

2006

## Managing the Regulatory State: The Experience of the Bush Administration

John D. Graham

Paul R. Noe

Elizabeth L. Branch

Follow this and additional works at: <https://ir.lawnet.fordham.edu/ulj>



Part of the [Administrative Law Commons](#)

---

### Recommended Citation

John D. Graham, Paul R. Noe, and Elizabeth L. Branch, *Managing the Regulatory State: The Experience of the Bush Administration*, 33 Fordham Urb. L.J. 953 (2006).

Available at: <https://ir.lawnet.fordham.edu/ulj/vol33/iss4/1>

This Article is brought to you for free and open access by FLASH: The Fordham Law Archive of Scholarship and History. It has been accepted for inclusion in Fordham Urban Law Journal by an authorized editor of FLASH: The Fordham Law Archive of Scholarship and History. For more information, please contact [tmelnick@law.fordham.edu](mailto:tmelnick@law.fordham.edu).

## MANAGING THE REGULATORY STATE: THE EXPERIENCE OF THE BUSH ADMINISTRATION

*John D. Graham\**

*Paul R. Noe*

*Elizabeth L. Branch*

The United States Office of Management and Budget (OMB), an organization within the Executive Office of the President, seeks to promote wise expenditures, regardless of whether those expenditures are made through budgetary programs or through unfunded mandates on states or the private sector. The lion's share of these unfunded regulatory mandates is aimed at businesses, but these rules also impact other entities such as state and local governments, unions, colleges and universities, and health care providers.<sup>1</sup>

One of the key roles of OMB's Office of Information and Regulatory Affairs (OIRA) is to review new rulemakings and stimulate modernization of existing rules.<sup>2</sup> OIRA performs its regulatory oversight with a team of

---

\* The views expressed herein solely reflect the personal opinions of the authors and do not necessarily reflect the opinions or positions of the Office of Management and Budget or of the U.S. Government.

John D. Graham, Ph.D., is Dean of the Pardee RAND Graduate School of Policy Analysis in Santa Monica, California. From 2001-2006, he served as Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, Washington, D.C.

Paul R. Noe, J.D., is a Partner with C&M Capitolink and Counsel in the law firm of Crowell & Moring, Washington, D.C. From 2001-2006, he served as Counselor to the Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, Washington, D.C.

Elizabeth L. Branch, J.D., is the Special Assistant to the Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, Washington, D.C.

1. See U.S. OFFICE OF MGMT. & BUDGET (OMB), OFFICE OF INFO. & REGULATORY AFFAIRS, VALIDATING REGULATORY ANALYSIS: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES, 137-81 (2005) [hereinafter OMB, 2005 REPORT TO CONGRESS].

2. OIRA's authority to oversee new and existing regulations can be found in Presidential Executive Order 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), and the Regulatory Right to Know Act of 1999, Pub. L. No. 106-554, §624, 114 Stat. 2763.

about thirty career OIRA analysts who apply a “soft” benefit-cost test.<sup>3</sup> OIRA asks whether the quantified benefits of a rule exceed the quantified costs, but OIRA also strives to be sensitive to important “intangible” considerations. These unquantified factors may reflect basic issues of fairness, such as civil rights, or they may reflect a key efficiency concern that cannot yet be fully measured and expressed in monetary units (e.g., homeland security). Considering both matters of efficiency and fairness, OIRA analysts ask whether a rule has adequate supporting analysis and whether the benefits of a rule justify its costs.<sup>4</sup>

The distinction between budgetary rules and unfunded mandates is important.<sup>5</sup> The new prescription drug benefit under Medicare was authorized by legislation and implemented through rulemaking.<sup>6</sup> It is considered a budgetary program, however, not an unfunded mandate, because the expenditures are paid for by taxpayers through the federal government’s Medicare appropriation. The Department of Transportation’s Corporate Average Fuel Economy (CAFE) program, the goal of which is to save oil by boosting the fuel economy ratings of cars, sport utility vehicles, vans and pick-up trucks, is an unfunded mandate.<sup>7</sup> The costs of meeting these federal standards are not paid through the federal appropriations process; they are presumably incurred by consumers, investors and employees in the motor vehicle industry. This Article focuses on unfunded mandates on the private sector.

The purpose of this Article is to explain how Presidential management of federal regulation, through OMB oversight, has been carried out in the first five years of the George W. Bush Administration, during the tenure of Dr. John Graham as the Administrator of OIRA. Part I traces the history of Presidential management of the regulatory state. Part II explores the

---

3. OIRA has an additional twenty career OIRA analysts who work on statistical and information policy. These analysts also assist in regulatory reviews and reviews of administrative (paperwork) burdens under the Paperwork Reduction Act.

4. See Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993) (“Each agency . . . shall propose a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”).

5. Under the Unfunded Mandates Reform Act of 1995, Congress recognized two types of unfunded mandates: “federal intergovernmental mandates” and “federal private sector mandates.” 2 U.S.C. §§ 658 (5), (7) (2000). The Act imposes special requirements on both Congress and the executive branch before these unfunded mandates may be imposed. *Id.* § 1501.

6. See Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066; 70 Fed. Reg. 4193 (Jan. 28, 2005).

7. See 49 U.S.C. § 32902 (2006) (average fuel economy standards for passenger automobiles); Average Fuel Economy Standards for Light Trucks Model Years 2008-2011, 71 Fed. Reg. 17,566 (Apr. 6, 2006).

concept of “smart regulations,” and the associated emphasis on rigorous benefit-cost analysis, that Dr. Graham implemented as OIRA Administrator. Part III summarizes the various critiques that have been offered against the “smart regulation” approach, and addresses those arguments. Part IV explores future challenges in regulatory policy.

### I. PRESIDENTIAL MANAGEMENT OF THE REGULATORY STATE

Every President from Richard Nixon to George W. Bush has embraced centralized executive oversight of agency regulations.<sup>8</sup> Even critics of OMB acknowledge the legitimacy of a centralized oversight function.<sup>9</sup>

---

8. See James Blumstein, *Presidential Administration and Administrative Law: Regulatory Review By the Executive Office of the President: An Overview and Policy Analysis of Current Issues*, 51 DUKE L.J. 851, 854-55 (2001) (“[C]entralized presidential regulatory review has now taken center stage as an institutionalized part of the modern American presidency.”). For a more detailed and skeptical account of the evolution of centralized OMB oversight under Presidents Nixon, Ford, Carter, and Reagan, see Robert V. Percival, *Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency*, 54 LAW & CONTEMP. PROBS. 127, 128-55 (1991); see also Michael Herz, *Imposing Unified Executive Branch Statutory Interpretation*, 15 CARDOZO L. REV. 219, 219 (1993) (with every President since Nixon, there have been “increasingly systematic efforts to gain control of the federal bureaucracy”); Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2283 (2001) (examining the “presidentialization of administration—the emergence of enhanced methods of presidential control over the regulatory state”); William F. West, *The Institutionalization of Regulatory Review: Organizational Stability and Responsive Competence at OIRA*, 35 PRESIDENTIAL STUD. Q. 76, 76-78 (2005) (“Modern Presidents have often found centralized forms of management to be appealing” and regulatory review “is consistent with this thesis.”).

9. See Alan B. Morrison, *OMB Interference with Agency Rulemaking: The Wrong Way to Write a Regulation*, 99 HARV. L. REV. 1059, 1064 (1986) (acknowledging that OMB can perform useful functions in coordinating disputes between agencies about rules and assuring that relevant scientific and economic information is shared between agencies; that agencies consider public comments submitted during the rulemaking process; and that agencies consider whether a rule is necessary and lawful). Elena Kagan has argued that “statutory delegation to an executive agency official . . . usually should be read as allowing the President to assert directive authority . . . over the exercise of the delegated discretion.” Kagan, *supra* note 8, at 2251. But see Lawrence Lessig & Cass R. Sunstein, *The President and the Administration*, 94 COLUM. L. REV. 1, 118 (1994) (“The framers did not constitutionalize presidential control over all that is now considered executive.”); Morrison, *supra*, at 1059 (over the last decade, as OMB’s role in the issuance of regulations has increased, questions have arisen as to the “legality and desirability of OMB’s role.”); Erik Olson, *The Quiet Shift of Power: Office of Management and Budget Supervision of Environmental Protection Agency Rulemaking Under Executive Order 12,291*, 4 VA. J. NAT. RESOURCES L. 1, 12 (1984) [hereinafter Olson, *The Quiet Shift of Power*] (“OMB Review of EPA rules raises constitutional, statutory, and policy concerns.”); Peter L. Strauss, *Presidential Rulemaking*, 72 CHI.-KENT L. REV. 965, 984 (1997) (stating that the President “disserves the democracy he leads when he behaves as if rulemakings were his rulemakings”); Cass R. Sunstein, *The Myth of the Unitary Executive*, 7 ADMIN. L.J. AM. U. 299, 299, 306 (1993) (stating that under the Constitution, the President does not have the power “to tell an agency what to do,” but as a matter of policy, “there should be presidential

Presidents have found regulatory oversight to be necessary and desirable because: (i) the regulatory state is a permanent part of the legal landscape of the United States; (ii) the economic costs of the regulatory state are substantial; (iii) a consensus is needed when executive branch disagreements about regulation arise; and (iv) federal regulations are often necessary to achieve legislative objectives and implement Presidential priorities and policy objectives.<sup>10</sup> Virtually all scholarship on this subject acknowledges the increasing importance of OMB's role in regulatory policymaking over the past thirty years.<sup>11</sup>

### A. President Nixon

President Nixon initiated efforts to centralize regulatory review in 1971 through his "Quality of Life" program. OMB established "a procedure for improving the interagency coordination of proposed agency regulations, standards, guidelines and similar materials pertaining to environmental quality, consumer protection, and occupational and public health and safety."<sup>12</sup> The Quality of Life program focused on rulemakings that could be expected to impact other agencies, impose significant costs or "negative benefits" on non-Federal sectors or increase the demand for Federal

---

oversight of the regulatory process").

10. For example, when Congress did not pass President George W. Bush's Clear Skies proposal, the Environmental Protection Agency (EPA) relied on its existing authority to accomplish many of the same results through rulemaking. See Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units, 70 Fed. Reg. 28,606 (May 18, 2005); Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone, 70 Fed. Reg. 25,162 (May 12, 2005).

11. See Christopher C. DeMuth & Douglas H. Ginsburg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075, 1075 (1986) ("In the 1970s, growing dissatisfaction with government regulation led to formal presidential oversight of executive branch rulemaking."); Herz, *supra* note 8, at 221-22 (starting with President Nixon, there were a "series of presidential initiatives to seize control of the federal bureaucracy via OMB"); Morrison, *supra* note 9, at 1059-63 (acknowledging and lamenting the growth of power of OMB in regulatory decision making under Nixon, Ford, and Reagan). For a review of the documentation of the history of OMB's regulatory policy, see the web site of The Center for Regulatory Effectiveness, <http://www.thecre.com/ombpapers/centralrev.html>.

12. The Quality of Life program had its genesis in a memorandum from OMB that was first directed to EPA and then to the heads of all of the departments. See Memorandum from George Shultz, OMB Director, to Heads of Departments and Agencies (Oct. 5, 1971), available at <http://www.thecre.com/ombpapers/QualityofLife1.htm> [hereinafter Schultz 1971 Memorandum]. Critics of the Quality of Life review process complained that it focused primarily, if not exclusively, on EPA rules. See Herz, *supra* note 8, at 221 (the Quality of Life review was primarily focused on EPA rulemakings); Olson, *supra* note 9, at 9 (stating that the Quality of Life review was "nominally applicable to all health and safety regulations, but in fact limited almost solely to review of EPA rules").

funding.<sup>13</sup> Agencies were required to provide an explanation of the principle objectives of the rulemaking, the alternatives that were considered, and a comparison of the expected benefits and the costs associated with the alternatives.<sup>14</sup> OMB managed the interagency review process by circulating the proposed rules, gathering comments from other agencies, and arbitrating interagency disputes. The Nixon program served as a foundation for later efforts to build a strong, coordinated system of regulatory review within the executive branch.<sup>15</sup>

### B. President Ford

In 1974, building on President Nixon's first steps, President Ford established the Council on Wage and Price Stability (CWPS) and the Review Group on Regulatory Reform to assess the inflationary aspects of government actions.<sup>16</sup>

In that same year, President Ford issued Executive Order 11,821 (Inflation Impact Statements) which required that "major" regulatory proposals "be accompanied by a statement which certifies that the inflationary impact of the proposal has been evaluated."<sup>17</sup> OMB was directed to develop criteria for identifying rules subject to the Executive Order and in so doing to consider the following general categories of significant impact:

- a. cost impact on consumers, businesses, markets, or federal, state or local government;
- b. effect on productivity of wage earners, businesses or government at any level;
- c. effect on competition;

---

13. See Schultz 1971 Memorandum, *supra* note 12, at 1.

14. *Id.*

15. DeMuth & Ginsburg, *supra* note 11, at 1075 ("Modest initial efforts [at formal presidential oversight of executive branch rulemaking] begun during the Nixon Administration have been strengthened and expanded by each president who followed.").

16. See Murray Weidenbaum, *Regulatory Process Reform*, 21 REGULATION 20, 20 (1997).

17. See Exec. Order No. 11,949, 42 Fed. Reg. 1,017 (Jan. 5, 1977) (amending (and extending) Executive Order 11,821 and changing the title to "Economic Impact Statements"); Exec. Order No. 11,821, 39 Fed. Reg. 41,501 (Nov. 27, 1974); see also Christopher C. DeMuth, *Constraining Regulatory Costs: The White House Review Programs*, 4 REGULATION 13 (1980) ("The first serious effort [at controlling regulatory costs] was the Inflation (or Economic) Impact Statement program instituted by President Ford early in his administration, which required the executive branch agencies to prepare evaluations of the expected impact of all major new regulations upon prices, productivity, and competition.").

d. effect on supplies of important products or services.<sup>18</sup>

While OMB had day-to-day responsibilities under the Executive Order, its overall involvement was limited; the agencies were responsible for ensuring their own compliance.<sup>19</sup> And while regulatory costs were to be considered, stringent analysis was not required of agencies.

### C. President Carter

President Jimmy Carter, a former small businessman, surprised some with his strong regulatory reform initiatives.<sup>20</sup> In 1978, President Carter issued an executive order<sup>21</sup> that required agencies to conduct a regulatory analysis of significant rules<sup>22</sup> that would include the economic consequences of the various alternatives considered by the agency.<sup>23</sup> Executive Order 12,044 stated that one of its purposes was to ensure that regulations “shall not impose unnecessary burdens on the economy, on individuals, on public or private organizations, or on State and local governments.”<sup>24</sup> The Executive Order also directed the agencies to conduct a periodic review of existing regulations to ensure that policy objectives were being met.<sup>25</sup> President Carter also established the Regulatory Analysis Review Group (RARG), a cabinet-level entity responsible for reviewing the regulatory analyses of a limited number<sup>26</sup> of

---

18. Exec. Order No. 11,821, 39 Fed. Reg. at 41,501.

19. *Id.* OMB’s review role was also limited because it occurred so late in the rulemaking process. See Percival, *supra* note 8, at 139 (“[T]he Ford Administration shifted the focus of regulatory review away from prepublication review toward review of proposed regulations during the public comment period.”).

20. See JAMES L. GATTUSO, THE HERITAGE FOUND., REINING IN THE REGULATORS: HOW DOES PRESIDENT BUSH MEASURE UP?, EXECUTIVE SUMMARY NO. 1801, at 4 (2004) [hereinafter GATTUSO, REINING IN THE REGULATORS] (“[T]he Carter Administration spurred more regulatory reform than any other Administration before or since” but “there was also a substantial increase in the number of new costly regulations imposed by agencies.”); Percival, *supra* note 8, at 142-43 (noting that President Carter surprised some environmentalists by being a strong proponent of White House oversight of expensive EPA regulations, and crediting the Carter Administration for creating “the most comprehensive regulatory review program that had ever been established”).

21. Exec. Order No. 12,044, 43 Fed. Reg. 12,661 (Mar. 24, 1978).

22. Significant rules included those that would result in “(a) an annual effect on the economy of \$100 million or more; or (b) a major increase in costs and prices for individual industries, levels of government or geographic regions.” *Id.* at 12,663.

23. *Id.*

24. *Id.*

25. *Id.* at 12,664-65. The Regulatory Flexibility Act also requires such periodic review of existing regulations that will have a significant economic impact upon a substantial number of small entities. 5 U.S.C. § 610 (2000).

26. The Executive Committee of the Regulatory Analysis Review Group (RARG)

major regulations, and the new Regulatory Council, responsible for the semi-annual Agenda of Regulations established in Executive Order 12,044.<sup>27</sup>

Perhaps more importantly,<sup>28</sup> in the late 1980s President Carter signed the Regulatory Flexibility Act<sup>29</sup> and the Paperwork Reduction Act (PRA).<sup>30</sup> The Regulatory Flexibility Act requires agencies to analyze and minimize regulatory impacts on small businesses. The PRA, which effects agencies intending to create additional paperwork, recordkeeping, or information collection burdens on ten or more members of the public, also created OIRA within OMB.<sup>31</sup> OIRA serves as the President's office of regulatory expertise and management, as well as overseer of paperwork burdens and information policy.

#### D. President Reagan

In his challenge to incumbent President Carter, Ronald Reagan ran on a platform of "regulatory relief" for businesses, since the "misery index" revealed serious economic problems: double-digit rates of unemployment, inflation, and interest.<sup>32</sup> The U.S. economy was entering the worst

---

selected ten to twenty regulatory analyses annually for its review, with no more than four from any one agency. *See* Memorandum from George Eads, Council of Economic Advisors to the Regulatory Analysis Review Group, to participants (Oct. 17, 1979) *available at* [http://www.thecre.com/pdf/Carter\\_CounEconAdvMemo101779.PDF](http://www.thecre.com/pdf/Carter_CounEconAdvMemo101779.PDF). RARG was chaired by the Council of Economic Advisors (CEA). Its Executive Committee was comprised of Council of Economic Advisors (CEA), OMB, and two rotating executive branch members, one an economic member and one a regulatory member. The RARG Review Group consisted of CEA, OMB, EPA, the Office of Science and Technology Policy, and the Departments of Commerce, Labor, Treasury, Agriculture, Energy, Health Education and Welfare, Housing and Urban Development, Justice, Transportation, and the Interior. The Domestic Policy Staff and the Council on Environmental Quality served as advisors and CWPS provided analytical staff support. RARG could decide to review a regulation for any number of reasons, but the main reasons were: (i) large total cost; (ii) large sectoral impact; (iii) deficient regulatory analysis; (iv) precedential importance; and/or (v) broad policy issues. *Id.*

27. Exec. Order No. 12,044, 43 Fed. Reg. at 12,661.

28. *See* Percival, *supra* note 8, at 147 (noting that President Carter signed two laws that dramatically increased the economic review of federal regulation, the Regulatory Flexibility Act, which was aimed at protecting small businesses from unnecessary regulatory burdens, and the Paperwork Reduction Act (PRA), which created OIRA).

29. Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq* (2006).

30. The Paperwork Reduction Act of 1980 was signed by President Carter on December 11, 1980 and took effect on April 1, 1981. *See* Paperwork Reduction Act of 1980, Pub. L. 96-511, 94 Stat. 2812.

31. *Id.*

32. *See* 1988 Republican Party Platform, ALLPOLITICS.COM, <http://www.cnn.com/ELECTION/2000/conventions/repUBLICAN/features/platform.88> (defining the misery index during the Carter era).



recession since the Great Depression. During his first days in office, President Reagan appointed a new Task Force on Regulatory Relief chaired by Vice President George H.W. Bush.<sup>33</sup> During the Reagan Administration, with the assistance of the newly-created OIRA, the focus shifted from agencies policing their own regulations to OMB review and oversight.<sup>34</sup>

On February 17, 1981, President Reagan signed Executive Order 12,291 which revoked Executive Order 12,044.<sup>35</sup> Executive Order 12,291 took bold steps in the efforts to improve the quality of Federal regulations by mandating how and why costs and benefits of regulatory actions<sup>36</sup> must be considered. It provided that:

- a. Administrative decisions shall be based on adequate information concerning the need for and consequences of proposed government action;
- b. Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society;
- c. Regulatory objectives shall be chosen to maximize the net benefits to society;
- d. Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and
- e. Agencies shall set regulatory priorities with the aim of

---

33. Blumstein, *supra* note 8, at 859 (“Because deregulation had been a centerpiece of his campaign, President Reagan was eager to begin the process.”); Percival, *supra* note 8, at 148 (on his first working day in office, President Reagan created a cabinet-level Task Force on Regulatory Relief chaired by the Vice President).

34. See generally ENVIRONMENTAL POLICY UNDER REAGAN’S EXECUTIVE ORDER: THE ROLE OF BENEFIT-COST ANALYSIS 75-81 (V. Kerry Smith ed., 1984) (examining how Executive Order 12,291 “consolidated” OMB’s oversight powers); see also Olson, *supra* note 9, at 5 (“A wide array of powers have made OMB an influential, new omnipresent force within the executive branch.”); Percival, *supra* note 8, at 149-50 (President Reagan centralized power in OMB to an “unprecedented degree” and “as a practical matter . . . gave OMB enormous power to influence the substance of regulatory decisions.”).

35. Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 17, 1981).

36. See MARLO LEWIS, JR., COMPETITIVE ENTER. INST., REVIVING REGULATORY REFORM: OPTIONS FOR THE PRESIDENT AND CONGRESS, ISSUE ANALYSIS NO. 3 (2005) (“President Reagan elevated the role of economics in regulatory oversight.”); DeMuth & Ginsburg, *supra* note 11, at 1075 (earlier regulatory review programs “directed agencies to assess the social costs and benefits” of rules; President Reagan’s program directed agencies “to *decide* regulatory questions according to the assessments of costs and benefits”) (emphasis in original); West, *supra* note 8, at 80 (“Reagan’s Executive Order 12,291 required cost-benefit analysis and centralized review for all (not just major) regulations.”).

maximizing the aggregate net benefits to society<sup>37</sup>

Under Executive Order 12,291, an agency had to prepare a Regulatory Impact Analysis for every major rule.<sup>38</sup> OMB was authorized to designate rules as “major” rules<sup>39</sup> and review the Regulatory Impact Analyses of the major rules.<sup>40</sup> Agencies, however, were not permitted to publish these rules in the *Federal Register* until OMB concluded its review.<sup>41</sup> The Presidential Task Force on Regulatory Relief had oversight over OMB actions under Executive Order 12,291.<sup>42</sup> Thus, President Reagan consummated the move to centralize regulatory review and strengthened the regulatory analysis requirements.

The creation of OIRA and President Reagan’s use of his power to curtail regulation, however, caused conflict with Congress.<sup>43</sup> Critics argued that OMB was interfering with the authority of the agencies, working in secrecy, and abusing its authority.<sup>44</sup> Advocates of strong worker, consumer, and environmental protections were especially disturbed.<sup>45</sup>

37. See Exec. Order No. 12,291, 46 Fed. Reg. at 13,193.

38. *Id.* at 13,194. President Reagan’s regulatory review program expanded previous efforts by requiring “White House review of virtually all rules.” DeMuth & Ginsburg, *supra* note 11, at 1075.

39. Exec. Order No. 12,291, 46 Fed. Reg. at 13,196.

40. *Id.* at 13,194.

41. *Id.* at 13,195; see also Percival, *supra* note 8, at 149 (noting that this Executive Order “purported to give OMB the authority to block publication of regulations for an indefinite period of time while review was pending”).

42. Exec. Order No. 12,291, 46 Fed. Reg. at 13,193.

43. Blumstein, *supra* note 8, at 860 (“But there are often costs to such a striking success, and that was the case with the ultimate implementation of the [E]xecutive [O]rder [12,291].”).

44. See DeMuth & Ginsburg, *supra* note 11, at 1085-86:

The private nature of the regulatory review process has been both a strength and a weakness. It has been a strength because, like any other deliberative process, it can flourish only if the agency head or his delegate, and OMB as the president’s delegate, are free to discuss frankly the merits of the regulatory proposal. . . . The necessity to proceed privately has been a weakness only because it has put OMB at a disadvantage in responding to allegations that it does, or at least could, act as a ‘conduit’ for information or influence to be introduced illicitly into the agency’s decision calculus. These concerns are, however, misplaced.

See also Morrison, *supra* note 9, at 1064 (expressing concern that OMB under Reagan operated in an “atmosphere of secrecy and insulation from public debate”); Morrison, *supra* note 9, at 1070-71 (stating that changes made by OMB during regulatory review have made rules more difficult to defend in court); Olson, *supra* note 9, at 55 (“OMB long has been criticized for the secrecy with which it operates.”); Strauss, *supra* note 9, at 983 (stating that viewing the President, rather than Congress, as “rulemaker” is “disturbing”).

45. See Morrison, *supra* note 9, at 1065 (expressing concern that OMB review delays issuance of vital health and safety rules while placing interests of industry over public health

Numerous reforms of OIRA were proposed.<sup>46</sup> In response to these concerns, the Reagan Administration agreed to two key OIRA reforms: Senate confirmation of the OIRA Administrator,<sup>47</sup> and certain public disclosures. To that end, OIRA Administrator Wendy Gramm issued a memorandum outlining disclosure procedures for, among other things, communications between OIRA and the public, and for certain drafts, documents, and correspondence exchanged with the agency.<sup>48</sup> Toward the end of the Reagan Administration, the first Senate-confirmed OIRA Administrator, S. Jay Plager, assumed the leadership of OIRA.<sup>49</sup>

---

and safety); Percival, *supra* note 8, at 186-87 (raising concerns that OMB review under Reagan was concerned only with costs, and not with benefits).

46. See Morrison, *supra* note 9, at 1071-73 (providing that Congress should prevent OMB intervention in regulatory matters by amending the Administrative Procedure Act or through an appropriations rider; the President should amend the Executive Order to limit OMB review to a few major rules each year and to make OMB's function advisory only; OMB should have staff in sufficient numbers with appropriate expertise; OMB communications on rulemakings should be publicized; OMB should not be permitted to interfere with agency discretion; regulatory review authority should be placed in an office separate from the one that determines agency budgets; and OMB, not the agency head, should have to elevate its regulatory policy concerns to the President); Olson, *supra* note 9, at 74-79 (providing that courts should ensure that OMB does not usurp the agency's discretion and should require the docketing of OMB contacts with the agency about rulemakings; Congress should establish a regulatory review board supervised by the President but outside of OMB and statutorily clarify that OMB-agency comments should be docketed); Percival, *supra* note 8, at 203 (noting that there are options for "preventing OMB from displacing EPA's exercise of decision-making authority"; namely, restructuring EPA as an independent agency, although it may not be a desirable method of improving agency accountability; restructuring regulatory review to restore the primacy of the agency's role in rulemaking; permitting the public to monitor the review process through increased disclosures; and transferring OIRA oversight authority to the CEA).

47. Paperwork Reduction Reauthorization Act of 1986, Pub. L. No. 99-500, 100 Stat. 1783-335.

48. Memorandum from Wendy L. Gramm, OIRA Administrator, to Heads of Dept's and Agencies Subject to Executive Order Nos. 12,291 and 12,498 on Additional Procedures Concerning OIRA Reviews Under Executive Order Nos. 12,291 and 12,498 [Revised] (June 13, 1986) [hereinafter Gramm Memorandum], reprinted in U.S. OFFICE OF MGMT. & BUDGET, REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT APRIL 1, 1992—MARCH 31, 1993, at 585 (1993) [hereinafter OMB, 1993 REGULATORY PROGRAM OF THE UNITED STATES]. The Gramm Memorandum built on an earlier memorandum from Robert Bedell, the Deputy Administrator of OIRA, outlining OIRA procedures with respect to record maintenance, public access to records, and meetings with the public. Memorandum of Robert P. Bedell, Deputy Administrator of OIRA, to OIRA Staff on OIRA Procedures (May 30, 1985), reprinted in OMB, 1993 REGULATORY PROGRAM OF THE UNITED STATES, *supra*, at 594-97.

49. The OIRA Administrators prior to Mr. Plager (July 1988 to Nov. 1989) were James Miller (Jan. 1981 to Oct. 1981), Christopher DeMuth (Oct. 1981 to Aug. 1984), Douglas Ginsburg (Aug. 1984 to Sept. 1985), and Wendy Gramm (Oct. 1985 to Feb. 1988).

### E. President George H. W. Bush

President George H.W. Bush did not have an OIRA Administrator to oversee the regulatory process. The President nominated Professor James Blumstein of Vanderbilt Law School to serve in this capacity, but his nomination was not considered on the Senate floor due to controversy over reauthorization of the Paperwork Reduction Act, despite his being an accomplished regulatory scholar.<sup>50</sup> Professor Blumstein's nomination was reported out of Committee with approval.<sup>51</sup>

Early in his Administration, as an analogue to the Task Force on Regulatory Relief, President George H. W. Bush created a new structure in the Executive Office of the President to serve a similar function—the Council on Competitiveness (the Council) run by Vice President Dan Quayle.<sup>52</sup> The Council assisted OMB with the regulatory review program under Executive Order 12,291.<sup>53</sup> Under President George H.W. Bush, the Council and OMB exercised oversight over a number of major rulemakings.<sup>54</sup> During his tenure, President Bush also signed several statutes which resulted in a large increase in regulatory burden—for example, the Clean Air Act amendments of 1990 and the Americans with Disabilities Act of 1990.<sup>55</sup>

---

50. See Peter M. Shane, *Political Accountability in a System of Checks and Balances: The Case of Presidential Review and Rulemaking*, 48 ARK. L. REV. 161, 167 (1995) (noting that OMB review of regulations “got caught in a crossfire” over the reauthorization of the Paperwork Reduction Act”). The nomination was not allowed to come to the Senate for a vote. See 136 CONG. REC. 36,321 (1990); Blumstein, *supra* note 8, at 860-61.

51. 136 CONG. REC. 36,320 (1990).

52. Percival, *supra* note 8, at 155 (the Quayle Council on Competitiveness was modeled after President Reagan's Regulatory Relief Task Force).

53. LEWIS, *supra* note 36, at 25; Shane, *supra* note 50, at 168 (“OIRA lacked an advice-and-consent appointee to wield its authority over executive agencies,” so “the Council on Competitiveness stepped in to fill the political void.”).

54. Herz, *supra* note 8, at 225 (noting that critics of the Council, including Representative Henry Waxman, were concerned that the Council was weakening health, safety, and environmental regulations, and charged that the Council was “an illegal shadow government.”). The D.C. Circuit Court of Appeals, however, rejected challenges to both President Bush's Council on Competitiveness and President Reagan's Presidential Task Force on Regulatory Relief. See *Meyer v. Bush*, 981 F.2d 1288, 1298 (D.C. Cir. 1993) (holding that President Reagan's Task Force is not subject to the Freedom of Information Act); *New York v. Reilly*, 969 F.2d 1147, 1152 (D.C. Cir. 1992) (rejecting a challenge to an EPA rule based on the argument that EPA acted improperly in relying on the opinion of the Council on Competitiveness, finding instead that EPA “exercised its expertise”).

55. GATTUSO, *REINING IN THE REGULATORS*, *supra* note 20, at 4 (stating that President George H. W. Bush's deregulatory efforts “were overshadowed” by “huge regulatory programs” under the Clean Air Act and the Americans with Disabilities Act); LEWIS, *supra* note 36, at 25 (stating that in part because the Council on Competitiveness did not have the resources to review many rules, and in part because President George H. W. Bush signed the

### F. President Clinton

President Clinton appointed Sally Katzen, a Washington attorney, and former Chair of the American Bar Association's Section on Administrative Law and Regulatory Practice, to serve as OIRA Administrator.<sup>56</sup> On September 30, 1993, President Clinton rescinded Executive Order 12,291 (implemented under Presidents Reagan and Bush) and issued Executive Order 12,866 to take its place.<sup>57</sup> Under Executive Order 12,866, OMB remained the central reviewer of agency regulations<sup>58</sup> and, while the Order highlighted non-quantifiable effects such as "distributional impact," "equity," and "qualitative measures," the importance of a cost-benefit analysis was reaffirmed.<sup>59</sup> Executive Order 12,866 reduced the scope of rules subject to interagency review, from all rules under Executive Order 12,291 (approximately 2,000 each year) to "significant" regulatory actions<sup>60</sup> (approximately 500 to 600 each year). Further, for each "significant" regulatory action, as determined by OMB, the agency was required to assess both the costs and benefits of the proposed regulatory action as well as those of the alternatives that were considered but not selected.<sup>61</sup> The Executive Order also "restored" the primacy of agency authority over regulatory decisions,<sup>62</sup> reaffirmed the public disclosure

---

Clean Air Act and Americans with Disabilities Act, the total number of pages in the *Federal Register* "shot up").

56. Toward the end of the Clinton Administration, Ms. Katzen (June 1993 to Jan. 1998) moved to serve in the White House, and John Spotila (July 1999 to Dec. 2000) became the OIRA Administrator.

57. Exec. Order 12,866, 58 Fed. Reg. at 51,735.

58. Exec. Order No. 12,866, 58 Fed. Reg. at 51,735. The order provides: "The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive Order and do not conflict with the policies or actions of another agency." *Id.*

59. The Order provides that, "in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits." *Id.* It further provides that "[e]ach agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." *Id.*

60. A "significant" regulatory action is one that is likely to result in a rule that may have an annual effect on the economy of \$100 million or more; create a serious inconsistency, or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, among other things; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. *Id.*

61. *Id.* at 51,737.

62. *Id.* at 51,735; see Shane, *supra* note 50, at 174 (noting that the Clinton Executive Order is "more deferential to policy making by individual agencies").

procedures established by the Gramm Memorandum,<sup>63</sup> and added a new requirement that OIRA disclose the fact that an agency has formally submitted a draft rule to OIRA for review.<sup>64</sup> Whether the full strength of the Executive Order was implemented under President Clinton has been debated.<sup>65</sup> In any event, the Administration of President George W. Bush has found it to be workable, as discussed below.<sup>66</sup>

## II. OIRA'S "SMART REGULATION" APPROACH DURING THE GEORGE W. BUSH ADMINISTRATION

### A. Philosophy

During the Administration of George W. Bush, OIRA embraced a "smart regulation" approach that was neither pro- nor anti-regulation. Under this approach, OIRA evaluated the merits of each rulemaking on a case-by-case basis using insights from economics, science, engineering, and law. Scholars have argued the merits of such a technocratic approach

---

63. See Exec. Order No. 12,866, 58 Fed. Reg at 51,737; Gramm Memorandum, *supra* note 48.

64. Exec. Order No. 12,866, 58 Fed. Reg at 51737. By requiring the contemporaneous disclosure of the fact that a draft rule has been formally submitted for OIRA review, Exec. Order No. 12,866 waived the deliberative process privilege that protects such a disclosure. See *Wolfe v. Department of Health and Human Services*, 839 F.2d 768, 773-76 (D.C. Cir. 1988) ("Congress adopted Exemption 5 [to the Freedom of Information Act, 5 U.S.C. § 552(b)(5) (2006)] because it recognized that the quality of administrative decision-making would be seriously undermined if agencies were forced to operate in a fishbowl.").

65. JAMES L. GATTUSO, THE HERITAGE FOUND., REGULATING THE REGULATORS: OIRA'S COMEBACK EXECUTIVE MEMORANDUM NO. 813 (May 9, 2002) [hereinafter GATTUSO, REGULATING THE REGULATORS] ("During the eight years of the Clinton Administration, OIRA rarely blocked, or even slowed, proposed regulations."); GATTUSO, REINING IN THE REGULATORS, *supra* note 20, at 4 (Under President Clinton, "limiting regulatory burdens was—for the first time in two decades—not made a priority."); Clyde Wayne Crews, Jr., *Promise and Peril: Implementing a Regulatory Budget*, 31 POL'Y SCI. 343, 348 (1998) [hereinafter Crews, *Promise and Peril*] ("The aggressive Office of Management and Budget regulatory review function maintained by Presidents Reagan and Bush has been scaled back by President Clinton.").

66. For a view that a new, stronger Executive Order is needed, see Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489, 1494-97 (2002) (proposing eight innovations over previous Executive Orders, including promoting agency compliance with Executive Orders; prompting regulation; considering substitute risks and abstaining from regulating trivial problems; explaining rationales for action when benefits do not exceed costs; making underlying analyses available; formulating an annual regulatory retrospective and regulatory plan, including independent agencies; and authorizing judicial review of documents generated as a result of the order) [hereinafter Hahn & Sunstein, *A New Executive Order*].

to regulation.<sup>67</sup>

OIRA's "smart regulation" agenda embraces technical and scientific expertise. The President selected one of the authors of this article, Dr. John Graham, who had been a faculty member at the Harvard School of Public Health for over seventeen years, to serve as OIRA Administrator.<sup>68</sup> Dr. Graham taught benefit-cost analysis at Harvard where he also created and led the Harvard Center for Risk Analysis. Disproving concerns raised during his confirmation process,<sup>69</sup> under Dr. Graham, OIRA moved toward case-by-case assessments, grounded in sound science and benefit-cost analysis, with a focus on the well-being of society as a whole.

### B. The Evolution of OIRA under Administrator Graham

What did OIRA and the agencies do during Administrator Graham's tenure to improve the performance of federal regulators? OIRA made progress without doing anything fancy. OIRA did not seek, nor did it receive, any new authority from Congress to reform regulations. OIRA simply implemented the requirements of President Clinton's 1993 executive order on regulatory planning and review<sup>70</sup> and two statutes

---

67. STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 55-81 (1993) (suggesting a change in administrative review to address the problems of risk regulation); *RISK, COSTS AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION* 104-34 (Robert W. Hahn ed., 1996) ("Benefit-cost analysis can be an extraordinarily valuable tool for policy analysis but it must be reformed."); CASS R. SUNSTEIN, *RISK AND REASON: SAFETY, LAW AND THE ENVIRONMENT* 99-132 (2002) (stating that the government should "assess the magnitude of risks"; "examine all the effects of risk reduction, including costs and additional hazards created by risk reduction itself"; and "explore alternatives to any proposed action"); Robert W. Hahn & Rohit Malik, *Is Regulation Good For You?*, 27 HARV. J.L. & PUB. POL'Y 893, 905-07 (2004) [hereinafter Hahn & Malik, *Is Regulation Good for You?*] (suggesting ways for OMB to improve the economic analyses provided by agencies in support of their regulations); John Morrall, *Saving Lives: A Review of the Record*, 27 J. RISK & UNCERTAINTY 221, 229 (2003) ("The range of cost-effectiveness among rules continues to be enormous."); Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 32 U. CHI. L. REV. 1, 72 (1995) (embracing cost-benefit analysis as playing "a useful role in policy analysis" but arguing that its inherent flaws warrant modification).

68. Dr. Graham was confirmed by the Senate on a vote of sixty-one to thirty-seven after a spirited debate about the proper role of benefit-cost analysis in regulatory policy. 147 CONG. REC. S7938 (daily ed. July 19, 2001) (U.S. Senate Roll Call votes). Dr. Graham served as OIRA Administrator from July 2001 to January 2006.

69. See *Nomination of John D. Graham as Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget: Hearing Before the Senate Committee On Governmental Affairs*, 107th Cong. (2001).

70. President Bush amended Executive Order 12,866 with Executive Order 13,258, 67 Fed. Reg. 9385 (Feb. 28, 2002). One of the changes was to shift the responsibility for resolving conflicts between agencies, or between an agency and OMB, from the Vice President to the Chief of Staff. *Id.* at 9386.

2006] *MANAGING THE REGULATORY STATE* 115

passed by Congress during the Clinton years: the Regulatory Right to Know Act<sup>71</sup> and the Information Quality Act.<sup>72</sup>

OIRA, under Administrator Graham, has done six things: (1) it has worked openly; (2) it has buttressed its staffing in science and engineering; (3) it has raised the analytic expectations of regulators; (4) it has developed a serious, government-wide information quality agenda; (5) it has taken a more proactive role in the development and modernization of rules; and (6) it has formed strong partnerships with the President's Council of Economic Advisors, Office of Science and Technology Policy, and Council on Environmental Quality, as well as with the Small Business Administration's Office of Advocacy and the Department of Commerce.

*i. Step 1: OIRA does its work openly*<sup>73</sup>

Executive Order 12,866 made the regulatory review process "more accessible and open to the public" by codifying disclosure procedures.<sup>74</sup> Pursuant to these procedures, when OIRA meets with people who have concerns about a rulemaking, these meetings are documented and updated daily on OMB's web site, including basic data on the rule being discussed,

---

71. See Regulatory Right to Know Act of 1999, Pub. L. No. 106-554, § 624, 114 Stat. 2763. The Regulatory Right to Know Act directs OMB to quantify annually the costs and benefits of federal regulations and prepare a report to Congress on the results of the analysis.

72. Information Quality Act of 2001, Pub. L. No. 106-554, § 515 app. C, 114 Stat. 2763A-153. The Information Quality Act amends the Paperwork Reduction Act, and attempts to increase the quality and accuracy of information disseminated by the federal government.

73. For a review of how OIRA has become more transparent since 2001, see U.S. OFFICE OF MGMT. & BUDGET, OFFICE OF INFO. & REGULATORY AFFAIRS, *STIMULATING SMARTER REGULATION: 2002 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES*, 11-13 (2002) [hereinafter OMB, 2002 REPORT TO CONGRESS]; GEN. ACCN'G OFFICE (GAO), *OMB'S ROLE IN REVIEWS OF AGENCIES' DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS* 52-58 (2003) [hereinafter GAO, 2003 REGULATORY REVIEW REPORT] (the General Accounting Office was renamed the Government Accountability Office in 2004). Some critics argue that OIRA's transparency is insufficient and that OIRA should disclose all drafts and communications exchanged by OIRA and the agencies prior to formal submission of the rulemaking package. See Curtis Copeland, Remarks at the Fordham Urban Law Journal Symposium on the Contemporary Regulatory State (Feb. 23, 2006). Transparency, however, must be balanced with the deliberative process necessary to open and frank communications within the Executive Branch. See DeMuth & Ginsburg, *supra* note 11, at 1086 ("The administration's deliberative process would be significantly compromised if the preliminary rounds in any such disagreement [between an agency and OMB] were routinely publicized." Further, "there are no statutory prohibitions of ex parte contacts by agencies engaged in informal rulemaking" and "criticism focusing on ex parte contacts by OMB misses the point because communications that remain secret cannot determine the outcome of the regulatory process.").

74. Exec. Order No. 12,866, 58 Fed. Reg. at 51,735.



and the names and affiliations of the participants.<sup>75</sup> OIRA invites the affected agencies to join these meetings but does not disclose minutes of these discussions so that the participants can speak candidly. OIRA does disclose any written materials distributed at these meetings.

This “climate of openness” has helped demystify OIRA’s work, reduced concerns previously raised by Congress and reporters during the initial years of the formal regulatory review process under Executive Order 12,291, and freed OIRA’s analysts to do their work instead of responding to critics’ process concerns. While controversy about regulatory policy in Washington will always exist, the debate now relates more to substance than process.

*ii. Step 2: OIRA buttressed its staffing in science and engineering*

Historically, OIRA staff had strong backgrounds in economics, statistics, and policy analysis.<sup>76</sup> The nature of federal regulation, however, has changed since OIRA was created in 1981. Most classic economic regulation has been rescinded or is produced by independent agencies which are not subject to OIRA regulatory oversight. The fastest area of growth has been public health, safety, and environmental regulation, sometimes referred to as science-based or social regulation. To respond to this trend, OIRA hired highly trained experts in fields such as environmental science, engineering, epidemiology, toxicology, public health, and health policy. Although the small number of new employees at OIRA may seem modest, OIRA’s ability to ask tough questions of regulators—and engage in technical dialogue with agency specialists—has increased substantially.

---

75. See OIRA Communications With Outside Parties, <http://whitehouse.gov/omb/oir/> (last visited Apr. 7, 2006).

76. Critics of OIRA have sometimes claimed that OIRA lacks needed technical and scientific expertise. See Morrison, *supra* note 9, at 1065-66 (expressing concern that OMB staff are asking technical questions, even though “virtually all of its reviewing staff are economists, lawyers, or public policy analysts, not scientists, pharmacologists, or doctors” and “lack the substantive backgrounds to make intelligent judgments”); Olson, *supra* note 9, at 14 (“While OMB oversight is intended to increase the objectivity and rationality of decisionmaking, the opposite effect may result due to the Office’s lack of staff and inadequate technical expertise.”); Percival, *supra* note 8, at 181-82 (raising concerns that OIRA’s career staff lack scientific and technical expertise on regulatory matters). In countering such criticisms, it has been asserted that “OMB staff is routinely able to ask hard questions, both substantive and methodological, to which an agency should be expected to have good answers before it proceeds to regulate. . . . The OMB staff is more expert than the agencies in one field—the field of regulation itself.” DeMuth & Ginsburg, *supra* note 11, at 1083-84. Further, OIRA’s recent hires address these criticisms.

*iii. Step 3: OIRA raised its analytic expectations of agencies*

OIRA began in 2001 by reviving the “return letter.”<sup>77</sup> Between July and December of 2001, OIRA issued over twenty return letters to agencies, suggesting that specific rulemaking proposals need to be reconsidered.<sup>78</sup> This rate of return, while modest compared to the hundreds of rules reviewed, was more than the total number of return letters in eight years of the Clinton Administration.<sup>79</sup> Four years later, OIRA rarely needs to issue a return letter. Agencies work with OIRA to fix problems or they persuade OIRA that there is no problem to fix.

In an admittedly obscure but readable document called OMB Circular A-4, OIRA has described—in less than fifty pages—what it expects to see in a regulatory analysis.<sup>80</sup> This guidance document was developed through an open process that included public comment, expert peer review, and formal interagency review. The changes in Circular A-4 were important refinements, not a revolution.

Circular A-4 prescribes that lifesaving gains from rules are valued in the range of \$1 million to \$10 million per statistical life saved; OMB does not pretend to have a more precise answer.<sup>81</sup> In other ways, however, the A-4 guidance is more prescriptive. Rules projected to have billion-dollar impacts must be accompanied by formal, probabilistic uncertainty analysis to help clarify when rulemaking decisions should be made promptly, and when delay can be justified by improved data and information.<sup>82</sup> Health and safety rules also must be accompanied by cost-effectiveness analysis that accounts for reductions in both mortality and morbidity.<sup>83</sup> OIRA worked with federal agencies and the Institute of Medicine to define common measures of effectiveness, such as the quality-adjusted life year,

---

77. During the course of OIRA’s review of a draft regulation, the Administrator may decide to send a letter to the agency that returns the rule for reconsideration. Such a return may occur if the quality of the agency’s analyses are inadequate, if the regulatory standards adopted are not justified by the analyses, if the rule is not consistent with the regulatory principles stated in Executive Order 12,866 or with the President’s policies and priorities, or if the rule is not compatible with other Executive Orders or statutes. See U.S. OFFICE OF MGMT. & BUDGET (OMB), OFFICE OF INFO. & REGULATORY AFFAIRS, MAKING SENSE OF REGULATION: 2001 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES, 41 (2001) [hereinafter OMB, 2001 REPORT TO CONGRESS].

78. OMB, 2001 REPORT TO CONGRESS, *supra* note 77, at 41.

79. During the last three years of the Clinton Administration, no return letters were issued. *Id.* at 39-43.

80. U.S. OFFICE OF MGMT. & BUDGET, REGULATORY ANALYSIS, CIRCULAR A-4 (2003).

81. *Id.*

82. *Id.*

83. *Id.*

that all health and safety agencies can use.<sup>84</sup>

The air office at EPA has done some work in this area that is promising. Even before the requirements of A-4 took effect, EPA prepared a formal probability analysis in support of a new rule that cuts by ninety percent the diesel exhaust from off-road engines. This rule will impose several billion dollars per year in compliance costs on refineries and engine suppliers, but the probability analysis shows that the agency is more than ninety percent certain that the benefits of this rule will exceed the costs.<sup>85</sup> Formal confidence measurement helps both the agency and the public.

*iv. Step 4: OIRA has developed an “Information-Quality” agenda*

OIRA recognized that the results of regulatory analysis—and policy making generally—are only as good as the quality of the input information. OIRA did not sanction a process of “garbage in, garbage out,” but instead shined a spotlight on information quality (IQ). OIRA’s new IQ policy requires that agencies: (i) develop minimum information-quality standards, (ii) utilize peer review prior to the release of official scientific information, and (iii) provide a new opportunity for the public to correct information that has been disseminated in error.<sup>86</sup> The IQ process is still a work in progress, but there already exist examples of its potential.<sup>87</sup>

---

84. The Institute of Medicine (IOM), at the request of OMB and several federal agency sponsors, developed guidance on conducting cost-effective analyses for regulations. INST. OF MED., VALUING HEALTH FOR REGULATORY COST-EFFECTIVENESS ANALYSIS (2006), available at <http://www.iom.edu/CMS/3809/19739/32029.aspx>.

85. See ENVTL. PROT. AGENCY (EPA), OFFICE OF TRANSP. & AIR QUALITY, FINAL REGULATORY ANALYSIS: CONTROL OF EMISSIONS FROM NONROAD DIESEL ENGINES (2004), available at <http://www.epa.gov/nonroad-diesel/2004fr/420r04007.pdf>.

86. U.S. OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, INFORMATION QUALITY GUIDELINES (2002), available at [http://www.whitehouse.gov/omb/inforeg/iqg\\_oct2002.pdf](http://www.whitehouse.gov/omb/inforeg/iqg_oct2002.pdf); Memorandum from Dir. Joshua B. Bolten to Heads of Dep’ts and Agencies, Final Information Quality Bulletin for Peer Review (Dec. 16, 2004), available at <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>.

87. For a critique of the implementation of the Information Quality Act, see THOMAS O. MCGARITY ET AL., CTR. FOR PROGRESSIVE REGULATION, TRUTH AND SCIENCE BETRAYED: THE CASE AGAINST THE INFORMATION QUALITY ACT, PUBLICATION NO. 502, at 1 (March 2005) (“Disgruntled industries have used the [Information Quality] Act as an end run around well-established procedures for promulgating rules to improve air quality, clean up toxic waste sites, and protect children and wildlife from pesticide residues.”); Lisa Heinzerling & Rena I. Steinzor, *A Perfect Storm: Mercury and the Bush Administration Part I*, 34 ENVTL. L. REP. 10,297, 10,302 (2004) [hereinafter, *A Perfect Storm, Part I*] (expressing concerns that industries can delay regulation by filing challenges to science under the Information Quality Act). For a response to these criticisms, see OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 64-66 (noting that agencies have not been

v. *Step 5: OIRA has taken a more proactive role*

Throughout most of the period of formalized regulatory review under Executive Orders 12,291 and 12,866, OIRA review occurred at the end of the process, after the rulemaking agency had devoted considerable time and resources in developing the draft rule. This end-of-the-pipe function allows OIRA to have substantial impact with limited resources, but can also result in an unfortunate loss of agency time and effort if problems are not diagnosed until late in the decision-making process. Moreover, focusing only on the fire “du jour” can neglect systemic problems.

Early involvement is about getting it right the first time. This is a simple, common sense idea, but it can have profound implications. In the face of world-wide competition, the American business community implemented this concept, and revitalized itself. In the 1980s, this was called “Total Quality Management.” It was based on the work of W. Edwards Deming, a former U.S. government statistician who brought a commitment to quality to post-war Japan, and similar concepts can be applied to the regulatory review process.<sup>88</sup>

Under the Bush Administration, OIRA has grappled with this problem by using different labels such as performance-based management, or managing for results. OIRA tried to think outside of the old paradigm of weeding out bad quality at the end of the line, and instead focusing on building good quality into the system from the start. Deming emphasized that quality must be built into the production process, not just inspected for at the end; it was the management system, not employees, that was the problem.<sup>89</sup> Through a series of process reforms detailed below, OIRA worked to build quality into the regulatory process, rather than just inspect it afterward.<sup>90</sup>

Under Dr. Graham, OIRA invented a new tool called the “prompt” letter—a public letter to an agency suggesting that it should consider

---

overwhelmed with correction requests; the Information Quality Act has been utilized by all sectors, not just industry; and OMB is not aware of any evidence that the Information Quality Act has slowed the regulatory process or chilled agency disseminations).

88. See E. Donald Elliott, *TQMing OMB: Or Why Regulatory Review Under Executive Order 12,291 Works Poorly and What President Clinton Should Do About It*, 57 *LAW & CONTEMP. PROBS.* 167, 177-79 (1994) (noting that to be effective, quality control must be utilized in the early stages, not at the end of the process).

89. *Id.*

90. For a criticism of early OMB involvement in EPA rulemakings, see Olson, *supra* note 9, at 47 (“Early OMB involvement compromises EPA’s role as the front-line expert decisionmakers in matters entrusted to EPA by Congress.”).

adopting a new regulation.<sup>91</sup> OIRA has issued roughly a dozen such letters, the first one resulting in a new Food and Drug Administration (FDA) labeling requirement for foods.<sup>92</sup> The food label must now contain data on the trans-fat content of foods as well as the saturated fat content.<sup>93</sup> FDA projects that this rule will produce benefits in heart-disease prevention that will pay for the costs of the rule 100-fold. This rulemaking was initiated in the Clinton Administration, and finished by FDA at OIRA's request.

Another notable success with the early involvement strategy was an EPA rule on emission from nonroad diesel engines. OIRA and the Office of Advocacy of the Small Business Administration collaborated with EPA as it developed a final rule on nonroad diesel engines.<sup>94</sup> By requiring dramatic reductions in the sulfur content of fuel, plus new control equipment on engines, this rule will cut the diesel exhaust from off-road engines used in mining, agriculture, construction, and other off-road applications by ninety percent. As a result of the panel process provided for in the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>95</sup> smaller horsepower engines were exempted from some of the

---

91. For more information on prompt letters, see [http://www.whitehouse.gov/omb/inforeg/prompt\\_letter.html](http://www.whitehouse.gov/omb/inforeg/prompt_letter.html). For skeptical views of the prompt letter, see DAVID M. DRIESEN, CTR. FOR PROGRESSIVE REG., IS COST-BENEFIT ANALYSIS NEUTRAL? AN ANALYSIS OF THE BUSH ADMINISTRATION'S APPROACH TO ENVIRONMENTAL, HEALTH AND SAFETY PROTECTION, WHITE PAPER NO. 507, at 13 (2005) [hereinafter DRIESEN, IS COST-BENEFIT ANALYSIS NEUTRAL?] (“[N]one of the letters sent to agencies protecting safety, public health and the environment urged them to adopt new regulations not already underway at the agencies or required by statute. Nor do the letters prompt agencies to adopt more stringent requirements than they were already likely to adopt on their own.”); Karen R. Harned & Elizabeth A. Gaudio, *OMB Prompt Letters: Are They Promoting (Smarter) Regulation?*, 6 ENGAGE: J. FEDERALIST SOC’Y PRAC. GROUPS 9-11 (2005) (arguing that prompt letters have “done little to promote agency priority setting” and that OIRA should focus its resources on reducing the regulatory burden on small businesses). For a favorable view of prompt letters, see Hahn & Sunstein, *A New Executive Order*, *supra* note 66, at 1494 (stating that prompt letters ensure that cost-benefit analysis will be used “not simply to reduce and limit regulation, but also to spur regulation in those cases where it will do more good than harm.”).

92. See Letter from John D. Graham, OIRA Administrator, to Hon. Tommy G. Thompson, Secretary, Health & Human Servs. (Sept. 18, 2001), available at [http://www.whitehouse.gov/omb/pubpress/hhs\\_prompt\\_letter.html](http://www.whitehouse.gov/omb/pubpress/hhs_prompt_letter.html).

93. Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434-01 (July 11, 2003) (to be codified at 21 C.F.R. pt. 101).

94. Press Release, Env’tl. Prot. Agency, EPA and OMB Working to Speed the Reduction of Pollution From Nonroad Diesel Engines (June 7, 2002), available at <http://whitehouse.gov/omb/inforeg/r-117.pdf>.

95. The Regulatory Flexibility Act of 1980, 5 U.S.C. §§ 601-612, was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). SBREFA

control requirements and small equipment manufacturers received flexibility provisions in the final rule. EPA took a giant step forward in improving air quality (\$78 billion in net benefits per year when fully implemented), but did so without jeopardizing the welfare of small equipment manufacturers.<sup>96</sup>

Through prompt letters and other proactive mechanisms, OIRA and federal agencies have worked together to save more lives in a cost-effective manner.<sup>97</sup>

OMB has also undertaken efforts to reform the sea of existing rules. Since OMB began to keep records in 1981, federal agencies published 118,375 new rules in the *Federal Register*.<sup>98</sup> Through 2005, a total of 20,928 of these rules were considered important enough for OMB review, and 1,164 were classified as “major” rules costing over \$100 million annually, and required to be supported by a regulatory impact analysis.<sup>99</sup> The vast majority of these rules have never been re-examined to determine whether they achieved their intended purpose, or what their actual costs and benefits were.<sup>100</sup>

Responding to a statutory requirement to develop “recommendations for reform,”<sup>101</sup> OIRA launched a public-nomination process in 2001 and 2002 to identify about 100 rules that agencies are now reforming.<sup>102</sup> In 2004, OIRA launched a more targeted effort to streamline rules impacting the manufacturing sector of the U.S. economy; about seventy-six such rules have been targeted by agencies for reform.<sup>103</sup>

As important as these reviews are, they should be compared to a more straightforward approach that was recently used by the Department of

---

requires that an agency convene a review panel prior to issuing the initial regulatory flexibility analysis of a regulation, if required. 5 U.S.C. § 609(b).

96. Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel, 69 Fed. Reg. 38,958 (June 29, 2004).

97. Morrall, *supra* note 67, at 233.

98. U.S. OFFICE OF MGMT. & BUDGET, DRAFT 2006 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS 26 (2006).

99. *Id.*

100. Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 601-612 (2000). Section 610 of the RFA requires the agencies to review periodically (and within ten years of the publication of the final rule) those rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.

101. Regulatory Right to Know Act of 1999, Pub. L. No. 106-554, § 624, 114 Stat. 2763.

102. U.S. OFFICE OF MGMT. & BUDGET, OFFICE OF INFO. & REGULATORY AFFAIRS, PROGRESS IN REGULATORY REFORM: 2004 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 150-210 (2004) [hereinafter OMB, 2004 REPORT TO CONGRESS].

103. OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 117-25.

Transportation (DOT) to discard old rules.<sup>104</sup> Since large airlines once owned the computerized reservation companies, DOT had adopted complex rules to protect consumers from deceptive ticketing information.<sup>105</sup> DOT concluded last year that it was no longer necessary to regulate the information provided to consumers of airline tickets.<sup>106</sup> The computerized reservation companies are now rarely owned by airlines, and the Internet has advanced to a point that consumers no longer need government assistance to purchase airline tickets. Importantly, the majority of the Computer Reservation System (CRS) rules could be efficiently discarded in large measure because of an unusual feature of the original rule: a “sunset” provision calling for removal of the regulation unless the agency decided affirmatively to retain it.

*vi. Step 6: OIRA formed strong partnerships within the federal government*

OIRA has strengthened its expertise in the review process through strong partnerships with several entities within and outside of the Executive Office of the President. The Council of Economic Advisors bolsters OIRA’s economic expertise.<sup>107</sup> The Office of Science and Technology Policy contributes greatly to discussions involving scientific research and analysis.<sup>108</sup> The Council of Environmental Quality provides support for review of environmental regulations.<sup>109</sup> The Office of Advocacy within the Small Business Administration provides input on small business concerns, thereby ensuring that a community greatly impacted by the substantial cost of regulations has a strong voice.<sup>110</sup> The Department of Commerce provides valuable data and analyses. With the support of these partnerships, OIRA is able to review regulations more efficiently and effectively.

---

104. Computer Reservations System (CRS) Regulations, 69 Fed. Reg. 976 (Jan. 7, 2004).

105. *Id.*

106. *Id.*

107. For more information on the Council of Economic Advisors, see <http://www.whitehouse.gov/cea/about.html> (last visited Apr. 7, 2006).

108. See <http://www.ostp.gov>.

109. See <http://www.whitehouse.gov/ceq>.

110. See generally U.S. SMALL BUS. ADMIN., THE SMALL BUSINESS ECONOMY (2005), available at [http://www.sba.gov/advo/research/sb\\_econ2005.pdf](http://www.sba.gov/advo/research/sb_econ2005.pdf) (annual report to the President regarding small businesses’ performance in the economy); see also Exec. Order 13,272, 67 Fed. Reg. 53,461 (Aug. 16, 2002) (providing the Office of Advocacy of the Small Business Administration a formal role in reviewing regulatory analyses).

### C. Results of “Smarter Regulation”

Although improving the federal regulatory process has value in its own right, it is also important to track how changes in process influence the flow of rulemakings and the resulting benefits and costs. OIRA has assembled summary information on federal rules each year since 1981 (the year OIRA was created) that satisfy the following criteria: the rule was issued by a Cabinet agency or EPA and was projected to have an annual economic impact of \$100 million per year or more on the private sector or state and local governments. These criteria exclude (1) “budgetary rules” where federal appropriations pay for all or much of the rulemaking costs; and (2) rulemakings by “independent” agencies, such as the Securities and Exchange Commission (SEC) and the Nuclear Regulatory Commission (NRC), that occur without OIRA oversight. In the discussion that follows, we refer to rulemakings meeting these criteria as “major rules.” Major rulemakings, which can be of a regulatory or deregulatory character, are the primary focus of OIRA’s regulatory oversight activities.

#### *i. Volume of Major Rules, 1981 - 2004*

During the 1981-2004 period, 234 major rules were issued by federal agencies, predominantly the Environmental Protection Agency, the Department of Transportation, the Department of Labor, the Department of Health and Human Services, the Department of Energy, the Department of Agriculture, and the new Department of Homeland Security. The volume of major-rule activity was not uniform throughout the period. The number of major rulemakings for each administration was: President Reagan (first term)—eighteen; President Reagan (second term)—twenty-four; President George H. W. Bush—fifty; President Clinton (first term)—thirty-nine; President Clinton (second term)—sixty-six; and President George W. Bush (first term and beginning of second term)—thirty-seven.<sup>111</sup>

The \$100 million-impact test has not been adjusted for inflation since it was established in 1981.<sup>112</sup> As a result, one would have expected that the measured volume of major-rule activity would have increased over this period, even if the actual volume of regulatory activity was unchanged,

---

111. These statistics were compiled from final rules (or regulatory impact analyses that were publicly available as part of agency rulemaking dockets) having societal costs and/or benefits in excess of \$100 million that were published in the *Federal Register* from 1981 to September 2005. As this article was written at the beginning of his second term, the figure for President George W. Bush covers only forty-four months.

112. The Consumer Price Index increased 108 percent from 1981 to 2004, from 90.9 to 188.9. See THE ECONOMIC REPORT OF THE PRESIDENT 279, tbl.B-60 (2005), available at <http://www.whitehouse.gov/cea/erpcover2005.pdf>.



since, as the Consumer Price Index (CPI) grew, more and more rulemakings would exceed the \$100 million threshold. Thus, this portrayal of rulemakings by year tends to overstate the volume of regulatory activity in the recent years relative to the early years.<sup>113</sup>

While it is interesting to group the major-rule counts by Administration, the differences in the counts between Administrations cannot be attributed exclusively to factors under a President's control. A major rule proposed in one Administration may not be finalized until the next Administration. Major rules that are mandated by Congress, especially those with statutory deadlines or court-ordered deadlines, are not fully within the discretion of an Administration. Even for mandatory rulemakings, Congress often gives the President significant leeway in how the rule will be crafted. Despite these qualifications, the major-rule counts are a rough indicator of rulemaking activity. Moreover, since most rulemakings add restrictions rather than remove them, the major rule counts are a rough indicator of the flow of new restrictions on the private sector and state and local governments.

The number of major rules issued is not a performance indicator. Major rules vary enormously in their projected costs and benefits. Although economic efficiency is not the only factor relevant to assessing governmental performance, it is useful to track how the projected benefits and costs of major rules have changed over time.

#### D. Projected Costs of Major Rulemakings, 1981-2004

From 1981 to 2004, 234 major rules were issued by Cabinet agencies and EPA.<sup>114</sup> Based on the agencies' regulatory impact analyses, the projected cost of each of these rules was identified and expressed in constant 2001 dollars. The sum of these 234 annualized cost estimates is \$117 billion per year, accounting for new regulatory costs as well as any reductions in regulatory burdens due to deregulation.<sup>115</sup> Thus, \$117 billion is an estimate of how much the flow of new rulemakings has added to annual regulatory burden in the United States over the last quarter century.<sup>116</sup> This figure, however, does not account for the burdens of the stock of existing rules, or rules issued by the "independent" agencies such as the SEC and the NRC. The costs of non-major rules, rules issued by

---

113. In 2005 dollars, a \$100 million threshold would pick up rules worth \$48 million in 1981 dollars.

114. See OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 37, fig. 2-1.

115. *Id.*

116. *Id.*

independent agencies, and rules adopted prior to 1981, are not known with any precision. In fact, estimates of the costs of the entire stock of existing federal rules range from several hundred billion dollars per year to more than a trillion dollars per year.<sup>117</sup> Even these large figures exclude the costs of state and local regulatory actions, some of which may be stimulated by federal laws and policies.

The flow of new regulatory costs has not been uniform across Administrations. During President Reagan's first term, when "regulatory relief" was pursued with determination, the burdens of new rules were actually less than the burdens removed by deregulatory activity, resulting in an average net change in regulatory costs of -\$0.2 billion per year for the 1981-1984 period.<sup>118</sup> Major-rule costs, however, climbed substantially during President Reagan's second term (1985 - 1988) to an average of more than \$5.2 billion per year—including a surprising \$8 billion annually averaged over his last two years.<sup>119</sup> During President George H.W. Bush's administration (1989-1993), major-rule costs continued to climb to \$8.5 billion per year while comparable figures for President Clinton's first term (1993-1996) and second term (1997-2000) were \$5.7 billion per year and \$8.5 billion per year, respectively.<sup>120</sup> For the first forty-four months of President George W. Bush's tenure, the major-rule costs averaged \$1.7 billion per year, or about sixty-eight percent lower than the annual average for the previous twenty years.<sup>121</sup>

#### **E. Projected Benefits and Costs of Major Rulemakings, 1981-2004**

OIRA is still collecting the fragments of agency information on the projected benefits of major rules for 1981 to 1991, a period when benefit estimation was in its infancy, especially for rules related to public health, safety, and environmental policy. OIRA has assembled what is known about agency benefit projections for major rules issued from 1992 to 2004,

---

117. See W. MARK CRAIN, *THE IMPACT OF REGULATORY COSTS ON SMALL FIRMS* 4 (2005) (estimating that the cost of federal regulations totals \$1.1 trillion).

118. See OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 37, fig.2-1.

119. *Id.*

120. Most of the costs incurred during President Clinton's second term were due to a flood of rules issued in the last year of his Administration, many just prior to the Florida recount in late 2000.

121. The major factor in the cost figure for 2001 was the repeal of OSHA's ergonomics rule on November 14, 2000. After the final rule was issued, Congress passed Senate Joint Resolution No. 6 to overturn the rule under the Congressional Review Act, and it was signed into law by President George W. Bush in March of 2001. The enactment of Senate Joint Resolution No. 6 was estimated to result in a \$4.8 billion cost savings in 2001. Pub. L. No. 107-5, 115 Stat. 7 (2001).

a subsample of 111 rules where agencies projected both benefits and costs.<sup>122</sup>

The good news is that, during this period, the average annual benefits of major rules, estimated at \$19.1 billion, exceeded the average annual costs of major rules, estimated at \$5.6 billion. These figures account for both the number of major rules and the benefits and costs of those rules. The overall rate of net benefits from major rules was significantly larger under President George W. Bush than in the 1990s.<sup>123</sup>

A different performance indicator is the average benefit and average cost of a major rule. During the thirteen-year period from 1992 to 2004, the average annualized benefit of a major rule was \$2.24 billion, a significantly larger amount than the average annualized cost of a major rule, which was \$0.48 billion per year. For the first forty-four months of the George W. Bush Administration, the average benefit to cost ratio for major rules was about thirteen, significantly larger than the average benefit-to-cost ratio for major rules during the previous nine years, which was approximately five.<sup>124</sup>

In assessing the meaning of these figures, it is important to keep several caveats in mind. First, many of these rules have unquantified benefits and unquantified costs. The figures only account for projected rulemaking consequences that the agency was able to express in monetary units. Second, the figures are computed relative to a “do nothing” or “baseline” policy alternative, which creates a fairly easy benefit-cost test for the major rule. A more difficult test would be a comparison of the adopted rule to the “next best” regulatory alternative, which is typically not to “do nothing” or adopt a simple “baseline” assumption. Agencies, however, may be reluctant to report analytic results for “next-best” alternatives out of a concern that such results may be used by opponents to argue against the agency’s preferred rulemaking action. Third, even when benefits exceed costs, net benefits are not necessarily maximized, which is a goal of Executive Order 12,866.

#### F. Are Projected Benefit and Cost Estimates Accurate?

The figures presented above are based on ex ante projections of regulatory costs and benefits, which means that the projections were made

---

122. See OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 38.

123. *Id.*

124. The figures were calculated using figure 2-2 from OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 38.

by agency analysts before the rule was issued and implemented.<sup>125</sup> It would be very useful to know whether ex ante projections are accurate. Unfortunately, the number of rules that have been analyzed retrospectively, using ex post data, is quite small. In fact, the “validation” literature on regulatory benefit-cost analysis amounts to a series of case studies.

In 2005, OIRA assembled forty-seven case studies of EPA, the Occupational Health and Safety Administration (OSHA), the National Highway Transportation Safety Administration (NHTSA) and NRC rules where validation information had been published by academic specialists, agencies, or think tanks.<sup>126</sup> OIRA found that sometimes the estimates were accurate (+/- 25%), sometimes they were too large, and sometimes they were too small. More frequently, however, both regulatory costs and benefits were overestimated, although the errors tend to be more frequent on the benefit side than the cost side of the ledger. It is not clear whether the extent of these errors are large enough to call into question the regulatory alternatives selected by agencies; nor is it clear how many of these errors should have been diagnosed and corrected ex ante.<sup>127</sup>

Although the forty-seven cases are the largest database ever assembled on the accuracy issue, it is not known whether the findings from these forty-seven cases are representative (i.e., the forty-seven cases are a convenience sample drawn from the available literature). More systematic research is needed to determine whether the estimates of projected costs and benefits published by federal agencies are accurate.

### III. RESPONDING TO COMMENTARY ON THE BENEFITS AND COSTS OF BENEFIT-COST ANALYSIS

It is now well accepted that benefit-cost analysis is playing a growing role in federal regulatory policy,<sup>128</sup> both in the United States and around the world.<sup>129</sup> Professor Cass Sunstein of the University of Chicago has summarized this trend as the rise of the “Cost-Benefit State.”<sup>130</sup>

The growing influence of benefit-cost analysis in federal regulatory

---

125. *Id.* at 41.

126. *Id.* at 41-43.

127. *Id.*

128. See Richard W. Parker, *Grading the Government*, 70 U. CHI. L. REV. 1345, 1415 (2003) (stating that “cost-benefit analysis is a *fait accompli*”) (emphasis added).

129. See OMB, 2002 REPORT TO CONGRESS, *supra* note 73, at 64-69 (providing information on regulatory governance documents in other developed countries).

130. See generally CASS R. SUNSTEIN, *THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION* (2002). But see Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7, 12 (1998) (“I am skeptical about Professor Sunstein’s cost-benefit state.”).

policy has stimulated concerns among scholars and activists. Some commentators argue that benefit-cost analysis has a systematic pro-business bias that will lead to insufficient federal regulation, particularly in fields of public health, safety, and environmental policy.<sup>131</sup> There are at least two strands to this argument: one concerns alleged flaws or biases in the analytic tool;<sup>132</sup> the other concerns the way in which OMB employs its various authorities to oversee the federal regulatory agencies.<sup>133</sup>

Other commentators argue that federal agencies can too easily “fudge the figures” (e.g., exaggerate benefits and low-ball costs), resulting in continued expansion of federal regulation and a corresponding intrusion

---

131. See WILLIAM BUZBEE ET AL., CTR. FOR PROGRESSIVE REGULATION, REGULATORY UNDERKILL: THE BUSH ADMINISTRATION’S INSIDIOUS DISMANTLING OF PUBLIC HEALTH AND ENVIRONMENTAL PROTECTIONS, 1 (2004) [hereinafter BUZBEE ET AL., REGULATORY UNDERKILL] (noting that “regulated corporations have made determined and concerted efforts to use their wealth and political power to diminish or even eliminate various health, environment, and safety protections”); DRIESEN, IS COST-BENEFIT ANALYSIS NEUTRAL?, *supra* note 91, at 4 (stating that cost-benefit analysis “enjoys strong support from regulated industry and the think tanks it funds”); DAVID M. DRIESEN, CTR. FOR PROGRESSIVE REGULATION, THE FEASIBILITY PRINCIPLE, WHITE PAPER NO. 407, at 2 (Dec. 2004) [hereinafter DRIESEN, FEASIBILITY] (noting that cost-benefit analysis permits companies to “kill and injure people if it would ‘cost too much to refrain’”); LISA HEINZERLING & FRANK ACKERMAN, GEORGETOWN ENVTL. LAW & POL’Y INST., PRICING THE PRICELESS: COST-BENEFIT ANALYSIS OF ENVIRONMENTAL PROTECTION 4 (2002) [hereinafter HEINZERLING & ACKERMAN, PRICING THE PRICELESS] (“[T]he case for cost-benefit analysis of environmental protection is, at best, wildly optimistic and, at worst, demonstrably wrong.”); THOMAS O. MCGARITY ET AL., SOPHISTICATED SABOTAGE: THE INTELLECTUAL GAMES USED TO SUBVERT RESPONSIBLE REGULATION 197-216 (2004); Parker, *supra* note at 128, at 1368 (stating that “ex ante predictions likely understate net benefits in many cases”); Frank Ackerman et al., *Applying Cost-Benefit Analysis to Past Decisions: Was Environmental Protection Ever a Good Idea?*, 57 ADMIN. L. REV. 155, 192 (2005) (“A rigid insistence on making regulations pass cost-benefit tests would, in retrospect, have gotten the wrong answer time after time.”); Herz, *supra* note 8, at 229 (“Regulatory review has always flourished in the context of environmental regulation.”).

132. See DRIESEN, FEASIBILITY, *supra* note 131, at 14 (endorsing the feasibility principle as a “rational alternative” to cost-benefit analysis); EILEEN GAUNA ET AL., CTR. FOR PROGRESSIVE REGULATION, ENVIRONMENTAL JUSTICE, WHITE PAPER NO. 505, at 18 (2005) (“Agencies should embrace a precautionary approach to dealing with risky activities.”); Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981, 2063-64 (1984) (noting that “fixation on quantified benefits to human health either assumes, as a normative matter, that benefits that cannot be counted do not count, or assumes, as a factual matter, that benefits that cannot be counted are not very big”)

133. See CTR. FOR PROGRESSIVE REGULATION, A NEW PROGRESSIVE AGENDA FOR PUBLIC HEALTH AND THE ENVIRONMENT: A PROJECT OF THE CENTER FOR PROGRESSIVE REGULATION, WHITE PAPER NO. 501, at 6 (Jan. 2005) (providing that agencies should not be subject to “overbearing supervision by the White House at the behest of regulated entities”); Morrison, *supra* note 9, at 1067 (stating that it is “one thing for OMB to play the role of institutional skeptic” and “another for it to second-guess technical decisions” made by career personnel, Cabinet officers or agency heads); Olson, *supra* note 9, at 14 (“OMB review politicizes technical issues, if only because of the office’s admitted anti-regulatory bias.”).

into personal freedom, privacy, and free enterprise.<sup>134</sup> They argue that alternative regulatory checks and balances are needed.<sup>135</sup> We address these concerns, with the benefit of almost five years of practical experience implementing a vigorous OIRA oversight program.

Some commentators, who see the growth of federal regulation as a problem per se,<sup>136</sup> believe that analytical requirements (e.g., benefit-cost tests on new rules) enforced through OIRA review (and/or judicial review) are not an adequate solution. They point to the fact that the federal regulatory establishment, measured by the number of agency employees, the number of new rules, and the estimated size of regulatory burdens, has grown steadily since 1981, despite the creation of a centralized office of regulatory oversight within the Executive Office of the President.<sup>137</sup> They also argue that OIRA's oversight staff is too small and powerless relative to the vast federal regulatory bureaucracy.<sup>138</sup> They also emphasize that the independent federal regulatory agencies operate outside of OIRA oversight.<sup>139</sup> These commentators argue for a variety of more fundamental

---

134. See LEWIS, *supra* note 36, at 16 (“Agencies have an obvious incentive to downplay the costs and exaggerate the benefits of the programs they administer.”); Crews, *Promise and Peril*, *supra* note 65, at 346 (“Agencies inevitably believe that all of their regulations confer net benefits.”); Clyde Wayne Crews Jr., *Regulatory Spending Escalation*, WASH. TIMES, Sept. 3, 2002, at A15 (noting that cost-benefit analysis of rules by agencies is a form of “self-policing”).

135. CLYDE WAYNE CREWS JR., REGULATORY REFORM PROJECT, JUMP, JIVE AN’ REFORM REGULATION: HOW WASHINGTON CAN TAKE A SWING AT REGULATORY REFORM 4-21 (2000) (suggesting various reforms of the regulatory system including Congressional approval of all agency rules before they are binding on the public) [hereinafter CREWS, JUMP JIVE].

136. See ROBERT W. HAHN, AEI-BROOKINGS JOINT CTR. FOR REGULATORY STUDS., REVIVING REGULATORY REFORM: A GLOBAL PERSPECTIVE 2 (2000) (“During the past two decades, the developed countries have witnessed an unparalleled rise in new regulations related to the environment, health, and safety.”); GATTUSO, REINING IN THE REGULATORS, *supra* note 20, at 2 (stating that “all rules come at a cost: a ‘regulatory tax’ imposed on all Americans”); LEWIS, *supra* note 36, at 12 (“The costs of federal regulation are large, growing, and, what is more disturbing, uncontrolled.”); Crews, *Regulatory Spending Escalation*, *supra* note 134 at A15 (“Estimated costs of meeting the demands of off-budget regulations hit \$854 billion in 2001.”).

137. See GATTUSO, REINING IN THE REGULATORS, *supra* note 20, at 3 (stating that “regulation has been growing in size and scope for decades”); LEWIS, *supra* note 36, at 8 (stating that “the cost of regulation may be much greater than official estimates suggest.”); MURRAY WEIDENBAUM, CTR. FOR THE STUDY OF AMER. BUS., PROGRESS IN FEDERAL REGULATORY POLICY, 1980-2000, CONTEMPORARY ISSUE SERIES No. 100, at 7 (2000) (stating that in the mid-1980s, “[a]ggregate regulatory costs resumed their upward climb”).

138. See GATTUSO, REGULATING THE REGULATORS, *supra* note 65, at 2 (“regulators have outmanned OIRA’s approximately 50 staffers by some 2,500 to one, making effective oversight difficult.”); LEWIS, *supra* note 36, at 17 (“Although agencies routinely claim high benefit-cost ratios for their rules, OMB does not—and due to resource restraints cannot—validate such claims.”).

139. See GATTUSO, REINING IN THE REGULATORS, *supra* note 20, at 13 (stating that

institutional reforms to reduce the size of the federal regulatory state: greater congressional accountability for new regulations,<sup>140</sup> automatic sunset provisions for existing rules,<sup>141</sup> and enactment of an annual regulatory budget for unfunded mandates on the private sector and state and local governments.<sup>142</sup> Insofar as OIRA is to be responsible for stimulating the quality of agency-conducted regulatory analysis, some commentators contend that OIRA should focus on accurate accounting of regulatory costs and dispense with the speculative task of estimating regulatory benefits,<sup>143</sup> since agencies can simply fudge the benefit figures to make a case for the rules that they desire.<sup>144</sup> We assess briefly below the views of these commentators.

The current structure of OIRA oversight, because it is aimed only at “significant” new rules, is not designed to restrain the total number of rules issued by the federal government. Each year, only approximately 600<sup>145</sup> out of approximately 8,000<sup>146</sup> new rulemakings are judged by OIRA and federal agencies to be significant enough to justify formal OIRA review. As long as OIRA is not reviewing most new rules, it is not reasonable to

---

independent agencies should be subjected to the OIRA review process or “at least be required to prepare cost-benefit analyses of all planned significant rules and to forward the analyses to OIRA for non-binding review”); LEWIS, *supra* note 36, at 53 (“Given the potentially devastating impacts of ill-designed economic rules . . . a strong case can be made for extending OMB review to independent agency rulemakings.”).

140. See CREWS, JUMP JIVE, *supra* note 135, at 4 (stating that there is a “compelling” case for sending rules to Congress for approval); LEWIS, *supra* note 36, at 8 (“Congress should have to approve economically significant rules before they go into effect.”); CREWS, *Regulatory Spending Escalation*, *supra* note 134 at A15 (“If Congress were to vote on agency rules (in an expedited fashion) before they are binding, it would fulfill citizens’ right to ‘No regulations without representation.’”); CREWS, *Promise and Peril*, *supra* note 65, at 364 (“[A]gency regulations should be turned into bills requiring passage by Houses of Congress and a Presidential signature.”).

141. CREWS, JUMP JIVE, *supra* note 135, at 20-21 (stating that Congress should consider sunseting existing regulations).

142. See LEWIS, *supra* note 36, at 72 (“Under a regulatory budget, agencies would be required, in advance of proposing rules, to meet a particular statutory objective, to obtain authority from Congress to spend private sector resources via regulation.”); WEIDENBAUM, *supra* note 137, at 2 (“Each congressional committee ought to be required to present estimates of the likely benefits and costs of regulatory actions necessary to implement proposed legislation.”).

143. CREWS, JUMP JIVE, *supra* note 135, at 9-11 (stating that, in order to stop the controversy over agency consideration of benefits, agencies “should concentrate solely on assessing and fully presenting the costs of their initiatives—much as the federal budget focuses only on the amount of taxes, not the benefits of dollars spent”).

144. See *supra* note 130 and accompanying text.

145. See OFFICE OF MGMT. & BUDGET, REGULATORY MATTERS: REGULATORY REVIEW: LISTS AND STATISTICS, available at <http://www.whitehouse.gov/omb/info/reg/regpol.html#rr>.

146. The number 8,000 is derived from a count of all documents (including both proposed and final rules) in the Rulemaking section of the FEDERAL REGISTER.

expect that OIRA review will result in fewer rules being issued by agencies.

In the Reagan years, under Executive Order 12,291, agencies submitted all new rules to OIRA for review. However, this system proved to be impractical since most rulemakings are of minor importance and did not justify centralized review by the Executive Office of the President. As a practical matter, most minor rules were not subjected to rigorous review, even in the Reagan years. When President Clinton designed Executive Order 12,866, with the explicit focus on OMB review of significant rules, he formalized a development that was already occurring on a more ad hoc basis during the Reagan and George H.W. Bush years.

The “smart-regulation” philosophy implemented by Dr. Graham during his tenure as OIRA Administrator is based on the premise that each rulemaking proposal should be reviewed on its merits, accounting for the benefits and costs of the proposal compared to the regulatory and non-regulatory policies already in place. According to this philosophy, regulatory burdens are not necessarily inappropriate if they can be justified by a valid benefits analysis, including a consideration of regulatory alternatives that might accomplish the same degree of benefit at lower cost to society.

Some commentators point out that “independent” regulatory agencies operate outside OMB oversight yet are responsible for a large volume of rulemaking that can be quite costly.<sup>147</sup> Scholars continue to question the legitimacy of the independent regulatory agency.<sup>148</sup> As a practical matter, however, the rulemakings of independent agencies are subject only to Congressional (and judicial) supervision because that has been the preference of the Congress.

Some have suggested requiring that the Congress vote to approve each

---

147. See *supra* note 135 and accompanying text.

148. See, e.g., Peter Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573, 663 (1984) (“The power to balance competing goals—and the concomitant power to influence at least to some degree the agencies’ exercise of discretion—can only be the President’s. . . . This outcome does not vary with whether the agencies are denominated independent.”); ABA COMM’N ON LAW AND THE ECON., REPORT TO THE HOUSE OF DELEGATES: RECOMMENDATION, SUPPORT FOR LIMITED PRESIDENTIAL AUTHORITY OVER MAJOR REGULATORY DECISIONS 6 (1999):P

While it may be that some agencies or issues should remain free of presidential review, it is urged that the exemptions be kept to a minimum. No clear or principled decision underlines the current distinctions between ‘independent’ agencies, executive branch agencies, and ‘independent agencies within the executive branch.’ Agencies of all kinds consider basic economic and social policy decisions that elected officials can and should be capable of addressing.



federal rule before it goes into effect.<sup>149</sup> The current disapproval mechanism in the Congressional Review Act, which enables congressional disapproval of rulemakings through expedited legislative procedures, places the burden on Congress to act against new rules.<sup>150</sup> Some commentators would like to see a reversal of the presumption so that new rules do not take effect unless Congress takes affirmative action—by enacting a law—to approve them. While these commentators can point to the rare use of the expedited CRA procedures, it is not clear whether a requirement for active legislative approval of each new rule would really impact the number of new rules that take effect.

Some also make the argument that OIRA should abandon the effort to improve agency analysis of regulatory benefits and instead focus primarily or exclusively on improved measurement of regulatory costs.<sup>151</sup> With more accurate cost figures, they argue, an annual cap on regulatory “expenditures” (i.e., unfunded mandates on the private sector and state and local governments) could be imposed on each regulatory agency, much like the annual appropriations limits that agencies face for “on-budget” expenditures.<sup>152</sup> Under this argument, the task of OIRA would then become an accounting exercise of making sure that new rules proposed by an agency do not have total annual costs that exceed the “budget” that has been allocated (by Congress and/or OIRA) to that agency.

Although we believe that the idea of a formal “regulatory budget” has promise (but would need to be subject to pilot projects and evaluation), the effort to improve the quality of benefits analysis at federal agencies would still need to continue. Presumably, programs with strong benefit justification should receive more generous treatment under a regulatory budget than programs without a strong benefit justification. Without information on benefits, however uncertain, there is no analytic basis for determining how large a regulatory “budget” or appropriation should be. In short, the interest in “regulatory budget” reform should accentuate the need for valid benefit measurement as well as cost measurement.

Some commentators are concerned that the emphasis on benefit-cost analysis in regulatory policy creates a pro-business bias in health, safety,

---

149. *See supra* note 140 and accompanying text.

150. Under the Congressional Review Act, 5 U.S.C. § 801 *et seq.* (2006), before a rule can take effect, the agency must submit a brief report on the rule to each House of Congress. 5 U.S.C. § 801(a)(1)(A). Congress can utilize expedited procedures to adopt a joint resolution of disapproval to disapprove the rule. 5 U.S.C. § 802.

151. *See supra* note 139 and accompanying text.

152. *See supra* note 138 and accompanying text.

and environmental rulemakings.<sup>153</sup> This bias, they argue, arises because the costs associated with the federal regulation of business tend to be overestimated, while many of the benefits of public health, safety, and environmental regulation are difficult to quantify or are simply intangible in nature.<sup>154</sup> They allege further that OIRA oversight of the rulemaking process is tilted too much toward finding cases of overregulation and not enough to finding cases of underregulation.<sup>155</sup> Finally, echoing technical concerns made decades ago, these commentators argue that there are technical flaws in benefit-cost analysis (e.g., the ways that lifesaving is valued in monetary units and the ways that future benefits are discounted to present value) that work against needed protective regulations.<sup>156</sup> Instead of emphasizing better benefit-cost analysis, these commentators argue for greater emphasis on “the precautionary principle” and “feasibility” in regulatory decision making.<sup>157</sup>

The technical concerns voiced in recent law review articles and book publications are not new. They do not differ significantly from similar

---

153. See DRIESEN, IS COST-BENEFIT ANALYSIS NEUTRAL?, *supra* note 92, at 17 (With cost-benefit analysis, OMB “has effectively created an additional hurdle that government officials must jump through to create enforceable standards protecting health, safety, and the environment. It has created a formidable presumption against the many rules that product non-quantifiable benefits.”); HEINZERLING & ACKERMAN, PRICING THE PRICELESS, *supra* note 131, at 27 (“[I]n practice, cost-benefit analysis tends to skew decision-making against protecting public health and the environment.”); MCGARITY ET AL., SOPHISTICATED SABOTAGE, *supra* note 131, at 197-216.

154. See DRIESEN, FEASIBILITY, *supra* note 131, at 9-10 (“For many important health and environmental effects, quantification [of benefits] is simply impossible” and so cost-benefit analysis can result in agency paralysis.); BUZBEE ET AL., *supra* note 131, at 4 (stating that industry “has a strong incentive to overstate the costs of regulation” and is “far more difficult to generate the benefits side of the regulatory equation.”).

155. DRIESEN, IS COST BENEFIT ANALYSIS NEUTRAL?, *supra* note 91, at 2 (“OMB has used [cost-benefit analysis] as a one-way ratchet that moves in a single direction if it moves at all, frequently weakening agency proposals, but never strengthening them.”).

156. See *id.* at 4 (“Data gaps usually make quantitative risk assessment impossible or very difficult.”); HEINZERLING & ACKERMAN, PRICING THE PRICELESS, *supra* note 131, at 22 (stating that “discounting ignores the possibility of catastrophic and irreversible harm”); Heinzerling, *Regulatory Costs of Mythic Proportions*, *supra* note 132, at 2055-56 (questioning “whether the future benefits of health and environmental regulation should be discounted at all, and, if so, at what rate”); Lisa Heinzerling & Frank Ackerman, *The Humbugs of the Anti-Regulatory Movement*, 87 CORNELL L. REV. 648, 657 (2002) (“Discounting . . . systematically downgrades the importance of actions taken to prevent long-latency diseases and long-term ecological harm.”); Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 948 (1999) (stating that the regulatory process should have “a more thoughtful valuation of human lives threatened by environmental carcinogens” and should not use “OMB’s deeply flawed technique of taking valuations from the workplace setting and reducing them by an inflated discount rate”).

157. See *supra* note 128 and accompanying text.

concerns that were raised in the 1970s and 1980s and addressed by proponents of benefit-cost analysis of regulation.<sup>158</sup> Rather than review this thirty-year literature and debate, we focus here on some technical and institutional developments that are relevant to these concerns.

*i. Validity of benefit and cost figures.*

While some commentators point to specific cases where the costs of rules were overstated and/or the benefits of rules understated,<sup>159</sup> there is very little systematic study of the validity of pre-regulation estimates, based on real-world information from the post-regulation period. The limited literature that does exist was recently reviewed by OMB in its final 2005 Report to Congress on the Costs and Benefits of Federal Regulation.<sup>160</sup> This literature reveals that all types of errors in estimation occur, with no clear indication of policy bias against regulation.<sup>161</sup> If anything, the anecdotal studies now available suggest that the benefit-cost ratios of new rules were more likely to have been overstated than understated by agency analysts, when real-world data are examined after a rule has been applied.

*ii. Cost measurement*

Some commentators allege that the costs of federal regulation are overstated by agency analysts who are compelled to rely uncritically on biased information submitted by regulated entities.<sup>162</sup> Moreover, they argue, the pre-regulation estimates of costs prepared by agency analysts do

---

158. Nicholas A. Ashford, *Alternatives to Cost-Benefit Analysis in Regulatory Decisions*, 363 ANN. N.Y. ACAD. SCI. 129 (1981) (criticizing cost-benefit analysis as a flawed decision-making tool).

159. Thomas McGarity & Ruth Rutenberg, *Counting the Cost of Health, Safety and Environmental Regulation*, 80 TEX. L. REV. 1997, 2042 (2002) [hereinafter, McGarity & Rutenberg, *Counting the Costs*] (“Numerous other studies support the general conclusion that ex ante cost estimates tend to be much higher than real-world compliance costs.”). *But see* ROBERT W. HAHN, AEI-BROOKINGS JOINT CTR. FOR REGULATORY STUDS., IN DEFENSE OF THE ECONOMIC ANALYSIS OF REGULATION 59 (2005) [hereinafter HAHN, ECONOMIC ANALYSIS OF REGULATION] (“The solution to legitimate concerns [about quantitative cost-benefit analysis and cost-effectiveness analysis] raised by the critics is not to eliminate the quantitative analysis, but to gain a deeper understanding of its strengths and weaknesses, and to use it wisely.”).

160. OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 41-52.

161. *Id.*

162. HEIZERLING & ACKERMAN, PRICING THE PRICELESS, *supra* note 131, at 28 (stating that cost estimates are “usually provided by the regulated industries themselves, which have an obvious incentive to offer high estimates of costs as a way of warding off new regulatory requirements”); McGarity & Rutenberg, *Counting the Costs*, *supra* note 159, at 1998 (“In preparing regulatory impact assessments for proposed rules, agencies are heavily dependent upon the regulated entities for information about compliance costs.”).

not account for the learning, innovation, and economies of scale that are accomplished by businesses after a regulation is adopted and implemented. Unlike other commentators, who fear that agency cost (and benefit) estimates are manipulated to make rules look artificially good,<sup>163</sup> these commentators fear that the analyses tend to inflate costs and thereby portray good rules in an unfavorable light.<sup>164</sup>

If agencies use state-of-the-art tools when estimating regulatory costs, they can minimize the potential for bias in cost estimation. One technique is to request confidential cost information from individual companies in a regulated industry, both aggregate compliance cost information for a rule and itemized cost estimates for particular technologies and compliance practices. By comparing the confidential information supplied by different regulated companies, agencies can identify estimates that appear to be outliers on the high side or low side. Another technique is to request confidential cost information from suppliers to regulated firms as well as from the regulated entities themselves. The incentives of suppliers may be different from regulated firms, since the supplier (e.g., a producer or distributor of pollution-control equipment) may benefit from a regulatory alternative that is burdensome to the regulated entity. Comparing cost estimates provided by suppliers and regulated firms is another useful way to identify outlier estimates.

In cases where a technology is already sold in the marketplace, the observed market price of the technology may be a useful surrogate for the marginal cost of production. Where the market price is likely to be an inaccurate estimate of producer cost (e.g., due to monopoly or externalities in the production process), the analyst can commission a “tear-down” study that constructs the cost of the technology from its original inputs, including the costs of both materials and labor. Analysts often find that the marginal costs of producing a new technology decline as producers learn about potential cost-saving measures and employ cost-saving innovations in the production process. Marginal costs may also decline as a producer achieves the economies of scale associated with mass production. Some agency analysts are already employing pre-regulation adjustment factors that reduce estimated regulatory costs based on projections of learning, innovation and economies of scale.

Given the various tools of cost estimation available to the agency analyst, it is feasible to estimate accurately the compliance costs associated with new technologies, usually with a margin of error that does not exceed

---

163. *See supra* note 130 and accompanying text.

164. *Id.*

a factor of two.

*iii. The discount rate*

For many health, safety, and environmental regulations, the costs of a rule are projected to occur before, sometimes years (or even decades) before, its benefits. The largest cost items associated with expensive federal rules are typically one-time capital costs associated with new technology, costs that can be considered investments in health, safety, and environmental improvement that may occur over the life of the new technology (or even further into the future). A longstanding technical issue in benefit-cost analysis concerns how benefits and costs that occur at different points in time should be compared. Some commentators are concerned that the discounting procedure used by economists is biased against health, safety, and environmental protection.<sup>165</sup>

The accepted technical solutions are to either (1) convert the stream of future benefits into present value, using an appropriate discount rate, thereby allowing proper comparison of benefits to capital and operating costs, or (2) annualize the capital costs over the life of the investment, using an appropriate interest rate, to facilitate comparison of costs to benefits (which presumably can be expressed as a smooth annual benefit stream). The difference between a present value and a smooth stream of payments is familiar to the mortgage purchaser, who faces a total mortgage and an annualized (or monthly) payment over the life of the mortgage, computed using an interest rate. It can be shown that the two procedures lead to identical rankings of policy alternatives based on net benefits (benefits minus costs). Consequently, the choice of computational procedure is really a matter of convenience and clarity of presentation. Note that the second procedure entails annualization—and enlargement—of costs, without any discounting of future benefits, while the first procedure adjusts future benefits downward as aggregation occurs, without adjusting costs.

The rationale for discounting needs to be considered because some commentators allege that the discounting procedure biases regulatory analysis against health, safety, and environmental protection. In particular, they are disturbed about the powerful mathematical impact of the discount rate on future benefits from many health, safety, and environmental regulations.<sup>166</sup>

---

165. *See supra* note 156 and accompanying text.

166. HEINZERLING & ACKERMAN, PRICING THE PRICELESS, *supra* note 131, at 21 (stating that “discounting looks like a fancy justification for foisting our problems off onto the

There are two economic arguments for giving more weight to an immediate cost (or benefit) than a future benefit or cost (of the same inflation-adjusted dollar value).<sup>167</sup> One is based on investment theory, while the other reflects consumption theory. Investment theory states that any immediate cost represents a foregone investment opportunity.<sup>168</sup> If the immediate cost is deferred, the resulting savings can be invested at a positive rate of return that is defined by the expected inflation-adjusted (“real”) rate of interest in the economy. (The inflation-adjusted rate of interest is also the real discount rate used by analysts when transforming a future cost or benefit into present value). Consumption theory posits that consumers generally prefer gratification from a good sooner rather than later.<sup>169</sup> Even public opinion surveys framed in a societal context suggest that people would prefer that lives be saved sooner rather than later. Implicitly, investment theory also relies on consumption theory, since the ultimate value of returns on investment is greater consumption (and consumer satisfaction) in the future.

Some commentators insist that the arguments for discounting may apply to money but do not necessarily apply to health protection.<sup>170</sup> There are two responses. First, the investment rationale for discounting can be used to annualize the one-time costs of rules, without making any assumption that saving lives in the future is less valuable than saving lives today.<sup>171</sup> Thus, the first accepted technical solution (described above) does not depend on a policy judgment that the intrinsic value of saving lives declines over time. Second, insofar as money and health are fungible in everyday life and both contribute to the welfare of consumers, then whatever time preference is observed in monetary transactions involving consumption is also, at the margin, applicable to consumer valuation of health gains.<sup>172</sup>

There is considerable debate about what numeric rate of discount should

---

people who came after us.”).

<sup>167</sup> J. Lipscomb et al., *Time Preference*, in *COST EFFECTIVENESS IN HEALTH AND MEDICINE* 214-46 (Marthe R. Gold et al., eds. 1996).

<sup>168</sup> *See id.* at 216-19.

<sup>169</sup> *Id.*

<sup>170</sup> *See supra* notes 151 and 160 and accompanying text.

<sup>171</sup> W. KIP VISCUSI, *DISCOUNTING HEALTH EFFECTS FOR MEDICAL DECISIONS IN VALUING HEALTH CARE* 133 (Frank A. Sloan ed., 1996) (providing a numeric example demonstrating how discounting future lives saved is equivalent to accounting for the opportunity cost of capital).

<sup>172</sup> W. KIP VISCUSI, *FATAL TRADEOFFS: PUBLIC AND PRIVATE RESPONSIBILITIES FOR RISK* 34-50 (1992) (presenting evidence of the value of life from labor market case studies).

be used in regulatory analysis,<sup>173</sup> but there is a strong technical consensus that the same numeric rate of discount should be applied to both benefits and costs. The following paradox results from applying a smaller annual rate of discount to benefits than to costs: delaying an investment that saves lives in the future will always be desirable if the analyst is permitted to assign a smaller discount rate to future benefits than to costs.

The most recent OMB guidance on selecting a discount rate for use in regulatory analysis has three prongs.<sup>174</sup> First, it instructs agency analysts to present analytic results based on real discount rates of three and seven percent, the former justified when the costs of the rule are likely to be incurred in the form of higher prices for consumer products (i.e., consumption losses) and the latter justified when the costs of the rule are likely to be incurred in the form of displaced private investment (e.g., loss of returns on investment).<sup>175</sup> Second, three and seven percent can be supplemented by another rate when a strong technical case is made in the context of a specific rulemaking.<sup>176</sup> Finally, when intergenerational impacts of a rule are important, the guidance authorizes presentation of results with a rate lower than three percent, since there is significant technical debate about what the intergenerational discount rate should be.<sup>177</sup> The new OMB policy is considerably different than the policy in place during the Clinton Administration, which gave primary emphasis to analytic results using a seven percent real rate of discount,<sup>178</sup> although EPA guidelines have given credence to three percent since the 1990s.

*iv. Unquantified benefits*

Some commentators are concerned that benefit-cost analyses are biased against health, safety, and environmental regulations because the benefits seem to be less quantifiable than the costs.<sup>179</sup> Conceptually, there

---

173. See HAHN, ECONOMIC ANALYSIS OF REGULATION, *supra* note 159, at 7; DISCOUNTING AND INTERGENERATIONAL EQUITY 6 (Paul R. Portney & John P. Weyant eds., 1999) (presenting a volume of papers that all assume that benefits and costs should be discounted at some positive rate but vary in opinion about the appropriate rate).

174. OFFICE OF MGMT. & BUDGET, CIRCULAR A-4, *supra* note 80.

175. *Id.*

176. *Id.*

177. *Id.*

178. See OFFICE OF MGMT. & BUDGET, ECONOMIC ANALYSIS OF FEDERAL REGULATIONS UNDER EXECUTIVE ORDER 12,866 (1996), *available at* <http://www.whitehouse.gov/omb/inforeg/riaguide.html>.

179. See DRIESEN, IS COST-BENEFIT ANALYSIS NEUTRAL?, *supra* note 91, at 4 (“Some health effects and most environmental effects cannot be quantified at all, because of large data gaps.”).

are two challenges in benefit measurement: quantifying the physical impacts of rules on human health and environmental quality, and quantifying the monetary value of the reductions in these impacts. For example, mortality impacts from cancer or heart disease may be more readily quantified than subtle forms of morbidity (e.g., neurological effects) and related impacts on quality of life. Even if human health impacts can be fully quantified, it may not be feasible to fully quantify the physical impacts of a rule on natural resources, endangered species, ecosystems and environmental quality. Once physical impacts are quantified, a complete monetary expression of benefits may not be feasible due to the lack of validated tools and data to express the public's economic demand for these benefits.

Unquantified benefits are a serious concern in regulatory analysis. In Circular A-4, OMB's most recent analytic guidance to agencies, agency analysts are instructed to identify and consider non-quantified benefits and costs:

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits and costs may be in the context of the overall analysis.<sup>180</sup>

OMB also instructs agency analysts to include a summary table that lists all of the unquantified benefits and costs.<sup>181</sup> They are also urged to use their professional judgment in highlighting the most important non-quantified or non-monetized impacts.<sup>182</sup>

Analysts in the European Commission are now taking even more seriously the need to weight non-quantifiable benefits and costs by some indication of their likely importance.<sup>183</sup> A categorical weighting scheme is used to place anywhere from one dot to four dots on each unquantified benefit and cost, representing the analyst's view as to the likely importance in the overall analysis.<sup>184</sup> It may be worthwhile for regulatory analysts in the United States to consider a similar approach.

---

180. OFFICE OF MGMT. & BUDGET, CIRCULAR A-4, *supra* note 80, at 2.

181. *Id.*

182. *Id.*

183. In October of 2005, the European Commission released a benefit-cost analysis of its thematic clean air strategy. See AEA Technology, Cost Benefit Analysis of the Thematic Strategy on Air Pollution (Oct. 2005), available at [http://ec.europa.eu/environment/air/cafe/general/pdf/cba\\_thematic\\_strategy\\_0510.pdf](http://ec.europa.eu/environment/air/cafe/general/pdf/cba_thematic_strategy_0510.pdf).

184. *See id.*



*v. Distributional concerns*

Some commentators are concerned that a pure benefit-cost analysis may ignore crucial “distributional” matters that should be of concern to policy makers.<sup>185</sup> OMB guidance, however, on regulatory-impact analysis already encourages agencies to provide a meticulous accounting of a wide range of distributional impacts including impacts on the environment, impacts on children, impacts on small businesses, impacts on state and local governments, impacts on the energy sector, and any transfers of income or wealth that are expected to occur between segments of society.<sup>186</sup> Since the number of distributional impacts to be considered is potentially infinite, relevant statutes and executive orders typically govern which distributional impacts are analyzed.

*vi. The policy impacts of interagency review*

Some commentators express concerns about the interagency reviews of rulemakings sponsored by OMB,<sup>187</sup> in addition to the alleged biases in the

---

185. Ashford, *supra* note 158, at 130 (“Environmental regulation is not really an instrument of economic policy; it is an instrument of social policy concerned with the nature and distribution of the effects of industrial activity. Therefore, environmental regulation cannot be judged by economic criteria alone.”).

186. OMB, CIRCULAR A-4, at 42-46.

187. Some are concerned that OMB review weakens rules. See DRIESEN, IS COST-BENEFIT ANALYSIS NEUTRAL?, *supra* note 91, at 3 (“Opportunities [for OMB] to weaken a rule before its submission may make it unnecessary to weaken it during the formal review process.”). It is just as plausible, however, to argue that OMB review strengthens rules. Some allege that OMB interferes with agency discretion by offering the agency a statutory interpretation different from the one the agency initially proposed when it submitted a draft rule for OMB review. See Lisa Heinzerling, Remarks at The Fordham Urban Law Journal Symposium on the Contemporary Regulatory State (Feb. 23, 2006). It is also well established, however, that the President is authorized to “supervise and guide” Executive Officers in “their construction of the statute under which they act in order to secure that unitary and uniform execution of the laws which Article II of the Constitution evidently contemplated in vesting general executive power in the President alone.” Dep’t of Justice/Office of Legal Counsel Opinion (Feb. 13, 1981) (quoting *Myers v. United States*, 272 U.S. 52, 135 (1936)). Some critics have urged courts to play a role in rules that have been changed due to OMB input. See Olson, *supra* note 9, at 74-77 (stating that courts should protect the agency’s statutory delegation of authority from OMB supervision and require that OMB comments to the agency be docketed to preserve the agency’s decisionmaking integrity”). Such litigation, however, is not likely to succeed. First, court decisions have recognized the legality of executive regulatory review. *Ruckelshaus v. Sierra Club*, 463 U.S. 680 (1983), *rev’d on other grounds*, 769 F.2d 796 (D.C. Cir. 1985); *Env’tl. Def. Fund v. Thomas*, No. 85-1747, 1985 U.S. Dist. LEXIS 13791, at \*13 (D.C. Cir. Nov. 18, 1985) (providing that the dialogue between OMB and an agency during OMB’s regulatory review “is entitled to deference even greater than that accorded intra-agency deliberations”); *Sierra Club v. Costle*, 657 F.2d 298, 405 (D.C. Cir. 1981) (“The Court recognizes the basic need of the President and his White House staff to monitor the

analytics of benefit-cost analysis. If interagency review were neutral, they argue, it would be just as likely to result in more stringent rules as less stringent rules.<sup>188</sup> In reality, they argue, interagency review is not neutral because it is much more likely to reduce (rather than increase) the stringency of public health, safety, and environmental rules.<sup>189</sup> The implication is that the interagency review process focuses only on ways to reduce the costs of rules, without considering ways to increase benefits. These commentators base their critique on a sample of rulemakings studied by GAO<sup>190</sup> where the impact of interagency review was documented, as well as on some anecdotal case studies of specific rules where information on the impact of interagency review can be gleaned from the publicly available information or deliberative information that has been disclosed.<sup>191</sup> The assumption that underpins this critique, that agency submissions of draft rules are just as likely to be insufficiently stringent as overly stringent, has not been validated. In any event, a neutral interagency review process—one faithful to both cost and benefit concerns—should address these critiques.

Moreover, Professor John Mendeloff of the University of Pittsburgh, in studies of risk regulation, has found that overregulation (defined as overly stringent rules) tends to cause underregulation (insufficient breadth and

---

consistency of executive agency regulations with Administration policy.”); *see also* Percival, *supra* note 8, at 197 (Questions about the legality (including constitutionality) of OMB’s oversight in rulemaking have sparked considerable scholarly debate, although the *Sierra Club* opinion is the clearest indication of the “legality and propriety of [White House] regulatory review.”). Second, “courts are eager to avoid what the District of Columbia Circuit has characterized as ‘difficult constitutional questions concerning the executive’s proper role in administrative proceedings and the appropriate scope of delegated power from Congress to certain executive agencies.’” Percival, *supra* note 8, at 167.

188. *See* DRIESEN, IS COST-BENEFIT ANALYSIS NEUTRAL?, *supra* note 91, at 2 (stating that OMB’s use of cost-benefit analysis under President George W. Bush “has been a tool often used to weaken standards, and never used by OMB to make agency proposals stricter or more extensive than what the agency was inclined to do on its own”).

189. *Id.* at 17; Lisa Heinzerling & Rena I. Steinzor, *A Perfect Storm: Mercury and the Bush Administration, Part II*, 34 ENVTL. L. REP. 10485, 10488 (2004) [hereinafter Heinzerling & Steinzor, *A Perfect Storm, Part II*] (“[C]ost-benefit analysis in the Bush Administration has been a one-way street—used to justify delaying or weakening regulation, not to strengthen it. When cost-benefit analysis almost certainly would justify strengthening regulation, especially environmental regulation, OIRA has kept it holstered in its belt.”).

190. GAO, 2003 REGULATORY REVIEW REPORT, *supra* note 73, at 69-102.

191. *See* HEINZERLING & ACKERMAN, PRICING THE PRICELESS, *supra* note 131, at 17-20 (examining cost-benefit analysis as applied to EPA’s 2001 arsenic rule); *see generally* Heinzerling & Steinzor, *A Perfect Storm, Part I*, *supra* note 87 (examining and criticizing EPA’s mercury rule); Heinzerling & Steinzor, *A Perfect Storm, Part II*, *supra* note 189 (same).

volume of rulemaking).<sup>192</sup> He argues that as the stringency of rules increases, the resulting costs trigger more resistance—technical, political, and legal—from the regulated community, forcing the regulatory agency to invest more staffing, time, and legal resources in the completion of each rulemaking. Mendeloff posits that a more moderate approach to stringency based on benefit-cost considerations may permit a regulatory agency to undertake more rulemakings than an approach that maximizes risk reduction in each rulemaking, without regard to costs.

In the final analysis, what matters are the benefits and costs of the final rules that are issued, not the various procedures and counter-pressures that influence the final product. Since the evidence suggests that the “smart regulation” approach to rulemaking—one with a combination of agency and OIRA initiation, as well as interagency review—is inducing an increase in net benefits compared to the Clinton Administration, there is no particular reason to suggest that OIRA (and other interagency) review activities should be curtailed or lessened.

OIRA’s role in facilitating strong federal regulations to protect public health, safety, and the environment is already well documented in the public record:

- In the first use of the “prompt” letter, OIRA encouraged the Food and Drug Administration to finalize a rule initiated in the Clinton Administration that requires the food industry to label foods for trans-fat content.<sup>193</sup> Like saturated fat, a growing body of scientific evidence links the trans-fat content of foods to the development of coronary heart disease. FDA projects that the new food-label requirement will stimulate almost \$100 in public health benefit for each one dollar in cost to industry and consumers.
- In an unusual collaboration that began early in the rulemaking process, OIRA worked with EPA on a new rule aimed at reducing the amount of diesel exhaust from off-road engines used in construction, mining and agriculture by ninety percent.<sup>194</sup> By 2030, this rule’s net benefits are expected to be \$76 billion annually, with \$78 billion in benefits and \$2 billion in costs (in 2000 dollars).

---

192. JOHN M. MENDELOFF, *THE DILEMMA OF TOXIC SUBSTANCES REGULATION: HOW OVERREGULATION CAUSES UNDERREGULATION AT OSHA* (1988).

193. Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrition Content Claims, and Health Claims, 68 Fed. Reg. 41,434 (July 11, 2003).

194. Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel, 69 Fed. Reg. 38,958 (June 29, 2004).

- OIRA also worked with EPA from the outset on a new rule aimed at reducing the sulfur and nitrogen emissions from coal-fired power-plants by seventy-percent.<sup>195</sup> When fully implemented in 2015, this rule's net benefits are expected to be \$83.2 billion annually, with \$86.3 billion in benefits and \$3.1 billion in costs (in 1999 dollars). This rulemaking is among the most important environmental policy initiatives in the Bush Administration.
- OIRA chaired the interagency task force that assisted DOT in two rulemakings related to the fuel economy of light trucks: the first rulemaking raised fuel-economy standards for model years 2005 to 2007,<sup>196</sup> the first increases in almost a decade; the second rulemaking reformed the structure of the program to enhance safety while further increasing fuel-economy standards for model years 2008 to 2011.<sup>197</sup> The more than eleven billion gallons of fuel savings from these two rulemakings are projected to be larger than any previous actions in the twenty-year history of DOT's fuel-economy program for light trucks.

These examples illustrate that OIRA is not reluctant to have a pro-regulatory impact when it is justified by sound science, engineering, and economics.

#### IV. FUTURE CHALLENGES IN REGULATORY POLICY

While there is much encouraging news to report, serious challenges remain.

##### A. Homeland Security

The issue of homeland security will likely remain a central concern for many years to come. While each passing day takes us farther away from the September 11 ("9/11") terrorist attacks on U.S. soil, these horrible acts remain in the forefront of our memories as attacks continue elsewhere, and our government discovers evidence and thwarts potential threats.

The 9/11 attacks revealed a regulatory issue that we must work to solve. While homeland security regulations accounted for approximately half of

---

195. Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule), 70 Fed. Reg. 25,162 (May 12, 2005).

196. Light Truck Average Fuel Economy Standards Model Years 2005-2007, 68 Fed. Reg. 16,868 (Apr. 7, 2003).

197. Average Fuel Economy Standards for Light Trucks Model Years 2008-2011, 71 Fed. Reg. 17,566 (Apr. 6, 2006).

the federal government's major-rule costs in 2004, there is not yet a feasible way to quantify benefits fully. How do we identify a potential target and determine the probability of an attack,<sup>198</sup> the benefit achieved by avoiding the damages associated with an attack, and the effectiveness of the various countermeasures in reducing risk?

In its rule adopting security procedures for and allowing transient operations at three Maryland airports near Washington, D.C., the Transportation Security Administration (TSA) of the Department of Homeland Security (DHS) examined the costs and benefits of the regulation.<sup>199</sup> While providing detailed compliance costs, TSA's benefits data was more limited; nonetheless, TSA concluded that the benefits of the rule would "vastly" exceed the costs:

[T]he primary benefit of the rule will be enhanced protection for a significant number of vital government assets in the National Capital Region, while keeping airports operational. . . . The security provisions contained in this rule are an integral part of the effort to identify and defeat the threat posed by members of foreign terrorist groups to vital U.S. assets and security. The TSA believes that the rule will reduce the risk that an airborne strike initiated from an airport moments away from vital national assets will occur. The TSA recognizes that such an impact may not cause substantial damage to property or a large structure; however, it could potentially result in an undetermined number of fatalities and injuries and reduced tourism. The resulting tragedy would adversely impact the regional economies.<sup>200</sup>

Similarly, in its proposed rule for flight restrictions in the Washington, D.C. Area, the Federal Aviation Administration (FAA) acknowledged that the cost of an act of terrorism "is extremely difficult to quantify" and can include direct and indirect costs that are very high.<sup>201</sup> Developing a methodology for estimating the benefits of avoiding a terrorist attack will

---

198. The Secretary of the Department of Homeland Security has embraced a risk-based approach for addressing threats to this nation. See Michael Chertoff, Secretary of the Dep't of Homeland Security, Address at the George Washington University Homeland Security Policy Institute (Mar. 16, 2005), available at <http://www.dhs.gov/dhspublic/display?content=4391>; Michael Chertoff, Secretary of the Dep't of Homeland Security, Address, Second Stage Review Remarks (July 13, 2005), available at <http://www.dhs.gov/dhspublic/display?content=4597>; Department of Homeland Security, Fact Sheet: Protecting America's Critical Infrastructure—Chemical Security (June 15, 2005), <http://www.dhs.gov/dhspublic/display?content=4543>.

199. Maryland Three Airports: Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC, Metropolitan Area Flight Restricted Zone, 70 Fed. Reg. 7150 (Feb. 10, 2005).

200. *Id.*

201. Washington, D.C. Metropolitan Area Special Flight Rules Area, 70 Fed. Reg. 45,250 (Aug. 4, 2005).

be a difficult but necessary task.

As we implement regulations designed to increase security to protect lives and essential structures, we will also need to balance national security and privacy needs with the public's right to know about the burdens imposed on them by these rules. As OMB explained in its 2003 Report to Congress:

Admittedly, it may be difficult for a regulatory agency to evaluate in specific instances the extent of the costs that a regulatory alternative would likely impose. In emergency situations, for example, an agency may not have much time to consider the various alternatives, much less the time to perform a full evaluation of their respective benefits and costs, before the agency must decide on a course of action. In such cases, agencies should conduct as much analysis as the situation permits. In addition, as commenters pointed out, it may be difficult for an agency to express the cost in quantifiable, as opposed to qualitative, terms. However, to the extent that an agency can quantify the regulatory impact, the agency should attempt to do so (e.g., by indicating the number of persons that would likely be affected by the regulation). This additional analysis is helpful in providing as complete a picture as possible of the implications and justification for the proposed regulatory approach.<sup>202</sup>

In the same report, OMB also emphasized that the same tools of benefit-cost analysis that are used in other regulatory contexts can—and should—be applied as well in the evaluation of homeland security rules:

Developing Federal regulations involves a series of steps: identifying the nature and extent of the problem; determining whether Federal action is needed or desirable; if it is determined that Federal action is needed or desirable, identifying the relevant legal authorities and the policy options; then evaluating those options based on their “pros” and “cons,” which includes an identification and consideration of the anticipated benefits and costs associated with each option; and, finally, concluding with a decision on which course of action to pursue.

Homeland security regulations raise new issues and pose new challenges for Federal agencies. However, the same general framework should apply to the development of homeland security regulations as agencies have applied over the years in their development of other types of regulations. Federal agencies that address homeland security matters need to go through the same general steps in deciding whether Federal action is needed and desirable and, if so, in determining what course of action to

---

202. OFFICE OF MGMT. & BUDGET, *INFORMING REGULATORY DECISIONS: 2003 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES* 85 (2003) [hereinafter *OMB, 2003 REPORT TO CONGRESS*].

pursue. In this regard, these agencies can and should, to the extent possible, use the standard tools of regulatory analysis that have been developed over the years to inform decision makers about the anticipated benefits and costs of the various policy options that they are considering.<sup>203</sup>

### B. The Sea of Existing Regulations

Another challenge faced not only by the newly-created DHS, which inherited many longstanding agencies with robust regulatory programs,<sup>204</sup> but also by most other federal departments, is the sea of existing regulations.

Notwithstanding its limited resources, OIRA has undertaken modest efforts to address the old regulations and to determine if they are necessary. In 2001, OMB solicited public nominations of existing rules that should be modified or rescinded.<sup>205</sup> OMB received seventy-one nominations and designated twenty-three as “high priority.”<sup>206</sup> The agencies with the largest number of nominations were the Department of Labor and EPA.<sup>207</sup> By December 2004, federal agencies had addressed most of the twenty-three priority nominations, as well as some of the lower-priority nominations. Most of the reforms were implemented by agencies without any need for legislative action.<sup>208</sup>

In 2002, OMB again solicited reform nominations after a significant outreach effort with the regulated communities.<sup>209</sup> The scope of eligible reforms was expanded to include guidance documents as well as rules.<sup>210</sup> OMB received 316 distinct nominations, a much larger number than it could evaluate in a priority-setting process.<sup>211</sup> After referral to the agencies for evaluation, over one hundred of them were identified by the agencies as worthy of further evaluation and action. Many of these one hundred are in the process of being reformed by agencies.<sup>212</sup>

---

203. *Id.* at 85-86.

204. The Department of Homeland Security (DHS) is comprised of various agencies formerly associated with other departments including the Bureau of Customs and Border Protection (CBP); U.S. Citizenship and Immigration Services (USCIS); TSA; and the U.S. Coast Guard (USCG).

205. OMB, 2001 REPORT TO CONGRESS, *supra* note 77, at 61-134.

206. *Id.* at 61-62.

207. *Id.* at 62.

208. OMB, 2004 REPORT TO CONGRESS, *supra* note 102, at 150-204.

209. OMB, 2002 REPORT TO CONGRESS, *supra* note 73, at 75-85.

210. *Id.*

211. *Id.*

212. OMB, 2003 REPORT TO CONGRESS, *supra* note 202, at 21-30.

2006] *MANAGING THE REGULATORY STATE* 147

In 2004, OMB chose to target the manufacturing sector of the U.S. economy for reform because economic studies indicate that this sector bears a disproportionate share of regulatory burden.<sup>213</sup> Of the 189 reform nominations received, OMB worked with federal agencies to identify seventy-six that justified priority review and response.<sup>214</sup> In its final 2005 Report to Congress on the Costs and Benefits of Federal Regulation, OMB documented agency progress in meeting deadlines for activity on these seventy-six priority reforms.<sup>215</sup>

Although the number of reforms being pursued by OMB and the agencies in the 2001-2005 period is small compared to the total number of rules on the books, this amount of simplification work is stretching the resources available to both federal agencies and OMB. While some of the reforms have been controversial in Congress (e.g., the streamlining of New Source Review procedures under the Clean Air Act and modernization of overtime regulations in the workplace), none of the reforms have been overturned by legislation or appropriations measures in the Congress.

### C. Collaboration with European Union Regulators

Since U.S. and European rules tend to have a huge influence around the world, it is especially important that the United States and the European Union (E.U.) collaborate on regulatory matters. Their track record in this regard, however, is mixed.

The inability of these two major economic powers to proceed collaboratively can lead to outcomes that are very difficult to explain. For example, the two sides of the Atlantic cannot agree on the proper design of the crash dummies that are used in automobile crash tests. That means that vehicle manufacturers doing business both in the U.S. and in Europe face the prospect of undertaking separate crash tests using American and European dummies. Actually, the difference between the two crash tests is not limited to the design of the crash test dummies. In addition, the European dummy wears safety belts but the American dummy does not.

All the news, however, is not bleak. The quality of dialogue between the European Union and the Bush Administration is improving on a wide range of issues. In September of 2005, OMB hosted a three-day visit by twelve

---

213. U.S. OFFICE OF MGMT. & BUDGET, REGULATORY REFORM OF THE U.S. MANUFACTURING SECTOR 1-66 (2005), available at [http://www.whitehouse.gov/omb/inforeg/reports/manufacturing\\_initiative.pdf](http://www.whitehouse.gov/omb/inforeg/reports/manufacturing_initiative.pdf).

214. *Id.*

215. OMB, 2005 REPORT TO CONGRESS, *supra* note 1, at 117-25.



senior career officials from the European Commission (E.C.).<sup>216</sup> The meeting participants compared notes on how the regulatory systems are evolving and how regulatory analysis is done in each system. In January of 2006, the E.C. hosted a meeting with OMB and agency personnel in Brussels, Belgium where information on the technical and institutional aspects of regulatory analysis in the U.S. and the E.U. was shared.<sup>217</sup> The E.C. has become quite serious about regulatory reform. The U.S. and E.C. agree that better regulation is a key to more jobs and prosperity.<sup>218</sup> Both sides are determined to make more tangible progress on the challenge of regulatory collaboration, which will result in gains for both the American and European economies.

## V. CONCLUSION

During the 2001-2006 period, OIRA led a government-wide effort to tighten benefit-cost scrutiny of new unfunded mandates, streamline or modernize about 100 existing regulations, and enhance the quality of scientific information and analysis used and disseminated by the federal government. It is too early to assess the long-term impacts of this effort on the quality of regulation and governmental information. However, the early indications are that the effort has slowed the growth of costly new federal rules (compared to previous Administrations) while permitting—and indeed encouraging—rules with benefits that justify their costs. As a result, the benefit-cost performance of federal regulators has improved.

The future challenges that remain in regulatory policy are considerable. The sea of existing federal regulations needs to be rationalized. A more systematic process for developing and reviewing homeland security rules needs to be established. Finally, the United States and the European Union need to do a better job of coordinating their regulatory programs.

---

<sup>216</sup> Meeting Agenda, U.S.-E.U. Dialogue on Regulatory Reform (Sept. 28-30, 2005), *available at*

[http://www.ustr.gov/assets/World\\_Regions/Europe\\_Middle\\_East/Europe/US\\_EU\\_Regulatory\\_Cooperation/asset\\_upload\\_file32\\_9163.pdf](http://www.ustr.gov/assets/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/asset_upload_file32_9163.pdf).

<sup>217</sup> Meeting Agenda, E.U.-U.S. Conference on Good Regulatory Practices, Brussels, (Jan. 26, 2006), *available at*

[http://www.ustr.gov/assets/World\\_Regions/Europe\\_Middle\\_East/Europe/US\\_EU\\_Regulatory\\_Cooperation/asset\\_upload\\_file229\\_9166.pdf](http://www.ustr.gov/assets/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/asset_upload_file229_9166.pdf).

<sup>218</sup> See Fact Sheet: U.S.—E.U. Summit: Continuing Our Cooperation to Expand Transatlantic Trade (May 7, 2001), <http://www.whitehouse.gov/news/releases/2004/06/20040626-12.html>.