate to analyze regulations. As part of a reorganization, the regulatory analysis staff of CWPS were transferred into OIRA. Executive Order 12291 required, to the extent permitted by law, that administrative decisions be based on adequate information concerning the need for and consequences of proposed government action, and that regulatory actions should maximize the net benefits to society. President George H. W. Bush continued the use of Executive Order 12291.

When President Clinton took office in 1993, he replaced Executive Order 12291 with Executive Order 12866. In many ways, Executive Order 12866 mirrors its predecessor, although it reduced the number of regulations reviewed by OMB from about 2,200 a year to about 600, a number that has remained relatively stable since Executive Order 12866 became effective. Executive Order 12866 reinforces the philosophy that regulations should be based on an analysis of the costs and benefits of all available alternatives, and that agencies should select the regulatory approach that maximizes net benefits to society, unless otherwise constrained by law.<sup>1</sup>

Over more than three decades, regulatory analysis has emerged as an integral part of government accountability – a non-partisan tool for understanding the likely effects of regulation. The principled approach to regulation articulated by Presidents Carter, Reagan, Clinton, and both Presidents Bush has withstood the test of time. The non-partisan nature of this approach is reinforced by the fact that, during the current Bush Administration, we have continued to operate under Executive Order 12866, with some minor amendments that I describe below.

### **Executive Order 12866**

President Clinton's Executive Order 12866 established OIRA as the entity that reviews significant regulations, observing that "[c]oordinated review of agency rulemaking is necessary

---

<sup>1</sup> Section 1 of Executive Order 12866, as amended.

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.”<sup>2</sup>

Executive Order 12866 embraces the regulatory philosophy 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,”<sup>3</sup> and lays out regulatory principles to which agencies should adhere, to the extent permitted by law.<sup>4</sup> I note these principles below:

- “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 . . . .”<sup>5</sup>
- “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.”<sup>6</sup>
- “Each agency shall indentify 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.”<sup>7</sup>
- “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.”<sup>8</sup>

---

<sup>2</sup> Section 2(b) of Executive Order 12866, as amended.

<sup>3</sup> Section 1(a) of Executive Order 12866, as amended.

<sup>4</sup> Section 1(b) of Executive Order 12866, as amended.

<sup>5</sup> Section 1(b)(1) of Executive Order 12866, as amended.

<sup>6</sup> Section 1(b)(2) of Executive Order 12866, as amended.

<sup>7</sup> Section 1(b)(3) of Executive Order 12866, as amended.

<sup>8</sup> Section 1(b)(4) of Executive Order 12866, as amended.

- “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. . . .”<sup>9</sup>
- “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.”<sup>10</sup>
- “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.”<sup>11</sup>
- “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.”<sup>12</sup>
- “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...”<sup>13</sup>
- “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.”<sup>14</sup>
- “Each agency shall tailor its regulations and guidance documents to impose the least burden on society . . . .”<sup>15</sup>
- “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.”<sup>16</sup>

---

<sup>9</sup> Section 1(b)(5) of Executive Order 12866, as amended.

<sup>10</sup> Section 1(b)(6) of Executive Order 12866, as amended.

<sup>11</sup> Section 1(b)(7) of Executive Order 12866, as amended.

<sup>12</sup> Section 1(b)(8) of Executive Order 12866, as amended.

<sup>13</sup> Section 1(b)(9) of Executive Order 12866, as amended.

<sup>14</sup> Section 1(b)(10) of Executive Order 12866, as amended.

<sup>15</sup> Section 1(b)(11) of Executive Order 12866, as amended.

Pursuant to Executive Order 12866, OIRA oversees the regulatory process for the Executive Branch by coordinating interagency review of significant agency regulations. As the office that reviews all of the significant regulations of the Federal government, OMB is in the best position to ensure that the regulatory process flows smoothly, just as it is with its other central review functions with respect to the fiscal budget, legislative proposals, and program management.<sup>17</sup> Additionally, court decisions have recognized the legitimacy of executive branch regulatory review.<sup>18</sup>

### **Enhancements to the Transparency and Accountability of the Regulatory Process During the Bush Administration**

Over the last seven years, the Bush Administration has built on the foundations laid by previous administrations to enhance the oversight and accountability of the regulatory process.

First, we have enhanced OIRA's transparency. As you know, the confidential nature of interagency deliberations is necessary to allow the Executive Branch to engage in open and candid discussions as policy decisions are debated. Over several administrations, OIRA has sought to strike a balance between this legitimate need to protect the deliberative process and the Congress's and the public's need for information from the Executive Branch. In this Administration, we have expanded public disclosure by providing on OIRA's website lists of all meetings held with outside parties on rules under review.<sup>19</sup> We also list on our website all regulations under review.<sup>20</sup> Additionally, once a rule has been published, the public has access to the OIRA docket which contains, among other things, a copy of the draft rule as originally submitted to OIRA by the agency and a copy of the draft rule once OIRA concluded review.

---

<sup>16</sup> Section 1(b)(12) of Executive Order 12866, as amended.

<sup>17</sup> Previous OIRA Administrators are supportive of OMB's role in centralized regulatory review. See Sally Katzen, "A Reality Check on an Empirical Study: Comments on 'Inside the Administrative State,'" 105 Mich. L. Rev. 1497, 1505 (2007) ("[The agency] is pursuing its parochial interest; OIRA is tempering that with the national interest, as it should."); Christopher C. DeMuth & Douglas H. Ginsburg, "White House Review of Agency Rulemaking," 99 Harv. L. Rev. 1075, 1081-85 (1986) (OMB is well-suited to perform centralized regulatory review because, among other reasons, it has no program responsibility and is accountable only to the president, it subjects proposed rules to a "hard look" before they are issued and ensures that serious policy disagreements will be brought to a president's attention, and its staff is expert in the field of regulation itself).

<sup>18</sup> See, e.g., *Sierra Club v. Costle*, 657 F.2d 298, 405 (D.C. Cir. 1981) ("The Court recognizes the basic need of the President [in that case, President Carter] and his White House staff to monitor the consistency of executive agency regulations with Administration policy.").

<sup>19</sup> See <http://www.whitehouse.gov/omb/oira/meetings.html>.

<sup>20</sup> See <http://www.reginfo.gov/public/do/eoPackageMain>.

Second, we have made strides in making rulemaking more accessible to the public through the advent of e-Rulemaking. Over the last five years, e-Rulemaking has transformed access to the federal government rulemaking process. Regulations.gov has brought government-wide information together, and made it searchable. Users of regulations.gov can locate regulations on a particular subject, determine whether the rules are open for public comment, access supporting documents, file comments on proposed rules, and even read comments filed by others. Another e-Rulemaking advancement is the online publication of the Unified Agenda and Regulatory Plan. Last fall, for the first time, they became available in an electronic format that offers users an enhanced ability to obtain and search for information on upcoming regulations.

Third, OIRA has undertaken several initiatives related to rulemaking: (i) Circular A-4; (ii) Information Quality Guidelines; (iii) Peer Review Bulletin; (iv) the Final Bulletin for Agency Good Guidance Practices, (v) amendments to Executive Order 12866; and (vi) the Updated Principles for Risk Analysis. All serve to reinforce OIRA's emphasis on well-reasoned rulemakings and the use of high quality information when making regulatory decisions.

#### ***Circular A-4***

For more than 20 years, OMB has reviewed the regulatory impact analyses produced by the agencies using economic "best practices," carefully developed through notice and comment procedures. OMB and the agencies currently use Circular A-4,<sup>21</sup> which was issued in 2003, after public comment, and interagency and peer review. OMB issued Circular A-4 to provide agencies with state-of-the-art guidance in complying with the requirements for regulatory analysis of economically significant rules as set forth in Executive Order 12866. This Circular advises agencies how to standardize the way that benefits and costs of Federal regulatory actions are measured and reported to ensure consistency and transparency across the Federal government. Circular A-4 refines OMB's "Best Practices" document of 1996, which was issued as a guidance in 2000 and reaffirmed in 2001. The 1996 Best Practices guidance reaffirmed guidance originally issued for notice and comment by OMB in 1988 as Appendix V of the Regulatory Program of the United States Government and issued in final form in the 1990 Regulatory Program.

---

<sup>21</sup> Circular A-4 is available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

### ***Information Quality Guidelines***

The Information Quality Act of 2001 required OMB to provide guidance to Federal agencies to ensure and maximize the quality, objectivity, and integrity of information they disseminate.<sup>22</sup> In 2002 after taking public comment, OMB issued Information Quality Guidelines that require agencies to establish basic standards of quality and administrative mechanisms to ensure such quality.<sup>23</sup> In turn, agencies issued their own information quality guidelines that can be located on their websites. In August 2004, OIRA issued a memorandum to agencies asking them to increase the transparency of the process by posting all Information Quality correspondence on agency websites.<sup>24</sup>

### ***Peer Review Bulletin***

OMB's Peer Review Bulletin became effective in 2005.<sup>25</sup> It established that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal government. Peer reviews serve to enhance the quality and credibility of the Federal government's scientific information that often serves as the basis for rulemakings. Agencies are also posting their peer review agendas on their websites.

### ***Final Bulletin for Agency Good Guidance Practices***

In 2007, after soliciting and responding to public and interagency comment, OMB issued a Final Bulletin for Agency Good Guidance Practices, to increase the quality, accountability, and transparency of agency guidance documents.<sup>26</sup>

The impetus behind the Good Guidance Bulletin is that while guidance documents do not have the force of law, they can nevertheless have a significant impact on American businesses, workers, consumers, and State, local and tribal governments. Well-designed guidance documents serve many important functions in regulatory programs, such as advising and assisting individuals, small businesses and other regulated entities in their compliance with agency regulations, as well as furthering consistency and fairness in an agency's enforcement of

---

<sup>22</sup> Section 515 of the Treasury and General Government Appropriations Act for FY2001 (Pub. L. No. 106-554).

<sup>23</sup> See [http://www.whitehouse.gov/omb/inforeg/iqq\\_oct2002.pdf](http://www.whitehouse.gov/omb/inforeg/iqq_oct2002.pdf).

<sup>24</sup> See [http://www.whitehouse.gov/omb/inforeg/info\\_quality\\_posting\\_083004.pdf](http://www.whitehouse.gov/omb/inforeg/info_quality_posting_083004.pdf).

<sup>25</sup> See <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>.

its regulations. However, agency guidance that has an impact on society equivalent to that of a regulation should be subject to an appropriate level of review, within an agency, by other agencies with related missions, and by the public. Many of those providing public comments on the draft bulletin expressed support for OMB's issuance of it.<sup>27</sup>

To accomplish its goal, the Bulletin established policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies:

- In each agency, appropriate officials will review and approve 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 the significant guidance documents of the agency. Agencies will advertise on their websites a means for the public to submit comments electronically on these guidance documents.
- For those guidance documents that are economically significant, agencies will publish notices in the Federal Register announcing that the draft documents are available (on the internet or in hard copy), invite public comment on them, and post on their websites response-to-comments documents.

Most agencies have substantially complied with these requirements by updating their websites. For example, the Department of Labor and the Environmental Protection Agency have done outstanding jobs of making their guidance documents available to the public. Other agencies have made a lot of progress but have not yet met all of the Good Guidance Practices Bulletin's requirements. For example, some have not completed cataloging their existing guidance

---

<sup>26</sup> See <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.

<sup>27</sup> See public comments on the draft Good Guidance Practices Bulletin, available at [http://www.whitehouse.gov/omb/inforeg/good\\_guid/c-index.html](http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html).



documents and some have not yet provided adequate contact information for the public. We will continue to work with the agencies but are pleased with their progress overall.

### ***Amendments to Executive Order 12866***

Another significant improvement to the agency guidance document process is Executive Order 13422,<sup>28</sup> issued by the President in January 2007, which amended Executive Order 12866 to clarify OMB's authority to coordinate interagency review of agencies' significant guidance documents.<sup>29</sup> Before the issuance of these amendments, OMB reviewed some agency guidance documents but the process was informal.

Executive Order 13422 also made several process amendments to Executive Order 12866 to encourage good government practices. The first recognizes that a good regulatory analysis is more than a summation of benefits and costs. Both President Reagan's & President Clinton's Executive Orders directed agencies and OIRA first to identify the need for the regulatory action before undertaking benefit-cost analysis. President Clinton was more explicit than President Reagan regarding this first step, stating in Executive Order 12866, Section 1, in the Statement of Regulatory Philosophy and Principles:

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.

President Bush's recent amendments to Executive Order 12866 left that language in place, but made the "market failure" language more prominent in a subsequent subsection of Section 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.

---

<sup>28</sup> See [http://www.whitehouse.gov/omb/inforeg/eo12866/fr\\_notice\\_eo12866\\_012307.pdf](http://www.whitehouse.gov/omb/inforeg/eo12866/fr_notice_eo12866_012307.pdf).

<sup>29</sup> Section 9 of Executive Order 12866, as amended.

Increased emphasis on first identifying the compelling public need before launching into a benefit-cost analysis perhaps reflects a growing awareness that the best benefit-cost analysis in the world cannot improve upon an outcome if the agency has not first identified a core problem that cannot be addressed by other means.

The amended Executive Order also required agency heads to designate one of the agency's Presidential Appointees to be its Regulatory Policy Officer (RPO), to advise OMB of the designation, and to update OMB annually on the status of this designation.<sup>30</sup> In testimony before this Subcommittee (see attachment) on February 13, 2007,<sup>31</sup> Steven Aitken, who was serving as the Acting OIRA Administrator when the Executive Order amendments and the Final Bulletin for Agency Good Guidance Practices were issued, explained the rationale behind the change to the Regulatory Policy Officer. I will not go over his testimony in detail but, in summary, he made five points that deserve emphasis:

- Regulatory Policy Officers are not new; in 1993, when President Clinton issued Executive Order 12866, he directed each agency head to designate an RPO;
- A Presidential Appointee is appointed by the President and should not be confused with “political appointees” appointed by the agency head;
- The amendments to the Executive Order place no restrictions on the agency head's discretion in choosing which Presidential Appointee within the agency to designate as the agency's Regulatory Policy Officer;
- The amendments to the Executive Order do not change the fact that the Regulatory Policy Officer reports to the agency head; and
- The chief advantage of having a Presidential Appointee serve as the Regulatory Policy Officer is that it ensures accountability. For example, the Regulatory Policy Officer can testify before Congress.

---

<sup>30</sup> Section 6(a)(2) of Executive Order 12866, as amended.

<sup>31</sup> See [http://www.whitehouse.gov/omb/legislative/testimony/oira/aitken\\_02132007.pdf](http://www.whitehouse.gov/omb/legislative/testimony/oira/aitken_02132007.pdf).

OMB has placed on its website a list of agency Regulatory Policy Officers, thereby making it quite transparent who is serving in this capacity for each of the agencies – for example, the General Counsel for the Department of Agriculture, the Deputy Secretary for the Department of Health & Human Services, the General Counsel at the Department of Housing & Urban Development, and the Assistant Attorney General for the Office of Legal Policy at the Department of Justice.

And to emphasize that these positions are not new, I would like to point out that there is substantial overlap between those serving as RPOs before the issuance of the Executive Order amendments and those serving as RPOs after. For example, those designations have not changed for the Departments of Commerce, Health & Human Services, Homeland Security, Justice, and Transportation. We do not know the extent of the overlap, however, because OIRA did not have an up-to-date listing of the RPOs when the Executive Order amendments were issued. The amendments provided us with an opportunity to get these important updates.

### ***Updated Principles for Risk Analysis***

Finally, in 2007, OMB and the Office of Science and Technology Policy jointly issued a memorandum to agencies on Updated Principles for Risk Analysis. This memorandum reiterates principles released by the Clinton Administration in 1995 and reinforced them with more recent guidance from the scientific community, Congress, and the Executive Branch.

The Memorandum reinforces generally-accepted principles for risk analysis articulated in 1995 related to environmental, health, and safety risks.<sup>32</sup> As a whole, the Memorandum endeavors to enhance the scientific quality, objectivity, and utility of Agency risk analyses and the complementary objectives of improving efficiency and consistency among the Federal family. For example, the Memorandum articulates the following principles: (i) the extent of analysis should be commensurate with the nature and significance of the determination; (ii) agencies should use the best reasonably available scientific information to assess risks; (iii) judgments

---

<sup>32</sup> While many of the principles presented in this Memorandum may be relevant to other fields, such as financial or information technology risk analyses, the focus of this Memorandum is on those risk analyses related to environmental, health, and safety risks.

used in developing a risk assessment should be stated explicitly; (iv) risk management goals should be stated explicitly; and (v) agencies should coordinate risk reduction efforts when feasible and appropriate.

### **Conclusion**

Executive oversight of agency rulemaking has a long history that transcends party lines. It is important for a well-functioning, accountable regulatory system that meets the needs of the American people. Thank you very much for the opportunity to testify in today's hearing. I would be happy to answer any questions you may have.