

Validating Regulatory Analysis:

**2005 Report to Congress on the
Costs and Benefits of Federal Regulations
and Unfunded Mandates on
State, Local, and Tribal Entities**



2005

**Office of Management and Budget
Office of Information and 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**

EXECUTIVE SUMMARY	1
PART I: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS.....	3
Chapter I: The Costs and Benefits of Federal Regulations	5
A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB	7
B. Estimates of the Benefits and Costs of This Year’s Major Rules	11
C. Regulations Implementing Federal Budgetary Programs	16
D. Major Rules for "Independent" Regulatory Agencies	18
E. Response to Peer Reviews and Public Comments on the Accounting Statement	19
F. The Impact of Federal Regulation on State, Local, and Tribal Government, Small Business, Wages, and Economic Growth	24
G. Response to Peer Review and Public Comments on Economic Growth and Related Macroeconomic Indicators.....	34
Chapter II: Trends in Federal Regulatory Activity	35
Chapter III: Validation of Benefit and Cost Estimates Made Prior to Regulation	41
A. Summary of the Validation Literature	42
B. Nature and Limitations of the Sample of Rules Examined	47
C. Discussion of Validity Estimates	48
D. Response to Peer Review and Public Comments on Validation of Benefit and Cost Estimates	50
E. References	52
Chapter IV: Implementation of the Information Quality Act	55
A. Correction Requests Processed by Agencies in FY03 and FY04	56
B. General Evaluation: Perceptions and Realities	63
C. Legal Developments under the Information Quality Act.....	67
D. Increasing Transparency under the Information Quality Act	68
E. Characteristics of an Effective Correction Request.....	70
F. Role of OMB’s New Peer Review Policy	71
G. Response to Peer Reviews and Public Comments on the Information Quality Chapter	72
Appendix A: Calculation of Benefits and Costs.....	79
Appendix B: Valuation Estimates for Regulatory Consequences	99
A. Adjustment for Differences in Time Frame across These Analyses.....	101
B. Further Caveats	101
Appendix C: The Benefits and Costs of 1992-1994 Major Rules	103
Appendix D: Regulatory Reform in the Bush Administration	107
A. Update on Regulatory Reforms Initiated During the 2001-2004 Period	107
B. Update on Regulatory Reforms of the U.S. Manufacturing Sector	117
Appendix E: FY04 Information Quality Reports.....	127
A. Department of Interior: Minerals Management Service	128
B. Department of the Treasury.....	130

Appendix F: Peer Review and Public Comments.....	135
PART II: TENTH ANNUAL REPORT TO CONGRESS ON AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT	137
Introduction.....	139
Chapter I: Impacts on State, Local, and Tribal Governments.....	141
Chapter II: A Review of Significant Regulatory Mandates.....	143
A. Department of Agriculture	143
B. Department of Health and Human Services	144
C. Department of Labor	144
D. Department of Transportation.....	145
E. Environmental Protection Agency	147
Appendix: Agency Consultation Activities Under the Unfunded Mandates Reform Act of 1995.....	149
A. Department of Agriculture	149
B. Department of Commerce	157
C. Department of Education	158
D. Department of Health and Human Services.....	159
E. Department of Homeland Security.....	163
F. Department of Justice	165
G. Department of Labor	166
H. Department of Transportation.....	168
I. Environmental Protection Agency.....	172

EXECUTIVE SUMMARY

This Report to Congress provides a statement of the costs and benefits of Federal regulations and recommendations for regulatory reforms. A key feature of this report is the estimates of the total costs and benefits of "major" regulations (e.g., rules likely to have an annual effect on the economy of \$100,000,000 or more) reviewed by the Office of Management and Budget (OMB). Similar to previous reports, Chapter 1 includes a 10-year look-back of major Federal regulations reviewed by OMB to examine their quantified and monetized benefits and costs:

- OMB reviewed 88 "major" final Federal regulations from October 1, 1994 to September 30, 2004, for which a substantial portion of the total costs and benefits could be monetized. The estimated annual benefits from these rules range from \$69.6 billion to \$276.8 billion, while the estimated annual costs range from \$34.8 billion to \$39.4 billion. A significant portion of both benefits and costs is attributable to a handful of Environmental Protection Agency clean-air rules that reduce public exposure to fine particulate matter.
- During the past year, 11 "major" final rules with quantified and monetized benefits and costs were adopted. These rules added \$12.6 billion to \$108.5 billion in annual benefits compared to \$3.8 billion to \$4.1 billion in annual costs.
- In the past year, there were an additional 15 final "major" rules that did not have quantified and monetized estimates of both benefits and costs. Seven of these 15 rules implemented homeland security programs where the benefits of improved security are, though real, difficult to quantify and monetize.

In Chapter 2, we report the latest results of our ongoing historical examination of trends in Federal regulatory activity. Last year's report included preliminary estimates of the overall costs of major rules issued by Federal agencies each year from 1987 to 2003, and also suggested that a better measure of the overall impact of regulation on the economy would be net benefits; that is, benefits minus costs. This year, the cost estimates are extended back to 1981, the beginning of the regulatory review program at OMB. Furthermore, this Report presents both benefit and cost estimates for the years 1992 to 2004. The expanded analysis reveals that we have made great strides towards "smarter" regulation in the past four years:

- Over the last 24 years, the 190 major regulations reviewed by OMB have added at least \$117 billion to the overall yearly costs of regulations on the U.S. economy. However, the average yearly cost of the major regulations issued between 2001 and 2004 is about 70 percent less than over the previous 20 years.
- The benefits of the major regulations issued from 1992 to 2004 exceed the costs by over three fold. Furthermore, the average yearly net benefit of the major regulations issued between 2001 and 2004 is over double the yearly average for the previous

eight years.

In Chapter 3, we compare the projected benefits and costs of 47 Federal regulations with benefit and cost information obtained after promulgation and implementation. Our results concerning accuracy of projected estimates indicate that analyses of Federal regulation in our sample tend to overestimate both benefits and costs, but they have a significantly greater tendency to overestimate benefits than costs. Specifically, we found:

- Eighteen rules with accurate benefit estimates, 19 rules with overestimates and two rules with underestimates.
- Twelve rules with accurate cost estimates, 16 with overestimates, and 12 with underestimates.
- Eleven cases of accurate benefit to cost ratios, 22 overestimates, and 14 underestimates.

Since the 47 rules are a convenience sample, more research is necessary to determine if these results are generalizable.

In this report, we also include an update of our FY 2003 *Information Quality: A Report to Congress*. This update includes discussion of the information quality correction requests received by agencies in FY 2003 and FY 2004. This chapter also includes discussion of the perceptions and realities related to some of the major concerns we have heard about Government-wide information quality initiatives. Additionally, we share progress that has been made in increasing agency transparency as well as helpful tips for stakeholders interested in writing an effective correction request.

In addition, we provide an update on the Bush Administration's regulatory reform activities. We include a progress report on selected regulatory reforms initiated from 2001 to 2004, with a focus on important regulations that agencies have acted on since the final 2004 Report. OMB is also reporting on the progress agencies are making on the 76 reform initiatives identified in OMB's March 2005 report, *Regulatory Reform of the U.S. Manufacturing Sector*. In the first year of the manufacturing initiative, agencies reached over 70 percent of their reform milestones.

This final Report was issued in draft form in March of this year and was, as a matter of policy, submitted for and revised in response to public comment, external peer review, and interagency review. OMB has already begun to prepare the *2006 Report to Congress on the Costs and Benefits of Federal Regulations*.

**PART I: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF
FEDERAL REGULATIONS**

CHAPTER I: THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

Section 624 of the Treasury and General Government Appropriations Act of 2001, often called the "Regulatory Right-to-Know Act," (Public Law 106-554, 31 U.S.C. 1105 note) calls for the Office of Management and Budget (OMB) to submit "an accounting statement and associated report" including:

(A) an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:

- (1) in the aggregate;
- (2) by agency and agency program; and
- (3) by major rule;

(B) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and

(C) recommendations for reform.

Since the statutory language does not further define "major," for the purposes of this Report, we were broadly inclusive in defining "major" rules. We have included all final rules promulgated by an Executive branch agency that meet any one of the following three measures:

- Rules designated as "major" under 5 U.S.C. 804(2);¹
- Rules designated as meeting the analysis threshold under 2 U.S.C. 1532;² and
- Rules designated as "economically significant" under section 3(f)(1) of Executive Order 12866.³

This chapter consists of two parts: the accounting statement, and a brief report on regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Part A revises the benefit-cost estimates in last year's Report by updating the estimates to the end of fiscal year 2004 (September 30, 2004). Like the 2004 Report, this chapter uses a

¹ A "major rule" is defined in Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996: Congressional Review of Agency Rulemaking (5 U.S.C. 804(2)) as a rule that is likely to result in: "(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets."

² A written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate is required under the Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532(a)) for all rules that may result in: "the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year."

³ A regulatory action is considered "economically significant" under Executive Order 12866 3(f)(1) if it is likely to result in a rule that may 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."

2005 Report to Congress on the Costs and Benefits of Federal Regulations

10-year look-back: estimates are based on the major regulations reviewed by OMB from October 1, 1994 to September 30, 2004.⁴ This means that 9 rules reviewed from October 1, 1993 to September 30, 1994 were included in the totals for the 2004 Report but are not included in the 2005 Report. A list of these rules can be found in Appendix C. Appendix C also includes a summary of 32 rules included in the 2003 Report but not included in the 2004 Report. All of the estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OMB.⁵ We also include in this chapter a discussion of major rules issued by "independent" regulatory agencies, although OMB does not review these rules under Executive Order 12866.⁶ This discussion is based on data provided by these agencies to the Government Accountability Office (GAO) under the Congressional Review Act.

⁴ All previous Reports are available at: http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

⁵ OMB used agency estimates where available. If an agency quantified but did not monetize estimates, we used standard assumptions to monetize them, as explained in Appendix A. Inflation adjustments are performed using the latest available GDP deflator and all amortizations are performed using a discount rate of 7%, unless the agency has already presented annualized, monetized results using a different explicit discount rate.

⁶ Section 3(b) of Executive Order 12866 excludes "independent regulatory agencies as defined in 44 U.S.C. 3502(10)".

A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB

Table 1-1 presents an estimate of the total costs and benefits of 88 regulations reviewed by OMB over the ten-year period from October 1, 1994 to September 30, 2004 that met two conditions.⁷ Each rule generated costs or benefits of at least \$100 million in any one year, and a substantial portion of its costs and benefits were quantified and monetized by the agency or, in some cases, monetized by OMB. The estimates are therefore not a complete accounting of all the costs and benefits of all regulations issued by the Federal government during this period.⁸ As discussed in previous Reports, OMB has chosen a 10-year period for aggregation because pre-regulation estimates prepared for rules adopted more than ten years ago are of questionable relevance today. The estimates of the costs and benefits of Federal regulations over the period October 1, 1994 to September 30, 2004 are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866.

The aggregate benefits reported in Table 1-1 are substantially larger than the aggregate benefits presented in the 2004 Report, while the aggregate costs are roughly comparable to the last Report's totals. This is due primarily to the addition of two Environmental Protection Agency (EPA) rulemakings: a final rule limiting emissions of air pollution from nonroad diesel engines (\$28.6 billion in annual benefits and \$1.3 billion in annual costs), and a final rule implementing National Emission Standards for Hazardous Air Pollutants from industrial, commercial, and institutional boilers and process heaters (\$17 billion in annual benefits and \$900 million in annual costs). As can be seen in Tables 1-1 and 1-2, EPA rules continue to be responsible for the majority of costs and benefits generated by Federal regulation during this time period.

⁷ OMB discusses, in this report and in previous reports the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies using different methodologies. Any aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable. In part to address this issue, the 2003 Report included OMB's new regulatory analysis guidance, OMB Circular A-4, which took effect on January 1, 2004 for proposed rules and January 1, 2005 for final rules. The guidance recommends what OMB defines as "best practice" in regulatory analysis, with a goal of strengthening the role of science, engineering, and economics in rulemaking. The overall goal of this guidance is a more competent and credible regulatory process and a more consistent regulatory environment. OMB expects that as more agencies adopt our recommended best practices, the costs and benefits we present in future reports will become more comparable across agencies and programs. OMB is working with the agencies to ensure that their impact analyses follow the new guidance.

⁸ In many instances, agencies were unable to quantify all benefits and costs. We have conveyed the essence of these unquantified effects on a rule-by-rule basis in the columns titled "Other Information" in the various tables reporting agency estimates in this and previous Reports. The monetized estimates we present necessarily exclude these unquantified effects.

Table 1-1: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1994 to September 30, 2004 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Agriculture	5	2,837-5,923	1,586-1,608
Department of Education	1	632-786	349-589
Department of Energy	6	5,194-5,260	2,958
Department of Health and Human Services	17	10,226-19,714	3,817-3,992
Department of Homeland Security (Coast Guard)*	2	60	869
Department of Housing and Urban Development	1	190	150
Department of Labor	4	1,138-3,440	349
Department of Transportation	11	4,979-7,742	3,591-5,617
Environmental Protection Agency	41	44,381-233,730	21,166-23,284
Total	88	69,638-276,846	34,836-39,416

*Presented here are the costs and benefits of two Coast Guard rules that pre-date the establishment of DHS. These totals do not include the 7 major homeland security regulations adopted in 2004 by DHS and HHS. These regulations imposed costs of approximately \$1.8 billion to \$3.7 billion per year, and are presented in more detail in Table 1-5.

Table 1-2 provides additional information on aggregate benefits and costs for specific agency programs. In order for a program to be included in Table 1-2, the program needed to have finalized 3 or more rules in the last 10 years with monetized costs and benefits. The Center for Medicare and Medicaid Services (CMS) in the Department of Health and Human Services (HHS) is a new entry on this table, due to the final rule published in the *Federal Register* on January 23, 2004 implementing requirements for a standard unique health care provider identifier.

The ranges of costs and benefits presented in Tables 1-1 and 1-2 are not necessarily correlated. In other words, when interpreting the meaning of these ranges, the reader should not assume that low benefits are associated with low costs and that high benefits are associated with high costs. Thus, for example, it is possible that the net benefits of EPA's water programs, taken together, could range from negative \$2.5 billion to positive \$5.1 billion per year.

Table 1-2: Estimates of Annual Benefits and Costs of Major Federal Rules: Selected Programs and Agencies, October 1, 1994-September 30, 2004 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Energy			
Energy Efficiency and Renewable Energy	6	5,194-5,260	2,958
Department of Health and Human Services			
Food and Drug Administration	12	3,348-12,399	985-1,160
Center for Medicare and Medicaid Services	3	5,634	2,538
Department of Labor			
Occupational Safety and Health Administration	4	1,138-3,440	349
Department of Transportation			
National Highway Traffic Safety Administration	7	4,154-6,917	2,267-4,292
Environmental Protection Agency			
Office of Air	29	41,292-217,721	15,171-16,765
Office of Water	9	1,165-8,307	3,160-3,684

Based on the information contained in this and previous Reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) may be significantly larger than the sum of the costs and benefits reported in Table 1-1. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program.

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, not all of which may be reflected in the available data. Any comparison or aggregation across rules should also consider a number of factors that our presentation does not address. To the extent that agencies have adopted different methodologies—for example, different monetized values for effects, different baselines in terms of the regulations and controls already in place, different rates of time preference, different treatments of uncertainty—these differences remain embedded in Tables 1-1 and 1-2. While we have relied in many instances on agency practices in monetizing costs and benefits, our citation of, or reliance on, agency data in this Report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefit and cost estimates.

Many of these major rules have important non-quantified benefits and costs, which may have been a key factor in an agency’s decision to promulgate a rulemaking. These qualitative issues are discussed in the agency rulemaking documents, in previous versions of this Report, and in Table A-1 of this Report.

The majority of the large estimated benefit of EPA rules is attributable to reduction in public exposure to a single air pollutant: fine particulate matter. Thus, the favorable benefit-cost results for EPA regulation should not be generalized to all types of EPA rules or even to all types of clean-air rules. In addition, the ranges of costs and benefits presented in Tables 1-2 need to be treated with some caution. To the extent that the reasons for uncertainty differ across individual rules, aggregating high- and low-end estimates can result in totals that are extremely unlikely. In the case of the EPA rules reported here, however, a substantial portion of the uncertainty is similar across several rules: uncertainty in the reduction of premature deaths associated with reduction in particulate matter and the monetary value of reducing mortality risk. We continue to work with EPA to revise these ranges to more fully reflect the uncertainty in these estimates.

As Table 1-2 indicates, the degree of uncertainty in benefit estimates for clean air rules is large. In addition, the wide range of benefits estimates for particle control does not capture the full extent of the scientific uncertainty. The five key assumptions in the benefits estimates are as follows:

- Inhalation of fine particles is causally associated with a risk of premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
- All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles formed from power plant SO₂ and NO_x emissions are chemically different from fine particles emitted directly from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects by particle type.
- The concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the estimates include health benefits from reducing fine particles in both attainment and non-attainment regions.
- The forecasts for future emissions and associated air quality modeling are valid.
- The valuation of the estimated reduction in mortality risk is largely taken from studies of the tradeoff associated with the willingness to accept risk in the labor market.

In response to recent recommendations from a committee of the National Research Council/National Academy of Sciences, EPA is working with OMB to improve methods to quantify the degree of technical uncertainty in benefits estimates.⁹

⁹ For more information on this study, please see *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, National Academy of Sciences, 2003. Available at <http://books.nap.edu/catalog/10511.html>.

B. Estimates of the Benefits and Costs of This Year's Major Rules

In this section, we examine in detail the benefits and costs of the 45 major final rules for which OMB concluded review during the 12-month period beginning October 1, 2003, and ending September 30, 2004. These major rules represent approximately 12 percent of the 364 final rules reviewed by OMB during this period, and approximately one percent of the 4,088 final rules published in the *Federal Register* during this period. OMB believes, however, that the costs and benefits of major rules capture the vast majority of the total costs and benefits of all rules subject to OMB review.¹⁰

Of the 45 rules, 26 regulations were “social regulations,” which may require substantial additional private expenditures as well as provide new social benefits.¹¹ Of the 26 “social regulations,” we are able to present estimates of both monetized costs and benefits for 11 rules. The estimates are aggregated by agency in Table 1-3, and each rule is summarized in Table 1-4. Seven of the rules for which we were not able to present estimates of both costs and benefits implemented homeland security programs where the benefits of improved security are very difficult to quantify and monetize.¹² All seven of these rules did estimate costs, and these costs, as well as the available information on benefits, are summarized in Table 1-5. The 8 other final rules did not include monetized or quantified estimates for both costs and benefits, thus we did not include those rules in the totals in Tables 1-1 through 1-3. We attempt to summarize the available information on the impact of these rules in the “other information” column of Table A-1.

The remaining 19 implemented Federal budgetary programs, which primarily caused income transfers, usually from taxpayers to program beneficiaries. Although rules that facilitate Federal budget programs are subject to E.O. 12866 and OMB Circular A-4, and are fully reviewed by OMB, this Report is focused on regulations that impose costs primarily through private sector mandates.

¹⁰ We discuss the relative contribution of major rules to the total impact of Federal regulation in detail in the “response-to-comments” section on pages 26-27 of the 2004 report. In summary, our evaluation of a few representative agencies found that major rules represented the vast majority of the costs and benefits of all rules promulgated by these agencies and reviewed by OMB.

¹¹ The *Federal Register* citations for these major rules are found in Table A-1 in Appendix A.

¹² See Chapter 4 in the 2003 Report (pp 64-80) for a more detailed discussion of this issue.

Social Regulation

Of the 45 economically significant rules reviewed by OMB, 26 regulations require substantial private expenditures or provide new social benefits. Of the 26 rules, we are able to present estimates of both monetized costs and benefits for 11 rules. Table 1-3 presents total benefits and costs by agency of these major rules reviewed by OMB over the past year and Table 1-4 provides a summary of each regulation. These tables are the basis for the totals in the accounting statement in Section A of this chapter.

In assembling these tables of estimates of benefits and costs, OMB has applied a uniform format for the presentation of benefit and cost estimates in order to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates); and has monetized quantitative estimates where the agency has not done so. For example, we have converted agency projections of quantified benefits, such as estimated injuries avoided per year or tons of pollutant reductions per year, to dollars using the valuation estimates discussed in Appendix A. Table A-1 in Appendix A also reports the available impact information, as reported by the agencies, on all 26 of the social regulations reviewed by OMB in the time period of this Report.

Table 1-3: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 01, 2003 to September 30, 2004 (millions of 2001 dollars)

Agency	Number of Rules	Benefits	Costs
Department of Health and Human Services	3	1,567-7,686	812-893
Department of Transportation*	2	94	-32
Environmental Protection Agency	6	10,935-100,703	3,060-3,211
Total	11	12,596-108,483	3,840-4,073

*Department of Transportation rules include the final rule reducing the vertical separation minimum in domestic U.S. airspace. Since this is a deregulatory action, we have subtracted the cost savings from the costs imposed by other rulemakings.

Table 1-4: Estimates of the Total Annual Benefits and Costs of Major Rules Issued Between October 1, 2003 to September 30, 2004 (millions of 2001 dollars per year)

Rule	Agency	Benefits	Costs	Explanation of OMB Calculations
Bar Code Label Requirements for Human Drug Products and Blood Products	HHS/ FDA	1,352- 7,342	647	The range of benefits reported in this table is based on the sensitivity analysis reported by FDA which assumed higher or lower interception rates of medical errors due to the rulemaking. This range encompassed the range of most of the other sensitivity analyses performed by FDA.
Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk	HHS/ FDA	0-130	7-89	No adjustments to agency estimates.
Health Insurance Reform: Standard Unique Health Care Provider Identifier	HHS/ CMS	214	158	We annualized the reported stream of impacts over 5 years at 7%.
Pipeline Integrity Management in High Consequence Areas (Gas Transmission Pipelines)	DOT/ RSPA	154	288	We annualized the reported stream of costs over 20 years at 7%.
Reduced Vertical Separation Minimum in Domestic United States Airspace	DOT/ FAA	-60	-320	We annualized the reported present value impacts over 15 years at 7%. We subtracted the impacts of this rulemaking from total costs and benefits because it is deregulatory.
Control of Emissions of Air Pollution From Nonroad Diesel Engines and Fuel	EPA/ Air	6,853- 59,401	1,336	We annualized the reported stream of impacts over 32 years at 7%. We also calculated an uncertainty interval for benefits using a method explained in Appendix B.
National Emission Standards for Hazardous Air Pollutants: Industrial/ Commercial/ Institutional Boilers and Process Heaters	EPA/ Air	3,752- 38,714	876	We calculated an uncertainty interval for benefits using a method explained in Appendix B.
National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products	EPA/ Air	152- 1,437	155- 291	No adjustments to agency estimates.
National Emission Standards for Hazardous Air Pollutants: Stationary Reciprocating Internal Combustion Engines.	EPA/ Air	105- 1,070	270	We calculated an uncertainty interval for benefits using a method explained in Appendix B. Note that EPA did present a monetized central estimate for benefits in this rulemaking of \$265 million per year (see Table A-1), which is somewhat lower than the midpoint of the uncertainty range presented here.
Establishing Location, Design, Construction, and Capacity Standards for Cooling Water Intake Structures at Large Existing Power Plants	EPA/ Water	72	383	No adjustments to agency estimates.
Effluent Guidelines and Standards for the Meat and Poultry Products Point Source Category (Revisions)	EPA/ Water	0-10	41-56	Although the annualized impact for this rule did not reach the economic significance threshold, this rule did have startup costs exceeding \$100 million in any one year.
Total		12,596- 108,483	3,840- 4,073	

Homeland Security Regulations

Table 1-5 presents the available impact information on the 7 major homeland security regulations adopted in 2004 by DHS and HHS. Because the benefits of homeland security regulations are a function of the likelihood and severity of a hypothetical future terrorist attack, they are very difficult to forecast, quantify, and monetize. For the purposes of this Table, we have annualized and converted the cost estimates to 2001 dollars in a manner similar to Table 1-4. We have also summarized the available information on how the agencies feel each of the rules will improve security or otherwise prevent or mitigate the consequences of a terrorist attack.

Table 1-5: Estimates of the Total Annual Benefits and Costs of Major Federal Rules: Major Homeland Security Regulation, October 1, 2003-September 30, 2004 (millions of 2001 dollars)

Rule	Agency	Benefits	Costs	Other Information
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	HHS-FDA	FDA will know in advance what articles of food are being imported or offered for import, before they arrive at the port of entry into the U.S. In the event of a credible threat, FDA will be able to mobilize and assist in the detention and removal of specific products that may pose a serious health threat to human or animals.	263	No adjustments to agency estimates.
Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	HHS-FDA	In the event of an actual or threatened bioterrorist attack on the U.S. food supply or other food-related emergency, this information will help FDA and other authorities determine the source and cause of the event, and communicate with potentially affected facilities.	187 - 305	We annualized the reported present value costs over 20 years at 7%
Required Advance Electronic Presentation of Cargo Information	DHS-CBP	The rule's primary benefit would be to improve cargo security. Once implemented, this rule will give CBP more time to analyze cargo data, thereby enabling it to target attention on high-risk cargo or carriers. In addition to improving the effectiveness of inspections, improved targeting may act as a deterrent.	334 - 2,094	No adjustments to agency estimates.
Area Maritime Security	DHS-USCG	This final rule, along with the Vessel Security and Facility Security final rules, was published jointly as part of the implementation of the National Maritime Security Initiative. This initiative is designed to reduce the risk and impact of a transportation security incident	66	Annualized costs derived from reported present value calculated over 10 years at 7%. Start-up costs estimated to be \$106 million in 2004.

Table 1-5: Annual Benefits and Costs of Major Homeland Security Regulations, Cont.

Rule	Agency	Benefits	Costs	Other Information
Vessel Security	DHS-USCG	Reduce the risk and impact of a transportation security incident	188	Annualized costs derived from reported present value calculated over 10 years at 7%.
Facility Security	DHS-USCG	Reduce the risk and impacts of a transportation security incident	743	Annualized costs derived from reported present value calculated over 10 years at 7%.
Authority To Collect Biometric Data From Additional Travelers and Expansion to the 50 Most Highly Trafficked Land Border Ports of Entry (US-VISIT)	DHS-BTS	The anticipated benefits of this rule include: (1) Improving identification, through the use of biometric identifiers, of travelers who may present threats to public safety; (2) enhancing the government's ability to match an alien's fingerprints and photographs to other law enforcement or intelligence data; (3) improving the ability to identify individuals who may be inadmissible to the United States; (4) improving cooperation across international, Federal, State and local agencies through better access to data on foreign nationals who may pose a threat; (5) improving facilitation of legitimate travel and commerce by improving the timeliness and accuracy of the determination of a traveler's immigration status and admissibility; (6) enhancing enforcement of immigration laws; (7) reducing fraud, undetected impostors, and identity theft; and, (8) increasing integrity within the Visa Waiver Program through better data collection, tracking, and identification.	27	DHS estimated a start-up cost of \$155 million in 2004, which they annualized over 7 years at 7%.
Total			1,808 – 3,686	

C. Regulations Implementing Federal Budgetary Programs

Of the 45 economically significant rules reviewed by OMB, Table 1-6 lists the 19 that implement Federal budgetary programs. The budget outlays associated with these rules are “transfers” from taxpayers to program beneficiaries (or fees collected from program beneficiaries); therefore in past reports OMB has referred to these rules as “transfer” rules. The totals are: USDA, 2 rules; Department of Defense (DOD), 2 rules; DOC, 1 rule; HHS, 9 rules; DHS, 1 rule; DOI, 2 rules; and DOT, 2 rules.

Table 1-6: Agency Rules Implementing Federal Budgetary Programs, October 1, 2003 to September 30, 2004

Department of Agriculture
2002 Farm Bill: Conservation Reserve Program
2001 Agriculture, Rural Development, Food & Drug Administration and Related Agencies Appropriation Act: Vehicle and Maximum Excess Shelter Expense Deduction Provisions
Department of Commerce
Fishing Capacity Reduction Program for the Crab Species Covered by the Fishery Management Plan for the Bering Sea/Aleutian Islands King and Tanner Crabs
Department of Defense
Programmatic Regulations for the Comprehensive Everglades Restoration Plan
TRICARE; CHAMPUS; Appeals and Hearings Procedures
Department of Health and Human Services
Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for CY 2004
Medicare Program: Changes to the Hospital Outpatient Prospective Payment System (OPPS) and CY 2004 Payment Rates
Medicare Program: Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for CY 2004
Medicare Program: Hospital Outpatient Prospective Payment System Payment Reform for CY 2004—CMS-1371-IFC
Medicare Program Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility
Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes
Medicare Program: Continuation of Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity – CMS-4018-F
Medicare Program: Medicare Ambulance MMA Temporary Rate Increases Beginning, July 1, 2004 – CMS-1492-IFC
Medicare Program Changes to the Hospital Inpatient Prospective Payment Systems and FY 2005 Rates – CMS-1428-F
Department of Homeland Security
Adjustment of the Immigration Benefit Application Fee Schedule
Department of Interior
Indian Roads Reservation Program
Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Relief or Reduction in Royalty Rates, Deep Gas Provisions
Department of Transportation
Automotive Fuel Economy Manufacturing Incentives for Alternative Fueled Vehicles
Maritime Security Program

I: The Costs and Benefits of Federal Regulations

In addition, there are 8 HHS/CMS “Notices” which are used to set parts of their payment systems such as premiums and annual deductibles. These notices are not final rules, since they implement changes to CMS payment systems driven by statutory formula and are not subject to notice and comment. We nonetheless list these notices below since they are considered "major" under (5 U.S.C. 804(2) and are reported to the GAO:

- Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2005 -- CMS-1360-N
- Medicare Program; Part A Premium for 2004 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement --CMS-8018-N
- Medicare Program: Part A Premiums for Calendar Year 2005 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement --(CMS-8022-N)
- Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2005 CMS-8020-N
- Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2005 (CMS-8021-N)
- Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Beginning January 1, 2004 -- CMS-8017-N
- Medicare Program: Notice of One-Time Appeal Process for Hospital Wage Index Classification
- Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2004 -- CMS-8016-N

Please note that rules that transfer Federal dollars often have opportunity costs or benefits in addition to the budgetary dollars spent. Including budget programs in the overall totals would, however, overwhelm the incremental new regulatory impacts identified by this Report and would confuse the distinction between rules that impose costs primarily through the imposition of taxes, and rules that impose costs primarily through mandates on the private sector. We also caution the reader not to assume that these rules were subject to less stringent analytical and review requirements based on our less-detailed presentation of Federal budget rules in this Report. In fact, agencies thoroughly analyze and OMB thoroughly reviews all significant Federal budget rules under E.O. 12866. If economically significant, these rules must be accompanied by regulatory impact analyses that comply with OMB Circular A-4.

D. Major Rules for "Independent" Regulatory Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) (Public Law 104-121) require the GAO to submit reports on major rules to the committees of jurisdiction, including rules issued by agencies not subject to Executive Order 12866, the so-called "independent" regulatory agencies. We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2003 to September 30, 2004. GAO reported that 4 of these agencies issued 4 major rules during this period.¹³

In comparison to the agencies subject to E.O. 12866, these agencies provided in their analyses relatively little quantitative information on the benefits of major rules: of the 19 economically significant rules reviewed by OMB that did not implement homeland security related regulations, about 60 percent (11) reported monetized benefits, whereas only 25 percent (1 of 4) of the rules finalized by independent agencies reported monetized benefits. As Table 1-7 indicates, most of the rules included some discussion of benefits and costs, and reported monetized costs. OMB does not know whether the rigor and extent of the analyses conducted by these agencies are similar to those of the analyses performed by agencies subject to the Executive Order, since OMB does not review rules from these agencies.

Table 1-7: Major Rules for "Independent" Regulatory Agencies, October 1, 2003 to September 30, 2004

Agency	Rule	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Communications Commission	Promoting Efficient Use of Spectrum Through Elimination of Barriers to the Development of Secondary Markets [68 FR 66252]	Yes	No	Yes
Federal Reserve	Availability of Funds and Collection of Checks [69 FR 47289]	Yes	No	No
Nuclear Regulatory Commission	Revision of Fee Schedules; Fee Recovery for FY 2004 [69 FR 22664]	Yes	No	Yes
Securities and Exchange Commission	Alternative Net Capital Requirements for Broker-Dealers that are Part of Consolidated Supervised Entities [69 FR 34428]	Yes	Yes	Yes

¹³ Rules promulgated by the Federal Communications Commission (FCC) under the authority of the Telecommunications Act of 1996 are exempt from the definition of "major rule" (5 U.S.C. 804). However, no FCC rules that would otherwise meet the criteria for "major rule" were identified for this period.

E. Response to Peer Reviews and Public Comments on the Accounting Statement

Many commenters supported OMB's general approach to the regulatory accounting statement. Several commenters (1, 4, 5, and E) stated that the accounting statement is a useful tool for informing the public and policymakers on the scope and impact of the Federal regulatory system.¹⁴ For example, peer reviewer 4 stated that the Report "improves incrementally on prior reports and lays out plans to make further improvements in the future. For the public it provides a useful window into the important, but obscure, world of regulation. For OMB and the agencies, as well of for Congress, it advances the state of the art and helps to institutionalize the process of evaluating regulatory benefits and costs." Other commenters, however, doubted the overall approach, stating that the accounting statement is highly misleading by its nature, and provides a false pretense of accuracy and objectivity (B, O).

Comments on Scope/Coverage

Commenters (1, C, and D) questioned OMB's decision to include only major rules in our benefit and cost totals. They questioned whether this practice led OMB to neglect reporting the impact of many important rules and therefore to underestimate the total costs and benefits of Federal rulemaking. Peer reviewer 1 stated that "it is not clear that a look at the handful of rules that qualify as 'major rules' can fully characterize the state of regulatory activity at the Federal level."

In the Draft Report, we stated that we included only information on the benefits and costs of major rules because we believe that these costs and benefits capture the vast majority of the total costs and benefits of all rules subject to OMB review. A comprehensive reassessment of every significant rulemaking is beyond the scope of this Report. In the final 2004 Report, we reassessed the relative importance of major versus non-major rules for a selected group of agencies (OSHA, FDA, and NHTSA) and found that the costs and benefits of their significant, non-major rulemakings reviewed by OMB were a small fraction of the costs and benefits of their major rulemakings. Peer reviewer 1 agreed that an annual assessment of all rulemakings was "impractical," and suggested that we focus on a particular agency each year in order to provide this more in-depth analysis. We do see merit in periodically providing in-depth focus on individual agencies in order to continually test our assumptions regarding the relative importance of major rules.

One commenter (C) also stated that since Federal agencies themselves determine which rules are major, using that screen for including rules in our Report is questionable. This characterization of the designation process is not correct. Under E.O. 12866, Section 6, the agencies must submit a list of planned regulatory actions to OIRA, and the agencies and OIRA jointly determine which of these actions are economically significant and major.

Other commenters (4, E, O) criticized the limitation of our accounting statement to final rules put in place over the previous 10 years. They stated that it is misleading to simply let

¹⁴ See appendix F for a listing of all the written comments we have received, and the numbers or letters we have assigned to their comments. The public and peer review comments are available for review at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.

regulatory programs drop off the radar screen after ten years, since some of them continue to have substantial economic effects. Furthermore, comment O claims that we did not address this criticism in previous years.

As we stated in the final 2004 Report in response to similar comments (see page 28), we continue to believe that the 10-year window is the appropriate time period for which to limit this accounting statement, since we do not believe that the pre-regulation estimates of the costs and benefits of rules issued over ten years ago are very reliable or useful for informing current policy decisions. In Chapter II, we discuss the many reasons why *ex-ante* estimates of regulations may not be accurate, and that inaccuracy almost certainly increases with time. We will continue, however, to document the estimated costs and benefits of rules outside of this time period in appendices and other analyses where we believe appropriate. Also, in order to provide transparency, we have expanded Appendix C to include all rulemakings that have been omitted because of our decision to limit our accounting statement to 10 years. In addition, in Chapter II, we present an analysis of the new yearly regulatory burden imposed by several administrations over the past 24 years. Although this analysis by necessity includes rules promulgated outside of the 10-year window, we believe it is a very useful study of the different burden administrations imposed on the private sector to realize regulatory benefits.

Several commenters (2, 4, B, O) criticized our treatment of homeland security regulations. Peer reviewer 4 stated that OMB should not automatically exclude the costs of any regulation, and homeland security regulations, in particular, for which agencies do not develop monetized estimates. Peer reviewer 2 suggested that OMB provide guidelines for how DHS should quantify and monetize the benefits of antiterrorism regulation, and peer reviewer 4 suggested that OMB encourage DHS to develop suitable analytical methods.

OMB encourages DHS and any other agency with a substantial focus on security to develop more systematic ways of judging the efficacy of their regulations. For example, we devoted a chapter in the 2003 Report to discuss the challenges in measuring anti-terrorism benefits and the direct and indirect costs of anti-terrorism rules. We also agree that homeland security regulations should be given a more prominent place and explanation in the Report, since security is such an important goal of government regulation. We disagree, however, with adding the costs of rulemakings that do not have monetized benefits to the accounting statement itself. We feel this would introduce bias into the presentation of the costs and benefits. Therefore, we have added to Chapter 1 a new Table, 1-5, which summarizes the annualized costs of the 7 major homeland security regulations finalized between October 1, 2003 and September 30, 2004. We also include a qualitative description of the expected benefits of these rulemakings.

Several commenters (3, 4, B, E, K, and O) criticized our treatment of rules that implemented Federal budgetary programs, including our practice of excluding rules of this type from the cost and benefit totals. Many of these comments point out that rules designed to spend budget dollars also generate costs and benefits. Costs include the opportunity costs of tax revenue, and benefits are derived from the behavioral changes caused by the spending programs. Peer reviewer (3) stated that there is no reason to suspect that benefits will equal costs, as OMB claims. Peer reviewer (3) also believes that the analysis that is performed on these budget rules is not nearly as systematic and comprehensive as the requirement for analyzing regulations.

Comment O claimed that we did not address this criticism in last year's Report, and comment B claimed that our treatment of these budgetary rules is not consistent with our own policies.

As we also stated in the response to comments in the final 2004 Report (see page 29), we agree that rules that transfer Federal budgetary programs often have opportunity costs or benefits in addition to the budgetary dollars spent. Our statement that the benefits and costs of budget rules would be equal referred to the transfer portion of the rule, or the actual budget expenditures associated with the rule, and not to the opportunity costs or behavioral changes caused by those budget expenditures. We have attempted to clarify the language on this point in Chapter 1.

Several commenters also seem to have assumed from our less detailed presentation of Federal budget rules in this Report that these rules were subject to less stringent analytical and review requirements. In fact, agencies thoroughly analyze and OMB thoroughly reviews all significant Federal budget rules under E.O. 12866. If economically significant, these rules must be accompanied by regulatory impact analyses that comply with OMB Circular A-4.

We continue to believe that our approach of separately identifying budgetary rules has merit. In this regard, we agree with peer reviewer (4) that perhaps the best argument for our separate treatment of budgetary rules is a "division of labor." OMB feels this Report is properly focused on regulations that impose costs primarily through private sector mandates, and not those regulations that facilitate Federal budget programs. We do see merit in providing more information about these rules, and we are considering feasible ways of providing this information.

Several commenters (2, 4, E) encourage us to present more detailed information on the costs and benefits of independent agency rulemakings. Commenter (E) stated that not including independent agency rulemakings causes the Report to underestimate the total regulatory burden imposed by the government. OMB agrees that it is important to assess the benefits and costs of independent agency regulatory actions, and we do encourage independent agencies to conduct benefit-cost analyses that conform to our regulatory analysis guidance, and to submit those analyses of major rules to OMB. Commenter (I) stated that Table 1-7 should either not include NRC's rule revising fee schedules as a "major rule" or at least clearly state NRC's rule is a "statutorily required rule." OMB is required by statute to include all major rules in this Report.

Two commenters (K and O) claim that OMB arbitrarily excludes deregulatory actions from review. Commenter (K) claims that OMB manipulates the process to declare deregulatory actions non-major in order to mask their effect. Commenter (K) cites an MSHA rule regulating diesel emissions as evidence of this. Comment (O) states that "OMB's single-edged sword fails to count lost benefits suffered by the public when safeguards are weakened or blocked." Comment (O) cites our treatment of an EPA rulemaking on the New Source Review program under the Clean Air Act. Comment (O) also states that we did not respond to a similar criticism in our 2004 report.

OMB disagrees with these commenters. As we stated in the response to comments in the final 2004 Report (see page 29), OMB does not exclude deregulatory actions from this Report. This Report includes all major final rules reviewed by OMB over a ten-year period from October

1, 1994 to September 30, 2004, whether or not they are regulatory or deregulatory. The 2005 Report discusses two deregulatory rulemakings both promulgated by DOT (liberalizing Computer Reservation System regulations and reducing the vertical separation minimum in domestic U.S. airspace). The MSHA rule cited by Commenter (K) fails to meet the objective criteria to be considered major; it did not have an estimated impact of \$100 million in any one year. In addition, the final 2004 Report stated we do not include information on EPA's Prevention of Significant Deterioration and Nonattainment New Source Review: Routine Maintenance and Repair Final Rule (68 FR 61247), because on December 24, 2003 the Court of Appeals for the District of Columbia Circuit stayed the effective date of the rule. As a result, the rule did not become effective on December 26, 2003, as originally intended by the Agency (see page 6). It is OMB's practice in these Reports to Congress to not include rulemakings that have been stayed or invalidated by a Court, as they no longer impose costs or generate benefits.

A peer reviewer (2) suggested that we include a discussion of the costs and benefits of anti-trust activities in the Report. OMB feels that a discussion of the costs and benefits of anti-trust activities is beyond the scope of this Report.

Comments on the Overall Quality of Analysis

Several comments (1, 4, B, G, E, and O) stated that costs and benefits of different regulations are difficult or impossible to compare due to methodological differences across agency analyses. Peer reviewer 4 is concerned with "inconsistent assumptions and baselines"; however, he also stated that aggregated costs and benefits are useful to "monitor trends, gauge general magnitudes, set priorities, and suggest directions for reform." Other commenters (B, K, and O) stated that they believed the methodologies so unsound that any attempt to add the results together in an accounting statement was inherently misleading. Most of these commenters suggest that we stress the limited nature of the statistics in the executive summary as well as throughout the Report.

Two commenters (2 and E) also suggest that OMB summarize agency compliance with OMB guidance. A commenter (G) suggested that OMB should encourage and provide technical assistance to agencies to develop a standardized methodology to account for substantial effects of regulations.

OMB agrees that we should emphasize the limitations of aggregating the costs and benefits of different regulations; we continue throughout these Reports to point out the inherent drawbacks of aggregating costs and benefits. We do not believe, however, that agency methodologies are so different that comparison across agencies is useless. For example, almost all agencies report results with a 7% discount rate, long required by OMB. Almost all agencies use similar methodologies for valuing fatalities avoided due to health and safety regulations. In addition, where benefits are primarily due to gains in economic efficiency, the market analysis that leads to an estimate of efficiency gains is fairly standardized.

We further note that in limited cases, as explained in the draft Report, OMB does adjust agency cost and benefit estimates to help ensure consistency in the context of this annual Report. First, all values were adjusted to 2001 dollars; next, quantified but non-monetized estimates

were monetized; and finally, estimates of net present values were annualized to provide a yearly stream of benefits and costs. Nevertheless, OMB agrees with the goal of further standardization of agency analyses, and believes the best way to promote this is through the application of the OMB Circular A-4, which was designed to promote consistent analytical approaches.

In addition to the uncertainties introduced by the aggregation of costs and benefits across regulations, some comments (1, B, E, and O) discussed the inherent uncertainty of regulatory analysis. Peer reviewer 1 stated that “the report does a good job presenting the available data and noting the areas where there is uncertainty and a need for further refinement.” Commenters (B and O), however, stated that the Report “provide a false pretense of accuracy and objectivity,” and “obscures the considerable uncertainty underlying its numbers.”

OMB disagrees with commenters B and O. We discuss throughout the Report the many sources of uncertainty within individual rulemakings and the difficulty and uncertainty of aggregating different estimates of costs and benefits. For EPA rulemakings, which these comments (B and O) discuss, the draft Report explained that the wide range of benefits estimates for clean air rules on controlling particulates does not capture the full extent of the scientific uncertainty.

Two commenters (B and O) suggest that the use of cost-benefit analysis has a major shortcoming. They state that cost-benefit analysis is inherently biased against regulation because it causes agencies to grossly overestimate the real cost to the economy and systematically underestimate the benefits of regulation. A major reason why benefits are underestimated, they contend, is that cost-benefit analysis de-emphasizes important benefits that are non-quantifiable.

OMB does not agree that cost-benefit analysis is inherently biased for or against regulation. Estimates are inherently uncertain, and we are aware of retrospective analyses that have found both *ex-ante* costs and benefits to be both under and over estimated.¹⁵ In addition, we explain in the Report that these major rules have important non-quantified benefits and costs, which may have been a key factor in an agency’s decision to promulgate a rulemaking. Table A-1 in the Report thoroughly describes the important non-quantified costs and benefits associated with particular rulemakings. Moreover, 15 of the 26 social regulations (reviewed by OMB between October 1, 2003 and September 30, 2004) did not quantify either benefits or costs, but these regulations were nonetheless finalized.

Several commenters made useful recommendations on the presentation of the Report. Peer reviewer (3) suggested that we switch Table 1-4 with Appendix Table A-1, since the latter table presents the annualized, 2001 dollar impact estimates that are the basis for the other tables presented in Chapter 1, Section A. We agree, and have made this modification. Peer reviewers (3 and 5) suggested that we present more systematic information on the non-quantified costs and

¹⁵ For example, Harrington et al (2000), in an analysis of a sample of EPA and OSHA regulatory impact analyses, found that *ex-ante* per-unit abatement costs were overestimated about as often as underestimated. They also found that *ex-ante* total abatement costs were more likely to be overestimated than underestimated. Overestimation of total costs was primarily due to errors in estimating the quantity of benefits achieved by the rule, which suggests that the benefits of these rulemakings were overestimated as well, and to unanticipated technological change. Chapter III discusses this and other retrospective studies of the impact of regulations in more detail.

benefits in what is now Table A-1. We agree, and have attempted to standardize and clarify this information. Peer reviewer (5) also suggested that we include a link to an electronic version of each rulemaking's Regulatory Impact Analysis. Oftentimes an agency will include their entire impact analysis in a final rule's Federal Register publication; we have indicated the rulemakings where this is the case in Table A-1. If the impact analysis is not published in full in the Federal Register, but is otherwise available on-line, we have added an electronic link to the analysis in the "other information" column in Table A-1.

F. The Impact of Federal Regulation on State, Local, and Tribal Government, Small Business, Wages, and Economic Growth

Sec. 624 (a)(2) of the Regulatory Right-to-Know Act (Public Law 106-554, 31 U.S.C. 1105 note) calls on OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth.

Impacts on State, Local, and Tribal Governments

Over the past 10 years, 6 rules have imposed costs of more than \$100 million per year (adjusted for inflation) on State, local, and tribal governments (and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995).¹⁶

1. *EPA's Rule on Standards of Performance for Municipal Waste Combustors and Emissions Guidelines (1995)*: This rule set standards of performance for new municipal waste combustor (MWC) units and emission guidelines for existing MWCs under sections 111 and 129 of the Clean Air Act [42 U.S.C. 7411, 42 U.S.C. 7429]. The standards and guidelines apply to MWC units at plants with combustion capacities greater than 35 mega grams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The EPA standards require sources to achieve the maximum degree of reduction in emissions of air pollutants that the Administrator determined is achievable, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements.

EPA estimated the annualized costs of the emissions standards and guidelines to be \$320 million per year (in constant 1990 dollars) over existing regulations. While EPA estimated the cost of such standards for new sources to be \$43 million per year, the cost to existing sources was estimated to be \$277 million per year. The annual emissions reductions achieved through this regulatory action include, for example, 21,000 Mg. of

¹⁶ We note that EPA's proposed rules setting air quality standards for ozone and particulate matter may ultimately lead to expenditures by State, local, or tribal governments of \$100 million or more. However, Title II of the Unfunded Mandates Reform Act provides that agency statements of compliance with Section 202 must be conducted "unless otherwise prohibited by law". The conference report to this legislation indicates that this language means that the section "does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule." EPA has stated, and the courts have affirmed, that under the Clean Air Act, the primary air quality standards are health-based and EPA is not to consider costs.

