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Federal Rulemaking: The Role of the Office of Information and Regulatory Affairs

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Summary

The Paperwork Reduction Act of 1980 created the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). Executive Order 12291, issued by President Reagan in 1981, gave OIRA the responsibility to review the substance of agencies' regulatory actions before publication in the *Federal Register*. The office's regulatory review role was initially highly controversial, and it has been criticized at different times as being both too active and too passive regarding agencies' rules. Although OIRA has a number of specific statutory responsibilities (e.g., paperwork review and regulatory accounting), as a component of OMB it is part of the Executive Office of the President, and helps ensure that covered agencies' rules reflect the President's policies and priorities.

OIRA's current regulatory review responsibilities are detailed in Executive Order 12866, which was issued by President Clinton in 1993. The office reviews significant draft rules from agencies (other than independent regulatory agencies) at both the proposed and final rulemaking stages, and also informally reviews certain rules before they are formally submitted. For rules that are "economically significant" (most commonly defined as those having a $100 million impact on the economy), OIRA also reviews the economic analyses. Since 1994, OIRA has reviewed between 500 and 700 significant proposed and final rules each year, and can clear the rules with or without changes, return the rules to the agencies for reconsideration, or encourage the agencies to withdraw them. The executive order also requires OIRA or the rulemaking agencies to disclose certain elements of the review process to the public, including the changes made at OIRA's recommendation. A September 2003 report by the General Accounting Office indicated that OIRA had a significant effect on more than a third of the 85 rules in the study, but OIRA's most common effect was to suggest changes to explanatory language in the preambles to the rules. At the start of the George W. Bush Administration, OIRA made a number of changes to its review process, including increased use of return letters, added emphasis on economic analysis to support the rules, and improvements in the transparency of the office's review process. Overall, in contrast to the "counselor" role it played during the Clinton Administration, OIRA appeared to have returned to the "gatekeeper" role that it had during its first 12 years of existence. An April 2009 report by GAO again noted changes made to rules at OIRA's suggestion.

Possible legislative issues involving OIRA include codification of the office's review function and principles, increasing or decreasing the office's funding and staffing, adding review of rules from independent regulatory agencies, and improvements in the transparency of OIRA's review process. In January 2009, President Obama requested recommendations from the Director of OMB for possible changes to Executive Order 12866. In January 2011, President Obama issued Executive Order 13563, which reaffirmed many of the principles in Executive Order 12866, but did not change OIRA's responsibilities.

This report will be updated if there are changes in OIRA's regulatory review responsibilities. For information, see CRS Report RL33862, *Changes to the OMB Regulatory Review Process by Executive Order 13422*, by Curtis W. Copeland; CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, by Curtis W. Copeland; and CRS Report RL32356, *Federal Regulatory Reform: An Overview*, by Curtis W. Copeland.

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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 currently reviews the substance of between 500 and 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. Between 70 and 100 of the rules that OIRA reviews each year are each considered "economically significant" or "major" (e.g., have a $100 million impact on the economy). The office was created by Congress and has a number of specific statutory responsibilities, but it also helps ensure that agencies' rules reflect the President's policies and priorities.

OIRA's role in the federal rulemaking process has been highly controversial in all five of the presidential administrations in which it has been in existence, but some of 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. At other times, though, OIRA has been accused of not exerting enough authority over the agencies' rules. 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 nongovernmental organizations can have on agencies' rules through those reviews.

This report describes how OIRA reviews covered agencies' draft rules, OIRA's effects on the rules, and changes in OIRA's procedures and policies in recent years. Much of that discussion is drawn from a September 2003 report on OIRA by the General Accounting Office (GAO, now the Government Accountability Office).[3] First, though, this report will provide a brief history of presidential regulatory review and describe how OIRA's review process was established. Finally, the report describes several potential legislative issues regarding OIRA's regulatory review authority.

The Establishment of Regulatory Review in OIRA

OIRA was created within OMB by Section 3503 of the Paperwork Reduction Act (PRA) of 1980 (44 U.S.C. Chapter 35).[4] The PRA provided that OIRA would be headed by an administrator, and designated the OIRA administrator as the "principal advisor to the Director on Federal information policy." The act also said that the Director of OMB "shall delegate to the (OIRA)

[1] The other statutory offices, which are collectively referred to as the "management" side of 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, which review agencies' budget submissions, are sometimes collectively referred to as OMB's "budget" side.

[2] The Administrative Procedure Act of 1946 (5 U.S.C. 551 et seq.). 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. For an overview of many of the statutes and executive orders governing federal rulemaking, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, by Curtis W. Copeland.

[3] U.S. General Accounting Office, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews*, GAO-03-929, Sept. 22, 2003.

[4] For a discussion of the PRA, see CRS Report RL30590, *Paperwork Reduction Act Reauthorization and Government Information Management Issues*, by Harold C. Relyea.

Administrator the authority to administer all functions under this chapter." 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.[5] 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.[6]

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 77 staff members when the PRA took effect in 1981, of which about half were involved in reviewing agencies' information collection requests. 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.[7] Many federal regulations have an information collection component, but the PRA did not authorize OIRA to review or comment on the non-paperwork elements of those regulations, or on regulations without an information collection component.[8]

OIRA and Reagan Executive Orders on Regulatory Review

In 1980, President Reagan was elected on a platform critical of government's role in society in general and of federal regulations in particular. 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. In relation 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 or the Environmental Protection Agency. Although the task force

[5] 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 "information policy" to "information resources management." As discussed later in this report, the 1986 amendment also required the administrator of OIRA to be appointed by the President, subject to advice and consent of the Senate.

[6] As used in this report, 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 (e.g., the Environmental Protection Agency and the Office of Personnel Management).

[7] For example, by 1989, OIRA's overall staffing had declined to fewer than 60 employees, of whom OIRA estimated 35 were reviewing information collection requests. By 1997, OIRA staffing declined 48 employees, of whom 22 were reviewing paperwork requests. See U.S. General Accounting Office, *Regulatory Management: Implementation of Selected OMB Responsibilities Under the Paperwork Reduction Act*, GAO/GGD-98-120, July 9, 1998.

[8] 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 created through collections of information imposed on businesses in order to inform the public about chemical hazards in their communities.

said that implementation of the changes it recommended would save more than $150 billion over the next 10 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." The task force's legislative efforts were less successful, failing to get Congress to enact revisions to clean air and water laws or to enact broad regulatory reform legislation that would have limited agencies' rulemaking powers.[9]

In February 1981—less than one month after taking office—President Reagan issued Executive Order 12291[10] on "Federal Regulation," which greatly increased both the scope and importance of OIRA's responsibilities.[11] Specifically, 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," select regulatory objectives to maximize net benefits to society, and select the regulatory alternative that involves the least net cost to society;
- prepare a "regulatory impact analysis" for each "major" rule, which was defined as any regulation likely to result in (among other things) an annual effect on the economy of $100 million. 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 why they weren't selected), and a determination of the net benefits of the rule. 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; and
- send a copy of each draft proposed and final rule to OMB before publication in the *Federal Register*. 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." Non-major rules were required to be submitted to OMB at least 10 days before publication, but major rules had to be submitted as much as 60 days in advance.

Executive Order 12291 authorized the director of OMB to review any draft proposed or final rule or regulatory impact analysis "based on the requirements of this Order." The executive order indicated that the review should be completed within 60 days, but allowed the director to extend that period whenever necessary. It also authorized the director to exempt classes of regulations from any or all of the order's requirements,[12] and generally required agencies to "refrain" from publishing any final rules until they had responded to OMB's comments. The executive order

[9] The task force was disbanded in August 1983 after issuing a final report.

[10] Executive Order 12291, "Federal Regulation," 46 *Federal Register* 13193, Feb. 19, 1981.

[11] 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 12291," *Virginia Journal of Natural Resources Law*, vol. 4 (Fall 1984), pp. 1-80.

[12] The exemptions that OMB granted fell into four broad categories: (1) rules that were essentially nonregulatory 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. OMB granted about 30 exemptions, most of which were established in 1981 or 1982.

made OMB's authority to review agencies' draft rules subject to the overall direction of the presidential task force on regulatory relief.[13]

Although the executive order did not specifically mention OIRA, shortly after its issuance 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. 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 12291—in addition to the nearly 5,000 paperwork review actions it took that year.

In 1985, President Reagan extended OIRA's influence over rulemaking even further by issuing Executive Order 12498, which required Cabinet department 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 underway or planned.[14] Previously, Executive Order 12291 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.[15] 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, saying that, except in "unusual circumstances," OMB could return any rule submitted for review under Executive Order 12291 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.

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 12291.[16] 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 lacks—review and approval by Congress.

Comparison to Previous Regulatory Review Efforts

The establishment of this regulatory review function within OIRA 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, Executive Orders 12291 and 12498 represented the continuation of presidential review of rules, not the start of such reviews. 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 1970's. For example:

[13] Although the task force was chaired by Vice President Bush, the executive director was the administrator of OIRA. Other members included the Director of OMB, the Attorney General, and the Secretaries of Commerce, Labor, and the Treasury.

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

[15] As discussed later in this report, President Carter first required the use of these agendas in 1978.

[16] An OIRA representative said that although the office had this authority it never used it, noting that would have been difficult to defend the return of an agency's rule for purely procedural reasons.

- 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 for comment.[17] 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.
- In 1974, President Ford issued Executive Order 11821, which required agencies to prepare an "inflation impact statement" for each "major" proposed rule.[18] 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 supplies 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 12044, 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 at least all rules with a $100 million impact on the economy.[19] 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. OMB was instructed to "assure the effective implementation of this Order," but was not given specific review responsibilities. 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.

In several ways, though, the analytical and review requirements in Executive Order 12291 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 12044, 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 12291 consolidated these

[17] This requirement was formally established through an October 1971 memorandum from then-OMB Director George Schultz. According to some observers, the requirements were routinely imposed only on the Environmental Protection Agency.

[18] Executive Order 11821, "Inflation Impact Statements," 39 *Federal Register* 41501, Nov. 29, 1974. The order also required such statements for agency-proposed major legislation.

[19] Executive Order 12044, "Improving Government Regulations," 43 *Federal Register* 12661, Mar. 24, 1978.

functions within OIRA.[20] Another major difference was the amount of influence that OIRA had compared to its predecessors. Under previous executive orders, CWPS and RARG had primarily an advisory role. In contrast, under Executive Order 12291, OIRA could overrule agency determinations regarding whether the rule was "major" (and therefore required a regulatory impact analysis), and could delay the regulation until the agency had adequately responded to its concerns (e.g., if it believed the agency had not considered all reasonable alternatives, that its analysis was not sound, or that it was contrary to administration policy). 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. Finally, and perhaps most importantly, the nature and transparency of the review process was significantly different under Executive Order 12291. Under the Carter Administration's approach, RARG and CWPS prepared and filed comments on agencies' regulatory proposals during the formal public comment period, *after* they were published in the *Federal Register*. In the case of RARG filings, a draft of the comments was circulated to all RARG members, and the comments and 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 12291 did not require that OIRA's comments on the draft rule be disclosed. This pre-publication review process made OIRA's regulatory reviews under Executive Order 12291 qualitatively different than its predecessors.

Early Views Regarding OIRA Reviews

The expansion of OIRA's authority in the rulemaking process via Executive Orders 12291 and 12498 was highly controversial. Although some believed that the authority did not go far enough (e.g., did not cover independent regulatory agencies), most of the 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 the effect that OIRA's review had on public participation and the timeliness of agencies' rules.[21] 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. Others indicated that OIRA did not have the technical expertise needed to instruct agencies about the content of their rules. 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 12291 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.[22]

Many of the early 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

[20] George Eads, "Harnessing Regulation: The Evolving Role of White House Oversight," *Regulation*, vol. 5 (May/June 1981), pp. 19-26.

[21] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Role of OMB in Regulation*, 97th Cong., 1st sess., June 18, 1981 (Washington: GPO, 1981). See also Morton Rosenberg, "Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12291," *Michigan Law Review*, vol. 80 (Dec. 1981), pp. 193-247.

[22] U.S. General Accounting Office, *Implementing the Paperwork Reduction Act: Some Progress, But Many Problems Remain*, GAO/GGD-83-35, April 20, 1983.

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.[23] 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. The memorandum did not, however, 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).[24] In 1985, five House committee chairmen filed a friend-of-the-court brief in a lawsuit brought against the Department of Labor regarding the department'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.

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. In an attempt to head off that legislation, in June 1986 the OIRA administrator issued a memorandum for the heads of departments and agencies subject to Executive Order 12291 describing new OIRA procedures to improve the transparency of the review process. 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. OIRA also said that it would, upon written request after a rule had been published, make available all written correspondence between OIRA and the agency head regarding the draft submitted for review.[25]

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.[26] 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." 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."

In 1988, the Administrative Conference of the United States also examined the issue of presidential review of agency rulemaking and concluded that the reviews could improve coordination and resolve conflicts among agencies.[27] The Administrative Conference also said,

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[23] Letter from James C. Miller III, administrator of OIRA, to the Honorable John D. Dingell, Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, April 28, 1981.

[24] OIRA's authorization for appropriation also expired in 2001, and (as of the date of this report) has not been reestablished.

[25] For further information on this policy, see Judith Havemann, "No 'Shade-Drawn' Dealings for OMB; Congress Gets Disclosure of Regulation-Review Procedures," *Washington Post*, June 17, 1986, p. A-21.

[26] National Academy of Public Administration, *Presidential Management of Rulemaking in Regulatory Agencies* (Jan. 1987).

[27] Administrative Conference of the United States, *Presidential Review of Agency Rulemaking*, Conference

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." The Conference 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."[28]

OIRA and the George H. W. Bush Administration

President George H. W. Bush continued the implementation of Executive Orders 12291 and 12498 during his administration, but external events significantly affected OIRA's operation and, more generally, the federal rulemaking process. In 1989, President Bush's nominee to head OIRA was not confirmed. Later, 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. Chaired by Vice President 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. According to OIRA representatives, 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.

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 secrecy in which the council acted.[29] The council attempted to maintain strict secrecy regarding both its deliberations and those in the private sector with whom it communicated or consulted.[30] 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. Meanwhile, OIRA continued its operations under Executive Order 12291, reviewing between 2,100 and 2,500 rules each year from 1989 through 1992.

Regulatory Review Under Executive Order 12866

In September 1993, President Clinton issued Executive Order 12866 on "Regulatory Planning and Review," which revoked Executive Orders 12291 and 12498 and abolished the Council on Competitiveness.[31] Although different from its predecessors in many respects, Executive Order 12866 (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*. The order also requires agencies to

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Recommendation 88-9 (1988). The Administrative Conference was established in 1968 to provide advice regarding procedural improvements in federal programs, and was eliminated by Congress in 1995.

[28] The National Academy of Public Administration and the American Bar Association have also recognized the potential value of presidential regulatory review. They also recommended reforms such as improved transparency and better communication between OIRA and agency staff.

[29] Christine Triano and Nancy Watzman, *All the Vice President's Men: How the Quayle Council on Competitiveness Secretly Undermines Health, Safety, and Environmental Programs* (Washington: OMB Watch/Public Citizen, 1991).

[30] See Bob Woodward and David Broder, "Quayle's Quest: Curb Rules, Leave 'No Fingerprints," *Washington Post*, Jan. 9, 1992, p. A1.

[31] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, Oct. 4, 1993. For an electronic copy of this executive order, see http://www.whitehouse.gov/omb/inforeg/eo12866.pdf.

prepare cost-benefit analyses for their "economically significant" rules (essentially the same as "major" rules under Executive Order 12291). As discussed in detail below, however, Executive Order 12866 established a somewhat new regulatory philosophy and a new set of rulemaking principles, limited OIRA's reviews to certain types of rules, and established transparency requirements that included but went beyond those that had been put in place by the administrator's June 1986 memorandum. Section 2(b) of the order assigns responsibility for review of agency rulemaking to OMB, and specifically names OIRA as "the repository of expertise concerning regulatory issues." The order also named the Vice President as principal advisor to the President on regulatory policy, planning, and review.[32]

Specific Provisions in the Executive Order

In its statement of regulatory philosophy, Executive Order 12866 says, among other things, that agencies should assess all costs and benefits of available regulatory alternatives, including both quantitative and qualitative measures. It also provides that agencies should select regulatory approaches that maximize net benefits (unless a statute requires another approach). Where permissible and applicable, the order states that agencies should adhere to a set of principles when developing rules, 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. 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." According to OIRA representatives, the "primacy" of the agencies provision signaled a significant change in regulatory philosophy, vesting greater control of the rulemaking process with regulatory agencies and taking away authority from OIRA. Also, the requirement that the benefits of a regulation "justify" its costs was a noticeably lower threshold than the requirement in Executive Order 12291 that the benefits "outweigh" the costs.

Section 6 of Executive Order 12866 established agency and OIRA responsibilities in the centralized review of regulations. In contrast to the broad scope of review under Executive Order 12291, 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:

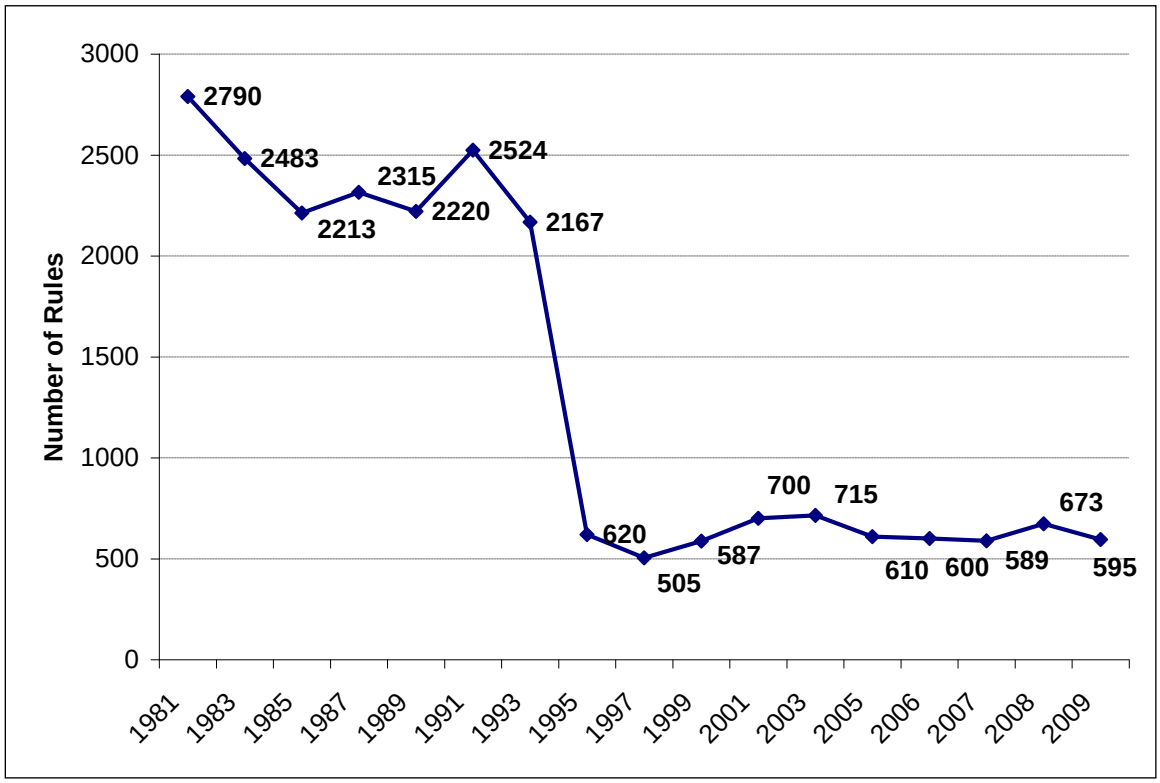
> "Any regulatory action that is likely to result in a rule that may (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, 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."

As **Figure 1** shows, 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

[32] Executive Order 13258, issued in February 2002, amended Executive Order 12866 and reassigned all roles originally assigned to the Vice President to the President's chief of staff. For a copy of this executive order, see http://www.whitehouse.gov/omb/inforeg/eo13258.pdf.

the Executive Order 12291 to between 500 and about 700 rules per year under Executive Order 12866.

Figure 1. The Number of Rules That OIRA Reviewed Dropped Under Executive Order 12866, Issued in 1993



Source: http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init

Executive Order 12866 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 90 calendar days,[33] and requires both the agencies and OIRA to disclose certain information about how the regulatory reviews were conducted. 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. 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. 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.[34]

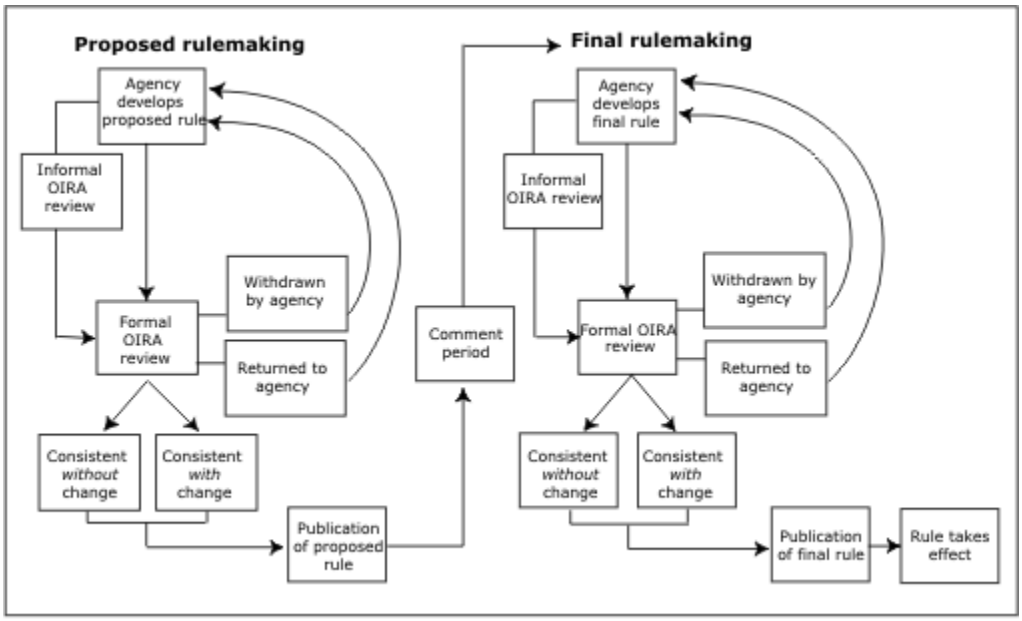
[33] Section 6(b)(2) of the executive order states that OIRA "shall waive review or notify the agency in writing of the results of its review," generally within 90 calendar days after a draft rule has been submitted. Nevertheless, in some cases, OIRA does not complete its review within 90 days. For example, as of January 8, 2008, one Department of Commerce rule (on "Right Whale Ship Strike Reduction") had been under review at OIRA for 322 days.

[34] For a discussion of the differences between the transparency requirements under Executive Order 12291 and Executive Order 12866, see William D. Araiza, "Judicial and Legislative Checks on Ex Parte OMB Influence Over Rulemaking," *Administrative Law Review*, 54 (Spring 2002), 611-630, and Peter M. Shane, "Political Accountability in

OIRA's Formal Review Process

As **Figure 2** shows, OIRA reviews agencies' draft rules at both the proposed and final stages of rulemaking.[35] 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. 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 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 executive order, 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. (Executive Order 12866 says that this comment period should, in most cases, be at least 60 days for significant rules reviewed by OIRA.) 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.

Figure 2. OIRA Reviews Draft Proposed and Final Rules



Source: GAO

In most of the years since Executive Order 12866 was issued, more than 90% of the rules that OIRA reviewed were coded in the database as either "consistent with change" or "consistent

a System of Checks and Balances: The Case of Presidential Review of Rulemaking," *Arkansas Law Review*, 48 (1995), 161-214.

[35] OIRA may also formally or informally review other rulemaking documents before proposed rules (e.g., advance notices of proposed rulemaking).

without change." (See **Table 1**.) 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 only somewhat lower than during most of the George W. Bush Administration (2002 through 2008). The data indicate that there were a relatively large number of rules that were withdrawn and returned in 2001 compared to other years. The withdrawn rules reflect actions taken at the start of the George W. Bush Administration pursuant to a memorandum issued by Assistant to the President and Chief of Staff Andrew H. Card, which generally directed Cabinet departments and independent agencies to (1) not send proposed or final rules to the Office of the Federal Register, (2) withdraw from the Office rules that had not yet been published in the *Federal Register*, and (3) postpone for 60 days the effective date of rules that had been published but had not yet taken effect.[36] (A somewhat similar effort was made at the start of the Obama Administration, reflected in the 10.4% of rules coded as withdrawn in 2009.) Also, as discussed in greater detail later in this report, OIRA returned a number of rules to the agencies for reconsideration shortly after a new administrator was appointed in 2001.

Table 1. Most Rules That OIRA Reviewed Were Coded in Database as Changed or Not Changed

Year	Percentage of rules OIRA reviewed that were coded:				
	Consistent with change	Consistent without change	Withdrawn	Returned	Other
1994	37.3	53.4	4.3	0.2	4.9
1995	39.0	53.1	5.2	0.5	2.3
1996	51.5	41.4	5.1	0.0	2.0
1997	56.0	37.4	5.1	0.8	0.6
1998	59.3	36.1	3.1	0.0	1.4
1999	62.2	31.5	3.1	0.0	3.2
2000	60.4	34.3	3.9	0.0	1.4
2001	45.6	28.1	22.0	2.6	1.7
2002	54.3	31.7	7.6	0.7	5.6
2003	60.3	30.1	6.9	0.3	2.2
2004	62.7	29.8	6.5	0.2	0.8
2005	65.4	27.0	6.6	0.2	1.0
2006	69.2	26.5	3.7	0.0	0.7
2007	72.3	21.1	6.3	0.2	0.2
2008	69.8	23.5	5.6	0.3	0.8
2009	71.6	17.1	10.4	0.5	0.4
2010	78.7	14.1	5.7	0.0	1.6

[36] Executive Office of the President, White House Office, "Regulatory Review Plan," 66 *Federal Register* 7702, Jan. 24, 2001. To view a copy of this memorandum, see http://www.whitehouse.gov/omb/inforeg/regreview_plan.pdf. For a discussion of the rules whose effective dates were postponed, see U.S. General Accounting Office, *Regulatory Review: Delay of Effective Dates of Final Rules Subject to the Administration's Jan. 20, 2001, Memorandum*, GAO-02-370R, Feb. 2002.

Source: OIRA.

Note: "Other" includes rules that were sent improperly, emergency rules, and rules with a statutory or judicial deadline. Numbers do not total to 100.0 due to rounding.

The type of review that OIRA conducts under Executive Order 12866 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.[37] 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.[38]

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 12866.[39] 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 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 13132 on "Federalism" and Executive Order 13175 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.

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 representatives, the desk officers always consult with the resource management officers on the budget side of OMB as part of their reviews, and reviews of draft rules are not completed until those resource management officers sign off. If the draft rule is economically significant, the desk officer would also consult with a government economist to help review the required economic analysis. 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. 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 Environmental Protection Agency rules).

Executive Order 12866 requires OIRA to complete its regulatory reviews within certain time frames—(1) within 10 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

[37] Section 3(f) of the executive order also defines 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."

[38] This guidance was issued as OMB Circular A-4 in September 2003. For a copy of this guidance, see http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.

[39] For a copy of this September 20, 2001 memorandum and the attachment, see http://www.whitehouse.gov/omb/inforeg/oira_review-process.html.

(2) within 90 calendar days of submission for all other regulatory actions (or 45 days if OIRA had previously reviewed the material). In some instances, however, agency officials said OIRA will ask the rulemaking agency to withdraw the rule and resubmit it, restarting the review period. 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 said it is often an iterative process in which the agencies and OIRA negotiate issues and clarify terms. 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

Figure 2 also shows that, for some rules, there is an additional phase of "informal review" before the rule is officially submitted to OIRA. 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."[40] 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. Therefore, OIRA indicated "there is value in promoting a role for OIRA's analytic perspective earlier in the process, before the agency becomes too entrenched." 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."

OIRA cannot informally review each of the hundreds of significant proposed and final rules that are submitted to the office each year. 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 not only OMB but also other federal agencies. The Environmental Protection Agency (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.

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 12866 was adopted in 1993 and OIRA's reviews were focused on "significant" rules. There have been some indications, though, that OIRA has 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 said "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." Separately, in 2002, the OIRA administrator said "an

[40] Office of Management and 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*, Dec. 2001, available at http://www.whitehouse.gov/omb/inforeg/costbenefitreport.pdf.

increasing number of agencies are becoming more receptive to early discussions with OMB, at least on highly significant rulemakings."[41]

The 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 create 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."[42]

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 those reviews result in substantive changes to the rules. One such study (using data prior to the advent of Executive Order 12988) 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.[43] 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 determine the significance of OIRA's effects on agencies' rules and whether those effects have changed over time.[44] As mentioned 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. "Returns" and "withdrawals" in OIRA's database also need careful interpretation. A return may be for purely administrative reasons, not for substantive OIRA objections. Conversely, a withdrawal of a rule by an agency may have been initiated by OIRA. 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 interviews with agency officials.[45] GAO reported that from July 1, 2001, through June 30, 2002, OIRA completed 642 reviews of agencies' draft proposed and final rules. Of these,

- About 33% (214) were coded in the database as "consistent with no change," indicating that OIRA considered the rules consistent with the executive order as submitted.

[41] Dr. John D. Graham, remarks prepared for the American Hospital Association, July 17, 2002. For a copy of this speech, see http://www.whitehouse.gov/omb/inforeg/graham_ama071702.html.

[42] Rebecca Adams, "Regulating the Rulemakers: John Graham at OIRA," *CQ Weekly*, Feb. 23, 2002, pp. 520-526.

[43] Scott Farrow, *Improving Regulatory Performance: Does Executive Office Oversight Matter?* (Pittsburgh: Carnegie Mellon University, July 26, 2000).

[44] See, for example, Steven Croley, "White House Review of Agency Rulemaking: An Empirical Investigation," *University of Chicago Law Review*, vol. 70 (Summer 2003), pp. 821-885.

[45] U.S. General Accounting Office, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews*, GAO-03-929, Sept. 22, 2003.

- About 50% (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.
- About 8% (50) were coded as "withdrawn" by the agency.
- About 3% (21) were coded as "returned" to the agency by OIRA.
- About 5% (35) had some other disposition (e.g., "sent improperly," "emergency," or "statutory or judicial deadline").

In order to make its review manageable, GAO focused on 85 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 within the Department of Health and Human Services; the Occupational Health and Safety Administration within the Department of Labor; the Federal Aviation Administration (FAA), the Federal Motor Carrier Safety Administration, and the National Highway Traffic Safety Administration (NHTSA) with the Department of Transportation (DOT); and the offices of air and radiation, water, and solid waste and emergency response within EPA. Seventy-one of the 85 rules had been coded "consistent with change," nine were coded as "returned," and five were coded as "withdrawn."

OIRA's Impact on Rules

GAO's analysis of the underlying documents indicated that OIRA had a significant effect on at least 25 of the 85 draft rules. Specifically:

- Of the 71 "changed" rules, GAO concluded that OIRA had suggested significant changes to 17 of them—changes that affected the scope, impact, or estimated costs or benefits of the rules as originally submitted. 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). Fourteen of the 17 significantly changed rules were from EPA's office of air and radiation or its office of water. 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. Of the remaining 54 "changed" rules, the most significant changes made at OIRA's suggestion involved adding explanatory language to the preambles of the rules and asking for comment on particular provisions. In 20 of the 54 rules, OIRA suggested only minor editorial changes (e.g., correcting spelling errors or citations) or made no suggestions at all.
- Of the nine rules that had been returned to the agencies by OIRA, two were returned because they had been improperly submitted, not because of substantive defect. OIRA returned the remaining seven rules because of concerns about the agencies' regulatory analyses or a perceived lack of coordination between rulemaking agencies. 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. Five of the seven rules returned for substantive reasons had been submitted by the FAA.
- Of the five rules that were withdrawn, GAO determined that only one had been withdrawn at OIRA's suggestion. The other four rules were withdrawn solely at

the agencies' initiative or as a result of a mutual decision by the agencies and OIRA.

If anything, GAO's analysis understates the influence that OIRA has on agencies' rules because its findings were often limited to the documentation that was available. If OIRA suggested a change to a rule before it was formally submitted to OIRA (e.g., during informal review), GAO's analysis would not reflect those changes. In fact, the rule might not have even been in the universe of rules that GAO examined (i.e., those coded as changed, returned, or withdrawn during OIRA's formal review). Other forms of OIRA influence 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.

Regulated Entities' Contacts with OIRA

GAO also reported that regulated entities directly contacted OIRA either before or during its review process regarding 11 of the 25 rules that OIRA significantly affected.[46] Eight of those 11 cases involved EPA rules, and the nature of the contacts ranged from meetings with OIRA representatives to letters sent to OIRA. In 7 of the 11 cases, GAO concluded that what OIRA ultimately recommended to the rulemaking agencies was similar to what these regulated parties recommended to OIRA—in some cases, using similar language to that used by the regulated entities. For example, 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.) 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. 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 this or other suggestions made by the regulated entities might have influenced OIRA's actions, if at all.

GAO's April 2009 Report

In April 2009, GAO again reported that OIRA's reviews often resulted in changes to draft rules. Of 12 rules that GAO examined in detail, 10 were changed at OIRA's suggestion.[47] Some of the changes resulted in alteration of regulatory text. GAO said that the agencies used a variety of methods to document OIRA's reviews, and that there was inconsistent interpretation of which changes were "substantive" enough to require documentation and "uneven attribution" of the sources of the changes made to the agencies' rules.

Changes in OIRA's Policies and Practices During the George W. Bush Administration

The formal process by which OIRA reviews agencies' draft rules has changed little since Executive Order 12866 was issued in 1993.[48] There have, however, been several subtle yet

[46] Environmental and public interest groups also contacted OIRA regarding three of the rules.

[47] U.S. Government Accountability Office, *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews*, GAO-09-205, April 20, 2009.

[48] There has been only one amendment to Executive Order 12866 since it was issued. As mentioned earlier in this

notable changes in OIRA policies and practices in recent years—particularly after Dr. John D. Graham became OIRA administrator 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."[49]

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. 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. In September 1996, the then-administrator of OIRA 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."[50] She also said she agreed with an article that said OIRA functioned during that period "more as a counselor during the review process than as an enforcer of the executive order."[51]

OIRA during the George W. Bush Administration returned to the role it had during the Reagan Administration, even describing itself in an annual report as the "gatekeeper for new rulemakings."[52] Then-OIRA Administrator Graham said one of the office's functions is "to protect people from poorly designed rules," and said OIRA review is a way to "combat the tunnel vision that plagues the thinking of single-mission regulators." He also compared OIRA's review of agencies' rules to OMB's role in reviewing agencies' budget requests. This return to the gatekeeper perspective of OIRA's role had implications for an array of OIRA's functions, and underlays many of the other changes described below.

Increased (and Decreased) Use of Return Letters

As noted previously in **Table 1**, during the Clinton Administration, OIRA only rarely returned rules to the agencies for reconsideration. 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.

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report, Executive Order 13258 reassigned all roles originally assigned to the Vice President in Executive Order 12866 (e.g., to be principal advisor to the President on regulatory policy, planning, and review) to the President's chief of staff.

[49] John D. Graham, "Presidential Oversight of the Regulatory State: Can It Work?," speech at the Heinz School, Carnegie Mellon University, Oct. 4, 2002.

[50] U.S. Congress, Senate Committee on Governmental Affairs, Subcommittee on Financial Management and Accountability, *Oversight of Regulatory Review Activities of the Office of Information and Regulatory Affairs*, 104th Cong., 2nd sess., Sept. 25, 1996 (Washington: GPO, 1997).

[51] William Niskanen, "Clinton's Regulatory Record: Policies, Process, and Outcomes," *Regulation*, vol. 19 (1996), pp. 27-28.

[52] Office of Management and Budget, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, Dec. 2002, available at http://www.whitehouse.gov/omb/inforeg/2002_report_to_congress.pdf.

In contrast, OIRA Administrator Graham referred to return letters as the office's "ultimate weapon," and viewed them as a way to make clear that the office is serious about the review process. In the first eight months after he took office in July 2001, OIRA returned 21 draft rules to the agencies for reconsideration. 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).[53] The letters commonly indicated that OIRA returned the rules because of concerns about the agencies' analyses (e.g., whether the agencies had considered all reasonable alternatives or had selected the alternative that would yield the greatest net benefits).

Subsequently, however, the pace of OIRA's return letters slowed. Although the average number of rules that OIRA reviewed each month stayed about the same, in the period from March 2002 until January 2008, OIRA returned a total of seven draft rules to the agencies—a dramatic decline from the 21 returns during Administrator Graham's first eight months in office.[54] OIRA officials attributed the decline in return letters to the improved quality of agencies' regulatory submissions after the initial flurry of returns.

Advent (and 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 website) suggesting that they develop regulations in a particular area or encouraging the agencies' ongoing efforts.[55] 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. Other prompt letters recommended that the agencies better focus certain research or programs. Between September 2001 and December 2003, OIRA sent a total of 13 prompt letters to regulatory agencies, and several of the agencies took action in response to the letters. Since then, however, the number of prompt letters diminished substantially. Only two prompt letters were issued in 2004, none in 2005, one in 2006, and none in 2007.

Increased Emphasis on Economic Analysis

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 has been 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-benefit analysis for every regulatory option that the agency considered, not just the option selected.

[53] Copies of OIRA's return letters are available on OMB's website at http://www.whitehouse.gov/omb/inforeg/return_letter.html.

[54] Two of the five returns during this period involved the same DOT rule.

[55] Copies of these prompt letters are available on OMB's website at http://www.whitehouse.gov/omb/inforeg/prompt_letter.html.

In September 2003, OIRA published revised guidelines for economic analysis under the executive order—updating "best practices" guidance issued in January 1996.[56] The new 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,[57] (2) use multiple discount rates when the benefits and costs of rules are expected to occur in different time periods,[58] 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).

Although OIRA has said that regulations based on economic analysis are more likely to be better than those that are not, it has also signaled that these analyses are sometimes difficult or impossible for certain types of rules. In November 2005, OIRA Administrator Graham said "[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."[59] He also said that cost-benefit analysis may not be appropriate for homeland security rules, and that a more practical "soft" test was being used for them.[60] Some have questioned why assessments of homeland security rules should be treated differently than health, safety, and environmental rules.[61]

Increased Transparency

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. Executive Order 12866 attempted to address some of those concerns, requiring (among other things) that agencies disclose after the publication of a rule the changes made to the rule during OIRA's review and the changes made at the suggestion or recommendation of OIRA. The 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, telephone calls) between OIRA staff and parties outside of the executive branch. 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 formal review period, not if they occurred during its informal reviews.

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[56] As noted earlier in this report, this guidance (OMB Circular A-4) is available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.

[57] 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).

[58] Discounting can have a significant effect on the present value of future health benefits. For example, in a February 2003 speech the OIRA administrator noted that the present value of 1,000 lives saved 50 years in the future is only 34 lives in present value when evaluated at a 7 % discount rate.

[59] John Graham, "The Smart-Regulation Agenda: Progress and Challenges," speech before the AEI-Brookings Joint Center for Regulatory Studies, Nov. 7, 2005.

[60] Nancy Ognanovich, "Head of OMB Regulatory Office Says Analyzing Homeland Security Rules Difficult," *BNA Daily Report for Executives*, Nov. 8, 2005, p. A39.

[61] For example, former OIRA administrator Sally Katzen said "when it matters to them to get rules out quickly, they wink and blink. But in the areas of public health and safety, where they have longstanding relations with the business communities involved, they're insistent on satisfying these standards," in Rebecca Adams, "Graham Leaves OIRA With a Full Job Jar," *CQ Weekly*, Jan 23, 2006, p. 226.

In October 2001, the OIRA administrator published a memorandum to OIRA staff on the office's website that extended the executive order's disclosure requirements in several areas. 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. OIRA also said it would disclose substantive telephone calls with outside parties that were initiated by the administrator, not just calls initiated by outside parties. OIRA has also posted on its website lists of regulations currently under review,[62] reviews concluded in the previous 30 days,[63] and its contacts with outside parties.[64] Although these changes have improved the transparency of OIRA's reviews, as discussed later in this report, the effects of OIRA's reviews (particularly informal reviews) are not always apparent.

Changes in OIRA Staffing

When OIRA was created in FY1981, the office had a "full-time equivalent" (FTE) ceiling of 90 staff members. By 1997, OIRA's FTE allocation had declined to 47—a nearly 50% reduction. Although Executive Order 12866 (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. Specifically, as discussed later in this report, OIRA was expected to perform various duties under the Unfunded Mandates Reform Act of 1995, the Small Business Regulatory Enforcement Fairness Act of 1996, and the Regulatory Right-to-Know Act of 2001.

Starting in 2001, OIRA's staffing authorization began to increase; by 2002, it stood at 55 FTEs. Between 2001 and 2003, OIRA hired five new staff members in such fields as epidemiology, risk assessment, engineering, and health economics. OIRA 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. Since 2003, OIRA staffing has been relatively stable.

Changes to OIRA Review by Executive Order 13422

On January 18, 2007, President George W. Bush issued Executive Order 13422, making the most significant amendments to Executive Order 12866 since it was published in 1993. The changes made by this new executive order were controversial, characterized by some as a "power grab" by the White House that undermined public protections and lessened congressional authority,[65] and by others as "a paragon of common sense and good government."[66]

The most important changes made to Executive Order 12866 by Executive Order 13422 fell into five general categories: (1) a requirement that agencies identify in writing the specific market

[62] See http://www.whitehouse.gov/omb/library/OMBREGSP.html.

[63] See http://www.whitehouse.gov/omb/library/OMBREGSC.html.

[64] A list of OIRA's meetings with outside parties can be found at http://www.whitehouse.gov/omb/oira/meetings.html. A list of its oral communications can be found at http://www.whitehouse.gov/omb/oira/oral_communications.html.

[65] Public Citizen, "New Executive Order Is Latest White House Power Grab," available at http://www.citizen.org/pressroom/release.cfm?ID=2361. See also Margaret Kriz, "Thumbing His Nose," *National Journal*, July 28, 2007, pp. 32-34.

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

failure or problem that warrants a new regulation, (2) a requirement that each agency head designate a presidential appointee within the agency as a "regulatory policy officer" who can control upcoming rulemaking activity in that agency, (3) a requirement that agencies provide their best estimates of the cumulative regulatory costs and benefits of rules they expect to publish in the coming year, (4) an expansion of OIRA review to include significant guidance documents, and (5) a provision permitting agencies to consider whether to use more formal rulemaking procedures in certain cases.

A separate CRS report discusses each of these changes, noting areas that are unclear and the potential implications of the changes; provides background information on presidential review of rules; discusses three congressional hearings on the executive order in 2007; and notes congressional efforts to block the implementation of the order.[67] It concludes by pointing out that the significance of the changes made to the review process by Executive Order 13422 may become clear only through their implementation. The changes made by this executive order represented a clear expansion of presidential authority over rulemaking agencies. In that regard, Executive Order 13422 can be viewed as part of a broader statement of presidential authority presented throughout the Bush Administration.

OIRA and the Barack Obama Administration

On January 30, 2009, President Barack Obama issued Executive Order 13497, which revoked both Executive Order 13422 and Executive Order 13258 (which had been issued in February 2002, and amended Executive Order 12866 to reassign all roles originally assigned to the Vice President to the President's chief of staff).[68] On March 4, 2009, however, the Director of OMB issued a memorandum to federal agencies instructing them to continue sending significant guidance documents to OIRA for review.[69]

On January 30, 2009, President Barack Obama issued a memorandum to the heads of executive departments and agencies instructing the Director of OMB, in consultation with representatives of regulatory agencies, to "produce within 100 days (i.e., by May 10, 2009) a set of recommendations for a new Executive Order on Federal regulatory review."[70] The memorandum said that the recommendations should, among other things:

> offer suggestions for the relationship between OIRA and the agencies; provide guidance on disclosure and transparency; encourage public participation in agency regulatory processes; offer suggestions on the role of cost-benefit analysis; address the role of distributional considerations, fairness, and concern for the interests of future generations; identify methods of ensuring that regulatory review does not produce undue delay; clarify the role of the behavioral sciences in formulating regulatory policy; and identify the best tools for achieving public goals through the regulatory process.

On February 26, 2009, the Director of OMB published a notice in the *Federal Register* requesting comments from the public on how to improve the regulatory review process.[71] The Director noted

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

[68] Executive Order 13497, "Revocation of Certain Executive Orders Concerning Regulatory Planning and Review," 74 *Federal Register* 6113, February 4, 2009.

[69] See http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_fy2009/m09-13.pdf. The OMB Director said these guidance documents had been reviewed by OIRA prior to the adoption of Executive Order 13422.

[70] The President, "Regulatory Review," 74 *Federal Register* 5977, February 3, 2009.

[71] U.S. Office of Management and Budget, "Federal Regulatory Review," 74 *Federal Register* 8819, February 26,

that although executive orders are not subject to notice and comment procedures, and public comments are not normally invited before their issuance, OMB was doing so in this case because there had been an "unusually high level of public interest," and because of the "evident importance and fundamental nature of the relevant issues."[72] The initial deadline for comments was March 16, 2009, but the comment period was extended until March 31, 2009, because of "requests from a number of interested members of the public."[73]

In response to its request, OMB received 183 comments from the public, including Members of Congress, representatives of public interest and private sector interest groups, academicians, and individuals.[74] The comments and suggestions varied widely, with some advocating a reduced role for OIRA, and others pushing for OIRA to assume a stronger role.[75] Some of the comments proposed a stronger role for cost-benefit analysis, while others suggested that the analysis be used only when required by statute.

Executive Order 13563

On January 18, 2011, President Obama issued Executive Order 13563 on "Improving Regulation and Regulatory Review."[76] In many respects, the new executive order simply restates many of the principles enunciated in Executive Order 12866, or in related documents.[77] In fact, Section 1(b) of the new order specifically states that "This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993." Perhaps most notably, Section 6 of Executive Order 13563 requires covered federal agencies (most agencies, excluding independent regulatory agencies) to submit to OIRA within 120 days "a preliminary plan, consistent with law and its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives." Although Section 5 of Executive Order 12866 had previously required agencies to develop a plan for retrospective reviews, this new requirement appears to require the development of a new plan.

2009.

[72] Ibid.

[73] U.S. Office of Management and Budget, "Federal Regulatory Review," 74 *Federal Register* 11383, March 17, 2009.

[74] The comments may be viewed at http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp.

[75] For a summary of these comments, see a series of reports by Ralph Lindeman: "Advocate Groups Want Reduced OIRA Role in OMB's Regulatory Review Revision Process," *BNA Daily Report for Executives*, April 2, 2009, p. A-13; "Business Groups Seek Stronger OIRA Role Written Into New Regulatory Review Process," *BNA Daily Report for Executives*, April 6, 2009, p. A-16; and "Lawyers, Lawmakers, Law Experts Differ on OMB Regulatory Review Changes," *BNA Daily Report for Executives*, April 9, 2009, p. A-20.

[76] Executive Order 13563, "Improving Regulation and Regulatory Review," 76 *Federal Register* 3821, January 21, 2011.

[77] Most new provisions in Executive Order 13563 seem to be covered in other documents. For example, Section 1(c) of the new executive order states that, in applying the order's rulemaking principles, each agency is to "use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." Although there does not appear to be any directly comparable language in Executive Order 12866, OMB Circular A-4 (issued in 2003) goes into great detail in describing what techniques should be used to quantify and monetize regulatory costs and benefits. Also, in November 2010, OMB published a checklist for agencies to use in conducting regulatory impact analyses under Executive Order 12866 and Circular A-4. To view this checklist, see http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA_Checklist.pdf.

On February 2, 2011, OIRA administrator Cass R. Sunstein issued a memorandum to federal agencies elaborating certain aspects of Executive Order 13563.[78] In particular, the memorandum described what agencies' plans for retrospective reviews should address (e.g., public participation, prioritization, and costs and benefits), and encouraged independent regulatory agencies to "give consideration" to the executive order's provisions, particularly the provisions relating to retrospective analysis. However, neither this memorandum nor Executive Order 13563 changed OIRA's regulatory review responsibilities.

OIRA's Other Responsibilities

In addition to its regulatory review responsibilities under Executive Order 12866 and its multiple responsibilities under the Paperwork Reduction Act (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 (2 U.S.C. 1532-1538) generally requires agencies to prepare written statements describing the effects of their rules that are subject to the act's requirements. 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. The OMB director has delegated these responsibilities to OIRA.[79]
- The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 note) required 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.[80] The act specifically requires the review panel to include full-time employees from OIRA as well as other agencies.
- 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 15 days of their issuance. 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.[81]
- Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (44 U.S.C. 3504 (d)(1) and 3516), 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). Specifically, the act required OMB to issue governmentwide guidelines that "provide policy and procedural

[78] See http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-10.pdf for a copy of this memorandum.

[79] For a more complete discussion of UMRA, see CRS Report RS20058, *Unfunded Mandates Reform Act Summarized*, by Keith Bea and Richard S. Beth.

[80] This requirement is codified at 5 U.S.C. 609.

[81] For a more complete discussion of the Congressional Review Act, see CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Update and Assessment of The Congressional Review Act after a Decade*, by Morton Rosenberg.

guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." OMB published those guidelines in final form on February 22, 2002.[82] 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 how such complaints were handled by the agency.

- Section 624 of the Treasury and General Government Appropriations Act, 2001, (31 U.S.C. 1105 note), 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 nonquantifiable effects) of federal rules and paperwork, to the extent feasible, (1) in the aggregate, (2) by agency and agency program, and (3) by major rule. 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.
- The same legislation requires OMB to include "recommendations for reform" in its cost-benefit reports. Rather than rely on its own expertise, OIRA decided to solicit suggestions from the public. For example, in March 2002, OIRA asked the public for recommendations to eliminate or modify existing rules as well as to expand or extend existing programs. In response, OIRA received more than 300 suggestions, which OIRA turned over to the appropriate agencies for prioritization. In February 2004, OIRA asked the public for suggested reforms of rules affecting the manufacturing sector. OIRA said it was focusing on manufacturing because of the relatively large impact that regulations have on that sector.[83]
- The Small Business Paperwork Relief Act of 2002 (P.L. 107-198) requires OMB to annually publish, in the *Federal Register* and on the Internet, a list of compliance assistance resources available to small businesses. The act also requires OMB to convene and chair a task force to study the feasibility of streamlining paperwork requirements on small businesses. The task force was required to file an initial report by the end of June 2003, and is required to file a second report by the end of June 2004.
- The E-Government Act of 2002 (P.L. 107-347) requires the OIRA administrator to work with the administrator of the Office of Electronic Government to establish the strategic direction of the governmentwide e-government program

[82] Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication," 67 *Federal Register* 8451, Feb. 22, 2002.

[83] A similar requirement for "recommendations for reform" was included in section 628(a)(3) of the FY2000 Treasury and General Government Appropriations Act. OIRA received 71 suggestions from the public in response to its call for "suggestions on specific regulations that could be rescinded or changed that would increase net benefits to the public," most of which came from the Mercatus Center at George Mason University. OIRA reviewed these suggestions and identified 23 as a "high priority" for review. Eight of the 23 high priority recommendations involved EPA rules, and five involved rules from the Department of Labor. Although business groups generally applauded this effort, environmentalists and public interest groups characterized it as the development of a "hit list" of rules that the Bush Administration wanted to eliminate.

and to oversee its implementation. OIRA has been particularly active in the Administration's e-rulemaking initiative.

- In the Treasury and General Government Appropriations Act, 2002 (P.L. 107-67), 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 should 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. 13166."[84]
- The conference report for OMB's appropriation for FY2004 (to accompany H.R. 2673) directed OIRA to submit a report to the House and Senate Committees on Appropriations by June 1, 2004, on "whether agencies have been properly responsive to public requests for correction of information pursuant to the (Data Quality Act)."[85]

Congress also sometimes limits OIRA's actions through riders on OMB's appropriation. For example, since 1983, language has been 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. Marketing orders, which cover dozens of commodities from lemons to milk, basically keep prices up by regulating supplies, and had been targeted for elimination or amendment by President Reagan's task force on regulatory relief in the early 1980s. 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.

In other cases, OIRA has taken on additional responsibilities, sometimes basing its actions on previous statutory or executive order authorities. For example:

- In December 2004, OIRA published a final bulletin establishing government-wide guidance aimed at enhancing the practice of peer review of government science documents.[86] The bulletin applied to all "influential scientific information" and "highly influential scientific assessments." The final version of the bulletin gave agencies significantly greater discretion to decide when information required peer review than the September 2003 proposed bulletin, but OIRA retained significant authority in certain areas (e.g., when information is "highly influential" and requires more stringent peer review).
- In November 2005, OMB published a proposed bulletin "Good Guidance Practices," saying that it was concerned that agency guidance documents "may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review.[87] OMB did not cite any specific statutes or executive orders as authorizing the issuance of the bulletin, but did indicate that it was "responsible both for promoting good management practices and for overseeing and coordinating the Administration's regulatory policy." The bulletin

[84] Executive Order 13166, "Improving Access to Services for Persons With Limited English Proficiency," 65 *Federal Register* 50121, Aug. 16, 2000. For a copy of the report, see http://www.whitehouse.gov/omb/inforeg/lepfinal3-14.pdf.

[85] OIRA submitted this report in April 2004. For a copy of the report, see http://www.whitehouse.gov/omb/inforeg/fy03_info_quality_rpt.pdf.

[86] To view a copy of this bulletin, see http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf.

[87] To view a copy of this document, see http://www.whitehouse.gov/omb/inforeg/good_guid/good_guidance_preamble.pdf.

would require agencies to develop written procedures for the approval of significant guidance documents, and to publish "economically significant" documents in the *Federal Register* and invite comments.

- In January 2006, OIRA published a proposed bulletin on agency risk assessment practices for public comment and peer review by the National Academy of Sciences (NAS).[88] However, in January 2007, an NAS committee reported that the proposed bulletin was "fundamentally flawed" and should be withdrawn. In September 2007, OMB withdrew the proposed bulletin and instead issued a memorandum reiterating and reinforcing principles for risk assessment that were originally written in 1995, indicating that agencies should comply with the principles.[89]

OIRA and the Future of Presidential Regulatory Review

For 30 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.[90]

OIRA is located within the Executive Office of the President and is the President's direct representative in the governmentwide rulemaking process. As Executive Order 12866 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 they are published in the *Federal Register*) to enable it to exert maximum influence.

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 *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.[91] She said he did so by exercising directive authority and asserting personal ownership over a range of agency actions, thereby making them "presidential" in nature. She also characterized this emergence of enhanced methods of presidential control over the regulatory state—what she

[88] To view a copy of this bulletin, see http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf.

[89] See http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/m07-24.pdf for a copy of this memorandum.

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

[91] Elana Kagan, "Presidential Administration," *Harvard Law Review*, vol. 18 (June 2001), pp. 2245-2385.

termed the "presidentialization of administration"—as "the most important development in the last two decades in administrative process."

Other observers, however, view OIRA (like other executive branch agencies) as having more of a shared allegiance between the President and the Congress. 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.[92] With both statutory and executive order responsibilities, OIRA embodies a broader tension between Congress 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's is undebatable. Rulemaking agencies formally challenge OIRA's returns and "suggestions" for change only rarely, and 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 sometimes holds hearings 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, section 632 of 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." The proposed legislation also would have placed in statute many of the transparency requirements in Executive Order 12866.

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 (H.R. 616) 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. 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. Neither of these bills was enacted.

[92] For example, David H. Rosenbloom, in *Building a Legislative-Centered Public Administration* (Tuscaloosa, AL: The University of Alabama Press, 2001) states that "where 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)."

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 increased somewhat during the Bush Administration, OIRA has still fewer staff than it had when its regulatory review function was first established in 1981. Currently, about 30 to 40 OIRA desk officers and branch chiefs review about 3,000 agency information collection requests each year and between 500 and 700 significant rules each year. 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.[93] 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.[94]

At other times, proposed legislation has been introduced designating how OIRA staff should be used. For example, in the 108th Congress, 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 2 full time staffers to review the Federal information collection burden on the public imposed by the Internal Revenue Service." The Internal Revenue Service accounts for more than 80% 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). The Bush Administration objected to this specific direction 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.

Addition of Independent Agencies' Rules

Although 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 Data Quality Act), the executive orders that have established regulatory review within OIRA have explicitly excluded rules issued by those agencies.[95] 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.[96] 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 inclusion of their rules under OIRA's would be counter to this purpose. 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.

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[93] 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. 13166. Also, in the conference report for OMB's FY2004 appropriation (under the heading "Office of Information and Regulatory Affairs"), the conferees directed that $1 million "be withheld from obligation until resolution of existing programmatic concerns by House conferees are addressed and the House and Senate Committee on Appropriations approve of such obligations."

[94] See, for example, Robert W. Hahn and Robert E. Litan, *Why Congress Should Increase Funding for OMB Review of Regulations*, AEI-Brookings Joint Center for Regulatory Studies, Policy Matter 03-33, Oct. 2003.

[95] For purposes of regulatory review, both Executive Order 12291 and Executive Order 12866 defined a covered "agency" as excluding those agencies specified in 44 U.S.C. 3502(10).

[96] See, for example, the Center for Regulatory Effectiveness, *A Blueprint for OMB Review of Independent Agency Regulations*, Mar. 2002. The previously mentioned bill (S. 746) that proposed to establish in law presidential review of rules would have included rules issued by independent regulatory agencies.

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 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 done, were not always clear or consistent. 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.
- 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.
- GAO also recommended refinements to the executive order's requirements applicable to OIRA (e.g., more clearly indicating on its website 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).

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. The administrator did not, however, 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. Disclosure of these informal review changes could be required through an administrative directive issued by the OIRA administrator or, alternatively, through legislation.

In April 2009, GAO again examined the changes made during OIRA's reviews, and concluded that OIRA had implemented only one of the eight recommendations in its 2003 report.[97] GAO recommended that OIRA (1) define in guidance what types of changes made as a result of those reviews are substantive and need to be publicly identified, (2) instruct agencies to clearly identify those changes made at OIRA's suggestion or recommendation, (3) direct agencies to clearly state in their final rules whether substantive changes were made to their rules as a result of OIRA's reviews, and (4) standardize how agencies label documentation of these changes in their

[97] U.S. Government Accountability Office, *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews*, GAO-09-205, April 20, 2009. OMB implemented GAO's recommendation to improve the clarity of OIRA's meeting log to better identify participants in OMB meetings with external parties.

rulemaking dockets. OMB said that these recommendations had merit and warranted further consideration.

Congressional Office of Regulatory Analysis

In the 112th Congress, H.R. 214 would, if enacted, establish a "Congressional Office of Regulatory Analysis." Among other things, the office would be required to "provide to the Committee on Oversight and Government Reform of the House of Representatives and the Committee on Homeland Security and Governmental Affairs of the Senate, information that will assist the committee in the discharge of all matters within its jurisdiction, including information with respect to its jurisdiction over authorization and oversight of the Office of Information and Regulatory Affairs of the Office of Management and Budget."

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Acknowledgments

This report originally was written by Curtis W. Copeland, who has retired from CRS. Congressional clients with questions about this report's subject matter may contact Maeve P. Carey.

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