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THE ROLE OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS IN FEDERAL RULEMAKING

*Curtis W. Copeland**

INTRODUCTION

The Office of Information and Regulatory Affairs (OIRA) is one of several statutory offices within the Office of Management and Budget (OMB),¹ and can play a significant—if not determinative—role in the rulemaking process for most federal agencies. In addition to its many other responsibilities, OIRA reviews the substance of about 600 to 700 significant proposed and final rules each year before agencies publish them in the *Federal Register*,² and can clear the rules with or without change, return them to the agencies for “reconsideration,” or encourage the agencies to withdraw the rules. About 100 of the rules that OIRA reviews each year are each considered “economically significant” or “major” (e.g., expected to have a \$100 million impact on the economy).³ OIRA was created by Congress and has a number of specific statutory responsibilities, but also helps ensure that agencies’ rules reflect the president’s policies and

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1. The other statutory offices, which are sometimes collectively referred to as the “management” side of Office of Management and Budget (OMB), are the Office of Federal Financial Management, the Office of Federal Procurement Policy, and the Office of Electronic Government and Information Technology. OMB’s resource management offices (RMOs) review agencies’ budget submissions, and are sometimes collectively referred to as OMB’s “budget” side. However, the RMOs also include management issues in their budget reviews, and do other “management” work as well.

2. The Administrative Procedure Act of 1946, 5 U.S.C. § 551 (2000), generally requires agencies to publish a notice of proposed rulemaking in the *Federal Register*, permit the public to comment on the proposed rule, and then publish a final rule addressing the comments provided.

3. To view the economically significant rules that OIRA reviews each year, in total or for particular agencies, see <http://www.reginfo.gov/public/> (last visited Apr. 21, 2006).

priorities.

OIRA's role in the federal rulemaking process has been highly controversial in all four of the presidential administrations in which it has been in existence, but the criticisms directed at the office have varied over time. In some administrations, OIRA has been accused of controlling the agenda of the rulemaking agencies too much, directing them to change substantive provisions in draft rules, or even stopping proposed regulatory actions that it believes are poorly crafted or unnecessary.⁴ At other times, though, OIRA has been accused of exerting inadequate authority over the agencies' rules.⁵ Other, more persistent criticisms have focused on the lack of transparency of OIRA's regulatory reviews to the public and the sometimes-unseen influence that regulated entities and other non-governmental organizations can have on agencies' rules through those reviews.⁶

This Article describes the process OIRA uses to review covered agencies' draft rules, OIRA's effects on the rules, and changes in OIRA's procedures and policies in recent years. Much of this discussion is drawn from a September 2003 report on OIRA that I helped develop when I was with the General Accounting Office (GAO, now the Government Accountability Office).⁷ First, though, this Article provides a brief history of presidential regulatory review and describes how OIRA's review process was established. Finally, the Article describes several potential legislative issues regarding OIRA's regulatory review authority, and makes a few concluding observations both about OIRA's recent initiatives and its future.

THE ESTABLISHMENT OF REGULATORY REVIEW IN OIRA

OIRA was created within OMB by the Paperwork Reduction Act (PRA) of 1980.⁸ The PRA provided that OIRA would be headed by an administrator who was designated the "principal advisor to the Director on

4. *See, e.g.*, GEORGE C. EADS & MICHAEL FIX, RELIEF OR REFORM? REAGAN'S REGULATORY DILEMMA 135-38 (1984).

5. JAMES L. GATTUSO, THE HERITAGE FOUND., EXEC. MEMO. NO. 813, REGULATING THE REGULATORS 2 (2002) (noting that "OIRA became a much less aggressive watchdog than it had been under previous Presidents," and citing as evidence the decline in the number of rules returned to the agencies).

6. U.S. GEN. ACCOUNTING OFFICE, GAO-03-929, RULEMAKING: OMB'S ROLE IN REVIEWS OF AGENCIES' DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS 54 (2003) [hereinafter GAO, RULEMAKING].

7. *Id.*

8. Paperwork Reduction Act (PRA) of 1980, 44 U.S.C. § 3503(a) (1980) (amended 1995).

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Federal information policy.”⁹ The Act also provided that the director of OMB “shall delegate to the [OIRA] Administrator the authority to administer all functions under this chapter.”¹⁰ Specific areas of responsibility in the PRA that were assigned to the director, and later delegated to OIRA, included information policy, information collection request clearance and paperwork control, statistical policy and coordination, records management, privacy, and automatic data processing and telecommunications.¹¹ With regard to paperwork reduction, the Act generally prohibited agencies from conducting or sponsoring a collection of information until they had submitted their proposed information collection requests to OIRA and the office had approved those requests.

The PRA’s requirements cover rules issued by virtually all agencies, including Cabinet departments, independent agencies, and independent regulatory agencies and commissions.¹²

Although the PRA gave OIRA substantive responsibilities in many areas, the bulk of the office’s day-to-day activities under the act were initially focused on reviewing and approving agencies’ proposed information collection requests. OIRA had ninety staff members when the PRA took effect in 1981, about half of whom were involved in reviewing agencies’ information collection requests.¹³ That year, OIRA took nearly 5,000 paperwork review actions—approving new and revised collections, extending existing collections, and reinstating expired collections. The office’s paperwork clearance workload since then has generally been between 4,000 and 6,000 actions each year, although the number of OIRA staff overall, and those reviewing proposed collections, has declined substantially.¹⁴ Although many federal regulations have an information collection component, the PRA did not authorize OIRA to review or

9. *Id.* § 3503(b).

10. *Id.*

11. *Id.* § 3504. The PRA was later amended in 1986, and again in 1995, and the list of OIRA’s duties changed somewhat. For example, the 1986 amendments sharpened the management focus of the act and changed the term “information policy” to “information resources management.” Paperwork Reduction Act of 1986, 44 U.S.C. § 3501(3) (1986) (amended 1995). The 1986 amendment also required the administrator of OIRA to be appointed by the President, subject to the advice and consent of the Senate. *Id.* § 3503(2).

12. As used in this Article, the term “independent regulatory agencies” refers to agencies established to be independent of the President, including the Federal Communications Commission, the Securities and Exchange Commission, and the Consumer Product Safety Commission. The term “independent agencies” refers to agencies that are independent of Cabinet departments, but not independent regulatory agencies, including the Environmental Protection Agency (EPA) and the Office of Personnel Management.

13. GAO, RULEMAKING, *supra* note 6, at 60.

14. *Id.*

comment on the substance of those regulations, or on regulations without an information collection component.¹⁵

OIRA AND THE REAGAN EXECUTIVE ORDERS ON REGULATORY REVIEW

In 1980, Ronald Reagan was elected President on a platform critical of government's role in society in general, and of federal regulations in particular.¹⁶ Shortly after taking office, he established a "Presidential Task Force on Regulatory Relief," headed by Vice President George H. W. Bush, and composed of Cabinet officers (although the bulk of the task force's work was reportedly performed by OMB staff). The task force's responsibilities included: (1) monitoring the establishment of OMB's responsibility to coordinate and review new rules, (2) the development of legislative changes to regulatory statutes, and (3) the revision of existing regulations.¹⁷ With respect to this last responsibility, the task force ultimately identified a total of 119 rules for alteration or cancellation by the issuing agencies, nearly half of which had been issued by the Department of Transportation (DOT) or the Environmental Protection Agency (EPA).¹⁸ Although the task force found that the implementation of recommended changes would save more than \$150 billion over the next ten years, critics charged that this estimate ignored the benefits associated with the rules on what they referred to as the administration's regulatory "hit list."¹⁹ The task force's legislative efforts were less successful, and failed to prompt Congress to enact revisions to clean air and water laws, or to enact broad regulatory reform legislation that would have limited agencies' rulemaking powers.²⁰

In February 1981—less than one month after taking office—President Reagan issued Executive Order 12,291, which greatly increased both the

15. In some cases, though, the paperwork requirement may be the essence of the regulation. For example, EPA's Toxics Release Inventory (TRI) program is essentially a database of information that is collected from the businesses that are required to provide it, which serves the purpose of making members of the public aware of chemical hazards in their communities. For more information on the TRI program, see U.S. Env'tl. Prot. Agency, Toxics Release Inventory Program, <http://www.epa.gov/tri/> (last visited Apr. 21, 2006).

16. See EADS & FIX, *supra* note 4, at 1-2.

17. Letter from Vice President George Bush, transmitting report on the status of the Reagan Administration's regulatory relief efforts (Aug. 11, 1983) (on file with author).

18. See PRESIDENTIAL TASK FORCE ON REGULATORY RELIEF, REAGAN ADMINISTRATION REGULATORY ACHIEVEMENTS (1983).

19. *Id.*

20. The task force was disbanded in August 1983 after issuing its final report.

scope and importance of OIRA's responsibilities.²¹ The executive order generally required covered agencies (Cabinet departments and independent agencies, but not independent regulatory agencies) to:

- Refrain from taking regulatory action “unless the potential benefits to society for the regulation outweigh the potential costs to society,” to select regulatory objectives to maximize net benefits to society, and to select the regulatory alternative that involves the lowest net cost to society;²²

- Prepare a “regulatory impact analysis” for each “major” rule,²³ which was defined as any regulation likely to result in (among other things) an annual effect on the economy of \$100 million.²⁴ Those analyses were required to contain a description of the potential benefits and costs of the rule, a description of alternative approaches that could achieve the regulatory goal at lower cost (and a list of reasons why they were not selected), and a determination of the net benefits of the rule.²⁵ The issuing agency was to make the initial determination of whether a rule was “major,” but the executive order gave OMB the authority to require a rule to be considered major;²⁶ and

- Send a copy of each draft proposed and final rule to OMB before publication in the *Federal Register*.²⁷ The order authorized OMB to review “any preliminary or final regulatory impact analysis, notice of proposed rulemaking, or final rule based on the requirements of this Order.”²⁸ Non-major rules were required to be submitted to OMB at least ten days before publication, but major rules had to be submitted as much as sixty days in advance.²⁹

Executive Order 12,291 indicated that OMB's review of rules and impact analyses should be completed within sixty days, but it allowed the director to extend that period whenever necessary.³⁰ It also authorized the director to exempt classes of regulations from any or all of the order's requirements, and generally required agencies to “refrain” from publishing

21. Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 19, 1981). For a description of the effects of this order, see Erik D. Olson, *The Quiet Shift of Power: Office of Management & Budget Supervision of Environmental Protection Agency Rulemaking Under Executive Order 12,291*, 4 VA. J. NAT. RESOURCES L. 1, 80 (1984).

22. Exec. Order No. 12,291, *supra* note 21, § 2(a)-(e).

23. *Id.* § 3(a).

24. *Id.* § 1(b).

25. *Id.* §§ 3(d)(1)-(5).

26. *Id.* § 3(b).

27. *Id.* § 3(c).

²⁸ *Id.* § 3(e)(1).

29. *Id.* § 3(c)(1)-(3).

30. *Id.* § 8.

any final rules until they had responded to OMB's comments.³¹ The executive order made OMB's authority to review agencies' draft rules subject to the overall direction of the presidential task force on regulatory relief.³²

Although the Executive Order did not specifically mention OIRA, shortly after it was issued the Reagan Administration decided to integrate OMB's regulatory review responsibilities under the executive order with the responsibilities given to OMB (and ultimately to OIRA) by the PRA.³³ As a result, OIRA's responsibilities for substantive review of rules under the executive order were added to the office's substantial responsibilities under the PRA. In 1981, OIRA reviewed the substance of nearly 2,800 rules under Executive Order 12,291—in addition to the nearly 5,000 paperwork review actions it took that year.³⁴

In 1985, President Reagan extended OIRA's influence over rulemaking even further by issuing Executive Order 12,498, which required Cabinet departments and independent agencies (but not independent regulatory agencies) to submit a "regulatory program" to OMB for review each year that covered all of their significant regulatory actions that were underway or planned.³⁵ Previously, Executive Order 12,291 had required each of those agencies to publish semiannual "regulatory agendas" of proposed regulations that the agency "has issued or expects to issue," and any existing rule that was under review.³⁶ These agendas were required to contain a schedule for completing action on any major rule for which the agency had published a notice of proposed rulemaking. The new executive order went further, providing that, except in "unusual circumstances," OMB could return any rule submitted for review under Executive Order

31. *See id.* The exemptions that OMB was authorized to grant fell into four broad categories: (1) rules that were essentially non-regulatory in nature; (2) rules that delegated regulatory authority to the States; (3) rules that generally affected individual entities and that did not involve broader policy issues; and (4) rules for which a delay of even a few days could have imposed substantial costs and that were unlikely to involve significant policy issues. *Id.* OMB granted about thirty exemptions, most of which were established in 1981 or 1982.

32. *Id.* § 3(e)(1). Although Vice President Bush chaired the task force, the administrator of OIRA served as its executive director. Other members of the task force included the Director of OMB, the Attorney General, and the Secretaries of Commerce, Labor, and the Treasury.

33. CONG. RESEARCH SERV., OFFICE OF MANAGEMENT AND BUDGET: EVOLVING ROLES AND FUTURE ISSUES 201-10 (1986) [hereinafter CRS, EVOLVING ROLES].

34. *See* U.S. GEN. ACCOUNTING OFFICE, GAO/GGD-89-101FS REGULATORY REVIEW: INFORMATION ON OMB'S REVIEW PROCESS 14 (1989).

35. Exec. Order No. 12,498, 50 Fed. Reg. 1036 (Jan. 8, 1985).

36. President Carter first required the use of these agendas in 1978. *See* Exec. Order No. 12,291, *supra* note 21, § 5.

12,291 to the issuing agency for “reconsideration” if it was not in the agency’s regulatory program for that year, or was “materially different” from what was described in the program.³⁷ In other words, OIRA could return a draft rule to an issuing agency if the office did not have advance notice of the rule’s submission, even if the rule was otherwise consistent with the requirements in Executive Order 12,291.³⁸ The regulatory agenda and program requirements in these executive orders also permitted OIRA to become aware of forthcoming agency actions well in advance of the submission of a draft proposed rule, thereby permitting the office to stop or alter an objectionable rule before the rulemaking process developed momentum. Although Reagan Administration officials compared this planning process to the process used to develop the President’s budget, critics noted that the budget process has a final step that the regulatory process lacked—review and approval by Congress.³⁹ Therefore, they argued, the insertion of OIRA into the regulatory planning process represented a further aggregation of at least potential policymaking power in the hands of the OIRA Administrator and, more generally, the Executive Office of the President.⁴⁰

COMPARISON TO PREVIOUS REGULATORY REVIEW EFFORTS

The establishment of a broad regulatory review function within OIRA by Executive Orders 12,291 and 12,498 was a significant development both in the office’s history and in the overall movement to reform the federal regulatory process. In another sense, though, these executive orders represented the continuation of the presidential review of rules, not the starting point thereof. Some form of centralized review of agencies’ regulations within the Executive Office of the President has been part of the rulemaking process since the early 1970s. For example:

- In 1971, President Nixon established a “Quality of Life Review” program in which executive departments and independent agencies submitted all “significant” draft proposed and final rules pertaining to “environmental quality, consumer protection, and occupational and public health and safety” to OMB, which then circulated them to other agencies

37. Exec. Order No. 12,498, *supra* note 35, §§ 3(d).

38. An OIRA representative said that the office had never used this authority, noting that it would have been difficult to defend the return of an agency’s rule for purely procedural reasons. Interview with OIRA representative, in Old Executive Office Building, Washington, D.C. (2003) (on file with author) (part of a series of interviews with various representatives from OIRA as research for GAO, RULEMAKING, *supra* note 6).

39. CRS, EVOLVING ROLES, *supra* note 33, at 201-04.

40. *Id.*

for comment.⁴¹ In their submissions, agencies were to provide a summary of their proposals, including their principal objectives, the alternatives that they considered, and a comparison of the expected benefits and cost of those alternatives. Agencies were also required to submit a schedule showing estimated dates of proposed and final significant rules.⁴²

• In 1974, President Ford issued Executive Order 11,821, which required agencies to prepare an “inflation impact statement” for each “major” proposed rule.⁴³ The statement was a certification that the inflationary impact of the rule had been evaluated in accordance with criteria and procedures developed by OMB. The executive order directed OMB to develop criteria for the identification of major rules that may have a significant impact on inflation, but specified that the office must consider costs, effects on productivity, effects on competition, and effects on the supply of important products and services. Before a major rule was published in the *Federal Register*, the issuing agency was required to submit the associated impact statement to the Council on Wage and Price Stability (CWPS). CWPS would then either provide comments directly to the agency or participate in the regular rulemaking comment process.

• In 1978, President Carter issued Executive Order 12,044, which (among other things) required agencies to publish semiannual agendas of any significant rules under development or review, and to prepare a regulatory analysis for all rules that have a more than \$100 million impact on the economy.⁴⁴ The analysis was to contain a succinct statement of the problem, a description of the alternative approaches considered, and the “economic consequences” of those alternatives.⁴⁵ OMB was instructed to “assure the effective implementation of this Order,” but was not given specific review responsibilities.⁴⁶ President Carter also established (1) a “Regulatory Analysis Review Group” (RARG) to review the analyses prepared for certain major rules, and to submit comments during the comment period; and (2) a “Regulatory Council” to coordinate agencies’ actions to avoid conflicting requirements and duplication of effort.⁴⁷

In several ways, though, the analytical and review requirements in

41. This requirement was formally established in October 1971. According to some observers, the requirements were routinely imposed only on EPA. Memorandum from George Schultz, Director, Office of Mgmt. & Budget (Oct. 1971), available at <http://thecred.com/ombpapers/qualityoflife.htm> (last visited Apr. 18, 2006).

42. *Id.*

43. Exec. Order No. 11,821, 39 Fed. Reg. 41,501 (Nov. 29, 1974).

44. Exec. Order No. 12,044, 43 Fed. Reg. 12,661, § 3(a)(1) (Mar. 24, 1978).

45. *Id.*

46. *Id.*

47. *Id.*

Executive Order 12,291 were significantly different from these previous efforts. For example, the requirement in the new executive order that agencies choose the least costly approach to a particular regulatory objective went further than the requirement in President Carter's Executive Order 12,044, which simply required agencies to analyze and consider alternative regulatory approaches. Also, whereas the regulatory oversight functions were divided among many offices (OMB, CWPS, RARG, and the regulatory council) during the Carter Administration, Executive Order 12,291 consolidated these functions within OIRA.⁴⁸

Another major difference was the amount of influence that OIRA had compared to its predecessors. Under previous executive orders, CWPS and RARG primarily had advisory roles. In contrast, under Executive Order 12,291, OIRA could overrule agency determinations regarding whether the rule was "major" (and therefore required a regulatory impact analysis), and could delay the regulation at either the proposed or final rulemaking stage until the agency had adequately responded to its concerns (e.g., if it believed the agency had not considered all reasonable alternatives, or that the agency's analysis was unsound, or contrary to the administration's policy viewpoint).⁴⁹ OIRA's significant influence on rulemaking was underscored by its organizational position within OMB, the agency that reviews and approves the rulemaking agencies' budget requests on behalf of the President. Finally, the nature and transparency of the review process was significantly different under Executive Order 12,291. Under the Carter Administration's approach, RARG and CWPS prepared and filed comments on agency proposals during the formal public comment period. In the case of RARG filings, a draft of the comments was circulated to all RARG members, and the comments, along with any dissents, were placed on the public record at the close of the comment period. In contrast, OIRA's reviews occurred before the rules were published for comment, and Executive Order 12,291 did not require that OIRA's comments on the draft rule be disclosed.

EARLY VIEWS REGARDING OIRA REVIEWS

The expansion of OIRA's authority in the rulemaking process via Executive Orders 12,291 and 12,498 was highly controversial. Although some believed that OIRA's authority did not go far enough (e.g., the review requirements did not cover independent regulatory agencies), most of the

48. George Eads, *Harnessing Regulation: The Evolving Role of White House Oversight*, 5 REGULATION 19, 26 (1981).

49. Executive Order No. 12,291, *supra* note 21, §§ 3(b), 3(f).

concerns were that the expansion had gone too far. For example, a number of the concerns raised by members of Congress, public interest groups, and others focused on whether OIRA's role violated the constitutional separation of powers, and on the effect that OIRA's review process had on public participation and the timeliness of agencies' rules.⁵⁰ Some believed that OIRA's new authority displaced the discretionary authority of agency decision makers in violation of congressional delegations of rulemaking authority, and that the President exceeded his authority in issuing the executive orders.⁵¹ Others indicated that OIRA did not have the technical expertise needed to instruct agencies about the content of their rules.⁵² Still other concerns focused on OIRA's ability to carry out its many responsibilities. In 1983, GAO concluded that the expansion of OIRA's responsibilities under Executive Order 12,291 had adversely affected the office's ability to carry out its PRA responsibilities, and recommended that Congress consider amending the act to prohibit OIRA from carrying out other responsibilities like regulatory review.⁵³

Other concerns about OIRA focused on the lack of transparency of the regulatory reviews, and specifically questioned whether OIRA had become a clandestine conduit for outside influence in the rulemaking process. Critics pointed out that, in the first few months after the executive order was issued, OIRA met with representatives from dozens of businesses and associations seeking regulatory relief and returned dozens of rules to the agencies for reconsideration.⁵⁴ In response to these concerns, the OMB Director issued a memorandum in June 1981 stating that any factual material provided to OIRA regarding proposed rules should also be sent to the relevant rulemaking agency.⁵⁵ This requirement did not, however,

50. *Role of OMB in Regulation, Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 97th Cong. (1981). See also Morton Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 MICH. L. REV. 193, 193-247 (1981).

51. For a discussion of this argument, see Olson, *supra* note 21, at 17-27.

52. Others, however, argued that OIRA provided expertise in the regulatory process, and could offer a wider range of options. See BARRY D. FRIEDMAN, *REGULATION IN THE REAGAN-BUSH ERA: THE ERUPTION OF PRESIDENTIAL INFLUENCE* 54-55 (1995).

53. U.S. GEN. ACCOUNTING OFFICE, *GAO/GGD-83-35, IMPLEMENTING THE PAPERWORK REDUCTION ACT: SOME PROGRESS, BUT MANY PROBLEMS REMAIN* 9 (1983).

54. See Letter from James C. Miller III, Administrator of OIRA, to the Honorable John D. Dingell, Chairman, Subcomm. on Oversight & Investigations of H. Comm. on Energy & Commerce (Apr. 28, 1981), available at <http://www.thecre.com/pdf/Dingell.pdf> (last visited May 12, 2006).

55. *Role of OMB in Regulation, Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 97th Cong. 46 (1981) (statement of James C. Miller III, OIRA Administrator, characterizing OMB Director Stockman's memorandum), available at <http://www.thecre.com/pdf/Reagan61881.PDF>.

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apply to information provided to OIRA orally, and did not require that OIRA's meetings with outside parties be disclosed to the public.

OIRA's role in the rulemaking process remained controversial for the next several years. In 1983, Congress was so dissatisfied with OIRA's performance in the areas of regulatory and paperwork review that it permitted the office's appropriation authority to expire (although the office's statutory authority under the PRA was not affected and it continued to receive an appropriation via OMB).⁵⁶ In 1985, five House Committee chairmen filed an amicus brief in a lawsuit brought against the Department of Labor (DOL) regarding the DOL's decision (reportedly at the behest of OMB) not to pursue a proposed standard concerning exposure to ethylene oxide, a sterilizing chemical widely used in hospitals and suspected of causing cancer. The chairmen claimed that OMB's actions represented a usurpation of congressional authority.⁵⁷

Congress reauthorized OIRA in 1986, but only after making the Administrator subject to Senate confirmation. By 1986, Congress began considering legislation to restrict OIRA's regulatory review role and to block OIRA's budget request.⁵⁸ In June 1986, in an attempt to head off that legislation, the presiding OIRA Administrator issued a memorandum to the heads of departments and agencies subject to Executive Order 12,291, describing new procedures to improve the transparency of the review process.⁵⁹ For example, the memorandum said that only the administrator or the deputy administrator could communicate with outside parties regarding rules submitted for review, and that OIRA would make available to the public all written materials received from outside parties.⁶⁰ OIRA also said that it would, upon written request after a rule had been published, make available all written correspondence between OIRA and

56. OIRA's authorization for appropriation also expired in 2001, and has not been reestablished. See 44 U.S.C. § 3520 (authorizing \$8 million for PRA-related activities "and for no other purpose" in fiscal years 1996 through 2001).

57. Morton Rosenberg, *Regulatory Management at OMB*, in CRS, *EVOLVING ROLES*, *supra* note 33, at 185, 218 (1986).

58. *Id.*

59. Memorandum from Wendy L. Gramm, OIRA Administrator, to Heads of Dept's and Agencies Subject to Executive Order Nos. 12,291 and 12,498 on Additional Procedures Concerning OIRA Reviews Under Executive Order Nos. 12,291 and 12,498 [Revised] (June 13, 1986), *reprinted in* U.S. OFFICE OF MGMT. & BUDGET, *REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT APRIL 1, 1992—MARCH 31, 1993*, at 585 (1993).

60. *Id.* For further information on this policy, see Judith Havemann, *No 'Shade-Drawn' Dealings for OMB; Congress Gets Disclosure of Regulation-Review Procedures*, WASH. POST, Jun. 17, 1986, at A21.

the agency head regarding the draft submitted for review.⁶¹

In 1987, the National Academy of Public Administration published a report on presidential management of agency rulemaking that summarized the criticisms of the OIRA review process, as well as the positions of its proponents.⁶² The report also described a number of issues in regulatory review and offered recommendations for improvement. For example, the report recommended that “regulatory management be accepted as an essential element of presidential management.”⁶³ It also recommended that regulatory agencies “log, summarize, and include in the rulemaking record all communications from outside parties, OMB, or other executive or legislative branch officials concerning the merits of proposed regulations.”⁶⁴

In 1988, the Administrative Conference of the United States (ACUS) examined the issue of presidential review of agency rulemaking and concluded that such reviews could improve coordination and resolve conflicts among agencies.⁶⁵ ACUS also said, though, that presidential review “does not displace responsibilities placed in the agency by law nor authorize the use of factors not otherwise permitted by law.”⁶⁶ ACUS recommended public disclosure of proposed and final agency rules submitted to OIRA under the executive order, communications from OMB relating to the substance of rules, and communications with outside parties, and also recommended that the reviews be completed in a “timely fashion.”⁶⁷

61. *Id.*

62. NAT’L ACAD. OF PUB. ADMIN., PRESIDENTIAL MANAGEMENT OF RULEMAKING IN REGULATORY AGENCIES (1987) [hereinafter NAT’L ACAD. OF PUB. ADMIN., PRESIDENTIAL MANAGEMENT OF RULEMAKING].

63. *Id.*

64. *Id.*

65. Recommendations of the Administrative Conference of the United States, 1 C.F.R. § 305.88-9 (1988), available at <http://www.law.fsu.edu/library/admin/acus/305889.html> (last visited May 3, 2006). The Administrative Conference was established in 1968 to provide advice regarding procedural improvements in federal programs, and was eliminated by Congress in 1995. See Cindy Skrzycki, *Interest Grows in Resurrecting Administrative Conference*, WASH. POST, May 25, 2004, at E01.

66. Recommendations of the Administrative Conference of the United States, *supra* note 65.

67. *Id.* The National Academy of Public Administration and the American Bar Association (ABA) have also recognized the potential value of presidential regulatory review, recommending such reforms as improved transparency and better communication between OIRA and agency staff. See NAT’L ACAD. OF PUB. ADMIN., PRESIDENTIAL MANAGEMENT OF RULEMAKING, *supra* note 62; see also Letter from William Funk, Chair-Elect, Am. Bar Ass’n, to Lorraine Hunt, Office of Info. & Reg. Affairs (Apr. 24, 2003), available at http://www.abanet.org/adminlaw/policy_letters/sec_comments_omb.doc (last visited Apr. 21, 2006) (summarizing the ABA’s previous recommendations).

OIRA AND THE GEORGE H. W. BUSH ADMINISTRATION

President George H. W. Bush continued the implementation of Executive Orders 12,291 and 12,498 during his administration, but external events significantly affected OIRA's operation and, more generally, the federal rulemaking process. In response to published accounts that the burden of regulation was once again increasing, President Bush established the President's "Council on Competitiveness" (also known as the Competitiveness Council) to review regulations issued by agencies.⁶⁸ Chaired by Vice President Dan Quayle, the council oversaw and was supported by OIRA, and reviewed particular rules that it believed would have a significant impact on the economy or particular industries. The council signified continued White House-level interest in the regulatory arena, and also represented a continuation of the type of role played by the Presidential Task Force on Regulatory Relief during the Reagan Administration.⁶⁹

Many of the Competitiveness Council's actions were highly controversial, with critics assailing both the effects of those actions (e.g., rolling back environmental or other requirements) and the fact that the council acted in secret.⁷⁰ The council attempted to maintain strict secrecy regarding both its deliberations and the identity of those in the private sector with whom it communicated or consulted.⁷¹ Critics decried what they believed to be "backdoor rulemaking" by the Competitiveness Council, but the council continued its operations until the end of the Bush Administration in 1993.⁷² Meanwhile, OIRA continued its operations under Executive Order 12,291, reviewing between 2,100 and 2,600 proposed and final rules each year from 1989 through 1992.⁷³

68. The Competitiveness Council was reportedly created in April 1989 when the Vice President issued a press release, causing some to question its legitimacy. See Caroline DeWitt, *The President's Council on Competitiveness: Undermining the Administrative Procedure Act with Regulatory Review*, 6 ADMIN. L. REV. 759, 800 (1993).

69. *Id.*

70. See CHRISTINE TRIANO & NANCY WATZMAN, OMB WATCH/PUB. CITIZEN, ALL THE VICE PRESIDENT'S MEN: HOW THE QUAYLE COUNCIL ON COMPETITIVENESS SECRETLY UNDERMINES HEALTH, SAFETY, AND ENVIRONMENTAL PROGRAMS (1991).

71. See Bob Woodward & David Broder, *Quayle's Quest: Curb Rules, Leave 'No Fingerprints,'* WASH. POST, Jan. 9, 1992, at A1.

72. For example, Representative Henry Waxman reportedly considered the Council a "shadow government." See FRIEDMAN, *supra* note 52, at 166.

73. For the number of OMB reviews conducted each year, see <http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init> (last visited May 12, 2006). The number of OIRA reviews is graphically depicted in GAO, RULEMAKING, *supra* note 6, at 24.

REGULATORY REVIEW UNDER EXECUTIVE ORDER 12,866

In September 1993, President Clinton issued Executive Order 12,866 on “Regulatory Planning and Review,” which revoked Executive Orders 12,291 and 12,498, and abolished the Council on Competitiveness.⁷⁴ Although different from its predecessors in many respects, Executive Order 12,866 (which is still in effect) continued the general framework of presidential review of rulemaking. For example, it requires covered agencies (again, Cabinet departments and independent agencies, but not independent regulatory agencies) to submit their proposed and final rules to OMB before publishing them in the *Federal Register*.⁷⁵ The order also requires agencies to prepare cost-benefit analyses for their “economically significant” rules (which are essentially the same as “major” rules under Executive Order 12,291).⁷⁶ As discussed in detail below, however, Executive Order 12,866 established a somewhat new regulatory philosophy and a new set of rulemaking principles, limited OIRA’s reviews to certain types of rules, and also put new transparency requirements in place. Section 2(b) of the order assigns responsibility for review of agency rulemaking to OMB, and specifically names OIRA “the repository of expertise concerning regulatory issues.”⁷⁷ The order also names the Vice President the principal advisor to the President on regulatory policy, planning, and review.⁷⁸

SPECIFIC PROVISIONS IN THE EXECUTIVE ORDER

In its statement of regulatory philosophy, Executive Order 12,866 says, among other things, that agencies should assess all costs and benefits of available regulatory alternatives, including both quantitative and qualitative measures.⁷⁹ It also provides that agencies should select regulatory approaches that maximize net benefits (unless a statute requires another approach).⁸⁰ Where permissible and applicable, the order states that agencies should adhere to a set of principles when developing rules,

74. Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), available at <http://www.whitehouse.gov/omb/inforeg/eo12866.pdf> (last visited Apr. 6, 2006).

75. *Id.* at 51,741.

76. *Id.*

77. *Id.* at 51,737.

78. *Id.* Executive Order 13,258, issued in February 2002, amended Executive Order 12,866 and reassigned all roles originally assigned to the Vice President to the President’s chief of staff. See Exec. Order No. 13,258, 67 Fed. Reg. 9,385 (Feb. 28, 2002), available at <http://www.whitehouse.gov/omb/inforeg/eo13258.pdf> (last visited Apr. 6, 2006).

79. Exec. Order No. 12,866, *supra* note 74, at 51,735.

80. *Id.*

including: (1) consideration of the degree and nature of risk posed when setting regulatory priorities, (2) adoption of regulations only upon a “reasoned determination that the benefits of the intended regulation justify its costs,” and (3) tailoring regulations to impose the least burden on society needed to achieve the regulatory objectives.⁸¹ Some of the stated objectives of the order are “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.”⁸² This reference to the “primacy of Federal agencies” signaled a significant change in regulatory philosophy, vesting greater control of the rulemaking process with regulatory agencies and taking away authority from OIRA. Further, the requirement that the benefits of a regulation “justify” its costs is a noticeably lower threshold than the requirement in Executive Order 12,291 that the benefits “outweigh” the costs.

Section six of Executive Order 12,866 established agency and OIRA responsibilities in the centralized review of regulations.⁸³ In contrast to the broad scope of review under Executive Order 12,291, the new order limited OIRA reviews to actions identified by the rulemaking agency or OIRA as “significant” regulatory actions, which are defined in section 2(f) of the order as the following:

Any regulatory action that is likely to result in a rule that may (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; (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 the Executive order.⁸⁴

By focusing OIRA’s reviews on significant rules, the number of draft proposed and final rules that OIRA examined fell from between 2,000 and 3,000 per year under Executive Order 12,291 to between 500 and about 700 rules per year under Executive Order 12,866.⁸⁵ Most of the rules no longer reviewed are “routine and frequent” or

81. *Id.* at 51,735-36.

82. *Id.*

83. *Id.* at 51,740.

84. *Id.* at 51,738.

85. GAO, RULEMAKING, *supra* note 6, at 24.

“informational/administrative” rules, though some have substantive impacts but fall short of the above definition of “significant.”⁸⁶

Executive Order 12,866 also differs from its predecessors in other respects. For example, the order generally requires that OIRA complete its review of proposed and final rules within ninety calendar days, and requires both the agencies and OIRA to disclose certain information about how the regulatory reviews were conducted.⁸⁷ Specifically, agencies are required 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.⁸⁸ OIRA is required to provide agencies with a copy of all written communications between OIRA personnel and parties outside of the executive branch, and a list of the dates and names of individuals involved in substantive oral communications.⁸⁹ The order also instructs OIRA to maintain a public log of all regulatory actions under review, and of all of the above-mentioned documents provided to the agencies.⁹⁰

OIRA'S FORMAL REVIEW PROCESS

OIRA reviews agencies' draft rules at both the proposed and final stages of rulemaking.⁹¹ In each phase, the review process starts when the rulemaking agency formally submits a regulatory review package to OIRA consisting of the rule, any supporting materials, and a transmittal form.⁹² The OIRA docket librarian then logs the receipt of the review package and forwards it to the appropriate desk officer. In some cases, agencies withdraw their rules from OIRA during the review period and the rules

86. GPO Access, The Unified Agenda of Regulatory and Deregulatory Actions, <http://www.gpoaccess.gov/ua/index.html> (last visited Apr. 6, 2006). These categories of rulemaking provide information in a consistent format about regulations that agencies are considering or reviewing.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.* For a discussion of the differences between the transparency requirements under Executive Order 12,291 and Executive Order 12,866, see William D. Araiza, *Judicial and Legislative Checks on Ex Parte OMB Influence Over Rulemaking*, 54 ADMIN. L. REV. 611 (2002); Peter M. Shane, *Political Accountability in a System of Checks and Balances: The Case of Presidential Review of Rulemaking*, 48 ARK. L. REV. 161 (1995).

91. GAO, RULEMAKING, *supra* note 6, at 30. In recent years, thirty-to-forty percent of OIRA's reviews have been proposed rules, and fifty-to-sixty percent have been final rules. OIRA also reviews other rulemaking documents (e.g., pre-rule documents and notices), accounting for ten-to-fifteen percent of its review actions.

92. *Id.*

may or may not be subsequently resubmitted. At the end of the review period, OIRA either returns the draft rule to the agency “for reconsideration” or OIRA concludes that the rule is consistent with the executive order. OIRA codes the rule in its database as “consistent with change” if there had been any changes to the rule, regardless of the source or extent of the change. OIRA codes rules in its database as “consistent with no change” only if they are exactly the same at the end of the review period as the original submission. If the draft rule is a proposed rule and is judged by OIRA to be consistent with the requirements in Executive Order 12,866, the agency may then publish a notice of proposed rulemaking in the *Federal Register*, obtain comments during the specified comment period, review the comments received, and make any changes to the rule that it believes are necessary to respond to those comments (the executive order says that this comment period should, in most cases, be at least sixty days for significant rules reviewed by OIRA).⁹³ If the draft is a final rule, the agency may publish the rule after OIRA concludes its review and the rule will generally take effect either at that point or at some later date specified by the agency.

OUTCOMES OF OIRA’S REVIEWS

As Table 1 indicates, in most of the years since Executive Order 12,866 was issued, more than ninety percent of the rules that OIRA reviewed have been coded in the database as either “consistent with change” or “consistent without change.”⁹⁴ Only a small percentage of rules were withdrawn, and even fewer were returned to the agencies. The proportion of rules coded as “changed” has varied somewhat over time, but the last several years of the Clinton Administration (1997 through 2000) were fairly similar to the first non-transition years of the George W. Bush Administration (2002 through 2004).

93. Exec. Order No. 12,866, *supra* note 74, §6(a)(1).

94. RegInfo.gov, Where to Find Federal Regulatory Information, <http://www.reginfo.gov/public/do/eoHistoricReport> (last visited May 1, 2006) (providing annual lists of concluded executive order reviews and statistics on OIRA’s past reviews).

TABLE 1: MOST RULES THAT OIRA REVIEWS ARE CODED AS “CHANGED”⁹⁵

Year	Number of proposed and final rules that OIRA reviewed	Percentage of rules OIRA reviewed that were coded:				
		Consistent with change	Consistent without change	Withdrawn	Returned	Other
1994	831	37.3	53.4	4.3	0.2	4.9
1995	620	39.0	53.1	5.2	0.5	2.3
1996	507	51.5	41.4	5.1	0.0	2.0
1997	505	56.0	37.4	5.1	0.8	0.6
1998	487	59.3	36.1	3.1	0.0	1.4
1999	587	62.2	31.5	3.1	0.0	3.2
2000	583	60.4	34.3	3.9	0.0	1.4
2001	700	45.6	28.1	22.0	2.6	1.7
2002	669	54.3	31.7	7.6	0.7	5.6
2003	715	60.3	30.3	6.9	0.3	2.2
2004	627	62.7	29.8	6.5	0.2	0.8
2005	610	65.4	27.0	6.6	0.2	1.0

As noted previously, however, in OIRA’s database, “consistent with change” simply means that the rule changed while it was under formal review—not that it was necessarily changed as a consequence of OIRA’s review. If an agency submits a new draft of a rule during this period (even to correct typographical errors), it is coded in the database as “changed.” Also, changes that OIRA may suggest outside of the formal review period are not reflected in these data. For example, if a rule is changed as a consequence of OIRA suggestions during an “informal” review (discussed in more detail later), but no changes are made during review, then the rule would be coded as “consistent with no change.”

The data indicate that there were a relatively large number of rules that were withdrawn and returned in 2001. The withdrawn rules reflect actions

95. These data are culled from a public database that OMB publishes online. See <http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init>. To get the numbers for any year, enter the year (e.g. “01/01/1994” to “12/31/1994”), click the “By OIRA conclusion action” option, then “search.”

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taken at the start of the George W. Bush Administration pursuant to a memorandum issued by Assistant to the President and former Chief of Staff Andrew H. Card, which generally directed Cabinet departments and independent agencies (1) not to send proposed or final rules to the Office of the *Federal Register*, (2) to withdraw from the Office rules that had not yet been published in the *Federal Register*, and (3) to postpone for sixty days the effective date of rules that had been published but had not yet taken effect.⁹⁶ As discussed in greater detail later in this article, OIRA returned a number of rules to the agencies for reconsideration shortly after a new administrator was appointed in 2001.⁹⁷

The type of review that OIRA conducts under Executive Order 12,866 sometimes depends on the type of draft rule submitted. For example, if the draft rule contains a collection of information covered by the PRA, the desk officer would also review it for compliance with that Act. If the draft rule is “economically significant” (e.g., has an annual impact on the economy of at least \$100 million), the executive order requires agencies to prepare an economic analysis describing, among other things, the alternatives that the agency considered and the costs and benefits of those alternatives.⁹⁸ For those economically significant rules, OIRA desk officers are to review the economic analyses using the office’s guidance on how to prepare regulatory analyses under the Executive Order.⁹⁹

An attachment to a September 20, 2001, memorandum to the President’s Management Council described the general principles and procedures that OIRA reportedly uses in the implementation of Executive Order 12,866.¹⁰⁰ For example, the attachment indicated that the office would, where appropriate, (1) include an evaluation of whether the agency has conducted an adequate risk assessment; (2) give “a measure of deference” to

96. Memorandum from Andrew H. Card to the Heads and Acting Heads of Executive Departments and Agencies (Jan. 20, 2001), *available at* http://www.whitehouse.gov/omb/inforeg/regreview_plan.pdf (last visited Apr. 6, 2006). For a discussion of the rules with postponed effective dates, see U.S. GEN. ACCOUNTING OFFICE, GAO-02-370R, REGULATORY REVIEW: DELAY OF EFFECTIVE DATES OF FINAL RULES SUBJECT TO THE ADMINISTRATION’S JAN. 20, 2001 MEMORANDUM (2002).

97. *See supra* notes 136-148.

98. Exec. Order No. 12,866, *supra* note 74, at 51,738 (defining an economically significant rule as adversely affecting “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”).

99. *See* OMB, CIRCULAR A-4 (2003), *available at* <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf> (last visited Apr. 6, 2006).

100. Memorandum from John D. Graham, OIRA Administrator, to the President’s Mgmt. Council (Sept. 20, 2001), *available at* http://www.whitehouse.gov/omb/inforeg/oira_review-process.html (last visited Apr. 6, 2006).

regulatory impact analyses and other supporting technical documents that have been peer reviewed in accordance with specified procedures; (3) ensure that regulatory clearance packages satisfy the requirements in other executive orders (e.g., include the certifications required by Executive Order 13,132 on “Federalism” and Executive Order 13,175 on “Consultation and Coordination with Indian and Tribal Governments”); (4) consult with the Small Business Administration (SBA) and the SBA Chief Counsel for Advocacy; and (5) ensure that agencies evaluate the possible impact of the draft rule on the programs of other federal agencies.¹⁰¹

There is usually some type of communication during the review process (often via e-mail or telephone) between the OIRA desk officer and the rulemaking agency regarding specific issues in the draft rule. Briefings and meetings are sometimes held between OIRA and the agency during the review process, with OIRA branch chiefs, the deputy administrator, or the administrator involved in some of these meetings. According to OIRA, the desk officers always consult with the relevant resource management office on the “budget side” of OMB as part of their reviews, and reviews of draft rules are not completed until those offices sign off.¹⁰² If the draft rule is economically significant, the desk officer would also consult with a government economist to help review the required economic analysis.¹⁰³ For other rules, the desk officer might consult with other OIRA staff on issues involving statistics and surveys, information technology and systems, or privacy issues.¹⁰⁴ In certain cases, OIRA may circulate a draft rule to other parts of the Executive Office of the President (e.g., the Office of Science and Technology Policy or the Council on Environmental Quality) or other agencies (e.g., the Departments of Energy, the Interior, or Transportation for certain EPA rules).

As noted previously, Executive Order 12,866 requires OIRA to complete its regulatory reviews within certain timeframes—(1) within ten working days of submission for any preliminary actions prior to a notice of proposed rulemaking (e.g., a notice of inquiry or an advance notice of proposed rulemaking) or (2) within ninety calendar days of submission for all other regulatory actions (or forty-five days if OIRA had previously reviewed the material).¹⁰⁵ In some instances, however, agency officials said OIRA will ask the rulemaking agency to withdraw the rule and

101. *Id.*

102. Interview with OIRA representatives, in Old Executive Office Building, Washington, D.C. (2003). *See* note 38 *supra*.

103. *Id.*

104. *Id.*

105. *See* Exec. Order 12,866, *supra* note 74, at 51,739.

resubmit it, restarting the review period.¹⁰⁶ The Executive Order does not permit OIRA to “approve” or “disapprove” a draft rule; it is up to the agency to decide whether to proceed with publication of a rule after it had been returned, or to accept OIRA’s suggested changes. OIRA representatives describe this as an iterative process in which the agencies and OIRA negotiate issues and clarify terms.¹⁰⁷ Nevertheless, agencies very rarely publish rules that OIRA returns or ignore substantive OIRA “suggestions.” In some instances, agency officials will formally or informally appeal OIRA determinations to the White House.

OIRA’S INFORMAL REVIEWS

For some rules, there is an additional phase of “informal review” before the rule is officially submitted to OIRA.¹⁰⁸ In its December 2001 report on the costs and benefits of federal regulations, OIRA stated that the office’s original review process “was designed as an end-of-the-pipeline check against poorly conceived regulations.”¹⁰⁹ OIRA also said, however, that by the time an agency formally submits a rule to OIRA for review, there may be “strong institutional momentum” behind the proposal and, as a result, the agency may be reluctant to address certain issues that OIRA analysts might raise.¹¹⁰ Therefore, OIRA indicated that “there is value in promoting a role for OIRA’s analytic perspective earlier in the process, before the agency becomes too entrenched.”¹¹¹ OIRA went on to state the following:

A common yet informal practice is for agencies to share preliminary drafts of rules and/or analyses with OIRA desk officers prior to formal decision making at the agency. This practice is useful for agencies since they have the opportunity to educate OIRA desk officers in a more patient way, before the formal 90-day review clock at OMB begins to tick. The practice is also useful for OIRA analysts because they have the opportunity to flag serious problems early enough to facilitate correction before the agency’s position is irreversible.¹¹²

OIRA cannot informally review each of the hundreds of significant proposed and final rules that are submitted to the office each year.

106. Interview with OIRA officials, in Old Executive Office Building, Washington, D.C. (2003). See note 38 *supra*.

107. GAO, *RULEMAKING*, *supra* note 6, at 81.

108. *Id.* at 30.

109. OFFICE OF MGMT. & BUDGET, *MAKING SENSE OF REGULATION: 2001 REPORT TO CONGRESS ON THE COST AND BENEFITS OF REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL AND TRIBAL ENTITIES* 43 (2001).

110. *Id.*

111. *Id.*

112. *Id.*

Informal reviews are most common when there is a statutory or legal deadline for a rule, or when the rule is extremely large and requires discussion with other federal agencies besides OMB. EPA and the Departments of Agriculture, Health and Human Services, and Transportation often issue those types of rules, and therefore are more likely to have their rules reviewed informally before formal submission.

Informal review can be much more important in the rule-development process than formal reviews, and can last much longer. For example, on October 30, 2001, EPA sent a draft proposed rule to OIRA in which the agency proposed that nonconformance penalties be made available for the 2004 and later model year non-methane hydrocarbons and nitrogen oxides standard for heavy-duty diesel engines and vehicles.¹¹³ To determine penalty amounts, EPA used a three percent discount rate in calculating certain compliance and fuel costs.¹¹⁴ During the next six weeks, EPA sent at least three other versions of the rule to OIRA for “informal review.”¹¹⁵ Throughout this period, OIRA suggested using a seven percent discount rate instead of three percent, which would have the effect of reducing the penalty amounts cited in the rule.¹¹⁶ By the time EPA submitted the rule to OIRA for formal review on December 10, 2001, EPA switched to the seven percent rate.¹¹⁷ OMB completed its review on December 20, 2001.¹¹⁸ The informal review period lasted four times as long as the formal period (at least forty-one days versus ten days) and most of the substantive changes to the rule appear to have occurred during informal review.¹¹⁹ In other cases, the formal OIRA review period for significant rules was as short as one day.¹²⁰

OIRA has informally reviewed agencies’ draft rules since its review function was established in 1981, but informal reviews reportedly became more common when Executive Order 12,866 was adopted in 1993 and

113. GAO, RULEMAKING, *supra* note 6, at 189-91.

114. *Id.* at 163.

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.* at 47 (“[T]he formal review period itself may be somewhat of an artificial construct.”).

120. *Id.* at 175. For example, OIRA formally reviewed a joint rule defining “fill material” under the Clean Water Act that had been developed by EPA and the Department of the Army’s Corps of Engineers in one day—from May 1, 2002, until May 2, 2002. The agencies made a number of changes to the rule at OIRA’s suggestion, indicating that the rule had been reviewed extensively before it was formally submitted. *See* Final Revisions to the Clean Water Act Regulatory Definitions of “Fill Material” and “Discharge of Fill Material,” 67 Fed. Reg. 31,129 (May 9, 2002).

OIRA's reviews were focused on "significant" rules.¹²¹ OIRA appears to have increased its use of informal reviews even further in recent years. For example, in its March 2002 draft report to Congress on the costs and benefits of federal regulation, OIRA wrote, "agencies are beginning to invite OIRA staff into earlier phases of regulatory development in order to prevent returns late in the rulemaking process. It is at these early stages where OIRA's analytic approach can most improve on the quality of regulatory analyses and the substance of rules."¹²² Separately, in 2002, the OIRA Administrator stated, "an increasing number of agencies are becoming more receptive to early discussions with OMB, at least on highly significant rulemakings."¹²³

The OIRA Administrator also indicated that agencies' "receptivity" to informal reviews may be enhanced by the possibility of a returned rule. For example, in early 2002, he said that OIRA was trying to:

[c]reate an incentive for agencies to come to us when they know they have something that in the final analysis is going to be something we're going to be looking at carefully. And I think that agencies that wait until the last minute and then come to us—well, in a sense, they're rolling the dice.¹²⁴

EFFECTS OF OIRA'S REVIEWS

Although a great deal has been written about OIRA's reviews of agencies' draft rules, few studies have systematically tried to determine the extent to which the office's reviews result in substantive changes to the rules. One such study concluded that OIRA's reviews resulted in the rejection of some regulations that would have been economically inefficient, but did not appear to have improved the cost-effectiveness (e.g., costs-per-life saved) of many of the rules.¹²⁵ Other studies have used OIRA's database showing the number of rules that were coded as "consistent with change" and "consistent without change" in an attempt to

121. Interview with OIRA representatives, in Old Executive Office Building, Washington, D.C. (2003). See note 38 *supra*.

122. Office of Mgmt. & Budget, Draft Report to Congress on the Costs and Benefits of Federal Regulations, 67 Fed. Reg. 15,014, 15,018 (Mar. 28, 2002), available at <http://www.whitehouse.gov/omb/inforeg/cbreport.pdf> (last visited Apr. 21, 2006).

123. John D. Graham, Remarks Prepared for the American Hospital Association (July 17, 2002), available at http://www.whitehouse.gov/omb/inforeg/graham_ama071702.html (last visited Apr. 6, 2006).

124. Rebecca Adams, *Regulating the Rulemakers: John Graham at OIRA*, CQ WEEKLY, Feb. 23, 2002, 520-26.

125. SCOTT FARROW, BROOKINGS INST., IMPROVING REGULATORY PERFORMANCE: DOES EXECUTIVE OFFICE OVERSIGHT MATTER? 24 (2000).

determine the significance of OIRA's effects on agencies' rules, and on whether those effects have changed over time.¹²⁶

As discussed previously, however, the "consistent with change" code includes changes made at the initiation of the agencies, as well as changes suggested by OIRA. Also, the code does not differentiate between minor editorial changes and changes that radically alter the effect of the rule. In addition, the terms "returns" and "withdrawals" in OIRA's database require careful consideration. A return may be made for purely administrative reasons, not for substantive OIRA objections. Conversely, an agency's withdrawal of a rule may have been initiated by OIRA. Therefore, in order to use these data effectively, researchers should examine the associated documentation in the agencies' and OIRA's rulemaking dockets.

GAO'S ANALYSIS OF OIRA'S EFFECTS

GAO published such an analysis in September 2003, supplementing information from OMB's database with information in the dockets and through interviews with agency officials.¹²⁷ GAO reported that, from July 1, 2001 through June 30, 2002, OIRA completed 642 reviews of agencies' draft proposed and final rules.¹²⁸ Of these:

- About thirty-three percent (214) were coded in the database as "consistent with no change," indicating that OIRA considered the rules as submitted consistent with Executive Order 12,866.¹²⁹

- About fifty percent (322) were coded as "consistent with change," indicating that the rules had changed after being submitted to OIRA, and that OIRA subsequently concluded that the rule was consistent with the Executive Order's requirements.¹³⁰

- About eight percent (fifty) were coded as "withdrawn" by the agency.¹³¹

- About three percent (twenty-one) were coded as "returned" to the agency by OIRA.¹³²

- About five percent (thirty-five) had some other disposition (e.g., "sent improperly," "emergency," or "statutory or judicial deadline").¹³³

126. See, e.g., Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 UNIV. CHI. L. REV. 821-885, 843-45 (2003).

127. GAO, RULEMAKING, *supra* note 6, at 27.

128. *Id.* at 69.

129. *Id.*

130. *Id.* at 70.

131. *Id.*

132. *Id.*

133. *Id.*

In order to make its review manageable, GAO focused on eight-five of those rules that were coded as changed, withdrawn, or returned, and that were submitted to OIRA by nine selected health, safety, or environmental agencies or offices: the Animal and Plant Health Inspection Service within the Department of Agriculture; the Food and Drug Administration (FDA) within the Department of Health and Human Services; the Occupational Health and Safety Administration (OSHA) within the Department of Labor; the Federal Aviation Administration (FAA), the Federal Motor Carrier Safety Administration, and the National Highway Traffic Safety Administration (NHTSA) within the Department of Transportation (DOT); and the offices of air and radiation, water, solid waste, and emergency response within EPA.¹³⁴ Seventy-one of the eighty-five rules had been coded “consistent with change,” nine were coded as “returned,” and five were coded as “withdrawn.”¹³⁵

OIRA’S IMPACT ON RULES

GAO’s analysis of the underlying documents indicated that OIRA had a significant effect on at least twenty-five of the eighty-five draft rules.¹³⁶ Specifically:

- Of the seventy-one “changed” rules, GAO concluded that OIRA had suggested significant changes to seventeen of them—changes that affected the scope, impact, or estimated costs or benefits of the rules as originally submitted.¹³⁷ In general, the focus of OIRA’s suggested changes appeared to be on reducing regulatory burden (and, in some cases, the expected benefits as well).¹³⁸ For example, at OIRA’s recommendation, EPA removed manganese from a list of hazardous wastes, deleted certain types of engines from coverage of a rule setting emissions standards, and delayed the compliance dates for two other types of emissions.¹³⁹ Of the remaining fifty-four “changed” rules, the most significant alterations made at OIRA’s suggestion involved adding explanatory language to the preambles of the rules and asking for comment on particular provisions. In twenty of the fifty-four rules, OIRA suggested only minor editorial changes (e.g., correcting spelling errors or citations), or made no suggestions at all.¹⁴⁰

- Of the nine rules that had been returned to the agencies by OIRA

134. *Id.* at 71.

135. *Id.*

136. *Id.* at 72.

137. *Id.*

138. *Id.* at 84.

139. *Id.* at 191-92.

140. *Id.* at 79.

during the review period, two were returned because they had been improperly submitted, not because of substantive defects.¹⁴¹ OIRA returned the remaining seven rules because of concerns about the agencies' regulatory analyses or a perceived lack of coordination between rulemaking agencies.¹⁴² For example, OIRA returned one EPA rule because the agency did not provide a quantitative analysis of costs and benefits, and returned a NHTSA rule because OIRA did not believe that the agency had demonstrated that it had selected the best available alternative.¹⁴³ Five of the seven rules returned for substantive reasons had been submitted by the FAA.¹⁴⁴

- Of the five rules that were withdrawn, GAO determined that only one had been withdrawn primarily at OIRA's suggestion.¹⁴⁵ The other four rules were withdrawn solely at the agencies' initiative or as a result of a mutual decision by the agencies and OIRA.¹⁴⁶

OIRA review had a greater effect on certain agencies' rules than others. As Table 2 illustrates, OIRA had a significant effect on thirteen (seventy-six percent) of the twenty-two rules submitted by EPA's Office of Air and Radiation and Office of Water (i.e., changes to the scope, impact, and estimated costs and benefits of the rules). In contrast, OIRA had a significant effect on only four (eight percent) of the forty-nine rules submitted by other agencies and offices. In these cases, OIRA review most frequently resulted in additional explanatory language in the rules' preambles, requests for comments on particular provisions, or minor editorial changes.

TABLE 2: EPA AIR/RADIATION AND WATER RULES WERE MOST AFFECTED BY OIRA REVIEW¹⁴⁷

Agency	Rules where changes suggested by OIRA were:			Total
	Significant	Material	Minor/None	

141. *Id.*

142. *Id.*

143. *Id.* at 80.

144. *Id.* at 79.

145. *Id.* at 81.

146. *Id.*

147. These data were prepared by the author as a summary of general research to be included in a 2003 GAO report. See GAO, RULEMAKING, *supra* note 6, at 75.

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EPA Office of Air and Radiation	7	4	3	14
EPA Office of Water	6	2	0	8
All other agencies and offices in review	4	28	17	49
Total	17	34	20	71

Although this GAO study highlights the effects that OIRA can have on agencies' rules, it also probably understates the influence that OIRA has on agencies' rules because the findings were often limited to the documentation that was available in agencies and OIRA's dockets. As noted previously, if OIRA suggested a change to a rule before it was formally submitted to OIRA (i.e., during informal review), GAO's analysis might not reflect those changes. In fact, if a rule was significantly changed by OIRA during several rounds of informal review, but was unchanged during formal review, it would not have even been in the universe of rules that GAO examined (i.e., those coded in the OIRA database as changed, returned, or withdrawn during OIRA's formal review). Other forms of OIRA influence on rulemaking may be even more indirect and harder to document. For example, some agencies have indicated that they do not even propose certain regulatory provisions because they believe that OIRA would find them objectionable.¹⁴⁸

REGULATED ENTITIES' CONTACTS WITH OIRA

GAO also reported in its study that regulated entities directly contacted OIRA either before or during its review process regarding eleven of the twenty-five rules that OIRA significantly affected.¹⁴⁹ Eight of those eleven cases involved EPA rules, and the nature of the contacts ranged from meetings with OIRA representatives to letters sent to OIRA.¹⁵⁰ In seven of the eleven cases, GAO concluded that what OIRA ultimately recommended to the rulemaking agencies was akin to what these regulated parties recommended to OIRA—in some cases, using similar language to that used

148. U.S. GEN. ACCOUNTING OFFICE, GAO/T-GGD-96-185, REGULATORY REFORM: IMPLEMENTATION OF THE REGULATORY REVIEW EXECUTIVE ORDER 10 (1996) [hereinafter GAO, REGULATORY REFORM]. DOT officials told GAO that they will not even propose certain regulatory provisions because they know that OIRA will find them unacceptable. *Id.*

149. GAO, RULEMAKING, *supra* note 6, at 89. Environmental and public interest groups also contacted OIRA regarding three of the rules. *Id.*

150. *Id.*

by the regulated entities.¹⁵¹ Some examples include the following:

- During OIRA's review of an EPA rule on identification and listing of hazardous waste, industry representatives met with, and sent letters to OIRA opposing the listing of manganese as a hazardous waste constituent (the industry representatives had made essentially the same argument to EPA during the public comment phase, but EPA did not agree).¹⁵² The main focus of OIRA's comments to EPA at the conclusion of its review was that final action on listing manganese as a hazardous contaminant should be deferred.¹⁵³

- Representatives of automobile manufacturers contacted OIRA and argued that a NHTSA draft final rule on tire pressure monitoring systems should have permitted the use of indirect, as well as direct, sensing technologies (not just direct technologies, as in the draft rule).¹⁵⁴ OIRA returned the rule to NHTSA for reconsideration, questioning whether the agency had selected the best available regulatory option. OIRA later approved (as "consistent with no change") a resubmitted rule that allowed either direct or indirect technologies until 2006.¹⁵⁵

Notwithstanding the congruence between the comments of the regulated entities and OIRA's comments, GAO said it was impossible to determine the extent to which these or other suggestions made by the regulated entities might have influenced OIRA's actions, if at all.¹⁵⁶ For example, OIRA may have independently reached the same conclusions as the regulated entities.

CHANGES IN OIRA'S POLICIES AND PRACTICES DURING THE GEORGE W. BUSH ADMINISTRATION

The formal process by which OIRA reviews agencies' draft rules has

151. *Id.* at 91.

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.* In August 2003, the U.S. Court of Appeals for the Second Circuit vacated this rule as inconsistent with the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act upon which it was based. *See Public Citizen, Inc. v. Mineta*, 340 F. 3d 39, 42 (2d Cir. 2003). NHTSA issued a new final rule on April 8, 2005. *See Rules and Regulations*, 67 Fed. Reg. 18,129, 18,136 (Apr. 8, 2005). According to one observer, the rule as initially provided to OIRA may have survived judicial review. *See Cindy Skrzycki, Public Citizen, Bridgestone Fight Tire Rule*, WASH. POST, Jun. 21, 2005, at D1.

156. GAO, RULEMAKING, *supra* note 6, at 91-92.

changed little since Executive Order 12,866 was issued in 1993.¹⁵⁷ There have, however, been several subtle yet notable changes in OIRA policies and practices in recent years—particularly after OIRA Administrator John D. Graham took office in July 2001. In October 2002, Administrator Graham said, “the changes we are making at OMB in pursuit of smarter regulation are not headline grabbers: No far-reaching legislative initiatives, no rhetoric-laden executive orders, and no campaigns of regulatory relief. Yet we are making some changes that we believe will have a long-lasting impact on the regulatory state.”¹⁵⁸

RETURN OF THE “GATEKEEPER” ROLE

As noted previously, during the Reagan Administration, OIRA was often criticized for acting as a regulatory “gatekeeper,” actively overseeing and recommending changes to agencies’ rules.¹⁵⁹ During the Clinton Administration, however, the opposite concerns were expressed. A number of observers criticized OIRA for not overseeing the actions of the rulemaking agencies more aggressively.¹⁶⁰ In September 1996, OIRA Administrator Sally Katzen testified that “we have consciously changed the way we relate to the agencies,” and described OIRA’s relationship with the rulemaking agencies as “collegial” and “constructive.”¹⁶¹ She also said she agreed with an article which stated that OIRA functioned during that period “more as a counselor during the review process than as an enforcer of the executive order.”¹⁶²

During the George W. Bush Administration, OIRA has returned to the role it assumed during the Reagan Administration, even describing itself in an annual report as the “gatekeeper for new rulemakings.”¹⁶³ OIRA

157. There has been only one amendment to Executive Order 12,866 since it was issued. As mentioned earlier, Executive Order 13,258 reassigned all roles originally assigned to the Vice President in Executive Order 12,866 (e.g., principal advisor to the President on regulatory policy, planning, and review) to the President’s Chief of Staff. *See supra* note 78 and accompanying text.

158. John D. Graham, OIRA Administrator, Presidential Oversight of the Regulatory State: Can It Work?, Address before the Heinz School, Carnegie Mellon University (Oct. 4, 2002).

159. *See, e.g.*, EADS & FIX, *supra* note 4 and accompanying text.

160. *See, e.g.*, GATTUSO, *supra* note 5 and accompanying text.

161. *See Oversight of Regulatory Review Activities of the Office of Information and Regulatory Affairs: Hearing before the U.S. Subcomm. on Financial Management & Accountability of the H. Comm. on Governmental Affairs*, 104th Cong. (1996).

162. William Niskanen, *Clinton’s Regulatory Record: Policies, Process, and Outcomes*, 19 REGULATION 3, 27-28, (1996).

163. OFFICE OF MGMT. & BUDGET, STIMULATING SMARTER REGULATION: 2002 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED

Administrator Graham has said that one of the office's functions is "to protect people from poorly designed rules," and that OIRA review is a way to "combat the tunnel vision that plagues the thinking of single-mission regulators."¹⁶⁴ He has also compared OIRA's review of agencies' rules to OMB's role in reviewing agencies' budget requests.¹⁶⁵ This "return to the gatekeeper" perspective of OIRA's role has implications for an array of OIRA's functions, and underlies many of the other changes described below.

INCREASED (AND THEN DECREASED) USE OF RETURN LETTERS

As indicated Table 1, during the Clinton Administration, OIRA only rarely returned rules to the agencies for reconsideration.¹⁶⁶ Specifically, according to OIRA's database, of the more than 4,000 rules that OIRA reviewed from 1994 through 2000, OIRA returned only seven rules to the agencies—three in 1995 and four in 1997. OIRA Administrators during that period said they viewed the use of return letters as evidence of the failure of the collaborative review process, since OIRA and the agencies were part of the same presidential administration.¹⁶⁷

In contrast, OIRA Administrator Graham referred to return letters as the office's "ultimate weapon," viewing them as a way to make clear that the office is serious about the review process.¹⁶⁸ In the first six months after he took office in July 2001, OIRA returned eighteen draft rules to the agencies for reconsideration.¹⁶⁹ DOT had the most rules returned during 2001 and 2002 (eight), followed by the Social Security Administration (five) and the Department of Veterans Affairs (four).¹⁷⁰ The letters

MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 14 (2002).

164. John D. Graham, OIRA Administrator, Remarks to the Board of Trustees, The Keystone Ctr., Washington, D.C., Jun. 18, 2002, *available at* http://www.whitehouse.gov/omb/inforeg/keystone_speech061802.html (last visited Apr. 21, 2006).

165. John D. Graham, OIRA Administrator, Remarks prepared for delivery to the National Economists Club, Presidential Management of the Regulatory State, Mar. 7, 2002, *available at* <http://www.whitehouse.gov/omb/legislative/testimony/graham030702.html> (last visited Apr. 27, 2006).

166. *See supra* tbl.1.

167. *See* GAO, RULEMAKING, *supra* note 6, at 42-43.

168. John D. Graham, OIRA Administrator, Remarks prepared for the American Hospital Association, Stimulating Smarter Regulation: OMB's Role, July 17, 2002, *available at* http://www.whitehouse.gov/omb/inforeg/graham_ama071702.html (last visited Apr. 27, 2006).

169. *See* GAO, RULEMAKING, *supra* note 6, at 41-42.

170. *See* Office of Mgmt. & Budget, OIRA Return Letters, *available at* http://www.whitehouse.gov/omb/inforeg/return_letter.html (last visited Apr. 6, 2006).

commonly indicated that OIRA returned the rules because of concerns about the agencies' analyses (e.g., questioning whether the agencies had considered all reasonable alternatives or had selected the alternative that would yield the greatest net benefits).¹⁷¹

Subsequently, however, the pace of OIRA's return letters slowed dramatically. Although the average number of rules that OIRA reviewed each month stayed about the same, in the four years from March 2002 until March 2006, OIRA returned a total of six draft rules to the agencies—a dramatic decline from the twenty-one returns during Administrator Graham's first eight months in office.¹⁷² Only one rule was returned in 2004, and one more in 2005—keeping about the same pace as the Clinton administration. OIRA officials attributed the decline in return letters to the improved quality of agencies' regulatory submissions after the initial flurry of returns.¹⁷³ For example, in his November 2005 comments marking the twenty-fifth anniversary of OIRA, Administrator Graham said, “we rarely need to issue a return letter” because agencies now “work with us to fix problems or they persuade us that there is no problem to fix.”¹⁷⁴

ADVENT (AND THEN DECLINE) OF PROMPT LETTERS

OIRA has traditionally been a reactive force in the rulemaking process, commenting on draft proposed and final rules that are generated by the agencies. Although OIRA occasionally suggested regulatory topics to the agencies during previous administrations, the practice was relatively uncommon and the discussions were not made public. In contrast, OIRA Administrator Graham was more publicly proactive, sending several agencies “prompt letters” (and posting them on the OIRA web site) suggesting that they develop regulations in a particular area or encouraging the agencies' ongoing efforts.¹⁷⁵ For example, one such letter encouraged NHTSA to give greater priority to modifying its frontal occupant protection standard, and another letter suggested that OSHA make the promotion of automatic external heart defibrillators a higher priority.¹⁷⁶ Other prompt

171. *See id.*

172. *See id.* Two of the five returns during this period involved the same DOT rule.

173. Interviews with OMB officials, in Old Executive Office Building, Washington, D.C. (2003). *See note 38 supra.*

174. JOHN GRAHAM, AEI-BROOKINGS JOINT CTR. FOR REGULATORY STUDIES, *THE “SMART-REGULATION” AGENDA: PROGRESS AND CHALLENGES* 5 (2005) [hereinafter GRAHAM, SMART REGULATION].

175. For sample OIRA prompt letters, see Office of Mgmt. & Budget, OIRA Prompt Letters, available at http://www.whitehouse.gov/omb/inforeg/prompt_letter.html (last visited Apr. 27, 2006).

176. Letter from John D. Graham, OIRA Administrator, to the Honorable Michael P.

letters recommended that the agencies better focus certain research or programs, and some made no recommendations at all.¹⁷⁷ Several of the agencies took action in response to the letters, but few new rulemakings have directly resulted from them. For example, one of OIRA's first prompt letters urged FDA to give greater priority to issuing a rule on the trans-fatty acid content of foods.¹⁷⁸ Although OIRA Administrator Graham cited the issuance of an FDA rule on trans-fats as an illustration of the effect of the prompt letters, he also noted that the rulemaking had begun during the previous administration.¹⁷⁹

OIRA sent agencies four prompt letters in September 2001, six by the end of that year, and a total of at least thirteen by the end of 2003.¹⁸⁰ Since then, however, the number of prompt letter has diminished substantially. OIRA issued only two prompt letters in 2004, and none were issued in 2005.¹⁸¹ It is not clear why OIRA's use of prompt letters has declined so sharply. However, it is possible that OIRA may have reverted back to its previous approach of making more private rulemaking and regulatory suggestions to the agencies.

INCREASED EMPHASIS ON ECONOMIC ANALYSIS (USUALLY)

Although OIRA has always encouraged agencies to provide well-developed economic analyses for their draft rules, Administrator Graham expressed greater interest in this issue than his predecessors. Also, according to agency officials, there was a perceptible "stepping up the bar" in the amount of support required for their rules, with OIRA reportedly more often looking for regulatory benefits to be quantified and a cost-

Jackson, Deputy Secretary, Dep't of Transp. (Dec. 7, 2001), *available at* http://www.reginfo.gov/public/prompt/nhsta_prompt120701.html (last visited Apr. 21, 2006); *see also* Letter from John D. Graham, OIRA Administrator, to the Honorable John Henshaw, Assistant Secretary of Labor, Occupation Safety & Health Admin. (Sept. 18, 2001), *available at* http://www.reginfo.gov/public/prompt/osha_prompt_letter.html (last visited Apr. 21, 2006).

177. For example, one such letter was essentially a press release that touted an effort by OIRA and EPA in which they worked together to develop a proposed rule on non-road diesel engines. *See* Env'tl Protection Agency, EPA and OMB Working To Speed the Reduction of Pollution From Nonroad Diesel Engines 1 (June 7, 2002), *available at* <http://www.reginfo.gov/public/prompt/r-117.pdf> (last visited Apr. 6, 2006).

178. Letter from John D. Graham, OIRA Administrator, to the Honorable Tommy G. Thompson, Sec'y of Health & Human Serv. (Sept. 18, 2001), *available at* http://www.reginfo.gov/public/prompt/hhs_prompt_letter.html (last visited Apr. 26, 2006).

179. GRAHAM, SMART REGULATION, *supra* note 174, at 5-6.

180. GAO, RULEMAKING, *supra* note 6, at 48.

181. *See* OIRA Prompt Letters, *supra* note 175. OIRA most recently issued a prompt letter to EPA in April 2006, which was the first since November 2004. *Id.*

benefit analysis for every regulatory option that the agency considered, not just the option selected.¹⁸² In September 2003, OIRA published OMB Circular A-4, which contained guidelines for economic analysis under the Executive Order that updated the “best practices” guidelines issued in January 1996.¹⁸³ The new economic analysis guidelines were generally similar to the earlier guidance, but differed in several key areas—e.g., encouraging agencies to (1) perform both cost-effectiveness and cost-benefit analyses in support of their major rules,¹⁸⁴ (2) use multiple discount rates when the benefits and costs of rules are expected to occur in different time periods, and (3) use a formal probability analysis of benefits and costs when a rule is expected to have more than a \$1 billion impact on the economy (unless the effects of the rule are clear).¹⁸⁵

In its December 2005 report to Congress on the costs and benefits of federal regulations, OMB asserted that, “[r]egulation that is based on solid economic analysis and sound science is also more likely to provide greater benefits to society at less cost than regulation that is not.”¹⁸⁶ However, OIRA has also signaled that these analyses are sometimes difficult if not impossible to conduct for certain types of rules. For example, as OIRA Administrator Graham said in November 2005, “[h]omeland security regulations account for about half of our major-rule costs in 2004 but we do not yet have a feasible way to fully quantify benefits. A moment’s reflection will reveal some of the perplexing issues: how do we identify targets of potential terrorist attacks, the probability of attacks and associated damages, and the effectiveness of various countermeasures in

182. See GAO, *RULEMAKING*, *supra* note 6, at 44-45.

183. See OMB, *CIRCULAR A-4*, *supra* note 99.

184. Cost-benefit analysis involves the systematic identification of all costs and benefits associated with a forthcoming regulation. Cost-effectiveness analysis seeks to determine how a given goal can be achieved at the least cost. In contrast to cost-benefit analysis, the concern in cost-effectiveness analysis is not with weighing the merits of the goal, but with identifying and analyzing the costs of alternatives to reach that goal (e.g., dollars per life saved).

185. See OMB, *CIRCULAR A-4*, *supra* note 99. Discounting can have a significant effect on the present value of future health benefits. For example, in a February 2003 speech, Administrator Graham noted that the present value of 1,000 lives saved fifty years in the future is only thirty-four lives in present value when evaluated at a seven percent discount rate. See John D. Graham, OIRA Administrator, *Valuing Health: An OMB Perspective*, Remarks Prepared for the Conference on Valuing Health Outcomes: An Assessment of Approaches (Feb. 13, 2003), available at http://www.whitehouse.gov/omb/inforeg/rff_speech_feb13.pdf (last visited Apr. 21, 2006).

186. OFFICE OF MGMT. & BUDGET, *VALIDATING REGULATORY ANALYSIS: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATION AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES* 33 (2005) [hereinafter *OMB, VALIDATING REGULATORY ANALYSIS*].

reducing risk?”¹⁸⁷ Administrator Graham reportedly said that cost-benefit analysis may not be appropriate for these homeland security rules, and that a more practical “soft” test was being used for them.¹⁸⁸

Some observers have questioned why assessments of costs or benefits for these homeland security rules are qualitatively different from, or more difficult than, assessing the costs and benefits associated with many health, safety, or environmental rules, and therefore why these homeland security rules appear to be less rigorously reviewed by OIRA. In the words of Sally Katzen, OIRA Administrator during the Clinton Administration: “So when it matters to them to get rules out quickly, they wink and blink. But in areas of public health and safety, where they have longstanding relations with the business communities involved, they’re insistent on satisfying these standards.”¹⁸⁹

INCREASED TRANSPARENCY (SOMEWHAT)

As noted previously, many of the longstanding concerns about OIRA’s role in the rulemaking process have centered on the perceived lack of transparency of its reviews.¹⁹⁰ Executive Order 12,866 attempted to address some of those concerns by requiring that, after a rule is published, an agency must disclose the changes it made to the rule during OIRA’s review, and the changes it made at the suggestion or recommendation of OIRA.¹⁹¹ This Executive Order requires OIRA to maintain a publicly available log disclosing the status of all regulatory actions under review, and the names and dates of those involved in substantive oral communications (e.g., meetings and telephone calls) between OIRA staff and parties outside of the executive branch.¹⁹² These requirements notwithstanding, concerns about the lack of transparency continued. For example, even after issuance of the executive order, OIRA disclosed contacts with outside parties only if they occurred during the office’s sometimes brief formal review period, not if they occurred during its informal reviews.

In October 2001, Administrator Graham published a memorandum to OIRA staff on the office’s web site that extended the Executive Order’s

187. GRAHAM, SMART REGULATION, *supra* note 174, at 8.

188. See Nancy Ognanovich, *Head of OMB Regulatory Office Says Analyzing Homeland Security Rules Difficult*, BNA DAILY REP. FOR EXECUTIVES, Nov. 8, 2005, at A39.

189. Rebecca Adams, *Graham Leaves OIRA With a Full Job Jar*, CQ WEEKLY, Jan. 23, 2006, at 226.

190. See, e.g., GAO, REGULATORY REFORM, *supra* note 148, at 8.

191. Exec. Order No. 12,866, *supra* note 74, at 51,739.

192. *Id.*

disclosure requirements in several areas.¹⁹³ For example, the memorandum said that OIRA would disclose substantive meetings and other contacts with outside parties about a rule under review even if OIRA was only informally reviewing the rule,¹⁹⁴ and that it would disclose substantive telephone calls with outside parties that were initiated by the Administrator, not just calls initiated by outside parties.¹⁹⁵ Further, OIRA announced that it would be expanding its web site, posting lists of regulations currently under review,¹⁹⁶ reviews it concluded in the previous thirty days,¹⁹⁷ and its meeting records with outside parties.¹⁹⁸

As discussed in more detail later in this Article, however, OIRA's regulatory reviews are still far from transparent. Agencies are still instructed not to disclose changes that OIRA suggests during informal reviews, and the meeting log on OIRA's web site does not clearly delineate the subjects of OIRA's outside meetings or the affiliations of those present at the meetings.¹⁹⁹ Also, as noted previously, OIRA's database showing rules "changed" during its review is not an accurate indication of the rules that were substantively changed by OIRA.

CHANGES IN OIRA STAFFING

When OIRA was created in fiscal year 1981, the office had a "full-time equivalent" (FTE) ceiling of ninety staff members.²⁰⁰ By 1997, OIRA's

193. Memorandum from John D. Graham, Administrator, for OIRA Staff (Oct. 18, 2001), available at http://www.whitehouse.gov/omb/inforeg/oira_disclosure_memo-b.html (last visited May 23, 2006).

194. *Id.*

195. *Id.*

196. See Office of Mgmt. & Budget, Executive Order Submission Under Review, <http://www.whitehouse.gov/omb/library/OMBREGSP.html> (last visited Apr. 6, 2006).

197. See Office of Mgmt. & Budget, Executive Order Review in the Last 30 Days, <http://www.whitehouse.gov/omb/library/OMBREGSC.html> (last visited Apr. 18, 2006).

198. For a list of OIRA's meetings with outside parties, see Office of Mgmt. & Budget, Meeting Records, available at <http://www.whitehouse.gov/omb/oira/meetings.html> (last visited Apr. 18, 2006). For a list of OMB's oral communications, see Office of Mgmt. & Budget, Oral Communications Record, available at http://www.whitehouse.gov/omb/oira/oral_communications.html (last visited Apr. 18, 2006).

199. To view OIRA's meeting log, see <http://www.whitehouse.gov/omb/oira/meetings.html> (last visited Apr. 21, 2006). As GAO indicated in its 2003 report, OIRA's descriptions of its contacts with outside parties did not always clearly indicate what rule was being discussed or what organizations those parties represented.

200. GAO, RULEMAKING, *supra* note 6, at 59. FTE data are typically used in a budgetary context, and are a useful way to compare staffing strength over time or across entities. For example, one employee working forty hours per week for a year would be considered one FTE, and two employees who each work twenty hours a week for a year would also be

FTE allocation had declined to forty-seven—a nearly fifty percent reduction.²⁰¹ Although Executive Order 12,866 (issued in late 1993) permitted OIRA to focus its resources on “significant” rules, this decline in OIRA staffing also occurred during a period in which regulatory agencies’ staffing and budgetary levels were increasing and OIRA was given a number of new statutory responsibilities.²⁰²

Starting in 2001, OIRA’s staffing authorization began to increase somewhat, and by 2003 it stood at fifty-five FTEs.²⁰³ Between 2001 and 2003, OIRA hired five new staff members in such fields as epidemiology, risk assessment, engineering, and health economics. OIRA representatives indicated that these new hires reflected the increasing importance of science-based regulation in federal agencies, and would enable OIRA to ask penetrating technical questions about agency proposals.²⁰⁴

OIRA’S OTHER STATUTORY RESPONSIBILITIES

In addition to its regulatory review responsibilities under Executive Order 12,866, and its multiple responsibilities under the Paperwork Reduction Act (including paperwork review, information resources management, statistical policy and coordination, records management, privacy and security, and information technology), Congress has assigned OIRA a number of other specific functions related to the rulemaking and regulatory process. For example:

- The Unfunded Mandates Reform Act of 1995 generally requires agencies to prepare written statements describing the effects of their rules that are subject to the Act’s requirements on state, local, and tribal governments, and the private sector.²⁰⁵ The Act requires the director of OMB to collect those written statements and provide them to the Congressional Budget Office, to establish pilot programs to test innovative regulatory approaches, and to prepare an annual report on the implementation of the act.²⁰⁶ The OMB director has delegated these responsibilities to OIRA.

considered one FTE.

201. *Id.*

202. See Regulatory Right-to-Know Act of 1999, 31 U.S.C. § 1105 (2000); Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. § 601 (2000); Unfunded Mandates Reform Act of 1995, 2 U.S.C. § 1532 (2000). These acts assigned OIRA various duties, which are further discussed in notes 205-209 *infra* and accompanying text.

203. GAO, RULEMAKING, *supra* note 6, at 60.

204. Interview with OIRA representatives, in Old Executive Office Building, Washington, D.C. (2003). See note 38 *supra*.

205. See Unfunded Mandates Reform Act of 1995 § 1532.

206. *Id.*

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• The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires EPA and OSHA to convene “advocacy review panels” before publishing proposed rules expected to have a significant economic impact on a substantial number of small entities.²⁰⁷ The Act specifically requires the review panel to include full-time employees from OIRA, as well as other agencies.²⁰⁸

• SBREFA also contains provisions commonly referred to as the “Congressional Review Act,” which (among other things) requires agencies to delay the effective date of “major” rules, and requires GAO to submit a report on those rules within fifteen days of their issuance.²⁰⁹ SBREFA defines a major rule as one that the OIRA administrator concludes has resulted or is likely to result in (among other things) a \$100 million annual effect on the economy.

• The Treasury and General Government Appropriations Act for 2001, generally known as the “Data Quality Act” or the “Information Quality Act,” directed OMB to take several actions, all of which were delegated to OIRA.²¹⁰ Specifically, the Act required OMB to issue government-wide guidelines that “provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.”²¹¹ OMB published those guidelines in final form on February 22, 2002.²¹² The Act also required agencies to develop their own guidelines (which were reviewed by OMB), and to report to OMB on the number and nature of complaints received and the manner in which such complaints were handled by the agency.²¹³

• Section 624 of the Treasury and General Government Appropriations Act of 2001, sometimes known as the “Regulatory Right-to-Know Act,” requires OMB to prepare and submit with the budget an annual “accounting statement and associated report” containing an estimate of the costs and benefits (including quantifiable and non-quantifiable effects) of federal

207. Small Business Regulatory Enforcement Fairness Act § 244.

208. *Id.*

209. For a more complete discussion of the Congressional Review Act, see Morton Rosenberg, *Whatever Happened to Congressional Review of Agency Rulemaking?: A Brief Overview, Assessment, and Proposal for Reform*, 51 ADMIN. L. REV. 1051, 1092 (1999).

210. Treasury and General Government Appropriations Act of 2001, 44 U.S.C. § 3516 (2001).

211. *Id.*

212. Office of Mgmt. & Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8,451 (Feb. 22, 2002).

213. Treasury and General Government Appropriations Act of 2001 § 3516.

rules and paperwork, to the extent feasible, (1) in the aggregate, (2) by agency and agency program, and (3) by major rule.²¹⁴ The accounting statement is also required to contain an analysis of impacts of federal regulation on state, local, and tribal governments, small businesses, wages, and economic growth. Similar one-year requirements were in previous appropriations acts.²¹⁵

- The Small Business Paperwork Relief Act of 2002 required OMB to annually publish, in the *Federal Register* and on the Internet, a list of the compliance assistance resources available to small businesses.²¹⁶ The Act also requires OMB to convene and chair a task force to study the feasibility of streamlining paperwork requirements on small businesses.²¹⁷ The task force was required to file an initial report by the end of June 2003, and to file a final report by the end of June 2004.²¹⁸

- The E-Government Act requires the OIRA administrator to work with the administrator of OMB's Office of Electronic Government to establish the strategic direction of the government-wide e-government program and to oversee its implementation.²¹⁹ As discussed later in this article, OIRA has been particularly active in the Administration's e-rulemaking initiative.²²⁰

- In the 2002 Treasury and General Government Appropriations Act,²²¹ Congress stated that about \$6.3 million of OMB's \$70.7 million appropriation was for OIRA, but stipulated that nearly \$1.6 million of that amount would not be obligated until OMB "submits a report to the Committees on Appropriations that provides an assessment of the total costs and benefits of implementing Executive Order No. 13,166."²²²

Congress also sometimes limits OIRA's actions through riders on OMB's appropriation. For example, since 1983, language has been

214. Regulatory Right-to-Know Act § 624.

215. OMB, VALIDATING REGULATORY ANALYSIS, *supra* note 186, at 141.

216. Small Business Regulatory Enforcement Fairness Act § 241.

217. *Id.*

218. See SMALL BUS. PAPERWORK RELIEF ACT TASK FORCE, FINAL REPORT (2004), available at <http://www.whitehouse.gov/omb/inforeg/sbpr2004.pdf> (last visited Apr. 6, 2006).

219. E-Government Act of 2002, 44 U.S.C. § 3501 (2002).

220. See note 257 *infra* and accompanying text.

221. Treasury and General Government Appropriations Act of 2002, Pub. L. No. 107-67, 115 Stat. 514.

222. *Id.* See also Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13,166: Improving Access to Services for Persons with Limited English Proficiency (Mar. 2002), available at <http://www.whitehouse.gov/omb/inforeg/lepfinal3-14.pdf> (last visited Apr. 6, 2006) (responding to congressional request by using available data to estimate benefits and costs).

included in OMB's appropriation stating that none of the funds appropriated to OMB could be used for the purpose of reviewing any agricultural marketing orders issued by the Department of Agriculture.²²³ Marketing orders, which cover dozens of commodities from lemons to milk and generally keep prices up by regulating supplies, were targeted for elimination or amendment by President Reagan's task force on regulatory relief in the early 1980s.²²⁴ In response, members of Congress have inserted this restriction in each subsequent appropriation bill, asserting that the Department of Agriculture, not OMB, has statutory authority in this area. At other times, riders have been included in OMB's appropriation preventing the office from taking other actions (e.g., altering the transcript of witnesses' testimony before certain committees).²²⁵

RECENT OIRA INITIATIVES

Although OIRA's workload has clearly increased as a consequence of a series of congressional requirements, OIRA has also voluntarily taken on additional responsibilities, often basing its actions on the office's interpretation of previous statutory or executive order authority or requirements. Some of these actions (e.g., the issuance of bulletins on peer review, guidance, and risk assessment) have been viewed as direct attempts by OIRA to expand its influence over agencies. Other OIRA initiatives may have that effect more indirectly, appearing in some cases to be similar in many respects to the unsuccessful legislative efforts at regulatory reform in the mid-to-late 1990s.

SOLICITING SUGGESTIONS FOR REFORM OF EXISTING RULES

In addition to requiring an annual "accounting statement" of the costs and benefits of regulations, the above-mentioned "Regulatory Right-to-

223. For example, OMB's appropriation for fiscal year 2006 provides, "none of the funds appropriated in this Act for the Office of Management and Budget may be used for the purpose of reviewing any agricultural marketing orders or any activities or regulations under the provisions of the Agricultural Marketing Agreement Act of 1937." *See* Transportation, Treasury, Housing and Urban Development, The Judiciary, The District of Columbia, and Independent Agencies Appropriations Act, H.R. 3058, 109th Cong. (2005), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ115.109.pdf (last visited May 12, 2006).

224. JAMES L. GATTUSO, HERITAGE FOUND., *THE HIGH COSTS AND LOW RETURNS OF FARM MARKETING ORDERS* (1985), available at <http://www.heritage.org/Research/Agriculture/bg462.cfm>.

225. *Id.* OMB's fiscal year 2006 appropriation excepted from this prohibition only the testimony of OMB witnesses before the committees on appropriations or their subcommittees.

Know Act” also requires OMB to include “recommendations for reform” in its cost-benefit reports.²²⁶ OIRA could have interpreted this requirement narrowly as requiring recommendations to reform the accounting statement or, more generally, to reform the rulemaking process. Instead, OIRA interpreted the provision to mean that OMB must make recommendations of specific rules to be reformed. Further, rather than relying on the expertise it honed in reviewing hundreds of significant rules each year, OIRA decided to solicit suggestions from the public regarding specific rules to be “reformed.” For example, in May 2001, OIRA asked for suggestions on specific regulations that could be “rescinded or changed that would increase net benefits to the public.”²²⁷ In response, OIRA received seventy-one suggestions, which it placed into high, medium, and low priority categories.²²⁸ In March 2002, OIRA asked the public for recommendations to eliminate or modify existing rules as well as to expand or extend existing programs.²²⁹ In response, OIRA received more than 300 suggestions, which it then turned over to the appropriate agencies for prioritization.²³⁰ In February 2004, OIRA asked the public for suggested reforms of rules affecting the manufacturing sector.²³¹ OIRA said it was focusing on manufacturing because of the relatively large impact that regulations have on that sector. In March 2005, OIRA reported that it received 189 reform nominations, of which federal agencies and OMB determined that seventy-six had “potential merit and justify further

226. A similar one-year requirement for “recommendations for reform” was included in the Fiscal Year 2000 Treasury and General Government Appropriations Act. *See* Treasury and General Government Appropriations Act of 2000 § 628(a)(3). Although business groups generally applauded this “look back” effort, environmentalists and public interest groups characterized it as the development of a “hit list” of rules that the Bush Administration wanted to eliminate.

227. OFFICE OF MGMT. & BUDGET, DRAFT REPORT ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS 25, *available at* http://www.whitehouse.gov/omb/fedreg/cb_report_notice.pdf (last visited Apr. 21, 2006).

228. GAO, RULEMAKING, *supra* note 6, at 104-105. Eight of the twenty-three suggestions that OIRA designated a “high priority” involved EPA rules, and five involved rules from the Department of Labor. *Id.*

229. Office of Mgmt. & Budget, Draft Report to Congress on the Costs and Benefits of Federal Regulations, 67 Fed. Reg. 15,013, 15,033 (Mar. 28, 2002), *available at* <http://www.whitehouse.gov/omb/inforeg/cbreport.pdf> (last visited Apr. 24, 2006).

230. GAO, RULEMAKING, *supra* note 6, at 108-09 (describing these responses and noting the ways in which the 2002 effort differed from the 2001 effort).

231. *See* OFFICE OF MGMT. & BUDGET, INFORMING REGULATORY DECISIONS: 2004 DRAFT REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATION AND UNFUNDED MANDATES ON STATE, LOCAL AND TRIBAL ENTITIES 1 (2004), *available at* http://www.whitehouse.gov/omb/inforeg/draft_2004_cbreport.pdf (last visited Apr. 24, 2006).

action.”²³²

PEER REVIEW BULLETIN

In September 2003, OIRA published a proposed bulletin in the *Federal Register* on “Peer Review and Information Quality” that would have, if made final, provided a standardized process by which all significant regulatory information would be peer reviewed.²³³ Issued under the authority of the Information Quality Act, the PRA, and Executive Order 12,866, the bulletin would have required agencies to (1) have all “significant regulatory information” that the agencies intend to disseminate peer reviewed, (2) have “especially significant regulatory information” peer reviewed according to even higher standards, and (3) provide OIRA with information on an annual basis about upcoming significant regulatory disseminations, and about the agency’s plans for conducting peer reviews.²³⁴ The proposed bulletin aroused significant controversy, with some observers expressing concern that it could create a centralized peer review system within OMB that would be vulnerable to political manipulation or control by regulated entities.²³⁵

In April 2004, OIRA published a revised version of the proposed bulletin in response to nearly 200 comments received from the public.²³⁶ The revised bulletin was broader in scope than the proposed bulletin in that it applied to “influential scientific information” (not just regulatory information) and “highly influential scientific assessments.”²³⁷ However, agencies were given substantial discretion to decide whether information was “influential” and therefore required a peer review, and the bulletin provided exemptions for certain classes of information (e.g., routine statistical information and products by government-funded scientists that

232. OFFICE OF MGMT. & BUDGET, REGULATORY REFORM OF THE MANUFACTURING SECTOR 2 (2005), *available at* http://www.whitehouse.gov/omb/inforeg/reports/manufacturing_initiative.pdf (last visited Apr. 6, 2006).

233. *See* OFFICE OF MGMT. & BUDGET, PEER REVIEW AND INFORMATION QUALITY (Aug. 2003), *available at* http://www.whitehouse.gov/omb/inforeg/peer_review_and_info_quality.pdf (last visited Apr. 24, 2006).

234. *Id.*

235. *See, e.g.*, Letter from Sidney A. Shapiro, Director, Ctr. for Progressive Regulation, to Dr. Margo Schwab, Office of Info. & Regulatory Affairs (May 27, 2004), *available at* <http://www.whitehouse.gov/omb/inforeg/peer2004/57.pdf> last visited Apr. 24, 2006).

236. *See* OFFICE OF MGMT. & BUDGET, REVISED INFORMATION QUALITY BULLETIN FOR PEER REVIEW (2004), *available at* http://www.whitehouse.gov/omb/inforeg/peer_review041404.pdf (last visited Apr. 6, 2006).

237. *Id.*

are not represented as the views of the agency).²³⁸ In January 2005, OIRA published a final version of the bulletin in the *Federal Register* that was similar in many respects to the revised version.²³⁹ OMB still retained significant authority in certain areas (e.g., when information is “highly influential”), so it is unclear how much discretion agencies will be given to decide when and what kind of peer review is required.

GOOD GUIDANCE PRACTICES BULLETIN

An even more recent potential expansion of OIRA’s influence occurred in November 2005, when OMB published a “Proposed Bulletin for Good Guidance Practices.”²⁴⁰ Noting that agencies have increasingly relied on guidance documents to inform the public about regulatory requirements and to provide direction to their staff members, OMB said it was concerned that these documents “may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review.”²⁴¹ OMB did not cite any specific statutes or executive orders as authorizing the issuance of the bulletin, but it did indicate that it was “responsible both for promoting good management practices and for overseeing and coordinating the Administration’s regulatory policy.”²⁴²

In essence, the proposed bulletin would require agencies (not including independent regulatory agencies) to develop written procedures for the approval of “significant” guidance documents (defined in essentially the same way as “significant” rules in Executive Order 12,866), to maintain a list of those documents on its web site, and to allow electronic comments on those documents. For “economically significant” guidance documents (e.g., those expected to have a \$100 million impact on the economy), agencies would be required to publish a notice in the *Federal Register* announcing that the draft guidance document is available, inviting public

238. *Id.*

239. See Office of Mgmt. & Budget, Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2,664 (Jan. 14, 2005). OMB published the final bulletin on its web site on December 15, 2004. Certain provisions took effect in June 2005, but others did not take effect until December 2005.

240. OFFICE OF MGMT. & BUDGET, PROPOSED BULLETIN FOR GOOD GUIDANCE PRACTICES (Nov. 23, 2005), available at http://www.whitehouse.gov/omb/inforeg/good_guid/good_guidance_preamble.pdf (last visited Apr. 6, 2006) [hereinafter OMB, PROPOSED BULLETIN]. On November 30, 2005, OMB published a notice and request for comments on the proposed bulletin (but not the bulletin itself) in the *Federal Register*. See Proposed Bulletin for Good Guidance Practices, 70 Fed. Reg. 71,866 (Nov. 30, 2005).

241. OMB, PROPOSED BULLETIN, *supra* note 240, at 2.

242. *Id.* at 1.

comments, and responding to those comments.²⁴³ Although the proposed bulletin does not specifically provide a role for OIRA in the approval process, some have expressed concerns that the bulletin could allow greater opportunities for the office and industry to influence agency decision making.²⁴⁴ As was the case with the peer review bulletin, OIRA is expected to retain significant discretion to decide which documents are subject to the bulletin's requirements.

RISK ASSESSMENT BULLETIN

As of early 2006, the most recent manifestation of OIRA's self-initiated expansion of its (at least potential) influence was its publication of a proposed bulletin on agency risk assessment practices.²⁴⁵ Released for public comment and peer review by the National Academy of Sciences on January 9, 2006, the stated purpose of the bulletin was "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards."²⁴⁶ The legal authority cited for the bulletin included the Information Quality Act, the Regulatory Right-to-Know Act, and "OMB's general authorities to oversee the quality of agency analyses, information and regulatory actions."²⁴⁷ Public comments were requested on the proposed bulletin by June 2006, with the bulletin going into effect twelve months after its publication in final form.²⁴⁸

Risk assessments are used in a variety of ways in the federal government, and are particularly important in developing regulations involving health, safety, or the environment. The OIRA bulletin described a series of general risk assessment and reporting standards (e.g.,

243. Because guidance is, by definition, nonbinding, it is not clear how it could have a \$100 million impact on the economy, and therefore qualify as "economically significant."

244. See, e.g., Cindy Skrzycki, *Finding a Way to Better Guidance*, WASH. POST, Dec. 20, 2005, at D1.

245. See OFFICE OF MGMT. & BUDGET, PROPOSED RISK ASSESSMENT BULLETIN (2006), available [at](http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf) http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf (last visited Apr. 6, 2006).

246. *Id.* at 3.

247. *Id.* at 7. Specifically, OIRA noted that section 515(a) of the IQA requires OMB to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by federal agencies. *Id.* at 7. Also, OIRA said that the Regulatory Right-to-Know Act directs OMB to "issue guidelines to agencies to standardize . . . measures of costs and benefits." *Id.* One could argue that OIRA had already satisfied these requirements through the issuance of its February 2002 IQA guidelines and OMB Circular A-4.

248. *Id.* at 1.

“summarize the scope of the assessment” and “be scientifically objective”), with one set of standards specifically for risk assessments used in regulatory analyses.²⁴⁹ It also laid out a set of “special standards for influential risk assessments” (i.e., those expected to have a “clear and substantial impact on important public policies or private sector decisions”).²⁵⁰ The scope of the bulletin is quite broad, subsuming all agencies covered by the PRA (including independent regulatory agencies), and defining risk assessment in sweeping terms.²⁵¹ The bulletin requires agencies to certify that each covered risk assessment has complied with its requirements, but allows agency heads to defer or waive some or all of its requirements.²⁵² OIRA and the White House Office of Science and Technology Policy were made responsible for overseeing the bulletin’s implementation.²⁵³

E-RULEMAKING OVERSIGHT

OIRA has also been significantly involved in the development of the Bush Administration’s electronic rulemaking (“e-rulemaking”) initiative, which some have also viewed as having the potential to increase the office’s and regulated entities’ influence over agencies’ regulatory actions.²⁵⁴ In January 2003, the Bush Administration launched the “Regulations.gov” web site as the first module of its e-rulemaking initiative.²⁵⁵ The web site permits the public to identify proposed rules that are open for comment government-wide, and permits the public to comment electronically on those rules. The second module of the initiative is the development of a single, government-wide electronic docket for proposed and final rules, thereby allowing the public to access regulatory supporting materials and the comments of others from one web site. The first agencies were placed on this government-wide docket in November

249. *Id.* at 10-11.

250. *Id.* at 16.

251. Risk assessment is defined as “a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment.” *Id.* at 23.

252. *Id.* at 21.

253. *Id.* at 1.

254. OMB oversees the e-rulemaking initiative, and it has named EPA as the lead agency for the effort, replacing DOT. For a discussion of this initiative, see U.S. GEN. ACCOUNTING OFFICE, GAO-05-777, ELECTRONIC RULEMAKING: PROGRESS MADE IN DEVELOPING CENTRALIZED E-RULEMAKING SYSTEM (2005) [hereinafter GAO, ELECTRONIC RULEMAKING].

255. The eRulemaking Initiative, <http://www.regulations.gov/fdmspublic/component/main> (last visited May 9, 2006).

2005, and other agencies are expected to move to the system during 2006 and 2007.²⁵⁶ Although some analysts believe that a government-wide electronic docket could improve the ability of the public to provide useful rulemaking comments, others are less sanguine about the influence of such a system:

A centralized docket would . . . dramatize and enhance OMB's and OIRA's already central role. Together with information specialists at EPA, they are the ones creating this new apparatus, and to have all information travel through their gateway only adds to the possibilities of their influence As agencies become more transparent, they become more transparent to the President as well as to the public. It used to be that the number of copies of materials in the docket was limited, and it was physically located at the agency. Now the docket is immediately available on equal and easy terms to all who want it, including the President, and politics will give him the incentive to attend to it.²⁵⁷

OIRA INITIATIVES AND PREVIOUS REFORM EFFORTS

Several of the OIRA initiatives since 2001 appear to be attempts to accomplish administratively (through circulars, bulletins, guidance, reports, and actions by OIRA desk officers) what regulatory reform advocates were not able to accomplish legislatively during the previous decade. During the mid-to-late 1990s, Congress considered a number of pieces of comprehensive regulatory reform legislation, none of which was ultimately enacted.²⁵⁸ For example, S. 746, considered by the 106th Congress in 1999, would have established detailed procedures for preparing cost-benefit analyses and risk assessments, and for using them in the rulemaking process.²⁵⁹ The specific requirements in the bill for cost-benefit analysis were generally similar to (although not as detailed as) those in OMB Circular A-4, issued in 2003. The requirements for risk assessment in the bill were generally similar to those in the proposed risk assessment bulletin issued in 2006, although the bulletin will (if adopted) apply more broadly. S. 746 would have also required agencies to provide for an independent peer review of any required risk assessments and cost-benefit analyses of

256. GAO, ELECTRONIC RULEMAKING, *supra* note 254, at 19.

257. Richard G. Stoll & Katherine L. Lazarski, *Rulemaking*, in DEVELOPMENTS IN ADMINISTRATIVE LAW AND REGULATORY PRACTICE, 2003-2004, at 160 (Jeffrey S. Lubbers ed. 2004).

258. *See* Regulatory Improvement Act of 1999, S. 746, 106th Cong. (1999); Comprehensive Regulatory Reform Act of 1995, S. 343, 104th Cong. (1995); Regulatory Improvement Act of 1997, S. 981, 105th Cong. (1997).

259. *See* Regulatory Improvement Act of 1999, S. 746, §§ 623, 624, 106th Congress (1999), available at <http://www.senate.gov/~govt-aff/s746.htm> (last visited May 12, 2006).

major rules that the agencies or OMB anticipated would have a \$500 million impact on the economy.²⁶⁰ OMB's bulletin on peer review contains many of the same requirements, but (like the risk assessment bulletin) applies to more rules than the legislation would have if it had been enacted.

Other recent initiatives are similarly reflective of previous legislative reform efforts. For example, OIRA's interpretation of the "recommendations for reform" provisions in the Regulatory Right-to-Know Act resulted in broad-scale calls for the public to nominate existing regulations for review and possible elimination or modification.²⁶¹ S. 343 in the 104th Congress would have also required a review of existing agency rules, although the reviews contemplated in the legislation would have been conducted by the agencies themselves, not the public, and were focused on major rules.²⁶²

OIRA AND THE FUTURE OF PRESIDENTIAL REGULATORY REVIEW

For twenty-five years, OIRA has played a central role in the federal rulemaking process. Although some argued early in OIRA's history that the office's regulatory review role was unconstitutional, few observers continue to hold that view. No court has directly addressed the constitutionality of the OIRA regulatory review process, but in 1981 (the year that OIRA was created) the D.C. Circuit said the following:

The court recognizes the basic need of the President and his White House staff to monitor the consistency of agency regulations with Administration policy. He and his advisors 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.²⁶³

OIRA is located within the Executive Office of the President and is the President's direct representative in the government-wide rulemaking process. As Executive Order 12,866 states, OIRA is the "repository of expertise on regulatory issues" within the executive branch, and is uniquely positioned both within OMB (with its budgetary influence) and within the federal rulemaking process (reviewing and commenting on rules just before

260. *See id.* at §§ 625.

261. *See* note 226 *supra* for a discussion of OMB's calls for "recommendations for reform."

262. *See* S. COMM. ON GOVERNMENTAL AFFAIRS, COMPREHENSIVE REGULATORY REFORM ACT OF 1995, S. REP. NO. 104-89 (1995) (noting that section 625 of the bill would have required the review of existing rules).

263. *Sierra Club v. Costle*, 657 F.2d 298 (D.C. Cir. 1981).

they are published in the *Federal Register*) to enable it to exert maximum influence.²⁶⁴

Variations in how OIRA operates—as a gatekeeper or a counselor—are largely a function of the wishes of the President that the office serves. For example, in a June 2001 article in the *Harvard Law Review*, Elena Kagan posited that, while it is generally acknowledged that President Reagan used OIRA's review function as a tool to control the policy and political agenda in an anti-regulatory manner, President Clinton did much the same thing to accomplish pro-regulatory objectives.²⁶⁵ She argued that Clinton did so by exercising directive authority and asserting personal ownership over a range of agency actions, thereby making them “presidential” in nature.²⁶⁶ She also characterized this emergence of enhanced methods of presidential control over the regulatory state—what she termed the “presidentialization of administration”—as “the most important development in the last two decades in administrative process.”²⁶⁷ Similarly, William F. West concluded that OIRA's regulatory review process “has promoted executive interests across administrations precisely because the process has internalized incumbents' political preferences.”²⁶⁸ Therefore, instead of the “neutral competence” that some assert that bureaucracy can best provide presidents, West characterizes OIRA's performance as “responsive competence.”²⁶⁹

Other observers, however, view OIRA (like other executive branch agencies) as having more of a shared allegiance between the President and the Congress.²⁷⁰ They point out that OIRA was created by Congress, and has been given a number of statutory responsibilities through the PRA and other laws. Nevertheless, even supporters of a strong legislative perspective recognize that OIRA is part of the Executive Office of the President, and that Congress gave OIRA its responsibilities because of its strategic position within that office.²⁷¹ With both statutory and executive order responsibilities, OIRA embodies a broader tension between Congress

264. Executive Order No. 12,866, *supra* note 74, at 51,736.

265. Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2248 (2001).

266. *Id.* at 2250.

267. *Id.* at 2383.

268. William F. West, *The Institutionalization of Regulatory Review: Organizational Stability and Responsive Competence at OIRA*, 35 PRESIDENTIAL STUD. Q. 76, 76 (2005).

269. *Id.* at 91.

270. See generally DAVID H. ROSENBLUM, BUILDING A LEGISLATIVE-CENTERED PUBLIC ADMINISTRATION, 1946-1999 (2001)

271. *Id.* at 56 (“[W]here coordinated government-wide clearance is required to achieve Congress' policy objectives, there may be few or no alternatives (to paperwork and regulatory review within OMB).”).

and the President for control of administrative agencies.

Although major differences of opinion exist among observers of the federal rulemaking process regarding the appropriateness of OIRA's regulatory review role, the broad reach and influence of the office is undebatable. Rulemaking agencies formally challenge OIRA's returns and "suggestions" for change only rarely, and (as noted previously) sometimes refrain from even submitting draft rules for review if they believe they will be opposed by OIRA. Regulated entities also recognize OIRA's influence, and seem to view the office as a "court of second resort" if they are unable to influence regulatory agencies to their position directly.

POSSIBLE LEGISLATIVE ISSUES

Congress also recognizes the importance that OIRA plays in the rulemaking process, and usually holds several hearings each year examining OIRA's implementation of its responsibilities pursuant to various statutes and executive orders. Proposals for changes to OIRA's authority and responsibilities have focused on such issues as (1) providing a statutory underpinning for regulatory reviews, (2) increasing or decreasing the office's funding and staffing, (3) including independent agencies' rules under the office's regulatory review function, and (4) improving the transparency of OIRA's regulatory review processes.

STATUTORY AUTHORITY FOR REGULATORY REVIEW

As noted previously, Congress has enacted legislation expanding OIRA's statutory responsibilities, and has considered (but not enacted) legislation that would provide a statutory basis for OIRA's regulatory review function. For example, in the 106th Congress, S. 746 (the Regulatory Improvement Act of 1999) would have required the President, via OMB and OIRA, to "establish a process for the review and coordination of Federal agency regulatory actions."²⁷² The proposed legislation also would have codified many of the transparency requirements in Executive Order 12,866.

Congress has also considered legislation that would affect OIRA as part of broader OMB changes. For example, during the 107th Congress, proposed legislation was introduced (but not enacted) that would have established an Office of Management within the Executive Office of the President and redesignated OMB as the Office of the Federal Budget.²⁷³

272. Regulatory Improvement Act of 1999, S. 746, 106th Cong. § 632 (1999).

273. See H.R. 616, 107th Cong. (2001).

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As part of that process, OIRA and other offices within OMB would have been abolished and their functions and authorities transferred to the new Office of Management.

FUNDING AND STAFFING

OIRA does not have a specific line item in the budget, so its funding is part of OMB's appropriation. Similarly, OIRA's staffing levels are allocated from OMB's totals. Although OIRA staffing has increased in recent years, OIRA still has fewer staff than it had when its regulatory review function was first established in 1981.²⁷⁴ Currently, about thirty OIRA desk officers and branch chiefs review about 3,000 agency information collection requests each year and about 700 significant rules each year.²⁷⁵ At various times in its history, certain members of Congress have attempted to reduce funding for OIRA in order to signal congressional displeasure with the office's actions.²⁷⁶ Other observers, however, believe that OIRA's funding should be increased, not reduced, arguing that a relatively small amount of additional resources for OIRA could yield substantial benefits.²⁷⁷

At other times, proposed legislation has been introduced that designates the manner in which OIRA staff should be used. For example, a provision in H.R. 2432, as originally introduced, would have required the OMB Director to "assign, at a minimum, the equivalent of at least two full time staffers to review the Federal information collection burden on the public imposed by the Internal Revenue Service."²⁷⁸ The Internal Revenue Service accounts for more than eighty percent of the estimated paperwork burden, but OIRA indicated that it devoted less than one FTE to reviewing the agency's paperwork requests (because much of the burden is mandated by statute).²⁷⁹ The Bush Administration objected to this specific direction

274. GAO, *RULEMAKING*, *supra* note 6, at 60.

275. *Id.* Although OIRA had fifty-five authorized full-time-equivalent positions in 2003, many of those staff worked in the office's non-regulatory branches (information policy and technology, and statistical and science policy) or as administrative staff.

276. For example, as noted previously, in OMB's appropriation for 2002, Congress stipulated that nearly \$1.6 million should not be obligated until OMB submitted a report assessing the total costs and benefits of implementing Executive Order No. 13,166. *See* note 222 *supra* and accompanying text.

277. *See, e.g.*, ROBERT W. HAHN & ROBERT E. LITAN, AEI-BROOKINGS JOINT CTR. FOR REGULATORY STUDIES, POLICY MATTERS 03-34, WHY CONGRESS SHOULD INCREASE FUNDING FOR OMB REVIEW OF REGULATIONS (2003).

278. Paperwork and Regulatory Improvements Act of 2004, H.R. 2432, 108th Cong. § 3 (2004).

279. *See Hearing Before the Subcomm. on Energy Policy, Natural Resources & Regulatory Affairs, H. Comm. on Gov't Reform*, 108th Cong. (Apr. 11, 2003) (statement of

of OIRA staff, so the sponsors of the bill agreed to delete this requirement before it was approved by the House of Representatives in May 2004.²⁸⁰

ADDITION OF INDEPENDENT AGENCIES' RULES

Several of the statutes that OIRA helps to administer include rules issued by independent regulatory agencies (e.g., the PRA, the Regulatory Flexibility Act, the Congressional Review Act, and the Information Quality Act). Also, several recent OIRA initiatives (e.g., the November 2005 bulletin on guidance practices and the January 2006 bulletin on risk assessment) cover those agencies as well as cabinet departments. However, the executive orders that have established regulatory review within OIRA have always explicitly excluded rules issued by those agencies.²⁸¹ Some observers have suggested that this limitation be lifted, arguing that independent regulatory agencies issue regulations that have a significant impact on the economy (about \$230 billion per year according to OIRA), but their rules often contain little quantitative information on regulatory costs and benefits.²⁸² Those opposed to this expansion in OIRA's duties point out that independent regulatory agencies were established to be relatively independent of the President, and the inclusion of their rules under OIRA's authority would threaten the basic structure on which they were founded. In response, proponents argue that independent regulatory agencies' rules are already reviewed for purposes such as paperwork clearance and ensuring that data quality requirements are met, so examining the substance of the rules is just an extension of those reviews.

TRANSPARENCY OF REVIEWS

One consistent area of concern to some observers has been the lack of transparency of the OIRA review process to the public. Notwithstanding recent improvements, they argue that it is difficult for the public to know

John D. Graham, OIRA Administrator, *available at* <http://www.whitehouse.gov/omb/legislative/testimony/graham041103.html> (last visited May 12, 2006).

280. As reported, the bill required the OMB Director to identify actions that IRS could take to reduce paperwork burden on small businesses.

281. *See, e.g.*, Exec. Order No. 12,866, *supra* note 74, § 2(b) (defining covered agencies as those "other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. § 3502(10)").

282. *See, e.g.*, CTR. FOR REGULATORY EFFECTIVENESS, A BLUEPRINT FOR OMB REVIEW OF INDEPENDENT AGENCY REGULATIONS (2002). The previously mentioned bill, S. 746, that proposed to establish the presidential review of rules in law, would have included rules issued by independent regulatory agencies.

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with any degree of certainty what changes OIRA has suggested to agencies' draft rules, what contacts OIRA has made with regulated entities and other outside parties regarding those rules, or whether documents were exchanged between OIRA and the agencies. In its September 2003 report, GAO said that the documentation that agencies are required to provide showing the changes made at OIRA's suggestion or recommendation were not always available and, when so provided, were not always clear or consistent.²⁸³ GAO also said that the transparency requirements incumbent on OIRA were not always clear, and recommended several improvements. For example:

- Although OIRA indicated that it can have its greatest impact on agencies' rules during informal reviews before review packages are formally submitted, OIRA indicated that agencies only had to disclose the changes made at OIRA's suggestion during formal review (some of which were as short as one day). GAO recommended that OIRA define this requirement in the executive order to include informal reviews, just as it did with regard to the requirements involving the office's communications with outside parties.²⁸⁴

- As noted previously, the "consistent with change" code in OIRA's database does not differentiate between OIRA- or agency-initiated changes, or changes that were major or minor in nature. GAO recommended that the database be changed to more clearly indicate which rules were substantively changed at OIRA's suggestion.²⁸⁵

- GAO also recommended refinements to the executive order's requirements applicable to OIRA (e.g., more clearly indicating on its web site the regulatory actions being discussed at meetings with outside parties and the affiliations of the participants) and the requirements applicable to the agencies (e.g., defining the types of "substantive" changes that agencies should disclose).²⁸⁶

In commenting on GAO's report, the Administrator of OIRA said that the office planned to review its implementation of the executive order's transparency requirements and would work to improve the clarity of its meeting log.²⁸⁷ However, he also said he did not believe that changes made during informal OIRA reviews should be disclosed—even though he said that OIRA can have its greatest influence during informal reviews.²⁸⁸

283. GAO, *RULEMAKING*, *supra* note 6, at 85.

284. *Id.* at 14-15.

285. *Id.* at 15.

286. *Id.*

287. *Id.* at 214.

288. *Id.*

CONCLUDING OBSERVATIONS

John Graham was sworn in as OIRA Administrator in July 2001, making him the ninth person to occupy that position since the office was created in 1981.²⁸⁹ In October 2005, Graham announced that he would leave the office in early 2006 and become dean of the Frederick S. Pardee Rand Graduate School in Santa Monica, California.²⁹⁰ Although the Executive Order governing the review process has not substantively changed since its issuance in 1993, Graham made numerous changes in how the order was implemented and, more generally, how the office operated, during his nearly five years as OIRA Administrator. Under his leadership, OIRA has become less of a reactive, “end of the pipeline” reviewer and more of an activist, instigative organization than under any previous administrator. Evidence of this activist philosophy can be found in virtually all of the initiatives begun during Graham’s tenure in office, and even in the manner that OIRA has interpreted certain provisions in law. For example, under some previous administrators, OIRA would not have been likely to interpret the “recommendations for reform” language in the Regulatory Right-to-Know Act as a requirement for agencies to solicit the public’s views regarding which regulations merited reconsideration.

Administrator Graham’s tenure at OIRA has been both criticized and praised, sometimes by the same observers. The actions generating the most criticism (particularly from those advocating stronger health, safety, and environmental rules) have often involved the assertion of OIRA’s authority over agency rules, either directly (e.g., through prompt and return letters and the general reassertion of the office’s “gatekeeper” role) or indirectly (e.g., through its recent bulletins on peer review, guidance documents, and risk assessment). There is some evidence that OIRA has more recently adopted a somewhat less confrontational (or at least less visibly confrontational) approach in its relations with the agencies. As noted previously, the number of OIRA return letters and prompt letters has declined precipitously in recent years. As one observer in 2004 said, “after three years both OMB and agencies have come to a sufficient level of mutual understanding and accommodation that such blunt tools are only needed in exceptional circumstances.”²⁹¹

289. Public Citizen, John Graham Nomination Confirmed, <http://www.citizen.org/congress/regulations/graham.html> (last visited May 12, 2006).

290. Press Release, The Frederick S. Pardee Rand Graduate School, OMB Regulatory Affairs Head and Former Harvard Professor John Graham Announced as New PRGS Dean (Oct. 18, 2005), available at http://www.prgs.edu/news/new_dean.1005.html (last visited May 11, 2006).

291. James W. Conrad, Jr., *Regulatory Policy*, in DEVELOPMENTS IN ADMINISTRATIVE

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The actions of Administrator Graham that have generated the most widespread praise have been those designed to improve the transparency of OIRA's review process, particularly the posting of the agency's meetings with outside parties on its web site. Of particular note and praise from virtually all observers was his decision to post a record of those meetings on the OIRA site even if they occurred before the rule was formally submitted to OIRA. In doing so, Graham implicitly recognized that presidential review of rulemaking can occur before the formal OIRA review process begins. On the other hand, as of early 2006, the changes that Administrator Graham committed to make to these postings to clarify the rules being discussed and the identities of the participants still had not been made. The meeting log on OIRA's web site still uses acronyms such as "CAIR" and "NBP" to indicate the subject of the meeting, and the affiliations of those attending the meetings (much less their clients) are still not clear. Also, OIRA's coding of the outcomes of its reviews in its database is still unclear. A rule coded as "consistent with change" suggests that OIRA's review had an effect on the rule, when in fact the agency may have simply submitted a new draft. OIRA's database also does not differentiate between a major change in the focus and effect of a rule, and a change that merely affects a matter so slight as a punctuation mark contained in the rule's text.

Even more importantly, OIRA still discourages agencies from disclosing changes made to their rules at OIRA's suggestion during "informal reviews"—the period when OIRA says it has its greatest influence on agencies' rules. Unless those changes are disclosed, any claims of OIRA transparency will ring somewhat hollow. No one has advocated that all informal discussions between the agencies and OIRA during the rule development process be made public, even after the fact. But certainly when agencies and OIRA are exchanging drafts of rules, and agencies are making changes to those drafts at OIRA's suggestion before formal submission, agencies could be required to disclose those changes after the rules have been published in the *Federal Register*. This is particularly important in those instances when informal reviews go on for weeks or months, but the period of formal review may be limited to one day.

Some might argue that even if these recommended improvements to OIRA transparency are implemented, the effect of OIRA's reviews on agencies rules can be hidden in other ways. For example, even if agencies or OIRA are required to disclose all of the changes made at the office's suggestion or recommendation, OIRA could simply channel its comments

through other entities (e.g., other parts of OMB, other parts of the Executive Office of the President, or even through other executive branch agencies as part of the interagency review process). Nevertheless, because it is clear that there is a lack of transparency in what OIRA itself calls the most important part of the process, improvements in OIRA transparency should not be dismissed simply because the office's effects may be disguised in other ways.

THE FUTURE

Although the effects of Administrator Graham's initiatives on OIRA in recent years are particularly notable, other OIRA administrators have also had a major effect on how the office operates. In many ways, OIRA usually assumes the personality of the administrator and, more indirectly, of the President whom the administrator serves. The President's nominee to succeed Administrator Graham is likely to continue this pattern, putting his or her stamp on the office while continuing the reforms that Graham initiated (at least until the end of this President's term). As noted previously, OIRA is the President's official agent in the rulemaking process, and helps ensure that the President's vision for agency rules is realized. OIRA's regulatory review role on behalf of the President, once controversial, is now virtually unchallenged. However, OIRA is also a creature of, and is funded by Congress, and therefore must answer to it regarding the implementation of its statutory authority and during the appropriations process. During the last few years, Congress has not significantly challenged OIRA's recent initiatives, or encouraged OIRA to go further in terms of its transparency. Whether this trend will continue in the future is, at this writing, unclear.