J O I N T  C E N T E R

AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

# Assessing the Quality of Regulatory Impact Analyses

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# J O I N T  C E N T E R

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## Executive Summary

This study provides the most comprehensive evaluation of the quality of recent economic analyses that agencies conduct before finalizing major regulations. We construct a new dataset that includes analyses of forty-eight major health, safety, and environmental regulations from mid-1996 to mid-1999. This dataset provides detailed information on a variety of issues, including an agency's treatment of benefits, costs, net benefits, discounting, and uncertainty.

We use this dataset to assess the quality of recent economic analyses and to determine the extent to which they are consistent with President Clinton's Executive Order 12866 and the benefit-cost guidelines issued by the Office of Management and Budget (OMB).

We find that economic analyses prepared by regulatory agencies typically do not provide enough information to make decisions that will maximize the efficiency or effectiveness of a rule. Agencies quantified net benefits for only 29 percent of the rules. Agencies failed to discuss alternatives in 27 percent of the rules and quantified costs and benefits of alternatives in only 31 percent of the rules. Our findings strongly suggest that agencies generally failed to comply with the executive order and adhere to the OMB guidelines. We offer specific suggestions for improving the quality of analysis and the transparency of the regulatory process, including writing clear executive summaries, making analyses available on the Internet, providing more careful consideration of alternatives to a regulation, and estimating net benefits of a regulation when data on costs and benefits are provided.

# ASSESSING REGULATORY IMPACT ANALYSES: THE FAILURE OF AGENCIES TO COMPLY WITH EXECUTIVE ORDER 12,866

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## I. INTRODUCTION

Although regulations often have no direct fiscal impact, they pose real costs to consumers as well as businesses. Regulations aimed at protecting health, safety, and the environment alone cost over two hundred billion dollars annually—about two-thirds as much as outlays for federal, nondefense discretionary programs.[1] Yet, the economic impacts of federal regulation

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1. *See* KENNETH J. ARROW ET AL., BENEFIT-COST ANALYSIS IN ENVIRONMENTAL, HEALTH, AND SAFETY REGULATION: A STATEMENT OF PRINCIPLES vii (1996); OFFICE OF MANAGEMENT & BUDGET, 1998 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS 4 (1999). <http://www.whitehouse.gov./omb/inforeg/costbenefitreport1998.pdf>. All dollar figures are presented as constant 1999 dollars, adjusted by using the consumer price index.

receive much less scrutiny than the budget.[2]

To encourage the development of more effective and efficient regulations, Presidents Reagan, Bush, and Clinton have directed agencies to perform economic analyses of major regulations that show whether a regulation's benefits are likely to exceed its costs and whether alternatives to that regulation are more effective or less costly. Each president also attempted to increase agency accountability for decisions by requiring that the President's Office of Management and Budget ("OMB") review all major regulations. More recently, Congress embraced regulatory reform and inserted accountability provisions[3] and analytical requirements into laws such as the Safe Drinking Water Act Amendments of 1996, the Small Business Enforcement and Fairness Act of 1996, and the Unfunded Mandates Reform Act of 1995.[4]

The most prominent and far-reaching of these regulatory reform efforts are President Reagan's Executive Order 12,291 and President Clinton's Executive Order 12,286. Both require agencies to prepare a Regulatory Impact Analysis ("RIA") for all major federal regulations.[5] Agencies have prepared RIAs for almost twenty years in accordance with the executive orders and guidelines for economic analysis provided by the OMB.[6]

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2. *See* JOINT ECONOMIC COMMITTEE STUDY, TRENDS IN CONGRESSIONAL APPROPRIATIONS: FISCAL RESTRAINT IN THE 1990S 8 tbl.3 (1998).

3. Some examples of accountability mechanisms include regulatory oversight, peer review, judicial review, sunset provisions, regulatory budgets, and requirements to provide better information to Congress.

4. Analytical requirements include mandates to balance costs and benefits, consider risk-risk tradeoffs, and evaluate the cost-effectiveness of different regulatory alternatives. *See* Robert W. Hahn, *The Impact of Economics on Environmental Policy*, JOURNAL OF ENVIRONMENTAL ECONOMICS AND MANAGEMENT (forthcoming).

5. President Reagan coined the term *regulatory impact analysis* in Executive Order 12,291, *see* 3 C.F.R. 128 (1981). President Bush also used Executive Order 12,291. President Clinton's Executive Order 12,866 changed the term *regulatory impact analysis* to *assessment*, *see* 3 C.F.R. 638 (1993). Executive Order 12,866 maintains most of Reagan's requirements, but places greater emphasis on distributional concerns. Executive Order 12,866 also directs agencies to show that the benefits of the regulation "justify" the costs, whereas Reagan's Executive Order required agencies to show that the benefits of the regulation "outweigh" the costs. *See* Exec. Order No. 12,291, 3 C.F.R. 128 (1981–1993); Exec. Order No. 12,866, 3 C.F.R. 638 (1993–2000), *reprinted in* 5 U.S.C. § 601 (1994).

6. *See* Office of Management & Budget, *Economic Analysis of Federal Regulations under Executive Order 12,866* (last modified Jan. 11, 1996) <http://www.whitehouse.gov/omb/inforeg/riaguide.html> [hereinafter *OMB Guidelines*].

This Article suggests that the impact of RIAs has fallen short of the expectations of regulatory reform advocates in part because agencies do not fully comply with OMB's guidelines.[7] The RIAs typically do not provide enough information to enable regulatory agencies to make decisions that will maximize the efficiency or effectiveness of a rule.[8]

This conclusion is based on the results of an evaluation of forty-eight major environmental, health, and safety regulations and their associated RIAs.[9] The authors completed a "regulatory scorecard" for each of the forty-eight regulations, which includes a checklist of the requirements for a good economic analysis outlined in the Executive Order and the OMB guidelines.[10] The study of RIAs shows that agencies only quantified net benefits—the dollar value of expected benefits minus expected costs—for 29 percent of the forty-eight rules, even though the Executive Order directs agencies to show that the benefits of a regulation "justify" the costs.[11] The agencies

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7. Others have reviewed the quality of RIAs, but to our knowledge no one has evaluated the impact on the regulatory process. *See, e.g.*, Robert W. Hahn, *Regulatory Reform: What do the Government's Numbers Tell Us?*, *in* RISKS, COSTS, AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION 208, 240–41 (Robert W. Hahn ed., 1996); Richard D. Morgenstern & Marc K. Landy, *Economic Analysis: Benefits, Costs, Implications*, *in* ECONOMIC ANALYSIS AT EPA: ASSESSING REGULATORY IMPACT 455, 463–74 (Richard D. Morgenstern ed., 1997); *see also* KENNETH J. ARROW ET AL., BENEFIT-COST ANALYSIS IN ENVIRONMENTAL, HEALTH, AND SAFETY REGULATION: A STATEMENT OF PRINCIPLES vii (1996).

8. Economists frequently measure the "economic efficiency" of a policy in terms of its impact on producers and consumers. In theory, this is done by estimating appropriate areas under demand and supply curves. There are different measures used for effectiveness. One measure is how closely a policy achieves a goal. Another measure economists frequently use is the average cost or marginal costs of achieving a specific goal.

9. While the definition of *major* has changed somewhat over times, it is currently defined as a rule that is expected to "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." *See* Exec. Order No. 12,866, 3 C.F.R. 638 (1993–2000), *reprinted in* 5 U.S.C. § 601 (1994).

10. The dataset includes regulations from April 1996 through July 1999. A complete list of the regulations is provided in Appendix 2. Additional information is available at the Joint Center website at http://www.aei.brookings.org, including links to the full text of the rules, the RIA when available, and the data used in this paper. The Joint Center undertook this study as the first phase of a project, termed the Joint Center Regulatory Improvement Project, designed to enhance regulatory accountability and transparency by making information about regulations more readily available on the Internet. This project will both provide information both on the quality of recent RIAs and other regulatory analyses through summary information and links to other on-line sources of regulatory information.

11. *See* Exec. Order No. 12,866, 3 C.F.R. 638.

also did not adequately evaluate alternatives to the proposed regulation, another element of the Executive Order. Agencies failed to discuss alternatives for 27 percent of the rules and quantified the costs and benefits of alternatives for only 31 percent. In addition, the agencies often failed to present the results of their analysis clearly. Agencies provided executive summaries for only 56 percent of the rules.

This Article also offers specific suggestions for improving the quality of RIAs, which will in turn improve the allocation of regulatory resources. These include: (1) the use of clear executive summaries; (2) the provision of on-line RIAs; (3) improved evaluation of regulatory alternatives; and (4) improved assessment of net benefits.

Part II of the paper describes the methodology of the study. Part III presents the results. Part IV describes in detail the policy recommendations to improve RIAs.

## II. METHODOLOGY

This study builds on previous efforts to evaluate the quality of RIAs.[12] Whereas previous studies evaluated a few RIAs in great detail, this study assesses the quality of forty-eight RIAs published from April 1996 to July 1999.[13] This approach is

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12. For a review of several economic analyses, see ECONOMIC ANALYSIS AT EPA: ASSESSING REGULATORY IMPACT (Richard D. Morgenstern ed., 1997); Arthur Fraas, *The Role of Economic Analysis in Shaping Environmental Policy*, 54 LAW & CONTEMP. PROBS. 113 (1991); ENVIRONMENTAL PROTECTION AGENCY, EPA'S USE OF BENEFIT-COST ANALYSIS 1981–1986 (1986); RESOURCES COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION, GENERAL ACCOUNTING OFFICE, COST-BENEFIT ANALYSIS CAN BE USEFUL IN ASSESSING ENVIRONMENTAL REGULATIONS, DESPITE LIMITATIONS, (1984). For a review of the regulatory oversight process, see KERRY V. SMITH, ENVIRONMENTAL POLICY UNDER REAGAN'S EXECUTIVE ORDER: THE RULE OF BENEFIT-COST ANALYSIS (1984).

13. The authors obtained from OMB a list of all the rules that OMB reviewed in the past four years. From that list, they eliminated all transfer rules and rules without an economic analysis. They then selected the economically significant rules that were finalized between the beginning of April 1996 and the end of July 1999. The criteria used for including a rule in our database are similar to OMB's criteria for major "Environmental" and "Other Social" rules. *See* OFFICE OF MANAGEMENT & BUDGET, 1998 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS, 10–11 (1999) <http://www.whitehouse.gov/omb/inforeg/costbenefitreport1998.pdf>. In several cases, an agency finalized an economically significant rule but did not produce an economic analysis because Congress prohibited funding the analysis. *See, e.g.*, Appropriations 2000—Department of Transportation and Related Agencies, Pub. L. No. 106-96 § 321, 113 Stat. 986, 1019 (1999) (preventing funds from being used to "prepare, promote or promulgate any regulations . . . prescribing corporate fuel economy standards for automobiles"). *See generally* Average Fuel Economy Standards, 49 U.S.C. § 32,902 (1994). The authors excluded those rules from our database because no analysis

advantageous because it is possible to identify common strengths and weaknesses among many RIAs, a task that no previous study has undertaken.

The authors included only major rules, also known as "economically significant" rules, in the study because they typically have annual costs or benefits in excess of one hundred million dollars per year. These rules have the largest impact on society and agencies should scrutinize them more than other rules.[14] Also, with a few exceptions, agencies produce RIAs for all major rules. The study excludes so-called "transfer" rules, or rules designed to move resources from the federal government to designated segments of the population, because agencies generally do not assess the costs and benefits of transfer rules.[15] The study only includes "non-transfer" rules, which are rules that address market failures and focus on achieving regulatory objectives, such as improving air quality.

The study further assumes that agency numbers presented in RIAs are accurate and complete. This approach allows third parties to easily reproduce the study's results. At the same time, this approach precludes critical evaluation of the agency estimates, which other authors suggest are often biased in support of the regulation or are compromised by analytical flaws.[16]

The study examines the extent to which agency RIAs meet the government's own standards for economic analysis, as described in the Executive Order and the OMB guidelines.[17] The Executive Order states, for example, that agencies shall provide "an assessment, including the underlying analysis," of

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was available.

14. Presidents Reagan and Clinton recognized the importance of careful analysis of economically significant rules when they issued Executive Orders 12,291 and 12,866, respectively. *See generally* Exec. Order No. 12,291, 3 C.F.R. 128 (1981-1993); Exec. Order No. 12,866, 3 C.F.R. 638 (1993-2000), *reprinted in* 5 U.S.C. § 601 (1994).

15. According to OMB, a transfer occurs when wealth or income is redistributed without any direct change in aggregate social welfare. *See* Office of Management & Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, 65 Fed. Reg. 7198-01 (2000) <http://www.whitehouse.gov/omb/inforeg/3stevensdraft.pdf>.

16. *See, e.g.*, RESOURCES FOR THE FUTURE, ECONOMIC ANALYSIS AT EPA: ASSESSING REGULATORY IMPACT (Richard D. Morgenstern ed., 1997).

17. Section 4(F)(7)(d) of the Executive Order requires the OMB to provide agencies guidance in writing economic analyses. *See* 3 C.F.R. 638, 643 (1993–2000), *reprinted in* 5 U.S.C. § 601 (1994). The OMB convened an interagency group to describe the best practices for preparing economic analyses. The results of that effort were presented in a paper in January 1996. *See OMB Guidelines*, *supra* note 8.

benefits and costs expected from a regulation and, "to the extent feasible," provide a quantification of those benefits and costs.[18] The OMB Guidelines further direct agencies to express benefits and costs in monetary terms "to the fullest extent possible."[19] The Executive Order also states that "agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating."[20] According to the Executive Order, the RIA must provide sufficient information to demonstrate that the agency is selecting the regulatory approach that maximizes net benefits, unless the approach is prohibited by statute.[21] The OMB Guidelines further provide agencies with a recommended approach for evaluating alternatives.[22]

The authors developed a "regulatory scorecard," based on the Executive Order and the OMB Guidelines, summarized in the Appendix. Each item listed on the scorecard represents an essential element of a good economic analysis. The researcher evaluating the RIA filled out the scorecard based on an evaluation of the *Federal Register* notice, the agency's formal description of the rule that is available to the public, and the RIA.[23] Another researcher then would validate the first

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18. Exec. Order No. 12,866 § 6(a)(3)(C)(ii), 3 C.F.R. 638, 645 (1993). It is arguably not always possible or desirable to monetize all benefits and costs. *See* Exec. Order No. 12,866, 3 C.F.R. 638, 638-39; *OMB Guidelines*, *supra* note 8.

19. *OMB Guidelines*, *supra* note 8. The OMB Guidelines discuss principles for putting an explicit value on benefits that are difficult to monetize, such as environmental amenities. *See also* Exec. Order No. 12,866, 3 C.F.R. 638, (1993); Unfunded Mandates Reform Act, 2 U.S.C. § 1501 (Supp. II 1996) (requiring an economic analysis that includes a quantification of impacts and consideration of alternatives).

20. Exec. Order No. 12,866 § 1(a), 3 C.F.R. 638, 638-39 (1993).

21. The Executive Order states that "agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributional impacts; and equity), unless a statute requires another regulatory approach." *Id.*

22. The OMB Guidelines urge agencies to define carefully the proper baseline, discuss uncertainty and bias in estimates, and carefully describe key assumptions used in developing estimates of benefits and costs. *See OMB Guidelines*, *supra* note 8.

Although agencies may present reasons not to quantify and monetize benefits and costs, and not consider alternatives for individual regulations, we believe they should be able to meet the requirements of the Executive Order for a majority of regulations. The authors recognize that quantification of costs and benefits may prove difficult in some cases and that a qualitative measure may prove valuable. Some of those cases appear in the OMB Guidelines. *See id.*

23. Whenever a discrepancy existed between the numbers presented in the *Federal Register* and the RIA, the authors used the data that appeared in the *Federal Register* because it is the official publication for agency documents.

researcher's findings by reviewing the same documents. If the findings of the two researchers differed for any part of the scorecard, the researchers resolved the differences by discussion.

Generally, there was little disagreement between researchers because completing the scorecard did not require researchers to subjectively assess the agency's compliance with the Executive Order and the OMB Guidelines.[24] Determining whether the agency "discussed alternatives," for example, is relatively easy because an agency must simply mention the existence of alternative regulatory approaches.[25] The most prominent exception is the scorecard item that measures whether the agency "considered the most important alternative approaches" to the regulation.[26] Although this is an important component of a good economic analysis, the authors did not include it in the summary presented in this Article because of concerns about subjectivity.[27]

## III. RESULTS

This Part describes the aggregate results of our study of agencies' economic analyses. In general, we find that most economic analyses do not meet the expectations set forth in the Executive Order and the OMB Guidelines, and a significant percentage clearly violate them. Specifically, agencies frequently do not provide the kind of information in the analyses necessary to select the best regulatory alternative or to show that the agency should proceed with the regulation.

This Part breaks the discussion of the results of the study into the following categories: estimation of costs, estimation of benefits, comparison of benefits and costs, evaluation of alternatives, clarity of presentation, and consistent use of analytical assumptions. It then discusses conclusions arising

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24. Given the complexity of the RIAs, the researchers may have made some errors when completing the scorecards. The authors welcome corrections. Please submit any comments to us through our web site at http://www.aei.brookings.org.

25. In EPA's "Federal Test Procedure Revisions" rule, for example, the agency did not discuss alternatives, except to claim the option selected "is the most cost-effective alternative currently available" and to refer the reader to a discussion elsewhere. Motor Vehicles Emissions Federal Test Procedure Revisions, 61 Fed. Reg. 54,851, 54,877 (1996). This rule was scored as considering alternatives.

26. *OMB Guidelines*, *supra* note 8.

27. For more information regarding the definition of scorecard items, please visit our on-line database at www.aei.brookings.org.

from the analysis. Three agencies have finalized more than five rules included in the database: the Department of Transportation ("DOT"), the Environmental Protection Agency ("EPA"), and the Department of Health and Human Services ("HHS"). This study presents the results from these agencies separately and grouped results from the remaining agencies together, simply because no other single agency finalized enough rules for meaningful summary statistics.[28]

The reader needs to interpret the statistics presented in this section with care. Some agencies noted, for example, that regulations have costs in addition to direct compliance costs and administrative costs. It would be misleading to suggest that these agencies performed a lower quality analysis simply because they noted the existence of some indirect costs of the regulations, but did not attempt to quantify them. In fact, the acknowledgment of indirect costs is arguably an indication of a more thorough analysis on the part of agencies.

### A. *Estimation of Costs*

Comprehensive estimates of regulatory costs allow decision makers to compare regulatory alternatives and identify the impact of a regulation on different groups to address distributional concerns. We found that agencies could present the results of their cost analyses more clearly and identify the impact on different groups more frequently, but in general, agencies attempt to evaluate the costs of regulation.

Agencies always define categories of costs associated with a proposed regulation and usually quantify some part of those costs. Approximately 95 percent of the economic analyses quantified some costs, and 90 percent of economic analyses monetized some costs.[29] Figure 1 shows that DOT, EPA, and HHS monetized costs in over 80 percent of their respective rules.

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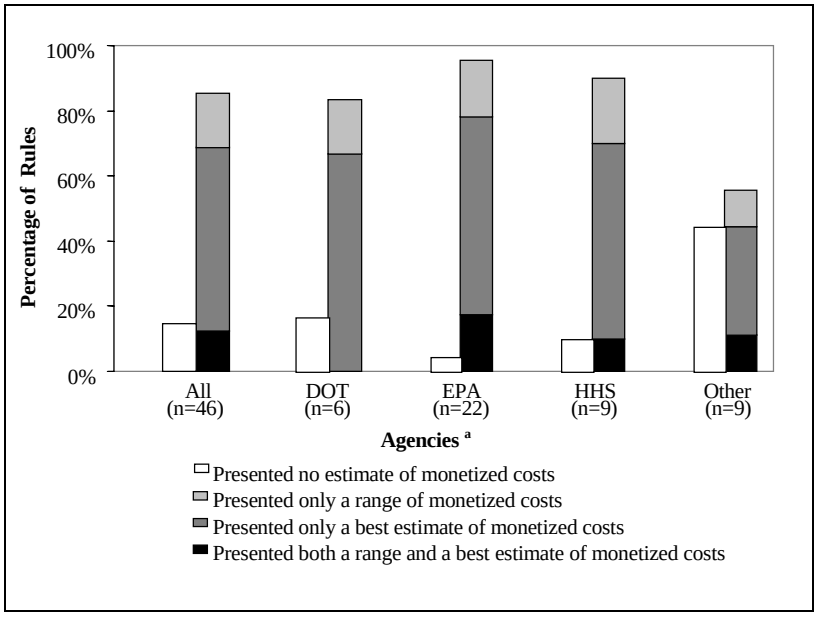
28. The other agencies include the Department of Commerce (DOC), the Department of Energy (DOE), the Department of Labor (DOL), and the Department of Agriculture (USDA).

29. By "monetized" we mean that an agency put a dollar value on at least some part of the relevant category, such as costs or benefits.

**Figure 1: Agency Analysis of Monetized Costs**




[a] DOT—Department of Transportation. EPA—Environmental Protection Agency. HHS—Health and Human Services. DOC—Department of Commerce. DOE—Department of Energy. DOL—Department of Labor. USDA—Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA.

The other agencies monetized some costs for only about one-half of the remaining rules. Agencies monetized all stated costs in only 63 percent of the rules.

Figure 1 also shows that agencies presented a "best estimate" of monetized costs far more often than they presented an actual range. Over two-thirds of the regulations gave a best estimate of costs, while only one-fourth presented a range of cost estimates. Only 13 percent of the regulations presented both a best estimate and a range of costs.

An improved understanding of the impact of regulatory costs on different groups allows policymakers to address distributional concerns more effectively. The study considers whether an economic analysis associated costs with the following groups: producers, nonfederal governments, and the

federal government.[30] Almost all economic analyses (94 percent) note that a regulation will impose compliance costs on producers. A third of the analyses identify costs to nonfederal governments, while about one-quarter of the regulations identify federal budgetary costs. Regulations impose costs on these groups both directly and indirectly, and agencies routinely identify and quantify some of these costs. For example, over two-thirds of the analyses note that the regulation will have administrative costs.[31] In contrast, the agencies rarely discuss and never quantify the macroeconomic impacts of regulations in their economic analyses.

### B. *Estimation of Benefits*

Similar to cost estimates, benefit estimates allow decision makers to compare regulatory alternatives and identify the groups that benefit from a regulation. We found that agencies were less likely to quantify benefits than costs, and rarely monetized benefits. Moreover, agencies generally did not present a range to represent uncertainties associated with benefits. Such evidence suggests that agencies can significantly improve their analyses of regulatory benefits.

Almost all of the regulations (96 percent) identified benefits.[32] The two rules that did not explicitly address benefits were designed to reduce the costs of existing regulations. Of those rules that listed benefits, approximately 70 percent described benefits in quantitative terms, either as a range or a best estimate. Only 17 percent of the rules presented both a best estimate and a range of those quantitative benefits.

Figure 2 provides information on the extent to which agencies monetized any benefits. Agencies converted benefits into dollar equivalents in less than one-half of regulations examined. Rarely did agencies give best estimates and ranges

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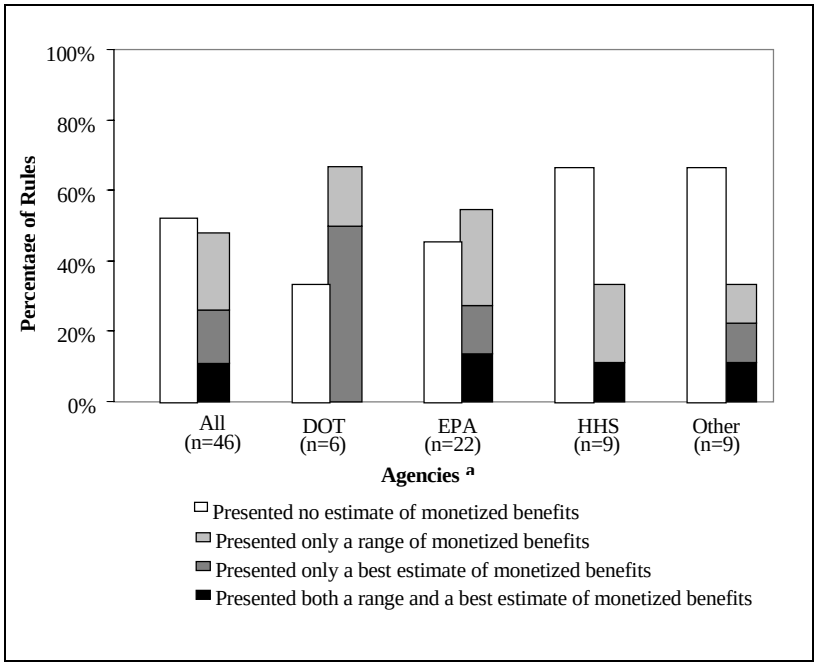
30. Although these categories are useful, it is not a simple matter to estimate the ultimate impact of costs on consumers and workers. Indeed, the data presented generally do not permit an assessment of the impact of regulations on consumers, workers, and owners of capital.

31. The Paperwork Reduction Act requires agencies to estimate the "paperwork burden" imposed by regulations. *See* Paperwork Reduction Act, 44 U.S.C. § 3504 (Supp. II 1996).

32. In addition to benefits, agencies often include cost savings as a category of regulatory impacts. The difference between cost savings and benefits is more a matter of semantics than economics, but we separated cost savings and benefits if the agency separated them.

for monetized benefits. DOT and EPA are the only agencies that monetized benefits with at least 50 percent frequency. DOT presented monetized benefits for two-thirds of their rules, while HHS only monetized benefits in one-third of their analyses.

**Figure 2: Agency Analysis of Monetized Benefits**




[a] DOT—Department of Transportation. EPA—Environmental Protection Agency. HHS—Health and Human Services. DOC—Department of Commerce. DOE—Department of Energy. DOL—Department of Labor. USDA—Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA. In two rules the agencies do not expect any benefits. These rules are excluded from this analysis.

Often agencies quantify and monetize only some of the explicitly stated benefits. Agencies quantified all of the stated benefits for 54 percent of the rules and monetized all benefits in only 28 percent of the rules. Determining whether the benefits that agencies chose not to quantify represent a significant portion of the total benefits was beyond the scope of this

analysis, although it is an important issue.

Also, agencies monetized certain categories of benefits more frequently than other categories. For example, in 83 percent of the rules for which agencies identified safety benefits, the agency presented a monetized estimate of those benefits. In contrast, agencies monetized benefits for only 54 percent of the rules that identified health benefits. Perhaps most starkly, in only 11 percent of rules for which agencies identify benefits from pollution reductions did the agency actually monetize those benefits.[33]

### C. *Comparing Costs and Benefits*

A comparison of costs and benefits of a regulation helps decision makers compare a specific regulation to other proposed or existing regulations. Without such a comparison, decision makers cannot know whether a regulation is the best use of available resources. We found that agencies routinely failed to compare their estimates of the costs and benefits, using either net benefits estimates or cost-effectiveness estimates.

Figure 3 reveals that only 28 percent of the rules present information on net benefits, a key indicator of economic efficiency. Of those, about one-third presented best estimates, while the other two-thirds presented a range. Only two rules presented both a range and best estimate of net benefits. [34]

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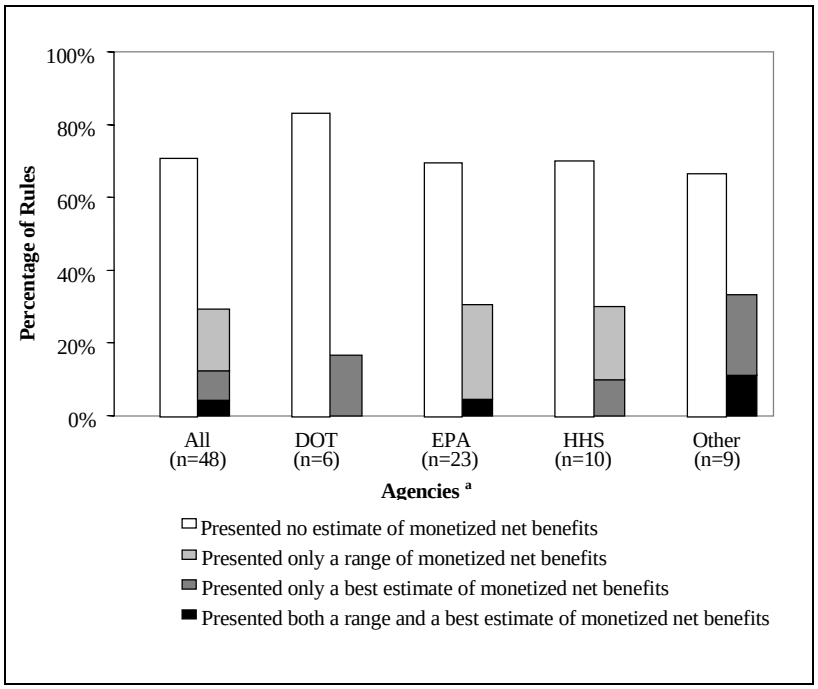
33. Most of the monetized benefits from pollution reduction are due to lower morbidity and mortality rates. The study includes pollution reduction benefits as a separate category because a substantial fraction of the rules in our database (44 percent) were expected to reduce pollution.

34. *See* Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Transport of Ozone, 63 Fed. Reg. 57,356 (1998) (to be codified at 40 C.F.R. pts. 51, 72, 75, 96); Energy Conservation Program for Consumer Products: Final Rule Regarding Energy Conservation Standards for Room Air Conditioners, 10 C.F.R. § 430.32 (1998).

**Figure 3: Agency Analysis of Monetized Net Benefits**




[a] DOT—Department of Transportation. EPA—Environmental Protection Agency. HHS—Health and Human Services. DOC—Department of Commerce. DOE—Department of Energy. DOL—Department of Labor. USDA—Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA.

Of the three agencies that promulgated more than five rules, HHS and EPA presented net benefits most often, while DOT never presented net benefits. Also, agencies tended to monetize costs more frequently than benefits.[35] Agencies monetized costs for 60 percent of the rules in the database, monetized all benefits for 49 percent of the rules, and monetized all costs and benefits for only 19 percent of rules.

Agencies failed to calculate net benefits for nearly half of the regulations with monetized figures for unclear reasons. Sometimes the agency provided enough information to calculate net benefits but did not perform the calculation, even though the calculation only requires the agency to subtract one

35. This finding is consistent with previous studies. *See generally* HAHN, ASSESSING THE GOVERNMENT'S NUMBERS, *supra* note 6.

estimate from the other estimate. One possibility is that agencies do not feel that the cost or benefit estimates are reasonable.[36] Thus, the difference between the two estimates would not provide a meaningful estimate of net benefits.

Another possibility is that agencies are reluctant to present net benefit estimates if those estimates are negative. In the database, of the thirty-one rules that provided estimates of costs and benefits sufficient to calculate net benefits, only one-half had benefits and costs savings that exceeded the costs.

The study further separates the thirty-one rules with benefit and cost estimates into rules for which the agency presented net benefits (twelve) and those where the agency did not (nineteen). In the first group, where the agency presented net benefits, three-quarters pass a benefit-cost test. In the second group, only one-third pass the same benefit-cost test. These results lend some support to the view that agencies present net benefits numbers more frequently when those numbers support their regulation while agencies tend to omit net benefits when the result would be negative.

Sometimes agencies present cost-effectiveness numbers, either in addition to or instead of information on net benefits. The agency calculated cost-effectiveness by dividing monetized costs by some nonmonetary quantitative measure of benefits.[37] The cost-effectiveness calculation allows the agency to describe the effectiveness of a regulation relative to alternative regulatory approaches without assigning an actual monetary value to quantified benefits.

Figure 4 shows that agencies presented an estimate of cost-effectiveness for only one-third of the rules for which the agency did not provide an estimate of net benefits. Thus, approximately half (48 percent) of the forty-eight rules examined in this Article provided no direct measures of net benefits or indirect measures based on cost-effectiveness. Only 6 percent of the forty-eight rules provided both an estimate of net benefits and an estimate of cost-effectiveness.[38] This

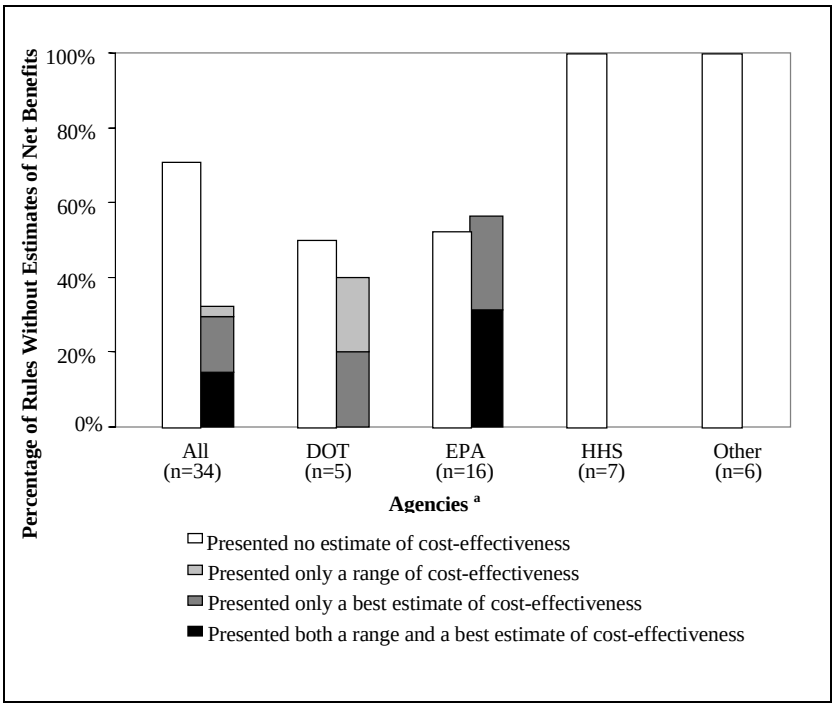
36. DOT does not present net benefits if it believes the benefit or cost numbers are not sufficiently robust. *See* Telephone Interview by Jason Burnett with the general counsel's office, U.S. Department of Transportation, Washington, D.C. (Oct. 20, 1999).

37. A cost-effectiveness measure works best when the rule has only one expected benefit. If the agency expects multiple benefits, it is difficult to sum such benefits to generate the denominator in the cost-effectiveness calculation.

38. This estimate could be a best estimate, a range, or both.

finding is important because cost-effectiveness calculations may be particularly useful when benefits are difficult to monetize or when agencies are simply reluctant to monetize them.

**Figure 4: Agency Analysis of Cost-Effectiveness**




[a] DOT—Department of Transportation. EPA—Environmental Protection Agency. HHS—Health and Human Services. DOC—Department of Commerce. DOE—Department of Energy. DOL—Department of Labor. USDA—Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA.

Figure 4 also reveals the extent to which the cost-effectiveness information varies by agency. EPA presented cost-effectiveness information for about half of the rules where it did not present net benefit numbers. DOT is the only other agency that provided any information on cost-effectiveness for rules in which net benefit information was not supplied. By

presenting cost-effectiveness numbers, agencies avoided the tasks of assigning a dollar value to estimates of pollution abatement and of assigning a monetary value to extending a human life.

Often, agencies do not present the results from cost-effectiveness calculations in an appropriate manner. For regulations designed to reduce several types of pollution, EPA often lumped all pollutants together in its calculation of cost-effectiveness.[39] Depending on the composition of pollutants reduced by the rule, that approach will either exaggerate or understate the costs relative to a net benefit calculation. On other occasions, EPA calculated the cost-effectiveness of reducing a single pollutant while ignoring the other benefits of the regulation.[40] This approach overstates the true cost that should be attributed to each ton abated.

### D. *Discussion of Alternatives*

The Executive Order and the OMB Guidelines direct agencies to ensure that the regulatory alternative chosen maximizes net benefits.[41] Unfortunately, the agencies generally did not provide a significant analysis of alternatives in RIAs, even when the agencies conducted a quantitative analysis of their preferred option.[42]

Figure 5 shows the extent to which different agencies analyzed alternatives. Although agencies discussed alternatives in over two-thirds of the rules examined, they quantified the costs and benefits of alternatives in only a quarter of these rules. The three agencies with more than five

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39. This aggregation may be more useful when using a weighted average. For example, DOT provides cost-effectiveness estimates for several of its regulations after combining injuries and deaths by employing a weighting system. See, e.g., Gas Pipeline Safety Standards, 61 Fed. Reg. 28,770 (1996).

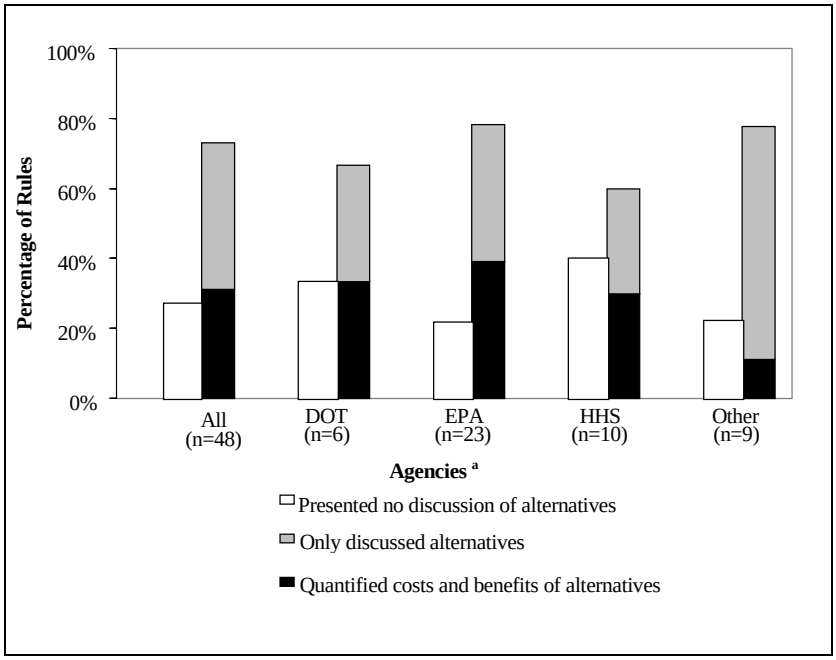
40. EPA did not include direct hydrocarbon and particulate matter reductions in its calculation of cost-effectiveness of oxides of nitrogen emission reduction in its rule governing locomotive emissions. *See* Emission Standards for Locomotives and Locomotive Engines, 63 Fed. Reg. 18,978 (1998) (to be codified at 40 C.F.R. pts. 85, 89, 92).

41. *See* Exec. Order No. 12,866, 3 C.F.R. 638 (1993-2000), *reprinted in* 5 U.S.C. § 601 (1994); *OMB Guidelines*, *supra* note 11.

42. For 35 percent of the rules, agencies presented estimates of benefits and costs for the chosen alternative but failed to present such estimates for other alternatives. If agencies can quantify costs and benefits for the chosen alternative, they likely should be able to quantify benefits and costs of relevant alternatives as well. So doing would presumably not require significant new information or modeling techniques.

rules in our database (DOT, EPA, and HHS) quantified benefits and costs of alternatives in approximately 20 percent to 35 percent of their analyses. No other agency quantified benefits and costs of alternatives for any of its rules. Only two rules out of forty-eight calculated incremental net benefits of the alternatives.[43] This incomplete consideration of alternatives makes it difficult to assess whether alternatives would actually be superior to an agency's preferred policy, even using an agency's own assessment.

**Figure 5: Agency Analysis of Alternatives**




[a] DOT—Department of Transportation. EPA—Environmental Protection Agency. HHS—Health and Human Services. DOC—Department of Commerce. DOE—Department of Energy. DOL—Department of Labor. USDA—Department of Agriculture. The category "Other" includes DOC, DOE, DOL, and USDA.

43. Both are EPA rules. *See* Findings of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Transport of Ozone, 63 Fed. Reg. 57,356 (1998) (to be codified at 40 C.F.R. pts. 51, 72, 75, 96); Regional Haze Rule, 64 Fed. Reg. 35,714 (1999) (to be codified at 40 C.F.R. pt. 51).

### E. *Clarity of Presentation*

RIAs are not transparent, in part because the results are not reported clearly and consistently. Improving the clarity of presentation in RIAs would help stakeholders understand the impact of regulations. Agencies provided completely consistent benefit numbers between the *Federal Register* and their RIA for less than 60 percent of the rules.[44] Only about one-half of the RIAs contained an executive summary. Only fourteen regulations (29 percent) used an executive summary to present tables of qualitative or quantitative estimates of benefits and costs. Although many of the other RIAs contained such information, it was not readily accessible.[45] RIAs often bury specific economic information within a technical discussion of the health or environmental impacts, making it difficult to find a specific piece of information.[46] Although some criticize the *Federal Register* notices for poor presentation of information, it is easier to navigate and offers information in a more uniform, accessible format than RIAs.[47]

### F. *Consistent Use of Analytical Assumptions*

Agencies often failed to use consistent analytical assumptions, the use of which would ensure that agencies are comparing and presenting consistent results. Only ten out of forty-eight rules used a consistent dollar year, a consistent discount rate, and a consistent estimate of benefits and costs. On a more positive note, almost three-fourths of the analyses used a consistent discount rate for costs and benefits, a generally accepted practice that permits the conversion of future benefits and costs into an equivalent present dollar value. Of the RIAs that relied on a single discount rate, 86 percent used the rate of 7 percent specified in the OMB

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44. Although such inconsistencies may reflect new information used in the analysis, the agencies made no attempt to explain them.

45. Several of the thirty-four regulations lacking data tables in the executive summary did, nevertheless, present their results in an useful format, albeit less accessible.

46. Often, rules describe basic economic concepts such as discounting and nonmarket valuation. Although such descriptions may be essential for an understanding of the analysis, a lengthy discussion of techniques detracts from and obscures the issues and assumptions that are unique to an individual analysis. Instead, the agencies should simply refer to OMB guidelines that address those more general concerns.

47. *See* Hahn, *Regulatory Accountability*, *supra* note 6, at 16 (describing the content and accessibility of information in the *Federal Register*).

guidelines, 14 percent used a discount rate less than 7 percent and only one used a discount rate greater than 7 percent.[48]

## IV. RECOMMENDATIONS AND CONCLUSIONS

The agencies' economic analyses generally did not provide adequate information about a proposed regulation to justify decisions to proceed with the regulation. The absence of information on net benefits suggests strongly that agencies largely have ignored the goal of the Executive Order and the OMB Guidelines. An agency's RIA should be the starting point for serious policy analysis rather than the end, and the agency should provide the results in a consistent and transparent manner. Even if the agency complies with the Executive Order and the OMB Guidelines, a deeper issue of assessing quality remains to be addressed.

The study did not directly measure the quality of the underlying analysis because it would have required knowledge of specific technical issues. Case studies by scholars suggest, however, that many RIAs suffer from serious shortcomings.[49] A low score on the regulatory scorecard is, however, an indicator of a potentially poor quality analysis, particularly if the agency did not assess key economic variables, such as the net benefits of a regulation. In addition, a high score using our criteria does not necessarily mean that the agency performed a high quality analysis because the agency could mask analytical flaws even if it complies with the Executive Order and the OMB Guidelines.

An agency's RIA could receive a low score for the following three reasons: first, the agency may face resource constraints; second, the agency does not want interested parties to know that the benefits of the regulation may not justify the costs; and third, the agency simply does not take the RIA requirement

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48. One HHS rule used a discount rate of 10 percent. *See* Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52,646 (1996) (codified at 21 C.F.R. pts. 808, 812, and 820).

49. Scholars also point out that some economic analyses are of high analytical quality. *See, e.g.*, Hahn, *Regulatory Reform*, *supra* note 4, at 240-41; Morgenstern & Landy, *supra* note 4, at 463-74; RANDALL LUTTER, AN ANALYSIS OF THE EPA'S PROPOSED LEAD HAZARD STANDARDS FOR HOMES 3, 12-15 (AEI-Brookings Joint Center for Regulatory Studies Working Paper 99-5, 1999) (discussing the shortcomings of the EPA's economic analysis of homeowner behavior, possible premature housing abandonment, and discounting future benefits).

seriously because it is not enforced. A complete discussion of options for improving regulatory analysis and the regulatory process is beyond the scope of this paper.[50] Nevertheless, several recommendations flow naturally from our analysis. These include:

> requiring an agency to calculate net benefits when it can estimate benefits and costs; and asking that agency to note the limitations of those estimates;
>
> requiring an agency to present both best estimates and ranges for benefits, costs, and net benefits; or, alternatively, asking an agency to justify why that cannot be done;
>
> requiring an agency to quantify any benefits or costs that it is unable or unwilling to monetize; or, alternatively, asking that agency to justify why that cannot be done;
>
> requiring an agency to expand its consideration of alternatives;
>
> requiring a clear executive summary along with a table that summarizes what is known about the likely benefits and costs of the regulation in a standard format;
>
> requiring RIAs to have a consistent format so that it is easier to obtain information from different RIAs and compare them;
>
> requiring that an RIA and supporting documents be posted on the Internet so that such analyses are more easily obtained by interested parties; and
>
> requiring OMB to provide clearer guidance on how cost-effectiveness numbers should be presented and calculated to avoid some of the current problems.

Forcing agencies to adhere to such standards poses a critical challenge. President Clinton, working with OMB, apparently has not been successful in implementing such reforms, probably due to a lack of interest and willingness to spend

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50. *See, e.g.*, Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 8 (1995) (proposing methods of "simultaneously promoting economic and democratic goals" through regulation); *see generally* STEPHEN G. BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION ix (1993) (providing political and institutional analysis of the "problems with the present regulatory system"); ROGER G. NOLL, THE ECONOMICS AND POLITICS OF THE SLOWDOWN IN REGULATORY REFORM (1999) (concluding that economic analysis can be influential in promoting regulatory reform only when such analysis is consensual, comprehensive, and objective).

political capital.[51] Such reforms likely may prove worthwhile, not necessarily because the analysis itself will improve dramatically, but rather because these reforms will enhance transparency in the regulatory process.

Congress could pass a bill that incorporates these suggestions. It could also give OMB greater enforcement authority and create an agency outside the executive branch to report on how such guidelines are being implemented and to review regulations.[52] This analysis recognizes the lack of political enthusiasm for making the process more transparent. At the same time, this issue could have some bipartisan appeal because it arguably would hold regulators more accountable for their policies, and more accountable to Congress.

Making the regulatory process more transparent will serve two purposes. First, it will give interested parties greater access to a key part of the regulatory process used to support a decision. Second, it will increase the probability that scholars will engage in independent regulatory analysis that could lead to improvements in both the regulatory process and regulatory outcomes.

## APPENDIX 1

### ECONOMIC ANALYSIS SCORECARD[A]

**General Information**

Regulation Name: _____

Agency and Department:_____ Date:_____

RIN#: _____ Status: final interim-final page

Economically Significant: yes no page Transfer Rule: yes no page

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51. Although the Clinton administration may deserve some blame, the problem was also relevant in earlier Republican administrations. Previous studies would suggest that economic analyses of regulations by agencies were not necessarily better during the Bush and Reagan administrations. *See* HAHN, ASSESSING THE GOVERNMENT'S NUMBERS, *supra* note 6, at 9; Morgenstern & Landy, *supra* note 4, at 463-74. Indeed, most presidents may be unwilling to spend the necessary capital to improve the quality of analysis.

52. For example, Congress could say that OMB should not generally make a decision on a proposed regulation unless the economic analysis satisfied certain guidelines. *See Hearings Before the Subcomm. on Regulatory Reform and Paperwork Reduction of the House Comm. on Small Business* (2000) (statement of Robert W. Hahn & Robert E. Litan, Directors, AEI-Brookings Joint Center for Regulatory Studies) (visited June 7, 2000) <http://www.aei.brookings.org/publications/testimony/testimony_00_01.pdf>.

| | Score | Page | Notes |
|---|---|---|---|
| Identified Discount Rate | | | |
| Used a Consistent Discount Rate | | | |
| Identified Baseline for Costs | | | |
| Identified Baseline for Benefits | | | |
| Used Consistent Baseline for Costs and Benefits | | | |
| Identified Dollar Year | | | |
| Used Consistent Dollar Year | | | |
| Performed Sensitivity Analysis | | | |
| Gave Executive Summary | | | |
| RIA is Available on the Internet | | | |
| The RIA was Peer-Reviewed | | | |
| Presented Best Estimate of Net Benefits | | | |
| Presented Range of Net Benefits | | | |
| Presented Best Estimate of Cost-Effectiveness | | | |
| Presented Range of Cost-Effectiveness | | | |
| Discussed Alternatives | | | |
| Quantified Costs and Benefits of Alternatives | | | |
| Quantified Incremental Net Benefits of Alternatives | | | |

**Costs**

| | Agency States Exist | | Agency Quanti-fied | | Agency Mone-tized | |
|---|---|---|---|---|---|---|
| | S | P | S | P | S | P |
| Private Sector Producer Compliance Costs | | | | | | |
| Federal Budgetary Costs | | | | | | |
| Local and/or State Government Costs | | | | | | |
| Other Costs | | | | | | |
| Presented Range of Cost Estimates | | | | | | |
| Presented Best Estimate of Costs | | | | | | |
| Presented Consistent Cost Figures B/t RIA and *Federal Register* | | | | | | |

s = score; p = page

[a] For a complete copy of this scorecard, including the factors analyzed for an agency's treatment of cost savings, benefits, uncertainty and bias, see <http://www.aei.brookings.org>.

# APPENDIX 2

## LIST OF FINAL REGULATIONS INCLUDED IN THE ANALYSIS[+]

| Agency | Department | RIN Number | Regulation title | Page Numbers in the *Federal Register* | Date of publication in the *Federal Register* |
|---|---|---|---|---|---|
| **DOC** | | | | | |
| | NOAA | 0648-AI94 | Northeast Multi-species Fishery Management Plan, Amendment 7 | Vol. 61 pg 27710-27750 | 5/31/1996 |
| | NOAA | 0648-AJ58 | Magnuson-Stevens Act Provisions; National Standard Guidelines | Vol. 63 pg 24212-24237 | 5/1/1998 |
| **DOE** | | | | | |
| | ECPCP | 1904-AA38 | Energy Conservation Program for Consumer Products; Conservation Standards for Room Air Conditioners | Vol. 62 pg 50122-50150 | 9/24/1997 |
| | ECPCP | 1904-AA47 | Energy Conservation Standards for Refrigerators, Refrigerator-freezers and Freezers | Vol. 62 pg 23102-23116 | 4/28/1997 |
| **DOL** | | | | | |
| | OSHA | 1218-AA05 | Respiratory Protection | Vol. 63 pg 1152-1200 | 1/28/1998 |
| | OSHA | 1218-AA98 | Occupational Exposure to Methylene Chloride | Vol. 62 pg 1493-1619 | 1/10/1997 |
| | OSHA | 1218-AB33 | Powered Industrial Truck Operator Training | Vol. 63 pg 66238-66274 | 12/1/1998 |
| **DOT** | | | | | |
| | FHWA | 2125-AD27 | Parts and Accessories Necessary for Safe Operation; lighting devices, reflectors, and electrical equipment | Vol. 64 pg 15588-15606 | 3/31/1999 |
| | FRA | 2130-AA86 | Roadway Worker Protection | Vol. 61 pg 65959-65983 | 12/16/1996 |
| | NHTSA | 2127-AG50 | Federal Motor Vehicle Safety Standards; Child Restraint Anchorage Systems, | Vol. 64 pg 10786-10850 | 3/5/1999 |

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|---|---|---|---|---|---|
| | | | Child Restraint Systems | | |
| | NHTSA | 2127-AG59 | Federal Motor Vehicle Safety Standards; Occupant Crash Protection (Airbag Depowering) | Vol. 62 pg 12960-12975 | 3/19/1997 |
| | NHTSA | 2127-AH38 | Incentive Grants for Use of Seat Belts, Allocation Based on State Seat Belt Use Rates | Vol. 63 pg 57904-57911 | 10/29/1998 |
| | NHTSA | 2127-AH39 | Operation of Motor Vehicles by Intoxicated Persons | Vol. 64 pg 35568-35573 | 7/1/1999 |
| **EPA** | | | | | |
| | OAR | 2060-AC62 | Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Hospital/medical/infectious Waste Incinerators | Vol. 62 pg 48347-48391 | 9/15/1997 |
| | OAR | 2060-AD33 | Emission Standards for Locomotives and Locomotive Engines | Vol. 63 pg 18978-19084 | 4/16/1998 |
| | OAR | 2060-AE27 | Final Regulations for Revisions to the Federal Test Procedure for Emissions from Motor Vehicles | Vol. 61 pg 54851-54906 | 10/22/1996 |
| | OAR | 2060-AE54 | New Gasoline Spark Ignition and Compression-Ignition Marine Engines; New Non-Road Compression-Ignition Engines and Spark-Ignition engines, Exemptions | Vol. 61 pg 52087-52169 | 10/4/1996 |
| | OAR | 2060-AE56 | Revision of Standards of Performance for Nitrogen Oxide Emissions From New Fossil-Fuel Fired Steam Generating Units; Revisions to Reporting Requirements for Standards of Performance for New | Vol. 63 pg 49442-49455 | 9/16/1998 |

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|---|---|---|---|---|
| | | Fossil-Fuel Fired Steam Generating Units | | |
| OAR | 2060-AE57 | National Ambient Air Quality Standards for Ozone; Final Rule | Vol. 62 pg 38855-38896 | 7/18/1997 |
| OAR | 2060-AE66 | National Ambient Air Quality Standards for Particulate Matter; Final Rule | Vol. 62 pg 38652-38760 | 7/18/1997 |
| OAR | 2060-AF48 | Acid Rain, Phase II, Nitrogen Oxides Emission Reduction Program | Vol. 61 pg 67111-67164 | 12/19/1996 |
| OAR | 2060-AF75 | New Motor Vehicles and New Motor Vehicle Engines Air Pollution Control: Voluntary Standards for Light-duty Vehicles; Final Rule | Vol. 62 pg 31191-31270 | 6/6/1997 |
| OAR | 2060-AF76 | Control of Emissions of Air Pollution from Highway Heavy-duty Engines | Vol. 62 pg 54693-54730 | 10/21/1997 |
| OAR | 2060-AG06 | Regulation of Fuels and Fuel Additives: Certification Standards for Deposit Control Gasoline Additives | Vol. 61 pg 35309-35381 | 7/5/1996 |
| OAR | 2060-AH10 | Findings of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Transport of Ozone | Vol. 63 pg 57356-57538 | 10/27/1998 |
| OAR | 2060-AE29 | Phase 2 Emission Standards for New Nonroad Spark-ignition Nonhandheld Engines at or below 19 kilowatts | Vol. 64 pg 15208 | 3/30/1999 |
| OAR | 2060-AF32 | Regional Haze Regulations | Vol. 64 pg 35714-35763 | 7/1/1999 |
| OPPTS | 2070- | Disposal of | Vol. 63 pg 35384- | 6/29/199 |

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|---|---|---|---|---|
| | AC01 | Polychlorinated Biphenyls | 35474 | 8 |
| OSWER | 2050-AD04 | Financial Assurance Mechanisms for Local Government Owners and Operators of Municipal Solid Waste Landfill Facilities | Vol. 61 pg 60327-60339 | 11/27/1996 |
| OSWER | 2050-AD26 | Accidental Release Prevention Requirements: Risk Management Programs under Clean Air Act Section 112(r)(7) | Vol. 61 pg 31667-31730 | 6/20/1996 |
| OSWER | 2050-AD38 | Land Disposal Restrictions Phase III; Decharacterized Wastewaters, Carbamate Wastes, and Spent Aluminum Potliners | Vol. 61 pg 15566-15596 | 4/8/1996 |
| TSCA | 2070-AC64 | Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities | Vol. 61 pg 45777-45830 | 8/29/1996 |
| TSCA | 2070-AC71 | Addition of Facilities in Certain Industry Sectors, Toxic Chemical Release Reporting, Community Right-to-Know | Vol. 62 pg 23834-23892 | 5/1/1997 |
| WATER | 2040-AB53 | National Emissions Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Pulp, Paper, and Paperboard Category | Vol. 63 pg 18504-18751 | 4/15/1998 |
| WATER | 2040-AB82 | National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts | Vol. 63 pg 69390-69476 | 12/16/1998 |

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|---|---|---|---|---|---|
| | WATER | 2040-AC91 | National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment | Vol. 63 pg 69477-69521 | 12/16/1998 |
| **HHS** | | | | | |
| | FDA | 0910-AA09 | Medical Devices: CGMP Quality Systems Regulation | Vol. 61 pg 52601-52662 | 10/7/1996 |
| | FDA | 0910-AA19 | Food Labeling Nutrition Labeling, Small Business Exemption | Vol. 61 pg 40963-40981 | 8/7/1996 |
| | FDA | 0910-AA24 | Quality Mammography Standards | Vol. 62 pg 55851-55994 | 10/28/1997 |
| | FDA | 0910-AA43 | Food Labeling: Warning and Label Statement, Labeling of Juice Products | Vol. 63 pg 37030-37056 | 7/8/1998 |
| | FDA | 0910-AA48 | Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents | Vol. 61 pg 44395-44618 | 8/28/1996 |
| | FDA | 0910-AA91 | Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed | Vol. 62 pg 30935-30978 | 6/5/1997 |
| | FDA | 0910-AB20 | Regulation Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs. Biological Products in Pediatric Patients | Vol. 63 pg 66632-66672 | 12/2/1998 |
| | HCFA | 0938-AI95 | Medicare and Medicaid Programs: Hospital Conditions of Participation Identification of Potential Organ Tissue, and Eye Donors and Transplant Hospitals' Provision of Transplant-Related Data | Vol. 63 pg 33856-33875 | 6/22/1998 |
| | HCFA | 0938-AI17 | Newborns' and Mothers' Health Protection Act | Vol. 63 pg 57546-57564 | 10/27/1998 |

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| | HSRA | 0910-AA32 | Organ Procurement and Transplantation Network | Vol. 63 pg 16296-16338 | 4/2/1998 |
| **USDA** | | | | | |
| | APHIS | 0579-AB01 | Solid Wood Packing Material From China | Vol. 61 pg 50099-50111 | 9/18/1998 |
| | APHIS | 0583-AB69 | Pathogen Reduction: Hazard Analysis and Critical Control Points | Vol. 61 pg 38805-38956 | 7/25/1996 |

✤ For the full text of these rules, see <http://www.aei.brookings.org>. The rules can also be found at National Archives and Records Administration, *Federal Register Online via GPO Access* (visited June 7, 2000) <http://www.access.gpo.gov/su_docs/aces/aces140.html>.