

CURRENT FEDERAL AGENCY PRACTICES
FOR
VALUING THE IMPACTS OF REGULATIONS ON HUMAN HEALTH AND SAFETY

Prepared for:

Committee to Evaluate Measures of Health Benefits
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PREFACE

This report was authored by Lisa Robinson, an independent consultant, who was commissioned by the Institute of Medicine (IOM) Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation. Its purpose is to provide the Committee and the consortium of federal agencies sponsoring the Committee's work with an overview of the economic valuation methods and practices that federal agencies employ in assessing the effects of economically significant health and safety regulations, consistent with the requirements of Executive Order 12866. The IOM Committee's broader charge from its sponsors* is to develop guidance for federal regulatory agencies on the conduct of cost-effectiveness analyses as part of their prospective economic analyses of regulations with health and safety impacts. More specifically, the Committee is to make recommendations for the selection and use of health-adjusted life expectancy measures (such as quality-adjusted life years or QALYs) to value health-related benefits, taking into account ethical considerations, methodological and theoretical soundness, and feasibility of alternative approaches. The Committee's report with recommendations will be completed by the end of 2005.

The Committee is releasing this authored background paper well in advance of its final report so that interested individuals and organizations, both in and outside government, can review the information it contains on how a number of federal programs now conduct their economic evaluations and value the health-related benefits of regulatory actions. It is not an exhaustive account of agency practices, nor does it address every aspect of regulatory authority and development. The paper traces the development of the U.S. Office of Management and Budget's guidance on regulatory analysis and documents individual agency policies and practices, focusing on those agencies that have recently issued, or are expected to issue in the near future, economically significant rules with quantified estimates of health or safety benefits. Because it is intended to inform the Committee's further deliberations, this background paper is largely descriptive, reflecting both the author's experience in conducting these types of assessments and information gained from public documents and personal interviews with federal officials. The Committee will build on the information presented in this background paper, and incorporate other sources, as it develops findings and recommendations.

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Institute of Medicine Committee to Evaluate Measures of Health Benefits
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EXECUTIVE SUMMARY

The Institute of Medicine's (IOM's) Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation has been chartered by a consortium of Federal agencies to make recommendations related to the use of cost-effectiveness analysis in assessing the impacts of regulatory options. In particular, the Committee is charged with evaluating alternative effectiveness measures that allow analysts to combine consideration of morbidity and mortality across different health conditions.

This report supports the work of the Committee by providing background information on current practices as context for its efforts. It is not intended to be a comprehensive review of all Federal regulatory analyses nor of all the factors that affect regulatory decisions. Rather, it focuses on illustrating the types of regulatory actions and analyses that may be most significantly affected by the Committee's recommendations in the near term.

ES.1 Background and Context

The IOM Committee was commissioned in response to revised guidance for the conduct of economic analyses of regulations by Federal agencies. This guidance, issued in September 2003 by the U.S. Office of Management and Budget (OMB), is contained in *Circular A-4* and substantially increases the emphasis on the use of cost-effectiveness analysis. Previous guidance focused on benefit-cost analysis; now both cost-effectiveness and benefit-cost analysis are required for economically significant health and safety rulemakings whenever feasible.

Benefit-cost analysis involves estimating the dollar value of benefits (e.g., improvements in human health), then subtracting regulatory costs (e.g., related to compliance) to determine the net benefits of regulatory options. Generally, the value of benefits is based on estimates of individual willingness to pay for the risk reductions or other impacts. In contrast, cost-effectiveness analysis involves dividing regulatory costs by a nonmonetary benefit measure (e.g., number of lives saved or cases of illness avoided) to determine the unit costs of achieving the benefits. When regulations reduce the risk of incurring more than one type of illness or injury, analysts may apply integrated measures of effectiveness, variously referred to as health-adjusted life expectancy (HALE), quality-adjusted life year (QALY), or health-related quality of life (HRQL) measures.

In its 2003 guidance, OMB recognizes that, although cost-effectiveness analysis avoids some of the complex issues associated with assigning dollar values to benefits, it poses a number of other challenges. In particular, integrated measures of effectiveness may not fully reflect all of the factors that influence individual preferences for risk reductions. In addition, in a regulatory context there is substantial public concern regarding the perceived fairness of the analytic approach. From this perspective, measures that reflect population averages may be preferred to measures that appear to place a lower value on life years saved for persons with disabilities or others in imperfect health. Because different measures of effectiveness may yield varying results and provide different perspectives, OMB recommends that agencies apply more than one effectiveness measure in their analyses.

In response to these types of concerns, OMB chartered the IOM Committee whose work this report supports. Specifically, the OMB guidance states:

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations. (OMB 2003a, p. 13).

The recommendations of the IOM Committee are likely to have substantial impact well beyond the types of regulatory decisions explicitly addressed by the OMB guidance. Federal agencies often apply the OMB guidance to regulations that are not economically significant or not subject to OMB review. In addition, the guidance is an important source of information on “best practices” for regulatory analysts outside of the Federal government, including those working in State and local government, industry associations and public interest groups, and academia.

ES.2 General Approach to Regulatory Analysis

This report focuses on current practices for assessing the benefits of regulations that would have been subject to the *Circular A-4* requirements, had the regulations been promulgated after the requirements took effect.¹ It considers the practices of seven Federal agencies that finalized economically significant rules with quantified health and safety impacts between January 2000 and June 2004 and/or that are currently in the process of developing such rules. These agencies include: (1) the U.S. Environmental Protection Agency (EPA); (2) the Food and Drug Administration (FDA); (3) the Food Safety and Inspection Service (FSIS); (4) the Occupational Safety And Health Administration (OSHA); (5) the National Highway Traffic Safety Administration (NHTSA); (6) the Federal Motor Carrier Safety Administration (FMCSA); and, (7) the Consumer Product Safety Commission (CPSC).²

Under previous guidelines, the economic analyses supporting these rules generally contained two components: an analysis of national benefits and costs, and a separate analysis of the distribution of impacts across certain subgroups of concern. This distributional analysis must, at minimum, address statutory requirements for assessing the costs imposed on small businesses and state and local governments. Existing Executive Orders also require consideration of whether a rule has disproportionate adverse impacts on low income and minority groups or children. In some cases, agencies will also disaggregate the results of the national benefit-cost analysis and separately report the risk reductions for particularly vulnerable

¹The effective date for the new OMB requirements is no later than January 1, 2004 for proposed rules and January 1, 2005 for final rules; hence agencies are required to begin applying integrated effectiveness measures in advance of when the IOM Committee completes its work.

²CPSC’s rulemakings are not subject to OMB review, but it is included in this report because it is currently developing economically significant rules.

groups, such as sensitive subpopulations with pre-existing conditions, children, or the elderly. In previous years, some agencies have provided estimates of cost-effectiveness rather than, or in addition to, the estimates of national net benefits. Under the new OMB guidance, both benefit-cost and cost-effectiveness analyses are required for major health and safety rules along with any relevant distributional analyses.

Review of agency procedures suggests that these economic analyses of regulations are usually completed under tight timeframes with limited staff and budgetary resources. Analysts often must make many decisions about the analytic approach early in the rule development process, when they face substantial uncertainty regarding the regulatory requirements to be assessed, the overall schedule for the rulemaking, and the resources likely to be available for completing the analyses. The rulemaking schedule is usually too tight to allow time for new primary research on benefit values; analysts generally rely on pre-existing studies and analytic methods. All of these factors pose significant challenges to the analysts involved in assessing the impacts of individual regulations.

ES.3 Agency Approaches to Benefits Valuation

While the OMB guidance on regulatory analysis provides a general framework for assessing the impacts of regulations, it allows the agencies substantial leeway in determining the details of the approach to valuation for both benefit-cost analysis and cost-effectiveness analysis. For benefit-cost analysis, OMB recommends that agencies apply estimates of willingness to pay to the extent possible to value benefits. For premature mortality, OMB instructs agencies to apply “value of statistical life” estimates, which reflect individual willingness to pay for small changes in the risk of premature mortality throughout a large population. OMB discusses the possible range of value of statistical life estimates and allows agencies to apply the estimates that they deem most appropriate for their rules, leading to the use of differing estimates across agencies.

To value morbidity in benefit-cost analyses, OMB recommends that agencies apply estimates of individual willingness to pay supplemented by estimates of any net changes in economic costs to society that are not captured in the willingness to pay values. When willingness to pay estimates are not available, OMB notes that agencies may combine the results of health utility studies with relevant dollar values; i.e., apply monetized estimates of quality of life impacts. Hence the OMB guidance also allows for a range of approaches to valuing nonfatal health effects.

The new 2003 guidance represents the first time that OMB has required agencies to complete cost-effectiveness analysis along with benefit-cost analysis for economically significant health and safety rules. OMB discusses two general approaches that could be used to measure benefits in these cost-effectiveness analyses. Under the first approach, analysts would choose a primary benefit category to use as the effectiveness measure, then subtract the dollar value of other benefits from regulatory costs before calculating the cost-effectiveness ratio. For example, analysts could calculate cost per life saved after subtracting the value of morbidity improvements from the costs attributable to the rule. Under the second approach, analysts could use quality of life indices that convert different types of health impacts into a single metric,

which then becomes the divisor in the cost-effectiveness calculation. These metrics include the approaches that are the focus of this IOM Committee.

Each of the seven agencies considered in this report have developed somewhat different approaches to valuing health and safety impacts, and these practices are now evolving in response to OMB *Circular A-4* and other factors. To value premature mortality in benefit-cost analyses, all of the seven agencies are currently using the value of statistical life in some form in their analyses. However, the base values vary, ranging from roughly \$3 to \$7 million per statistical life. Some of these agencies adjust these base values to reflect the economic costs of illness or differences between the scenarios from which the estimates were derived and the regulatory scenario, such as income growth over time or the latency of the health impacts.

For nonfatal illnesses and injuries, each agency uses a slightly different approach in its benefit-cost analyses. EPA values morbidity based on willingness to pay estimates to the extent possible. When suitable willingness to pay estimates are not available, EPA relies instead on estimates of the costs of illness. OSHA has recently changed its approach, and is now using morbidity values developed by EPA for certain of its forthcoming rules. The remaining five agencies all use quality of life indices in some form when valuing nonfatal illnesses and injuries. The details of the approaches vary; however, each agency uses annualized value of statistical life estimates to monetize quality of life impacts. The quality of life impacts are estimated from existing studies or by using expert judgment to apply available indices to the health effects of concern. In addition, each agency adds the economic costs of illness to these monetized quality of life measures when estimating total benefits, although the types of costs considered vary across agencies.

Many of these agencies are in the process of developing methods for cost-effectiveness analysis to implement the new OMB guidelines. In particular:

- EPA is in the process of developing approaches that rely on the results of completed studies for the health effects of concern; e.g., transferring estimates of quality of life impacts from the Harvard Center for Risk Analysis' Catalog of Preference Scores.
- FDA already uses monetized quality of life measures in its benefit-cost analyses, and has started to report the results as both costs per QALY and net benefits. The FDA approach includes transferring estimates from the Harvard Catalog, using expert judgment to apply existing indices (e.g., the Quality of Well-Being Scale) to the health effects of concern, and calculating condition-specific QALY weights based on an approach developed by Cutler and Richardson. FSIS reports that it is considering approaches similar to those used by FDA.
- NHTSA currently conducts cost-effectiveness based on estimates of "equivalent lives saved," which represent the ratio of the dollar value of injuries (including monetized quality of life impacts and economic costs) to the dollar value of fatalities. NHTSA plans to continue to apply this approach, and to use the underlying values to calculate net benefits as well as cost-effectiveness ratios.

The remaining agencies' plans are uncertain.

In sum, the review of current practices across agencies suggests that there is significant variation in the approaches used to value health and safety-related benefits. Those agencies that currently use integrated measures of effectiveness in their analyses generally rely on estimates transferred from existing studies or use expert judgment to apply available quality of life indices to the health effects of concern.

ES.4 Types of Regulations and Health Outcomes Assessed

This report includes an inventory of all the economically significant health and safety regulations finalized between January 1, 2000 and June 30, 2004, focusing on those regulations that could be subject to cost-effectiveness analysis (i.e., that include quantitative assessment of both costs and health-related impacts (i.e., cases of injury or illness avoided). Over the time period covered, 18 such regulations were published. While few in number, the impact of these regulations are substantial, accounting for almost \$200 billion in monetized annual net benefits.

Of these 18 regulations, five were developed by EPA's Office of Air and Radiation and five were developed by FDA. The other agencies and EPA offices were responsible for one or two major health and safety regulations over this time period, except for CPSC, which did not finalize any economically significant rules. The impact of the EPA rules appears substantially greater than the impacts of all the other rules combined. The monetized net benefits of the EPA air rules were \$174 billion compared to roughly \$14 billion for all of the remaining rules.³ The difference in impact may be greater than indicated by these monetary estimates, because EPA reports a much larger range of nonquantified benefits than noted by the other agencies, including several types of ecological effects. However, care must be taken in interpreting these results because they reflect varying approaches to valuation and the resulting estimates are uncertain.

For the five EPA air rules, the health effects of concern include a number of respiratory and cardiovascular impacts. The other rules include five that address injuries related to vehicle crashes or workplace accidents, as well as three that address pathogen-related illnesses. The other five rules address a wide variety of health impacts ranging from lead-related IQ point losses to various cancers.

Review of the regulatory plans for these agencies indicates that they are in the process of proposing or finalizing several economically significant rules that are likely to include quantified health or safety impacts in the supporting analyses. For these rules, it appears that cardiovascular and respiratory conditions will continue to be a significant concern, as will pathogen-related illnesses and injuries stemming from different types of accidents. In addition, cancers and a broad range of other conditions will be addressed. Thus the new OMB guidelines for cost-effectiveness analysis, as well as the IOM Committee recommendations, are likely to be applied to a wide variety of health and safety impacts.

³This calculation excludes two NHTSA rules for which monetized estimates of benefits were not reported.

1.0 INTRODUCTION

The Institute of Medicine's (IOM's) Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation has been chartered by a consortium of Federal agencies to make recommendations related to the use of cost-effectiveness analysis in assessing the impacts of regulatory options. In particular, the Committee is charged with evaluating alternative effectiveness measures that allow analysts to combine consideration of morbidity and mortality across different health conditions, sometimes referred to as health-adjusted life expectancy measures.

This report supports the work of the Committee by providing background information on current practices as context for its efforts. It is not intended to be a comprehensive review of all Federal regulatory analyses nor of all the factors that influence regulatory decisions; rather, it focuses on illustrating the types of regulatory actions and analytic approaches that may be most significantly affected by the Committee's recommendations.

This introductory chapter provides more information on the context for this report as well as on the approach used to identify the agencies and rulemakings that it addresses. It is followed by several chapters that first describe government-wide guidance for the economic analysis of regulations, and then discuss the practices currently used by individual agencies. The final chapter summarizes these practices across agencies.

1.1 Background and Context

IOM's Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation was commissioned in response to revised guidance for the conduct of the economic analysis of regulations by Federal agencies. This guidance, issued in September 2003 by the U.S. Office of Management and Budget (OMB), is contained in OMB *Circular A-4* and substantially increases the emphasis on the use of cost-effectiveness analysis to evaluate regulatory impacts. Previous guidance focused on the use of benefit-cost analysis; now both cost-effectiveness and benefit-cost analysis are required for major health and safety rulemakings. In addition, agencies are required to assess certain distributional impacts of their rules under both the old and new guidance.

Benefit-cost analysis involves estimating the dollar value of benefits (e.g., improvements in human health), then subtracting regulatory costs (e.g., related to compliance) to determine the net benefits of regulatory options. Ideally, the value of benefits is based on estimates of willingness to pay (WTP) for the risk reductions or other impacts. In contrast, cost-effectiveness analysis involves dividing regulatory costs by a nonmonetary benefit measure (e.g., number of lives saved or cases of illness avoided) to determine the unit costs of achieving the benefits. When regulations reduce the risk of incurring more than one type of illness or injury, analysts may apply integrated measures of effectiveness, variously referred to as health-adjusted life expectancy (HALE), quality-adjusted life year (QALY), or health-related quality of life (HRQL) measures.

Specifically, the guidance contained in *Circular A-4* applies to regulations subject to OMB review and identified as economically significant under Executive Order 12866 (which is discussed in more detail later in this paper). OMB requires that agencies complete both benefit-cost and cost-effectiveness analyses for these rulemakings “whenever possible” (OMB 2003a, p. 9). In particular, OMB notes that cost-effectiveness analysis should be completed for “all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed...” (OMB 2003a, p. 9). Cost-effectiveness analysis also should be completed for other major rulemakings when “some of primary benefit categories cannot be expressed in monetary units” (OMB 2003a, p. 9).

In this guidance, OMB recognizes that, although cost-effectiveness analysis avoids some of the complex issues associated with assigning dollar values to benefits, it poses a number of other challenges. In particular, many, if not most, Federal regulations lead to more than one type of benefit, and it can be difficult to aggregate these benefits to form a single effectiveness measure by which costs can be divided. In some cases, analysts may be able to allocate costs to different outcomes (or benefit categories) and estimate separate cost-effectiveness measures. Alternatively, as discussed in the OMB guidance, analysts may choose a primary benefit category to use as the effectiveness measure, then subtract the dollar value of the other benefits from regulatory costs before calculating the cost-effectiveness ratio.

For example, if a regulation both reduces the incidence of lung cancer and increases visibility at national parks, the first approach would require allocating related costs to either the lung cancer reductions or the visibility improvements. The second approach could involve subtracting the dollar value of improved visibility from the regulatory costs, then dividing the remaining costs by the number of cases of lung cancer avoided. Whether either approach is possible will depend on the nature of the rulemaking and the extent to which the data needed for these calculations are available. The first approach may not be feasible because it is often difficult, if not impossible, to allocate costs across different beneficial outcomes. The second approach will be difficult to implement if defensible estimates of the value of the ancillary benefits are not available. In such cases, OMB indicates that analysts must clearly acknowledge that the cost-effectiveness ratio will be overstated.

Alternatively, in some cases analysts may be able to convert different types of benefits into a single metric, which then becomes the divisor in the cost-effectiveness calculation. Such metrics are well-established in the health economics literature, and researchers have developed a number of approaches that can be used to convert differing health effects into standardized measures of impact on the quality of life. In their simplest form, these approaches involve assigning index values (or condition weights) to the quality of life impacts for each health-related outcome, multiplying the weighted values by the duration of each condition, then adding the results together across conditions to create a single effectiveness measure.

The OMB guidance recognizes that such integrated measures of effectiveness may be quite useful in regulatory analysis, and recommends that analysts apply these types of measures whenever a rule significantly affects both mortality and morbidity. However, OMB suggests that analysts should be aware of the following issues and concerns.

- *Relationship of health state weights to individual preferences:* OMB indicates that these integrated measures “must meet some restrictive assumptions to represent a valid measure of individual preferences. For example, a QALY measure implicitly assumes that the fraction of remaining lifespan an individual would give up for an improvement in health-related quality of life does not depend on the remaining lifespan. ...To the extent that individual preferences deviate from these assumptions, analytic results from CEA [cost-effectiveness analysis] using QALYs could differ from analytic results based on willingness-to-pay measures.” (OMB 2003a, p. 12-13)
- *Incorporation of equity considerations:* In a regulatory context, there is substantial public concern regarding the perceived fairness of the analytic approach, and OMB recommends that agencies “should be prepared to make appropriate adjustments to ensure fair treatment of all segments of the population.” (OMB 2003a, p. 13)¹ For example, rather than apply approaches that appear to assign lower values to life years saved for persons with disabilities, OMB recommends that values be adjusted so that they reflect population averages. In other words, each year of life saved for persons with disabilities (or other subpopulations of concern, such as the ill or elderly) should be assigned the same value as a year of life saved for the general population.
- *Application of alternative HALE measures:* Because different measures of effectiveness may yield varying results and provide different perspectives, OMB recommends that agencies apply more than one effectiveness measure in their analyses. In addition, OMB instructs agencies to disclose the underlying data used in their calculations so that OMB and the public can, if desired, recalculate the results using alternate measures and compare the findings across different rulemakings.

In response to these types of concerns, OMB chartered the IOM Committee whose work this report supports. Specifically, the OMB guidance states:

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations. (OMB 2003a, p. 13).

¹Although not explicitly discussed by OMB, this recommendation is a departure from the traditional focus of benefit-cost analysis on assessing the economic efficiency of regulatory options. Many economists suggest that the equity or fairness of regulatory options should be addressed separately, because it involves different types of considerations and trade-offs which must ultimately be weighed by decision-makers. This separation between efficiency and equity has been difficult to maintain in practice (particularly in the case of regulations that reduce the risks of premature mortality) due to the public outcry over analytic approaches that appear to assign lower values to life years saved for persons who have disabilities, are in poor health, or are elderly.

When considering these issues, it is important to note that the OMB guidance has impact well beyond the types of regulations it explicitly covers. Federal agencies often apply the guidance to regulations that are not economically significant, and independent Federal agencies (not subject to OMB review) also tend to follow these guidelines. In addition, the guidance is an important source of information on “best practices” for analysts outside of the Federal government, including those working in State and local government, industry associations and public interest groups, and academia.

1.2 Contents of this Report

To provide context for the IOM Committee’s efforts, this report reviews the current practices of those Federal agencies that are most likely to be significantly affected by the Committee’s recommendations. The report focuses on seven agencies that have recently finalized major health and safety rulemakings and/or are in the process of developing such rulemakings, including the following.

1. U.S. Environmental Protection Agency (EPA)
2. Food and Drug Administration (FDA)
3. Food Safety and Inspection Service (FSIS)
4. Occupational Safety And Health Administration (OSHA)
5. National Highway Traffic Safety Administration (NHTSA)
6. Federal Motor Carrier Safety Administration (FMCSA)
7. Consumer Product Safety Commission (CPSC)²

For each of these agencies, this report discusses the characteristics of their recent and forthcoming rules and the supporting economic analyses, as well as their general approach to benefits valuation. The specific regulations described were identified through a review of all recent health and safety rulemakings, focusing on rulemakings that met three criteria.³ First, to reflect the Committee’s interest in understanding current analytic practices, the review focused on those social regulations published in final form in the *Federal Register* between January 1, 2000 and June 30, 2004.⁴ Second, the review considered regulations that would have been

²As discussed in Chapter 5, CPSC is an independent agency not subject to OMB review, and is included in this report as an example of an independent agency that is currently working on economically significant rules.

³OMB distinguishes between economically significant regulations that provide transfers (e.g., between taxpayers and program beneficiaries) and regulations with net social welfare impacts; i.e., “transfer” and “social” regulations. This report considers only regulations in the later category.

⁴Regulations finalized between January 1, 2000 and September 30, 2003 were identified from review of OMB’s annual reports on the costs and benefits of Federal regulations (OMB 2001b, p. 30 and Table 4; OMB 2002a, pp. 46-47 and Table 9; OMB 2003b, p. 6 and Table 4; OMB 2004, p. 3 and Table 4) More

subject to the new OMB guidance on cost-effectiveness analysis (i.e., economically significant health and safety rules) if that guidance had been in place before they were finalized.⁵ Third, the review considered only those regulations for which cost-effectiveness analysis using integrated HALE-type measures may be feasible; it excludes regulations for which costs could not be quantified and/or health-related physical impacts (e.g., the number of cases of illness or injury averted) could not be estimated. This lack of quantification may occur in cases where the cost or health and safety impacts are negligible or where the available data are not sufficient to support any sort of numerical analysis.

In addition, this report identifies forthcoming health and safety regulations that may be subject to the new OMB requirements for cost-effectiveness analysis. Review of agency regulatory plans and discussions with agency staff suggest that no additional agencies (other than the seven listed above) are likely to promulgate economically significant health and safety regulations with quantifiable health or safety impacts in the near term. However, this conclusion is somewhat uncertain, because it is not always clear from the planning documents whether health impacts are likely to be quantified and new legislation and other unforeseen factors often alter agency regulatory plans.

It is important to note that it is impossible to fully capture all of the characteristics of these complex (and often idiosyncratic) analyses in the type of brief overview contained in this report. Analytic practices are constantly evolving, and many agencies were in the process of implementing significant changes in their practices in response to OMB *Circular A-4* as this report was being developed. Hence the report does not reflect the full implementation of the new OMB requirements, and may not fully capture recent developments.

This report begins by summarizing (in Chapter 2) government-wide guidance on the conduct of regulatory analysis. The next three chapters are organized around regulations that are similar in intent and analytic approach, addressing environmental protection (Chapter 3), food and drug safety (Chapter 4), and traffic, worker, and product safety (Chapter 5). The report concludes by summarizing the results of the review across rulemakings and agencies (Chapter 6).

In discussing current practices for economic analyses, this report focuses largely on the approaches used to value health and safety benefits. It also provides a brief overview of other aspects of the analyses, such as the characteristics of the regulations and related legal authorities, the approaches used to estimate costs, issues related to discounting, requirements for consideration of special populations and distributional impacts, and concerns related to addressing nonquantifiable impacts and uncertainty. More information on these topics is available in the guidance documents, *Federal Register* notices, and regulatory analyses referenced in this report.

recent regulations were identified through online searches of *Federal Register* notices (www.gpoaccess.gov/fr/index.html) conducted in September 2004, as well as through discussions with the agency staff listed on the Acknowledgements page of this report.

⁵The effective date for the new OMB requirements is no later than January 1, 2004 for proposed rules and January 1, 2005 for final rules.

2.0 GOVERNMENT-WIDE GUIDANCE

Within the Executive Branch of the Federal government, the U.S. Office of Management and Budget (OMB) has primary responsibility for coordinating and reviewing the conduct of economic analyses of regulations across agencies. This chapter reviews the evolution of OMB's role, discusses Executive Order requirements for regulatory analysis, and summarizes the contents of recent guidance on conducting these analyses. Because many of the regulations discussed in this report were finalized under guidance published by OMB in March 2000, rather than the more recent guidance issued in September 2003, this chapter discusses the contents of both the 2000 and 2003 documents.

2.1 Evolution of OMB's Review Role

In its 1997 report on the costs and benefits of Federal regulations, OMB describes the evolution of the Federal regulatory program as well as related analytic and review requirements. OMB's discussion is summarized below, followed by a brief note on more recent developments.

The rapid expansion of Federal health, safety, and environmental regulations in the late 1960s and early 1970s led to increasing emphasis on evaluation. Initially, assessment efforts focused narrowly on particular types of impacts. In 1971, the Nixon Administration conducted a "Quality of Life Review" that concentrated solely on reducing the burden of environmental regulations on business. Under the Ford Administration, the focus shifted to inflation, leading to the issuance of Executive Order 11821 which required that government agencies prepare inflation impact statements. Ultimately, the members of Ford's Council on Wage and Price Stability (CWPS), who were responsible for reviewing these statements, concluded that a regulation would not be truly inflationary unless its social costs exceeded its benefits. As a result, benefit-cost analysis was required for major regulations; this requirement has persisted in modified form through today.

President Carter built on the Ford legacy, issuing Executive Order 12044, *Improving Government Regulations*, in 1978. This Executive Order both established general principles for regulatory development and required analysis of regulations with major economic impacts. President Carter also created the Regulatory Analysis Review Group and instructed it to examine selected significant regulations. These actions were supported by an U.S. Court of Appeals ruling in 1981 (in *Sierra Club v. Costle*) which found that the President was responsible for reviewing regulations issued by the agencies.

President Reagan then made regulatory relief a cornerstone of his economic program. He issued Executive Order 12291, *Federal Regulation*, in 1981, which substantially expanded the requirements for regulatory review and analysis. OMB notes that:

...the Reagan regulatory oversight program differed from the Carter Program in a number of important respects. First, it required that agencies not only prepare cost-benefit analyses for major rules, but also that they issue only regulations that maximize net benefits (social benefits minus social costs). Second, OMB, and within OMB the

Office of Information and Regulatory Affairs (OIRA), replaced CWPS as the agency responsible for centralized review. Third, agencies were required to send their proposed regulations and cost-benefit analyses in draft form to OMB for review before they were issued. Fourth, it required agencies to review their existing regulations to see which ones could be withdrawn or scaled back. Finally, President Reagan created The Task Force on Regulatory Relief, chaired by then-Vice President Bush, to oversee the process and serve as an appeal mechanism if the agencies disagreed with OMB's recommendations. Together these steps established a more formal and comprehensive centralized regulatory oversight program. (OMB 1997, p. 12)

President Reagan further strengthened this program in 1985 by issuing Executive Order 12498, *Regulatory Planning Process*, which required that agencies annually submit a detailed plan (or “Regulatory Agenda”) that discussed the major regulations they are developing. These Reagan initiatives were continued by the first President Bush, who also created a task force (the Competitiveness Council) to look for opportunities for regulatory relief.

In 1993, President Clinton issued Executive Order 12866, *Regulatory Planning and Review*, replacing Reagan’s Executive Orders 12291 and 12498. OMB indicates that this Executive Order:

... reaffirmed the legitimacy of centralized review but reestablished the primacy of the agencies in regulatory decision making. It retained the requirement for analysis of benefits and costs, quantified to the maximum extent possible, and the general principle that the benefits of intended regulations should justify the costs. In addition, while continuing the basic framework of regulatory review established in 1981, it made several changes in response to criticisms that had been voiced against the Reagan/Bush programs. (OMB 1997, p. 13).

These changes included focusing OMB's attention on the most significant rules, limiting OMB’s review to a 90-day period, establishing a mechanism for resolving disputes between OMB and the agencies, and providing more information to the public on the review process. President Bush has continued the process established under Executive Order 12866, amending it (under Executive Order 13258) only to change the roles and responsibilities of some of the individuals involved in regulatory review.

2.2 Executive Order 12866 Requirements

As introduced above, current government-wide requirements for regulatory economic analyses are based on Executive Order 12866, initially issued in 1993 by President Clinton. This Order sets out the basic principles for decision-making and establishes a process for ensuring that regulations meet these principles. The economic analysis required under the Executive Order is largely focused on the comparison of benefits and costs, although the Order also notes that regulations should be designed to meet their goals in a cost-effective manner.

The general regulatory philosophy supported by the Executive Order is expressed in its first section as follows:

Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach. (Executive Office of the President (EOP) 1993, p.1).

While the Executive Order establishes a number of requirements for regulatory planning and review, the requirements likely to be most relevant to the work of the IOM Committee are those that address regulatory analysis. Such analysis is required for those regulations identified as “economically significant regulatory actions” under Section 3(f)(1) of Executive Order 12866. These actions are defined as those for which the resulting rule is likely 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 (EOP 1993, p.4).

For economically significant rules, Section 6(a)(3)(C) of Executive Order 12866 requires agencies to assess the impacts of regulatory alternatives as follows, unless prohibited by law:

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable

nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives. (EOP 1993, p. 7).

Rules that are considered significant for other (non-economic) reasons are subject to less extensive analytic requirements. The Executive Order (under Sections 3(f)(1) and 3(f)(2)) defines these other significant rulemakings as those that lead to serious inconsistencies or conflicts between the policies of different agencies, or that substantially affect transfer programs (such as those providing grants or loans). In these cases, assessment of costs and benefits is required for the planned regulatory action, but not for alternatives, under Section on 6(a)(3)(B) of the Executive Order.

Whether a particular regulation is likely to be significant is jointly determined by the agency and OMB under Section 6(3)(A) of the Order. Agencies periodically provide OMB with lists of the rules they believe will be significant; OMB then reviews these lists and notifies the agencies if it believes that additional rules should be so designated. In addition, OMB may waive its review of significant rulemakings at its discretion.

As a result of these requirements, Federal regulatory agencies have developed varied approaches for assessing the costs and benefits of regulatory options. Although the analytic requirements under Executive Order 12866 apply specifically to significant regulations subject to OMB review (where not prohibited by law), such analyses are now often carried out for more minor rulemakings as well as by independent agencies such as the Consumer Product Safety Commission and the Nuclear Regulatory Commission.

2.3 March 2000 and Preceding OMB Guidelines

The comparison of benefits and costs required under Executive Order 12866 has led OMB to issue a series of guidance documents on the conduct of benefit-cost analysis. These documents generally provide both requirements that OMB expects agencies to follow and information on preferred practices. OMB recognizes that certain preferred or “best” practices may be difficult to implement for particular regulations due, for example, to limitations in the available research base. The details of the analytic approach are often negotiated between OMB and the individual agencies as part of OMB’s review of specific rulemakings under Executive Order 12866.

Prior to the publication of *Circular A-4* in September 2003, the OMB guidance documents paid relatively little attention to cost-effectiveness analysis, noting only that it can be useful in certain cases where benefits are difficult to value in monetary terms. Most of the analyses discussed in this report were conducted under this older guidance (generally under guidelines issued in March 2000), as described in more detail below.⁶

⁶Agencies were aware of the likely content of the 2003 guidance long before it was published due to their involvement in its development. However, the 2003 guidelines did not become effective until January 2004 for economically significant proposed rules, and until January 2005 for economically significant final rules (OMB 2003a).

The first major guidance document issued under Executive Order 12866 was published in January 1996 as the result of an extensive two-year effort by an interagency work group convened by OMB. This guidance describes best practices based on review of the state-of-the-art for economic analysis of regulations, replacing less detailed guidance previously published as part of the 1992 to 1993 *Regulatory Program of the United States Government* (OMB 1996). In response to new Congressional requirements for standardizing the measurement of benefits and costs, OMB then issued a modified, shorter version of these guidelines in March 2000.⁷ The Bush Administration affirmed its commitment to these guidelines (and to Executive Order 12866) in June 2001 (OMB 2001a); issuing updated guidelines in 2003.

The March 2000 guidelines are divided into two major sections. The first provides OMB's guidance for regulatory analysis; the second describes the standardized presentation of the results in the form of an accounting statement. Both sections, as well as the introduction, are organized around a series of questions as listed in Exhibit 1.

⁷In the March 2000 guidance, OMB notes that agencies can continue to refer to the more detailed 1996 best practices document as "supplementary material to illustrate further specific issues or techniques" although it was no longer considered official guidance (OMB 2000, p. 2).

Exhibit 1

**CONTENTS OF MARCH 2000
OMB GUIDELINES TO STANDARDIZE MEASURES OF COSTS AND BENEFITS
AND THE FORMAT OF ACCOUNTING STATEMENT**

Introduction

1. Why do we need to do Economic Analysis?
2. What are the major parts of an Economic Analysis?

Section I: Guidelines for the Analysis of Benefits and Costs of Major Final Rules

A. General Considerations

1. Is there a need for regulatory action?
2. What alternatives should I evaluate?
3. How do I choose a baseline?
4. What should I do with nonmonetized benefits and costs?
5. How do I take into account the timing of benefits and costs?

B. Benefit Estimates

1. What key concepts do I need to know to estimate benefits?
2. How should I value benefits directly traded in markets?
3. How should I value benefits that are indirectly traded in markets?
4. How should I value benefits that are not traded directly or indirectly in markets?
5. How should I account for health and safety benefits?

C. Cost Estimates

1. What key concepts do I need to know to estimate costs?
2. What is the difference between real costs and transfer payments?

D. Other Key Considerations

1. How do I treat risk and uncertainty?
2. How should I treat alternative assumptions?
3. How should I treat distributional effects and equity?
4. What should I assume about compliance?

Section II: Accounting Statement

1. How should we categorize benefits and costs?
2. Do we need to quantify and monetize whenever possible?
3. How do we deal with time and inflation?
4. How do we treat risk and uncertainty?
5. How do we reflect precision?
6. Do we report transfers separately?
7. What about effects on State, local, and tribal governments, small business, wages and economic growth?

Source: U.S. Office of Management and Budget (OMB). 2000. *Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements (Memorandum M-00-08)*.

The sections below first summarize key aspects of the general guidance, then provide more information on recommended practices for valuing health and safety-related benefits.

2.3.1 General Guidance

The March 2000 OMB guidelines indicate that an economic analysis of a regulation should be designed to provide information to decision-makers and the general public on the

potential benefits and costs to society of alternative regulatory and nonregulatory approaches for addressing particular problems. OMB emphasizes the need for transparency; i.e., for clear communication of the regulatory options and analytic steps, including information on important assumptions and the sensitivity of the results to these assumptions. OMB also notes that professional judgment plays an important role:

You will find that you cannot write a good regulatory analysis according to a formula. The preparation of high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analyses, depending on the importance and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to key assumptions. (OMB 2000, p. 2)

As discussed in the guidelines, regulatory analysis involves comparing various regulatory options to a baseline (sometimes referred to as the “no action” alternative), which represents current and potential future conditions in the absence of the regulation.⁸ OMB encourages agencies to consider a wide range of regulatory options that vary, for example, in terms of stringency and/or the nature of the requirements (e.g., providing information, creating market-based approaches, or establishing performance standards). When statutory language limits the consideration of desirable alternatives, OMB requires that the agency discuss these constraints and estimate their impacts.

In comparing regulatory options, OMB notes that the valuation of both costs and benefits should be based on the concept of “opportunity cost.” This concept recognizes that, because resources are limited, any decision to use them for one purpose means that they cannot be used for other purposes. Hence the value of a resource can be determined based on the value of its next best use.

The discussion of costs in the March 2000 guidance is relatively brief (the benefits guidance is described below). OMB notes that regulatory costs may include those related to private sector compliance with the regulations, government administration, discomfort or inconvenience, or loss of time. Costs may also include losses in consumer or producer surpluses.⁹

The guidance requires the use of discounting to reflect the timing of the impacts when costs and benefits accrue during different time periods or are distributed unevenly over time.¹⁰

⁸OMB recognizes that in some cases it will be desirable to present multiple baselines that differ, for example, in terms of assumptions regarding the future impact of other regulations or compliance with existing regulations.

⁹Consumers’ surplus refers to the difference between price and maximum WTP. At a given market price, some consumers will be able to purchase a good or service for less than they are willing to pay. Price increases reduce the difference between WTP and price, i.e., reduce consumer surplus, while price decreases have the opposite effect. Producers’ surplus is a similar concept applied to suppliers; for some units, the marginal costs of production will be less than the market price.

¹⁰For example, most individuals generally would prefer to receive money today rather than at a later date since they can invest it and earn interest. Discounting involves adjusting numerical values to account for these types of time preferences.

In addition to presenting information on the time periods within which undiscounted impacts are likely to occur, OMB recommends estimating the net present value of both benefits and costs using a seven percent discount rate. This rate represents the opportunity cost of capital; i.e., the real (net of inflation) before-tax rate of return on incremental private investment. OMB also encourages agencies to present sensitivity analyses using other discount rates, such as those representing the social rate of time preference (roughly three percent), sometimes referred to as the consumption rate.¹¹

Throughout the March 2000 guidance, OMB emphasizes the need to report the uncertainty associated with the estimates, noting that in this context the term “uncertainty” refers to incomplete knowledge regarding the likely outcomes. OMB recommends that the full probability distribution of the results be reported whenever possible, along with estimates of central tendency and upper and lower bounds. When it is not possible to estimate these probabilities, OMB suggests that the results be calculated using plausible alternative assumptions. OMB also stresses the importance of providing information on impacts that cannot be quantified or that can be quantified in physical terms (e.g., stream miles affected) but not assigned a dollar value.

In addition to estimating the total national impacts of the regulatory options, OMB notes that agencies should consider how these impacts are distributed across different segments of the population, including across generations. If the distribution of impacts is important in the context of a particular regulation, the analysis should report disaggregated results that indicate the effects of the regulation on different subgroups of concern. In this distributional analysis, OMB indicates that analysts should consider both the allocation of total social costs and benefits (included in the national benefit-cost analysis) and of impacts that represent transfers between different subgroups. OMB notes that it is important to present these results without judging their fairness, since in most cases there will be no general agreement on what constitutes an equitable distribution. It is then up to decision-makers to weigh these distributional impacts along with other policy considerations; the economic analysis is only one of several inputs into the regulatory decision-making process.

2.3.2 Benefits Valuation Guidance

A relatively lengthy section of the March 2000 OMB guidelines is devoted to describing the monetary valuation of benefits, including specific discussion of the valuation of morbidity and mortality impacts. In general, OMB notes that estimates of individual WTP are the appropriate measure of benefit values because (consistent with the concept of opportunity cost) such estimates reflect what members of society would be willing to give up to gain the benefits provided by the regulation.

For types of benefits that are directly bought and sold, OMB notes that market values can be used to estimate WTP. However, many benefits (including decreased health risks) are not directly traded in markets; in these cases stated preference studies (e.g., surveys) or revealed

¹¹The seven percent rate assumes that the economic impacts of the regulation will primarily affect investment, while the three percent rate assumes that the regulation will primarily affect consumption. As noted in the guidance, there is substantial debate regarding which assumption is most appropriate.

preference studies (based on related market goods) must be used to estimate their value. For example, in a stated preference study, survey researchers may ask individuals what they would be willing to pay for increased access to a public park. Alternatively, in a revealed preference study, analysts could estimate the value of such access based on the sale prices of homes at different distances from such a park, using statistical techniques to separate out other factors (such as the number of rooms) that also affect price.

For morbidity, OMB recommends that agencies use stated or revealed preference studies to estimate WTP for the risk reductions of concern. If well-conducted WTP studies are not available, OMB indicates that estimates of avoided direct costs (i.e., costs of illness or COI) can be used for valuation. However, such cost estimates are likely to understate the true value of related benefits.

For premature mortality, OMB also recommends that agencies apply estimates of WTP, generally referred to as the “value of statistical life” (VSL). OMB notes that this term is often misunderstood; VSL estimates reflect individual WTP for small changes in the risk of premature mortality, not the value placed on saving a particular person’s life. The guidance recognizes that these values are an area of active research and debate. Rather than requiring that all agencies follow a single approach for valuing premature mortality, OMB discusses the range of estimates recently used by different agencies and allows agencies to apply the approach that they deem most appropriate. OMB indicates that some agencies use estimates of the value of a statistical life year (VSLY), but cautions that the number of years of life extension is only one of the many dimensions of the risk reduction that should be considered.

2.4 September 2003 OMB Guidelines

In September 2003, OMB issued *Circular A-4, Regulatory Analysis*, replacing the preceding guidance. This Circular was finalized after extensive public comment, interagency review, and peer review by independent experts. While agencies are urged to comply with its provisions as soon as possible, *Circular A-4* becomes fully effective in January 2004 for proposed rules and in January 2005 for final rules.

Circular A-4 includes a number of similarities to the earlier guidelines both in terms of the overall framework and the contents of some individual sections. However, it provides substantially more detailed information on the criteria for identifying high quality analyses, imposes some new requirements, and alters the details of some of the pre-existing guidance. Chief among the new requirements are those related to the use of cost-effectiveness analysis, as introduced in Section 1.1 of this paper. The *Circular* notes:

We expect you to provide a benefit-cost analysis of major health and safety rulemakings in addition to a CEA [cost-effectiveness analysis]. The BCA [benefit-cost analysis] provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some

different strengths and drawbacks, it is important that you provide decision makers with both perspectives. (OMB 2003a, p. 28)

In addition to helping analysts in “defining good regulatory analysis,” *Circular A-4* is intended to help in “standardizing the way benefits and costs of Federal regulatory actions are measured and reported.” (OMB 2003a, p. 1). It is divided into several sections as listed below.

Exhibit 2	
CONTENTS OF SEPTEMBER 2003	
OMB CIRCULAR A-4, REGULATORY ANALYSIS	
A.	<i>Introduction</i>
	1. The need for analysis of proposed regulatory actions
	2. Key elements of a regulatory analysis
B.	<i>The Need for Federal Regulatory Action</i>
	1. Market failure or other social purpose
	2. Showing that regulation at the federal level is the best way to solve the problem
	3. The presumption against economic regulation
C.	<i>Alternative Regulatory Approaches</i>
	1. Different choices defined by statute
	2. Different compliance dates
	3. Different enforcement methods
	4. Different degrees of stringency
	5. Different requirements for different sized firms
	6. Different requirements for different geographic regions
	7. Performance standards rather than design standards
	8. Market-oriented approaches rather than direct controls
	9. Informational measures rather than regulation
D.	<i>Analytical Approaches</i>
	1. Benefit-cost analysis
	2. Cost-effectiveness analysis
	3. The effectiveness metric for public health and safety rulemakings
	4. Distributional effects
E.	<i>Identifying and Measuring Benefits and Costs</i>
	1. General issues
	2. Developing benefit and cost estimates
	3. Discount rates
	4. Other key considerations
	5. Treatment of uncertainty
F.	<i>Specialized Analytical Requirements</i>
	1. Impact on small businesses and other small entities
	2. Analysis of unfunded mandates
	3. Information collection, paperwork, and recordkeeping burdens
	4. Information quality guidelines
	5. Environmental impact statements
	6. Impacts on children
	7. Energy impacts
G.	<i>Accounting Statement</i>
	1. Categories of benefits and costs
	2. Quantifying and monetizing benefits and costs
	3. Qualitative benefits and costs
	4. Treatment of benefits and costs over time
	5. Treatment of risk and uncertainty
	6. Precision of estimates
	7. Separate reporting of transfers
	8. Effects on state, local, and tribal governments, small business, wages and economic growth
H.	<i>Effective Date</i>

Source: U.S. Office of Management and Budget (OMB). 2003. *Circular A-4, Regulatory Analysis*.

The following sections first briefly summarize the general contents of the 2003 guidance (focusing on the changes from the March 2000 guidance as described above) then discuss the valuation of health and safety benefits in more detail.

2.4.1 General Guidance

Similar to the March 2000 guidance, *Circular A-4* emphasizes the need for transparency as well as the role of professional judgment in determining the focus of the economic analyses of regulations. The *Circular* discusses information quality standards in more detail, instructing agencies that they “should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available. To achieve this, you should rely on peer-reviewed literature, where available, and provide the source for all original information” (OMB 2003a, p. 17) OMB also references the need to comply with new data quality guidelines prepared by OMB and the individual agencies (see OMB 2002b).

As did the preceding guidelines, *Circular A-4* discusses the comparison of regulatory options to a baseline or “no action” alternative and encourages the consideration of a range of regulatory and nonregulatory approaches. The *Circular* also retains the requirement that agencies should evaluate the impact of statutory limitations on the consideration of desirable alternatives.

In the *Circular*, OMB generally indicates that the assessment of costs should follow the same guidance as the assessment of benefits, and identifies relatively few issues that only impact the cost side of the analysis. OMB notes that the analysis should address both costs and savings related to private sector compliance and government administration, as well as changes in consumer or producer surpluses, discomfort or inconvenience, and time spent in work, leisure, commuting or travel. OMB also discusses the need to consider how changes in technology or innovation may affect both the baseline and the impacts of the regulations over time.

For benefit-cost analysis, OMB notes that countervailing costs and benefits can be included in either the “cost” or “benefit” side of the analysis (as long as they are not double-counted) since the end result is the calculation of net benefits (benefits minus costs). However, for cost-effectiveness analysis, which involves the calculation of a ratio, the appropriate categorization of benefits and costs requires more attention. In constructing the cost-effectiveness ratio, OMB notes:

With regard to measuring costs, you should be sure to include all the relevant costs to society - whether public or private. Rulemakings may also yield cost savings (e.g., energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred to comply with the requirements (sometimes called “total” costs) minus any cost savings. You should be careful to avoid double-counting effects in both the numerator and the denominator of the cost-effectiveness ratios. (OMB 2003a, pp. 11-12)

Circular A-4 requires discounting of both costs and benefits at seven and three percent (representing investment and consumption rates respectively) as well as presentation of the undiscounted results, rather than continuing to suggest that the three percent rate be applied in sensitivity analysis. OMB notes that benefits should be discounted regardless of whether they are presented in dollar terms or as physical or quality of life impacts. OMB also indicates that that time delays in achieving health-related benefits (e.g., latency periods or cessation lags) should be taken into account when performing this discounting. The *Circular* discusses cases where other discount rates may be considered, and includes information on discounting intergenerational effects.

The *Circular* includes substantially expanded discussion of uncertainty. OMB notes that analysts should, as relevant, qualitatively discuss the main uncertainties in the calculations, use sensitivity analysis to assess the effects of changes in the approach on the resulting estimates, and develop formal probabilistic analysis of uncertainty using simulation models and/or expert judgment. Such formal probabilistic analysis is now required for all rules with impacts that exceed \$1 billion annually. As in the earlier guidance, OMB also emphasizes the importance of providing information on impacts that cannot be quantified or that can be quantified in physical terms but not assigned a monetary value.

The *Circular* discusses the interpretation of the results of both benefit-cost and cost-effectiveness analysis, including the importance of considering nonquantifiable impacts. In the case of cost-effectiveness analysis, OMB notes that ratios based on averages can be misleading, and that instead analysts “should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements.” (OMB 2003a, p. 11)

Similar to the preceding guidance, *Circular A-4* indicates that agencies should consider the distribution of impacts across different segments of the population (including both transfers and total social costs and benefits), and quantify important distributional effects whenever possible. The *Circular* defines distributional effects as “the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography).” (OMB 2003a, p. 14). It also notes that regulatory analyses “should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency.” (OMB 2003a, p.14) The *Circular* also briefly summarizes the requirements of several statutes and Executive Orders that mandate analyses of certain types of impacts (e.g., on energy use), including distributional effects (e.g., on small business or children).

2.4.2 Benefits Valuation Guidance

Circular A-4 provides guidance on the valuation of benefits in the context of both cost-effectiveness and benefit-cost analysis. Some of this guidance was summarized earlier in this report; Section 1.1 discusses OMB’s guidelines on the use of integrative measures (such as HALE, QALY, or HRQL-type approaches) in cost-effectiveness analysis. This section

summarizes the guidance on the dollar valuation of benefits for benefit-cost analysis as well as the more general guidance that applies in both a cost-effectiveness and benefit-cost context.

Similar to its predecessors, the most recent guidance devotes significant portion of its contents to the valuation of benefits. *Circular A-4* includes substantially more discussion of the criteria that agencies should apply in evaluating related data, however, addressing issues related to the use of market values as well as revealed and stated preference studies. It also provides new guidance on methods for transferring benefits from available studies to the policy context. In addition, OMB discusses the appropriate consideration of ancillary (indirect) benefits and countervailing risks, as well as the treatment of impacts that cannot be quantified or monetized.

In *Circular A-4*, OMB revises the guidance on assigning dollar values to morbidity impacts, suggesting that these values include both: “(1) the private demand for prevention of the nonfatal health effect, to be represented by the preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production that are not experienced by the target population.” (OMB 2003a, pp. 28-29). The first component can be estimated from revealed or stated preference studies, whereas the second component can be derived from a variety of published sources that report health-related expenditures. OMB notes that if suitable WTP studies are not available, agencies may combine health utility studies “typically...based on the standard gamble, the time tradeoff or the rating scale methods...with known monetary values for well-defined health states...to estimate monetary values.” (OMB 2003a, p. 29)

For premature mortality, the *Circular A-4* guidance is similar to the March 2000 guidance with some additions. OMB again notes the confusion over the meaning of the term “value of statistical life” as well as the on-going research and debate surrounding estimation of these values, and continues to allow agencies to use the approach that they deem most appropriate. In the *Circular*, OMB adds discussion of possible VSL adjustments for income growth over time and for the time lag between exposure and occurrence of adverse health impacts, but indicates that it is inappropriate to make adjustments for the age of the affected population given the mixed results of the available empirical studies.

While recognizing that at times analysts may prefer to use VS LY estimates to better reflect remaining life-expectancy, OMB suggests that agencies provide both VSL and VS LY estimates and cautions them about potential problems with the latter approach. OMB also notes that “when you present estimates based on the VS LY method, you should adopt a larger VS LY estimate for senior citizens because senior citizens face larger overall health risks from all causes and they may have accumulated savings to spend on their health and safety.” (OMB 2003a, p. 30)

Circular A-4 also adds specific guidance on valuing health risks to children. OMB indicates that:

Where the primary objective of a rule is to reduce the risk of injury, disease or mortality among children, you should conduct a cost-effectiveness analysis of the rule. You may also develop a benefit-cost analysis to the extent that valid monetary values can be

assigned to the primary expected health outcomes. For rules where health gains are expected among both children and adults and you decide to perform a benefit-cost analysis, the monetary values for children should be at least as large as the values for adults (for the same probabilities and outcomes) unless there is specific and compelling evidence to suggest otherwise. (OMB 2003a, p. 31)

The *Circular* also reminds analysts that special attention to disproportionate adverse impacts on children is required under Executive Order 13045, *Protection of Children from Environmental Health Risks and Safety Risks*, which was issued by President Clinton in 1997.

Circular A-4 provides detailed information on the use of stated preference and other methods for valuing benefits, noting in particular that the criteria for evaluating stated preference studies also apply to the health utility studies used in cost-effectiveness analysis. While some of these criteria (listed in Exhibit 3) refer specifically to monetization, most appear relevant to both types of research.

Exhibit 3
OMB CRITERIA FOR EVALUATING STATED PREFERENCE STUDIES
<p>“When you are designing or evaluating a stated-preference study, the following principles should be considered:</p> <ul style="list-style-type: none">• the good or service being evaluated should be explained to the respondent in a clear, complete and objective fashion, and the survey instrument should be pre-tested;• willingness-to-pay questions should be designed to focus the respondent on the reality of budgetary limitations and alerted to the availability of substitute goods and alternative expenditure options;• the survey instrument should be designed to probe beyond general attitudes (e.g., a "warm glow" effect for a particular use or non-use value) and focus on the magnitude of the respondent's economic valuation;• the analytic results should be consistent with economic theory using both "internal" (within respondent) and "external" (between respondent) scope tests such as the willingness to pay is larger (smaller) when more (less) of a good is provided;• the subjects being interviewed should be selected/sampled in a statistically appropriate manner. The sample frame should adequately cover the target population. The sample should be drawn using probability methods in order to generalize the results to the target population;• response rates should be as high as reasonably possible. Best survey practices should be followed to achieve high response rates. Low response rates increase the potential for bias and raise concerns about the generalizability of the results. If response rates are not adequate, you should conduct an analysis of non-response bias or further study. Caution should be used in assessing the representativeness of the sample based solely on demographic profiles. Statistical adjustments to reduce non-response bias should be undertaken whenever feasible and appropriate;• the mode of administration of surveys (in-person, phone, mail, computer, internet or multiple modes) should be appropriate in light of the nature of the questions being posed to respondents and the length and complexity of the instrument;• documentation should be provided about the target population, the sampling frame used and its coverage of the target population, the design of the sample including any stratification or clustering, the cumulative response rate (including response rate at each stage of selection if applicable); the item non-response rate for critical questions; the exact wording and sequence of questions and other information provided to respondents; and the training of interviewers and techniques they employed (as appropriate);• the statistical and econometric methods used to analyze the collected data should be transparent, well suited for the analysis, and applied with rigor and care.”
Source: Extract from U.S. Office of Management and Budget (OMB). 2003. <i>Circular A-4, Regulatory Analysis</i> , p. 23.

OMB notes that expert judgment is needed in applying these criteria to determine whether a study is suitable for use in regulatory analysis:

Professional judgment is necessary to apply these criteria to one or more studies, and thus there is no mechanical formula that can be used to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used despite having weaknesses on one or more of these criteria, those weaknesses should be acknowledged in the regulatory analysis, including any resulting biases or uncertainties that are likely to result. If a study has too many weaknesses with unknown consequences for the quality of the data, the study should not be used. (OMB 2003a, p. 23)

In a subsequent section of the *Circular*, OMB discusses the use of benefit transfer; i.e., the practice of taking estimates from a study context and applying them to the somewhat different context of a rulemaking. OMB notes that:

Although benefit-transfer can provide a quick, low-cost approach for obtaining desired monetary values, the methods are often associated with uncertainties and potential biases of unknown magnitude. It should therefore be treated as a last-resort option and not used without explicit justification. (OMB 2003a, p. 24)

The *Circular* describes the steps analysts should follow in conducting such transfers as well as the criteria for selecting studies. These criteria address the quality of the study and its suitability for the regulatory context; e.g., the adequacy of the data and analytic methods, as well as the similarities of the affected populations, the nature of the good (or health condition), and the magnitude of the change.

2.5 Comparison of 2000 and 2003 Guidance

As discussed above, the 2003 OMB guidance contained in *Circular A-4* is substantially more detailed than the 2000 guidance, although both cover a number of similar topics. Much of the additional length of the 2003 guidance is devoted to providing more information on the concepts discussed as well as explicit criteria for identifying good analyses. Some of the key recommendations of the two sets of guidance are summarized below.

Exhibit 4		
COMPARISON OF MARCH 2000 AND SEPTEMBER 2003 OMB GUIDELINES		
Component	2000 Guidance	2003 Guidance
Type of analysis	Primarily benefit-cost analysis	Both benefit-cost and cost-effectiveness analysis
Monetary valuation of morbidity	Prefer estimates of willingness to pay from stated or revealed preference studies, may use direct costs of illness	Prefer estimates of willingness to pay from stated or revealed preference studies plus any additional economic costs of illness, may use health utility studies
Monetary valuation of mortality	Agency discretion in selecting value of statistical life estimates, caution on use of value of statistical life year	Agency discretion in selecting value of statistical life estimates, may adjust for income growth or time lag but not age, caution on use of value of statistical life year
Effectiveness measures for health and safety	Not discussed in detail	Use integrated measures that combine consideration of morbidity and mortality where appropriate
Effects on children and the elderly	Not discussed in detail	Avoid measures that place lower values on benefits accruing to these subpopulations
Cost estimates	Include costs related to private sector compliance, government administration, losses in consumers' or producers' surplus, discomfort or inconvenience, or loss of time.	Include costs and savings related to private sector compliance, government administration, losses in consumers' or producers' surplus, discomfort or inconvenience, or loss of time in work, leisure, commuting or travel.
Discounting	Present costs and benefits undiscounted and discounted at 7 percent, may apply other rates in sensitivity analysis	Present costs and benefits undiscounted and discounted at both 3 and 7 percent, includes criteria for considering other rates
Uncertainty analysis	Present full probability distribution if possible, if not, present sensitivity analysis	Discuss qualitatively, present sensitivity analysis, and complete probabilistic analysis as appropriate. Probabilistic analysis required if impact is greater than \$1 billion annually
Nonquantified or nonmonetized effects	Highlight in presentation of impacts	Highlight in presentation of impacts
Distributional impacts	Quantify impact on different segments of the population when important, including both transfers and total social costs and benefits	Quantify impact on different segments of the population when important, including both transfers and total social costs and benefits
Sources: U.S. Office of Management and Budget (OMB). 2000. <i>Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements (Memorandum M-00-08)</i> ; U.S. Office of Management and Budget (OMB). 2003. <i>Circular A-4, Regulatory Analysis</i> .		

As indicated by this comparison, many features of the economic analyses completed before the guidance was issued are likely to be retained in more recent studies. The major difference is the requirements for cost-effectiveness analysis. As indicated by the discussion of current practices in the following chapters, agencies differ in terms of their historical use of cost-effectiveness analysis as well as in how they have implemented OMB's guidance on cost-benefit analysis in recent rules.

3.0 ENVIRONMENTAL PROTECTION

Federal responsibility for environmental protection is spread across several agencies; however, the U.S. Environmental Protection Agency (EPA) is the chief agency involved in developing related regulations. Review of recent major rules indicates that EPA is the only agency that has promulgated environmental protection regulations with quantified health impacts in recent years. Therefore, this chapter focuses on EPA practices for the economic analysis of regulations.

EPA was established in 1970 with the mission of protecting human health and the environment, focusing largely on the prevention and control of pollution.¹² To achieve this mission, EPA develops and enforces regulations, sponsors voluntary efforts, conducts research, and supports education. Regulatory development is largely the responsibility of four program offices: the Office of Air and Radiation, the Office of Water, the Office of Solid Waste and Emergency Response, and the Office of Prevention, Pesticides, and Toxic Substances. In addition, several other offices have cross-program responsibilities for related activities such as legal counsel, research, and methods development.

Under the leadership of EPA's National Center for Environmental Economics, the Agency published detailed guidelines for the conduct of regulatory analysis in September 2000. EPA is now updating these guidelines, in part to include more detailed guidance on cost-effectiveness analysis consistent with the new requirements of the U.S. Office of Management and Budget (OMB) *Circular A-4*. The contents of EPA's guidelines have been significantly influenced by research undertaken to support its retrospective and prospective studies of the costs and benefits of the Clean Air Act. While these studies address a complete statutory program, rather than the selection of regulatory options, they have acted as a catalyst for the development of analytic methods that are useful in a number of other contexts. Most recently, the analytical plan for the next Clean Air Act study included a proposal for conducting a quality adjusted life year (QALY)-based cost-effectiveness analysis, which was reviewed by a panel of independent experts convened by EPA to guide these studies.

EPA regulations represent a significant share of all major health and safety rules subject to OMB review, both in terms of the number of rules and the dollar value of the impacts. Most of these rules address air pollution; a few address other types of contamination.¹³ The following sections first provide an overview of the EPA process for developing regulations, then discuss the general EPA guidance on benefit-cost analysis as well as the Clean Air Act studies, next describe the analytic approaches applied in recent major rulemakings, and finally provide information on the types of health impacts likely to be assessed in forthcoming rules.

¹²General information about EPA is taken from: <http://www.epa.gov/epahome/aboutepa.htm>, as viewed September 2004.

¹³EPA has also promulgated several major rules that primarily affect the environment and do not include quantified health impacts; rules without quantified health or safety impacts are excluded from this discussion.

3.1 Regulatory Development Process

The EPA program offices generally lead the regulatory development process and oversee the completion of supporting analyses. Staff from other offices are members of the Agency work group for each regulation and are often involved in developing the supporting analyses as well as in reviewing the results. Each program office has a slightly different organizational structure, but generally employs a small number of economists who oversee their economic analyses. An individual economist is likely to be involved in several on-going rulemakings at any given time, and generally receives contractor support.¹⁴

It is hard to estimate the dollar costs or level of effort devoted to the economic analyses for individual regulations because the staff involved generally split their time across a number of different activities. These activities may include the analyses for a number of proposed and final rules and involve work on both the economically significant rules that are the focus of this report and less significant rulemakings. In addition, it is often difficult to separate activities that support other aspects of the rulemaking process from the activities that support the economic analyses. Some tasks serve multiple purposes and related contracts often include efforts that are not directly related to the economic assessments. For instance, review of pollution control technologies may be needed both to support the economic analysis of costs and to determine the level of control that is technically feasible, and data collection or methods development projects may address more than one rulemaking.

For example, EPA's Office of Air and Radiation, which is responsible for a substantial fraction of all the major Federal health and safety rules promulgated in recent years, employs roughly 20 economists who work on regulatory analyses.¹⁵ Each of these economists is usually involved in multiple analyses as well as methods development projects at any given point in time. Different economists often are responsible for different components of the analyses; the analyses of human health benefits, ecological and nonquantified benefits, and cost and economic impacts may each involve one or two economists for each rule. This Office is investing heavily in the development of data and tools (including complex computerized models) that can be used across different regulatory analyses, and as a result is decreasing its reliance on contractor support. Most of its resources are devoted to modeling air quality and emissions changes.

A significant proportion of the work on developing the analytic approach for an individual rulemaking often occurs before the rule is proposed. This analysis may then be adapted to reflect new information as well as any changes made in the final rule, but often relies on much of the same data and models as the proposal. EPA's ability to make changes in the final analysis is somewhat constrained by the need to meet requirements for public comment as well as by the time and resources available. Under the Administrative Procedure Act, the final rule must be based on information previously made public by EPA or provided to the rulemaking docket by public commenters. Any other significant new information considered by EPA generally must be publicized in a Federal Register Notice of Data Availability, which can delay

¹⁴This discussion is based on my own 14 years of experience as an EPA consultant as well as information provided by the Agency staff listed in the Acknowledgments for this report.

¹⁵Personal communication from Bryan Hubbell, Office of Air and Radiation, EPA, October 20, 2004.

the rulemaking process. Thus EPA often makes many of the major analytic decisions affecting the final rule while the proposed rule is being developed, sometimes before many of the regulatory requirements and options to be considered are fully specified.

Once the rulemaking process is initiated, EPA rarely has the time or resources to engage in new primary research on benefit values, and generally relies on pre-existing studies (including EPA-funded research as discussed in Section 3.2).¹⁶ The length of time that elapses between initiation of the rulemaking process and publication of a proposed rule is often constrained by statutory requirements, court orders, and/or political pressures, and varies significantly from rule to rule. The economic analysis generally must be largely completed several months in advance of the rule publication date, since it is needed to brief upper level EPA management as well as for OMB review.

The time available for the economic analysis, the budgetary resources, and the types of regulatory options considered can change substantially over the course of the rule development process due to legislative or judicial action, changes in EPA or Administration priorities, or responses to preliminary analytic results. Budgetary resources are often constrained by Congressional action that reduces EPA funding significantly from prior year levels, either in total or by shifting resources from on-going functions to new activities (such as homeland security).

3.2 General Analytic Approach

EPA first issued formal guidelines for the preparation of regulatory impact analyses in 1983 in response to Executive Order 12291 (the predecessor to the current Executive Order 12866). EPA then amended these guidelines and added new appendices in 1991. Beginning in 1996, the Agency undertook a major effort to update and revise its guidance, finalizing its *Guidelines for Preparing Economic Analyses* in September 2000 after extensive internal and external review (EPA 2000a). The result was a book-sized document, over 200 pages in length, with substantially more detailed information than either the 2000 or 2003 OMB guidelines (which are 21 and 48 pages long respectively).

EPA's September 2000 *Guidelines* generally follow the same framework as did the OMB guidelines in place at the time. EPA places a similar emphasis on applying best practices consistent with the theory underlying welfare economics, using informed professional judgment to appropriately design and implement the analysis, and ensuring that the analytic methods, results, and effects of uncertainty are clearly communicated. In general, given the limited resources available for regulatory analysis, EPA encourages analysts to focus their efforts on those impacts that are expected to be significant enough to affect the selection of regulatory options.

As indicated by the table of contents summarized in Exhibit 5, EPA's *Guidelines* generally cover the same topics as the OMB guidelines. However, while EPA's basic approach to each analytic component is similar to the approach recommended by OMB in March 2000,

¹⁶Federally-funded survey research must be cleared through OMB under the Paperwork Reduction Act, which substantially increases the amount of time needed to complete such projects.

EPA provides substantially more information on the underlying concepts as well as on the types of data and mathematical models that may be useful.

Exhibit 5 CONTENTS OF SEPTEMBER 2000 EPA GUIDELINES FOR PREPARING ECONOMIC ANALYSIS
<ol style="list-style-type: none">1. Introduction2. Statutory and Executive Order Requirements for Conducting Economic Analyses3. Statement of Need for the Proposal4. Regulatory and Non-Regulatory Approaches to Consider5. Overview of Economic Analysis of Environmental Policy6. Analysis of Social Discounting7. Analyzing Benefits8. Analyzing Social Costs9. Distributional Analysis: Economic Impact Analysis and Equity Assessments10. Using Economic Analysis in Decision-Making
Source: U.S. Environmental Protection Agency (EPA). 2000. <i>Guidelines for Preparing Economic Analyses</i> . EPA 240-R-00-003.

For example, OMB's discussion of regulatory costs is very brief, while EPA includes extensive description of the options for estimating costs based on an understanding of the supply and demand conditions in affected markets. EPA also includes more detailed discussion of the studies it uses to value premature mortality, describes a number of considerations related to the valuation of morbidity using willingness to pay (WTP) or cost of illness (COI) estimates, and provides guidance on using benefits transfer techniques. Other topics, including discounting, uncertainty analysis, and distributional assessment also receive in-depth treatment.

As did the preceding OMB guidance, EPA's September 2000 *Guidelines* primarily consider the conduct of benefit-cost analysis, discussing cost-effectiveness analysis only briefly as an approach that can be useful when benefit values cannot be monetized. EPA also notes that cost-effectiveness analysis may be appropriate when all the regulatory options must meet an identical, specified objective (e.g., to reduce emissions of a contaminant by a certain amount) and the policy choice is constrained to determining which option most effectively meets that objective. EPA is now developing new guidance on cost-effectiveness analysis as part of its efforts to update its *Guidelines*.¹⁷

EPA's guidance is based on several data collection and methods development projects conducted by internal staff as well as through contracts and grants issued by its program offices, its National Center for Environmental Economics, and its Office of Research and Development. This research is on-going, and often conducted independently of individual rulemaking processes. EPA's current research plans are summarized in its draft Environmental Economics Research Strategy, which sets priorities based on the identified needs of the individual offices and was recently reviewed by the Environmental Economics Advisory Committee (EEAC) of

¹⁷Personal communication from Chris Dockins and Nathalie Simon, National Center for Environmental Economics, EPA, July 1, 2004.

EPA's Science Advisory Board (EPA 2003b, EEAC 2004b). This plan addresses a number of issues related to the valuation of premature mortality and morbidity, such as the need to better understand the relationship of available value of statistical life estimates to differences in population and risk characteristics and to develop WTP estimates for a broader range of nonfatal effects.

EPA's retrospective and prospective studies of the costs and benefits of the Clean Air Act have had a major influence on the contents of the EPA *Guidelines* (EPA 1997, 1999). Required by Section 812 of the 1990 Clean Air Act Amendments, these periodic reports have provided an opportunity for the Agency to research and develop analytic methods without the severe time pressures and other constraints commonly associated with regulatory development. These analyses have been subject to on-going independent peer review and extensive public scrutiny.

Two aspects of the EPA *Guidelines* and Clean Air Act analysis deserve particular attention in the context of this report. First, the approach used by EPA to value premature mortality is very similar to the approach used by a number of other agencies. Second, EPA's planning for the next Clean Air Act prospective analysis includes recommendations relevant to the charter of the IOM Committee for whom this report was prepared. These topics are discussed in more detail below.

3.2.1 Valuation of Fatal Risk Reductions

The types of fatalities addressed by EPA regulations generally involve small reductions in the risks of premature mortality associated with cancers and other illnesses. As introduced in the discussion of the OMB guidance (Section 2.3 above), the monetary value of these risk changes is generally referred to as the "value of statistical life" (VSL). A statistical life is the aggregation, across a population, of small reductions in the risk of premature death. Estimates of WTP for these individual reductions are then summed across the affected population to determine the value of a statistical life saved (or premature death avoided) by a regulation. For example, if members of a population of 100,000 are each willing to pay \$50 on average for a 1/100,000 risk reduction, the corresponding value of a statistical life would be \$5 million (i.e., $\$50 * 100,000$).

EPA developed its initial approach for valuing premature mortality in the early 1990s to support its retrospective analysis of the costs and benefits of the Clean Air Act (EPA 1997). EPA began by reviewing several evaluations of existing VSL studies, ultimately relying largely on studies identified by W. Kip Viscusi (Viscusi 1992, 1993). As the result of these efforts, EPA identified 26 VSL estimates suitable for use in environmental policy analysis; 21 from wage-risk studies and five from contingent valuation studies.¹⁸ In 1990 dollars, the best estimates from each of these studies ranged from \$0.6 million to \$13.5 million, with a mean value of \$4.8

¹⁸Wage-risk studies are a revealed preference method that uses labor market data to establish the relationship between wages and the risk of on-the-job fatalities across a broad spectrum of industries. Researchers use statistical methods to separate out the effects of other factors on wages, so that the results indicate only the incremental wage differential needed to compensate workers for added risk. Contingent valuation surveys are a stated preference method that allows researchers to ask respondents what they would be willing to pay for a specified risk reduction.

million. Updated to 2002 dollars (using the Gross Domestic Product deflator), the mean value becomes \$6.2 million.

These studies focus on accidental deaths associated in most cases with job-related risks; none of the 26 studies address premature mortality resulting from illness. Hence EPA's approach represents a "benefit transfer;" i.e., the application of estimates from a study context to a regulatory context that has somewhat different characteristics. The available VSL studies address different types of risks (e.g., work place accidents rather than illness-related fatalities) and reflect a population (e.g., workers) that may differ from the population of regulatory concern (e.g., the elderly).

Given these differences, EPA has explored a number of options for adjusting the resulting values to better fit the characteristics of its regulations, based on available empirical research. In the 2000 *Guidelines*, EPA summarizes some of the key differences between the study context and the regulatory context, including the age of the affected population, its baseline health status, the characteristics of the risks, latency rather than immediate death, and the effects of altruism. EPA recommends that analysts discuss the resulting limitations qualitatively and/or explore their implications through sensitivity analysis.

At the same time as it was preparing its *Guidelines* for publication, EPA asked the EEAC (a panel of independent experts) to review VSL adjustments related to the valuation of cancer-related risks (EPA 2000b). The EEAC concluded that it may be appropriate to adjust for the timing of the risk (i.e., delays due to latency or cessation lag) using discounting, and to adjust for changes in real income over time based on income elasticity estimates (EEAC 2000).¹⁹ The EEAC did not believe that the available research supported adjustments for other differences such as age, health status, or risk attitudes.²⁰ These conclusions were subsequently reflected in OMB's 2003 guidance, as discussed in Section 2.4.2 of this report.

EPA has long recognized that more research is needed on the appropriate valuation of mortality risk reductions, a conclusion that has been supported by both the EEAC and the expert panels responsible for reviewing the prospective and retrospective Clean Air Act analyses. EPA has funded several related studies and recently completed a review of the new evidence related to the valuation of premature mortality (EPA 2004a). EPA presented its findings to the EEAC for examination in May 2004; the results of the discussion suggest that the EEAC members have mixed reactions to the question of whether EPA's VSL approach should be revised at this point in time, given the status of related research (EEAC 2004a).

3.2.2 Application of Cost-Effectiveness Analysis

As noted earlier, the 2000 EPA *Guidelines* provide little information on the conduct of cost-effectiveness analysis. However, the expert panels responsible for review of the

¹⁹In this context, elasticity refers to the percent change in VSL that results from a one percent change in real income. EPA has developed estimates of this elasticity based on review of related empirical research.

²⁰Adjustments for age have been particularly controversial due to concerns regarding the equitable treatment of the elderly; Congress recently prohibited the Agency from making any age-based adjustments to VSL estimates in Section 419 of the *Consolidated Appropriations Act* for 2004.

retrospective and prospective analyses of the Clean Air Act have in the past encouraged the Agency to include estimates of cost-effectiveness in these studies. In response, EPA developed a proposal for implementing QALY-based cost-effectiveness analysis in its analytical plan for the second prospective study of the Clean Air Act (EPA 2003a). While these program-wide evaluations are not regulatory analyses subject to OMB *Circular A-4*, the methods they apply have often been adapted for use in the economic analyses of EPA regulations.

In its plan for the next in this series of studies, EPA notes that the Agency was reluctant to use a QALY-based approach in previous analyses for the following reasons:

- (1) the lack of generally accepted data and methods applicable to QALY computation in an air pollution context,*
- (2) potential biases in the implicit cost-effectiveness results caused by incomplete netting out of other health and ecological benefits from the numerator,*
- (3) concerns about the distortionary effect of the simplifying assumptions pertaining to time and quality trade-offs required to estimate QALYs, and*
- (4) the general disconnect between available QALY methodologies and standard economic utility theory.*

In addition, EPA is seriously concerned about the requirement imposed by the QALY methodology to assign lower values to the lives, and the quality of the lives, of people of advanced age and/or impaired health status. (EPA 2003a, pp. 8-11 to 8-12)

Despite these concerns, EPA's recent analytical plan includes a proposed approach for a QALY-based assessment (as an adjunct to its main benefit-cost analysis) in response to the recommendations of previous expert panels.

To implement this approach, EPA proposes to focus on four health endpoints (premature mortality, chronic bronchitis, chronic asthma, and nonfatal myocardial infarctions) because information on the utility associated with other air pollution-induced health effects is sparse. Before calculating the cost-effectiveness ratio, EPA notes that it would subtract the value of non-health improvements (e.g., visibility and ecological impacts) from program costs, and also subtract the costs of illness associated with those health endpoints for which QALY-based measures would be difficult to estimate (e.g., restricted activity days and acute bronchitis).²¹ EPA recognizes that the remaining costs still will lead to overstatement of the costs per QALY, particularly because many of the beneficial effects of the Clean Air Act cannot be quantified; hence there is no basis for subtracting the value of these impacts from program costs so as to avoid biasing the cost-effectiveness ratio.

For the four health endpoints of concern, EPA proposes to estimate health state utility scores based on the existing QALY literature, including studies from Harvard Center for Risk Analysis' Catalog of Preference Scores and other information sources.²² EPA provides

²¹The Agency notes that it would be preferable to use WTP rather than COI estimates in these calculations, but such estimates are not available for these health endpoints. EPA recognizes that the use of COI estimates is likely to understate WTP for health risk reductions, leading to overstatement of net program costs.

²²This Catalog is available at: <http://www.hsph.harvard.edu/cearegistry/>, as viewed September 2004.

information on the specific studies it is considering for each health effect, noting that the number of relevant studies is limited both because few studies consider these endpoints and many of the studies focus on the effects of different treatments rather than on the overall impact of the illness. To estimate the duration of each health state and the age of the affected population, EPA proposes to rely on data from its own modeling, supplemented with general disease-specific or population-wide data as needed.

EPA's plans were reviewed by the Advisory Council for Clean Air Act Compliance Analysis, an independent expert panel charged with review of EPA's approach to the Clean Air Act analyses (ACCACA 2004). The Council's report raises concerns about the inconsistencies between a QALY-type approach and the utility theory that underlies benefit-cost analysis, suggesting that EPA defer further work on this particular analysis until the IOM Committee concludes its deliberations (ACCACA 2004, p. 60).²³ More detailed information on the Council's concerns is provided in Appendix A of this report, which provides the relevant sections from the Council's report.

3.3 Recent Regulatory Analyses

This section summarizes the characteristics of EPA's recent major health and safety rules, focusing on those finalized between January 1, 2000 and June 30, 2004 that were subject to OMB review under Executive Order 12866 and include quantified estimates of costs and health impacts.²⁴ Specifically, the subsections first describe the general characteristics of each rule, present the overall results of the analyses, and then discuss the approaches used to value benefits in more detail. As noted in the introduction to this report, agency practices are continuing to evolve, especially as EPA works towards implementing the new OMB guidance in *Circular A-4*.

3.3.1 Characteristics of Recent Major Health and Safety Rules

Seven EPA major health and safety rules were finalized between January 2000 and June 2004 that include quantified estimates of costs and human health impacts. These rules are listed in Exhibit 6 below and briefly summarized in the following sections. More information on these rules is available in the *Federal Register* notices and supporting analyses referenced below.

²³This review applies only to the Clean Air Act analysis, which is not a regulatory analysis subject to Executive Order 12866. For its regulatory assessments, EPA is required to begin implementing cost-effectiveness analysis under *Circular A-4* prior to completion of the IOM Committee's work, and has begun to develop related approaches as noted in section 3.3.4 below.

²⁴This discussion focuses on the approach used for economically significant rules; EPA follows similar practices for other (less significant) rulemakings.

Exhibit 6			
EPA MAJOR HEALTH AND SAFETY RULEMAKINGS			
January 1, 2000 – June 30, 2004			
Regulation	Publication Date	Federal Register Citation	Statutory Authority
<i>EPA Office of Air and Radiation:</i>			
New vehicle emissions	February 10, 2000	65FR6698	Clean Air Act
Heavy duty diesel engines	January 18, 2001	66FR5002	Clean Air Act
Spark ignition engines	November 8, 2002	67FR68243	Clean Air Act
Reciprocating internal combustion engines	June 15, 2004	69FR33474	Clean Air Act
Nonroad diesel engines	June 29, 2004	69FR38958	Clean Air Act
<i>Other EPA offices:</i>			
Lead in paint	January 5, 2001	66FR1206	Toxic Substances Control Act
Arsenic in drinking water	January 18, 2001	66FR6976	Safe Drinking Water Act
<p>Sources: Information on statutory authorities was taken from the <i>Federal Register</i> notices cited. Rules finalized between January 1, 2000 and September 30, 2003 were identified through review of: (i) U.S. Office of Management and Budget (OMB). 2001. <i>Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>. p. 30 and Table 4; (ii) U.S. Office of Management and Budget (OMB). 2002. <i>Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, pp. 46-47 and Table 9; (iii) U.S. Office of Management and Budget (OMB). 2003. <i>Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>. p. 6 and Table 4; (iv) U.S. Office of Management and Budget (OMB). 2004. <i>Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>. p. 3 and Table 4. Rules finalized between October 1, 2003 and June 30, 2004 were identified through on-line search of the <i>Federal Register</i> (http://www.gpoaccess.gov/fr/index.html) in September 2004 as well as information provided by agency staff.</p>			

As indicated by the exhibit, five of these rules address air emissions, in four cases from mobile sources and in one case (reciprocating engines) from stationary sources. The remaining two rules set allowable levels for drinking water and paint contaminants. Of these seven rules, three were issued at the very end of the Clinton Administration in January 2001, often under unusually tight deadlines. The general characteristics of the rules are summarized below.²⁵

Air Emissions: Over the past several years, EPA has promulgated a number of rules that regulate emissions from mobile and stationary sources. Four of the rules in Exhibit 6 deal with

²⁵Information in the following sections is based on the *Federal Register* notices identified in Exhibit 6 unless noted otherwise.

mobile sources; each addresses different types of engines or vehicles and concurrently establishes numerical standards for engine emissions and fuel content in most cases. One rule (reciprocating internal combustion engines) addresses stationary sources; such rules are generally referred to as National Emissions Standards for Hazardous Air Pollutants (NESHAPs).

More specifically, the major rules included in Exhibit 6 address the following.

- The *new vehicles emissions* rule sets emissions standards for new passenger cars, light trucks, and larger passenger vehicles and limits the amount of sulfur allowed in gasoline. The rule was proposed in May 1999 and finalized in February 2000.
- The *heavy duty diesel* rule sets emissions standards for heavy duty highway engines and vehicles, including those powered by diesel fuel or gasoline. It also limits the amount of sulfur allowed in highway diesel fuel. The rule was proposed in June 2000 and finalized in January 2001.
- The *spark ignition* rule sets emissions standards for nonroad large and recreational spark ignition engines, including large industrial engines (such as those used in forklifts) and recreational vehicles (such as snowmobiles and marine craft), but does not alter the pre-existing fuel requirements. The proposed rule was published in October 2001, and the final rule was published in November 2002.
- The *reciprocating internal combustion* rule sets emissions standards for hazardous pollutants from stationary engines, such as those used in the oil and gas industry. It was proposed in December 2002 and finalized in June 2004.
- The *nonroad diesel* rule sets emissions standards for new nonroad engines (e.g., those used in construction equipment) and limits the amount of sulfur in nonroad, locomotive, and marine diesel fuel. It was proposed in May 2003 and finalized in June 2004.

The sections of the Clean Air Act authorizing the standards for mobile sources differ somewhat in the types of factors that they compel EPA to consider as well as in the extent to which they prescribe specific regulatory requirements. For engine emissions, EPA generally must take into account the availability of technology able to achieve the desired pollution reductions, including its costs and other impacts such as lead time, noise, energy use, and safety. In addition, in most cases EPA must also consider the need for, and cost-effectiveness of, the emissions standards, as well as alternative methods for meeting air quality goals. The fuel standards are generally authorized by Section 211 of the Act, which requires that EPA regulate fuels as needed to reduce adverse effects on human health or welfare as well as to prevent impairment of emissions control devices. For stationary sources, authorization is provided under Section 112(d) of the Act, which requires use of the maximum achievable control technology (MACT).

In each of these rules, the emissions requirements vary depending on the characteristics of the engines and the pollutants addressed. In most of the mobile source rules, EPA establishes numerical limits that are phased in over time for both emissions and fuel content. These rules

also generally provide an averaging, banking and trading program which allow flexibility in industry implementation of the requirements.²⁶ Each of the mobile source analyses considers a number of alternatives to the final rule that vary in terms of characteristics such as the implementation schedule, the stringency of the standards, and the types of engines addressed. For stationary sources, the rule consists of technology-based requirements; risk-based approaches were also assessed in the analysis supporting the proposed rule.

Arsenic in Drinking Water: The arsenic rule was promulgated under the Safe Drinking Water Act (SDWA). This Act requires that the Agency publish a non-enforceable Maximum Contaminant Level Goal (MCLG) which represents the concentration at which there are no known or anticipated adverse health effects associated with exposure to the contaminant, taking into account an adequate margin of safety and considering the effects on sensitive subpopulations. The Agency must then establish the Maximum Contaminant Level (MCL), which water systems are required to meet, that is as close to the MCLG as is “feasible,” taking cost into consideration (SDWA, Section 1412(b)). EPA can, at its discretion, establish a less stringent MCL that “maximizes health risk reduction benefits at a cost that is justified by the benefits” (SDWA, Section 1412(b)), with certain exceptions related to consideration of the impacts on small water systems.

The arsenic rule was proposed in June 2000 and finalized in January 2001. For the final rule, EPA exercised its discretion to set a standard above the lowest feasible level. The Agency assessed four regulatory options, including the lowest feasible level and three less stringent standards. EPA’s analysis suggested that the costs of all four options may exceed the benefits if only quantifiable health impacts are considered. However, EPA was unable to quantify many potential health effects due to gaps in the available scientific research, and noted that the data on the quantified impacts were uncertain. EPA’s analysis was subsequently examined by three expert panels; EPA delayed the effective date of the rule to allow time for these reviews, but ultimately decided to not change the MCL nor revise the supporting analyses.²⁷

Lead in Paint: This rule defines residential lead paint hazards based on evidence of deterioration, and establishes numerical standards for allowable levels of lead in dust and soils. This rule is somewhat unusual in that it establishes national standards but not the requirements for enforcing them. Hence in this case the analysis was based on assumptions regarding the implementing regulations (only some of which had already been promulgated), while the other regulatory actions discussed in this chapter include the implementation requirements as well as the numeric standards. This rule was authorized under Section 403 of the Toxic Substances Control Act (TSCA); the statute requires EPA to establish standards for determining whether lead poses a threat, or would result in adverse effects on human health, considering primarily its risks to children (TSCA, Section 401).

The lead rule was proposed in June 1998 and finalized in 2001. The *Economic Analysis* for the final rule considered standards for identifying deteriorated interior and exterior lead paint

²⁶For example, refiners can receive credits when they produce cleaner gasoline than required, then use these credits in cases where their gasoline is slightly below the standards.

²⁷Information about this review is taken from: <http://www.epa.gov/safewater/arsenic.html>, as viewed September 2004.

based on location and the extent of deterioration, as well as 12 options for numerical floor dust standards, 15 options for numerical window sill dust standards, and 13 options for numerical soil standards.

3.3.2 Results of Benefit-Cost Analyses

Exhibit 7 provides information on the monetized costs and benefits of each rule.²⁸ Caution must be exercised in comparing these results; the methods used in the analyses are evolving, many impacts of these rules were not quantified, and the findings are often highly uncertain. However, the exhibit suggests that the impact of these EPA rules is substantial. In combination, these seven rules provide over \$176 billion in net benefits annually, considering only those impacts that could be valued in monetary terms. The most recent rule, for nonroad diesel engines, accounts for about 45 percent of the total net benefits, followed by the heavy duty diesel rule, which accounts for 38 percent of the total; the other five rules in combination account for the remaining 17 percent. As indicated in the percentages reported in the “total benefits” column, almost all of the monetized benefits of these rules are impacts on human health.²⁹ EPA indicates that many of the benefits of each of these rules could not be quantified (including both human health and ecological effects), while the cost analyses generally appear to capture more of the major impacts.

²⁸This section summarizes the estimates of total costs and benefits for the final rule provisions; the *Federal Register* notices and supporting documents provide more information on these estimates as well as the benefit and cost estimates for the other regulatory options considered.

²⁹Because the IOM Committee’s charter focuses on the valuation of human health impacts, this discussion excludes those EPA rules for which only environmental impacts were quantified.

Exhibit 7			
SUMMARY OF ANNUALIZED MONETIZED IMPACTS: EPA RULES¹			
Regulation (dollar year)	Total Costs	Total Benefits (health and safety benefits as a percent of total benefits)	Net Benefits (total benefits minus total costs)
<i>EPA Office of Air and Radiation:</i>			
New vehicle emissions ² (1997 dollars)	\$5,300 million	\$25,200 million (98 percent)	\$19,900 million
Heavy duty diesel engines ² (1999 dollars)	\$4,200 million	\$70,400 million (94 percent)	\$66,200 million
Spark ignition engines ² (2001 dollars)	(\$554 million) ³	\$7,880 million (100 percent)	\$8,434 million
Reciprocating internal combustion engines (1998 dollars) ⁴	\$248 million	\$280 million (not reported)	\$32 million
Nonroad diesel engines ^{2,5,6} (2000 dollars)	\$2,000 million	\$80,500 million (98 percent)	\$79,500 million
<i>Other EPA offices:</i>			
Lead in paint ⁷ (1995 dollars)	\$2,682 million	\$4,683 million (100 percent)	\$2,001 million
Arsenic in drinking water ⁵ (1999 dollars)	\$193 million	\$169 million (100 percent)	(\$24 million)
Total	\$14,069 million	\$189,112 million	\$176,043 million ⁹
<p>Sources: Calculated from information provided in <i>Federal Register</i> notices cited in Exhibit 6 above, supplemented by information in: U.S. Environmental Protection Agency (EPA). 2000c. <i>Economic Analysis of Toxic Substances Control Act Section 403: Lead-Based Paint Hazard Standards</i>.</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. Exhibit reports “best” or “central tendency” estimates for the final rule based on information provided by the agencies unless otherwise noted, and does not reflect the often extensive analyses of uncertainty contained in the underlying analyses nor the analyses of regulatory options. 2. Estimates reflect full implementation in the year 2030. 3. Value is negative because the rule is expected to lead to net cost savings due to fuel efficiency gains. 4. Estimates reflect fifth year after implementation. 5. Value in exhibit is mid-point of estimates reported in the <i>Federal Register</i> notice, which use discount rates of 3 and 7 percent. 6. Values are reported by the Agency rounded to the nearest billion; reported net benefits do not equal benefits minus costs, possibly due to rounding in the reported results. 7. Exhibit provides average annualized impacts calculated based on information reported in the <i>Federal Register</i> notice, which reports present values for a 50 year period. 8. Net benefits do not equal benefits minus costs due to impact of nonroad rule, as indicated under note (6) above. 			

These rules vary in the both the types of costs and benefits assessed, as well as in the magnitude of the resulting estimates. The types of costs assessed for each rule, as well as the discount rates used, are summarized below; the following section provides more information on the benefits analyses.

Air Emissions: The cost analyses of the four mobile source air emissions rules have several common features. In general, EPA estimates the incremental costs of producing and operating engines that meet the new emissions requirements, as well as the impacts of the rule (if any) on the costs of refining and distributing fuel. As relevant, EPA also assesses the effects of the resulting price changes on related markets. EPA considers how the costs imposed by the rule will change over time (reflecting the phase-in of the new requirements) and reports the present value of both costs and benefits applying a three and seven percent discount rate. EPA also reports the annual value of the impacts in the year 2030, by when virtually all engines in use are expected to meet the standards due to the replacement of older engines.

For the spark engine rule, EPA finds that savings in fuel efficiency may outweigh the engine-related costs, so that the social welfare costs of the rule are positive; i.e., the rule will result in savings of about \$0.5 billion in the year 2030. For the other three mobile source rules, annual costs in the year 2030 are expected to range from \$2.0 to 5.3 billion. The cost estimates are generally accompanied by several analyses of uncertainty, including assessment of the sensitivity of the results to changes in the values of key parameters as well as qualitative discussion of related concerns. For each rule, EPA also reports the costs per ton of emissions reduced for individual pollutants of concern.

For the one rule addressing stationary sources (the reciprocating engine rule), EPA assesses both the direct costs of compliance imposed on affected industries and the market impacts of the resulting price changes. In the supporting analysis, EPA reports the results using both a three and seven percent discount rate. The annual results are reported for the fifth year after the rule is first implemented.

Arsenic in Drinking Water: For the arsenic rule, regulatory costs include those incurred by affected water systems to implement and operate additional treatment, as well as the costs of complying with related monitoring and reporting requirements. EPA also estimates the state agency costs associated with overseeing and administering the new standards. Costs and benefits are discounted using rates of both three and seven percent.

Lead in Paint: The lead rule considers the costs associated with testing and intervention activities related to controlling or removing lead contaminated paint, dust, and soils for varying types of housing units. The costs are assessed for interventions occurring over a 50 year period, and both costs and benefits are discounted using a three percent rate. The results of applying a seven percent discount rate, as well as of varying other assumptions, are provided in sensitivity analysis.

3.3.3 Approaches for Valuing Human Health Impacts

The five air emissions rules address similar types of pollutants and health impacts and use relatively similar approaches to determine the monetary values of these impacts. The other two rules consider differing health outcomes, but use the same general types of approaches for valuation. Selected aspects of the benefits analyses are summarized in Exhibit 8. For all of the rules except lead in paint, the total value of monetized benefits is driven primarily by the reduction in premature mortality because the per-case values are substantially larger than those used for nonfatal health impacts.

Exhibit 8					
VALUATION OF ANNUAL HEALTH IMPACTS: EPA RULES ¹					
Regulation	Premature Mortality		Morbidity		Significant nonquantified impacts
	Cases averted²	VSL per case³	Types of health impacts averted	Valuation approach	
<i>EPA Office of Air and Radiation:</i>					
New vehicle emissions (1997 dollars)	4,300 PM-related	\$5.9 million	Various acute and chronic PM and/or ozone related respiratory and cardiovascular conditions	Varies, based on WTP or COI estimates	Numerous additional respiratory, cardiovascular and other health impacts associated with PM, ozone, air toxics and other contaminants; additional ecological effects and/or material damages.
Heavy duty diesel engines (1999 dollars)	8,300 PM-related	\$6.0 million			
Spark ignition engines (1999 dollars)	1,000 PM-related	\$6.0 million			
Reciprocating internal combustion engines (1998 dollars)	not reported ⁴	\$6.0 million			
Nonroad diesel engines (2000 dollars)	12,000 adult PM-related; 22 infant	\$6.8 million			
<i>Other EPA offices:</i>					
Lead in paint (1995 dollars)	none	N/A	IQ point loss	Lost earnings per IQ point lost	Numerous other lead-related hazards for children and adults; increased energy efficiency and aesthetic appeal of housing
Arsenic in drinking water ⁵ (1999 dollars)	21-30 lung and bladder cancer related	\$6.1 million	16-26 nonfatal cases of lung and bladder cancer	WTP transfer	Skin, kidney, nasal, liver, and prostate cancers; cardiovascular and pulmonary effects; immunological, neurological, and endocrine effects
<p>Sources: <i>Federal Register</i> notices cited in Exhibit 6 above; U.S. Environmental Protection Agency (EPA). 2000c. <i>Economic Analysis of Toxic Substances Control Act Section 403: Lead-Based Paint Hazard Standard</i>; U.S. Environmental Protection Agency (EPA). 2002. <i>Final Regulatory Support Document: Control of Emissions from Unregulated Nonroad Engines</i>. EPA 420-R-02-022; U.S. Environmental Protection Agency (EPA). 2004b. <i>Final Regulatory Impact Analysis: Control of Emissions from Nonroad Diesel Engines</i>. EPA 420-R-04-07; and, U.S. Environmental Protection Agency (EPA). 2004c. <i>Regulatory Impact Analysis for the Stationary Internal Combustion Engine (RICE) NESHP</i>.</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. Exhibit reports “best” or “central tendency” estimates for the final rule provided by the agency, and does not reflect the often extensive analyses of uncertainty contained in the underlying analyses nor the analyses of regulatory options. 2. Reported as statistical cases; i.e., the aggregation of small changes in risks across a large exposed population, for the year 2030 (once the rule is fully implemented) unless otherwise noted. 3. VSL estimates in exhibit are not adjusted for income growth over time, except for the value reported for the nonroad diesel rule which reflects income growth through the year 2030. 4. Benefit values are transferred from other rules and reflect the fifth year after implementation. 					

EPA's valuation of benefits in each of these analyses involves first assessing how baseline levels of contamination would change under each of the regulatory options, then estimating how these changes in contamination levels would affect risks to human health. In broad terms, these analyses follow EPA's general risk assessment framework, which includes hazard identification, dose-response assessment, and exposure assessment.³⁰ In applying this framework, risk assessors usually begin by reviewing the health science literature to identify studies suitable for use in the regulatory analysis, then develop models that incorporate data from these studies to estimate the impacts of different regulatory options. The approach used for the risk assessment in these major rules often undergoes substantial expert panel review and is frequently considered the most uncertain component of the analysis.

EPA uses relatively consistent approaches to value these risk reductions, as summarized below.

Air Emissions: The air emissions rules are very similar in terms of the types of effects considered and the valuation approaches used, largely relying on analytic methods and values adapted from the Agency's prospective and retrospective studies of the Clean Air Act. The rules address direct emissions of particulate matter (PM) as well as other pollutants that form PM once emitted and/or that contribute to the creation of ozone. While the rules also decrease the emissions of air toxics, EPA was not able to quantify related impacts.

For all of these rules, EPA assesses the effects of PM exposure on premature mortality; EPA also considers the mortality impacts of ozone for some rules. For morbidity, the monetized benefits include a broad range of nonfatal respiratory and cardiovascular effects, generally addressing chronic bronchitis, asthma, hospital admissions from several respiratory and cardiovascular conditions, the occurrence of respiratory symptoms, and impacts on work loss days and restricted activity days. EPA reports values separately for certain subpopulations of concern, including children, asthmatics, and (in some cases), African Americans. In the reciprocating engine rule, EPA transfers benefits estimates from other regulatory analyses rather than directly estimating the impacts of this particular rule.

To value fatal risks, EPA applies VSL estimates adjusted for income growth, and also adjusts for the lag between exposure reduction and reduction in premature mortality. Some of the rules include sensitivity analyses of other VSL adjustments; e.g., for the age of the affected population. The base values (reported in Exhibit 8) are the averages of the 26 VSL estimates discussed in Section 3.1.1 above, except for the nonroad diesel rule which considers the results of more recent meta-analyses. The monetary values vary primarily due to the dollar year used for the analysis. To value morbidity effects in each of these rules, EPA adapts WTP values from stated preference studies for chronic bronchitis and restricted activity days. For other nonfatal respiratory and cardiovascular effects, EPA relies on data on the medical costs of illness and lost earnings due to the lack of suitable WTP estimates.

For most of these rules, EPA also estimates the value of some of the environmental impacts of the requirements, including the effects on visibility at selected recreational sites as well as on crop yield in some cases. As noted earlier (in Exhibit 7), these environmental impacts

³⁰See, for example, EPA 2000d for more information on EPA's general approach to risk assessment.

represent a small proportion of the total monetized benefits due to difficulties related to their quantification.

In addition to the primary benefits estimates, EPA generally conducts a number of analyses to address uncertainty. The sources of uncertainty are discussed qualitatively and EPA assesses the sensitivity of the results to changes in the values of several key parameters. EPA believes that the monetized benefits may significantly understate the total benefits of each of these regulations. The analyses provide quantified estimates for only some of the expected impacts on human health and the environment, and EPA presents relatively lengthy lists of other impacts that could not be quantified.

Arsenic in Drinking Water: The arsenic rule uses a similar approach for valuing premature mortality, using an unadjusted VSL estimate of \$6.1 million in its base case analysis, and presenting sensitivity analyses that report the effects of adjusting these values to account for income growth over time, latency, and other risk characteristics. For lung and bladder cancer, EPA notes that suitable WTP estimates are not available, and instead transfers an estimate of WTP to avoid chronic bronchitis (\$607,000 per case).³¹ In addition to sensitivity analyses, EPA provides extensive qualitative discussion of key uncertainties and lists a number of health impacts that could not be quantified. The distribution of benefits across different subgroups of concern is not reported; EPA indicates that the available health science data are not sufficient to support determination of the impacts on specific sensitive subpopulations.

Lead in Paint: This rule assesses the benefits related to avoidance of IQ losses in children exposed to lead between the ages of zero and six. The value of these benefits is estimated based on the change in lifetime earnings associated with each IQ point lost, using a base value of \$8,346 per IQ point. Due to substantial uncertainties in the risk data, EPA assesses these impacts using two different models of the relationship between environmental lead and blood lead levels in children. EPA also provides sensitivity analysis using an alternative value for each lost IQ point. EPA notes that its analysis understates the likely benefits of the rule, which will reduce other risks as well as affect property values.

The above rules largely reflect analyses completed before the effective date of OMB *Circular A-4*. EPA is now considering approaches for implementing the new guidelines on the use of integrated cost-effectiveness measures in its regulatory analyses. In addition to the proposed approach included in the analytical plan for the Clean Air Act analysis (see Section 3.2.2 above), one of the lead economists in EPA's Office of Air and Radiation has drafted an article illustrating an approach that could be used to address PM-related health effects (Hubbell 2004). This analysis assesses the cost-effectiveness of a one microgram reduction in fine PM nationally, considering impacts on premature mortality as well as nonfatal chronic bronchitis and acute myocardial infarction. The author does not, however, assign a QALY weight to premature mortality, which is equivalent to assuming that the life years gained would be assigned a quality weight of "1" for perfect health. Hubbell describes this approach as a "fair QALY" since it

³¹A subsequent expert panel review of the valuation approach for the arsenic rule recommended that, given the limitations of the existing research, the Agency should present a bounding analysis using the estimate for chronic bronchitis (\$607,000 per case) and an estimate from another study of nonfatal lymphoma (\$3.6 million per case) (ARBRP 2001).

avoids the equity concerns inherent in approaches that assign lower quality weights to individuals who live longer with pre-existing conditions, addressing related OMB guidance as discussed in Section 1.1 of this report. For nonfatal chronic bronchitis and acute myocardial infarction, Hubbell applies quality weights derived from a review of the literature, relying largely on studies cited in the Harvard Center for Risk Analysis' Catalog of Preference Scores.

3.4 Characteristics of Potential Future Rules

EPA is in the process of finalizing a number of economically significant rules with quantified health impacts and is beginning work on some new regulatory efforts. Twice each year, Federal agencies publish their regulatory plans in the *Federal Register*, in a document referred to as the "Unified Agenda." The most recent version of this Agenda was published on June 28, 2004. According to the Agenda and discussions with Agency staff, the rulemakings listed in Exhibit 9 are likely to be promulgated in the near future.³² The exhibit includes all forthcoming economically significant rules listed in the Agenda that are likely to involve quantified estimates of impacts on human health.

³²As indicated in the exhibit notes, some of these rules were published subsequent to the time period that is the focus of this report; i.e., after June 28, 2004. (Some rules initially planned for publication in 2004 have not yet been promulgated.)

Exhibit 9 FORTHCOMING EPA MAJOR HEALTH AND SAFETY RULEMAKINGS¹ (June 28, 2004 “Unified Agenda”)		
Rule	Status (“Unified Agenda” citation)	Potential Quantified Health Impacts (proposed rule citation)
<i>EPA Office of Air and Radiation:</i>		
Review of National Ambient Air Quality Standards (NAAQS) for Particulate Matter	Proposed rule planned in 2005 (69FR38184)	Numerous respiratory and cardiovascular conditions
Clean Air Interstate	Final rule planned in 2004 (69FR38197)	Numerous respiratory and cardiovascular conditions (69FR4566)
NESHAP: Industrial, Commercial, and Institutional Boilers and Process Heaters	Final rule planned in 2004 (69FR38210) ²	Not quantified for proposed rule (68FR1660)
NESHAP: Plywood and Composite Wood Products	Final rule planned in 2004 (69FR38213) ³	Cancer risk reductions (68FR1276)
Electric Utility Steam Generating Unit Maximum Achievable Control Technology (MACT)	Final rule planned in 2004 (69FR38215)	Numerous respiratory and cardiovascular conditions (69FR4652)
Clean Air Visibility	Final rule planned in 2005 (69FR38211)	Numerous respiratory and cardiovascular conditions (69FR25184)
<i>Other EPA offices:</i>		
Groundwater and Pesticide Management Plan	Date for final rule to be determined (69FR38261)	Not quantified for proposed rule (61FR33260)
Management of Coal Combustion Wastes Generated by Commercial Electric Power Producers	Proposed rule planned in 2007 (69FR38291)	Not yet determined
Management of Coal Combustion Wastes Generated by Non-Power Producers and Minefilling	Proposed rule planned in 2007 (69FR38292)	Not yet determined
National Primary Drinking Water Regulations (NPDWR): Groundwater	Final rule planned in 2004 (69FR38314)	Viral and bacterial illness associated with waterborne pathogens (65FR30194)
NPDWR: Radon	Final rule planned in 2005 (69FR38314)	Lung and stomach cancer (64FR59246)
NPDWR: Long Term 2 Enhanced Surface Water Treatment	Final rule planned in 2005 (69FR38315)	Cryptosporidiosis (68FR47640)
NPDWR: Stage 2 Disinfection By-Products Rule	Final rule planned in 2005 (69FR38315)	Bladder cancer (68FR49548)
Sources: The Unified Agenda published in the <i>Federal Register</i> on June 28, 2004 (specific page numbers are cited in final column above), supplemented by information from the <i>Federal Register</i> notice for the proposed rule where referenced. Notes: 1. Includes rules identified as economically significant for which human health-related benefits are likely to be quantified. 2. This rule was finalized on September 13, 2004 (69FR55218). 3. This rule was finalized on July 30, 2004 (69FR45944).		

Six of these forthcoming economically significant rules will govern air emissions, in most cases addressing respiratory and cardiovascular effects similar to the recently completed rulemakings discussed earlier in this section. EPA is also in the process of finalizing four rules governing drinking water contaminants, that address illnesses related to microbial pathogens as well as various cancers. Two of the remaining rules address waste disposal and one addresses pesticide contamination of groundwater. For these latter rules, plans for quantifying human health effects are uncertain and many of the effects may more directly relate to environmental impacts.³³

As indicated by this exhibit, EPA's current plans extend only over the next two or three years, although rules may be delayed beyond their expected completion dates. Information provided by EPA staff suggests that with the exception of the air program, regulatory activities in many of its programs are likely to decrease over time, as most of the major regulations required under existing authorities have been, or are about to be, promulgated. It is difficult to predict whether Congress is likely to make significant changes to EPA's authorizing legislation that will require a substantial alternation in regulatory activity.

³³For example, human exposure to groundwater contaminated by pesticides or waste disposal practices may be limited if the affected aquifers are not likely to be used for drinking water or if the contaminants of concern are addressed by existing drinking water treatment systems.

4.0 FOOD AND DRUG SAFETY

Primary Federal responsibility for the safety of the nation's food supply is split across two Cabinet-level departments: the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA). In addition, HHS is the primary agency responsible for the safety of medical devices and drugs. Within these departments, review of recent rules indicates that both HHS' Food and Drug Administration (FDA) and USDA's Food Safety and Inspection Service (FSIS) have promulgated economically significant regulations with quantified health impacts since January 2000. Available planning documents also suggest that only these two agencies are developing forthcoming rules that meet these criteria. Therefore, this chapter focuses on the practices of these two agencies after providing some general information on the departments within which they are housed.

HHS is one of the largest Federal agencies, representing almost 25 percent of all Federal spending and operating more than 300 programs.³⁴ It is the principal agency responsible for protecting health and providing a broad range of human services. However, most of its regulations address the operations of its own programs rather than the activities of organizations outside of the Federal government. Several of its rules are categorized as economically significant but generally do not involve assessment of quantified impacts on human health. Many of these regulations (which largely address the Medicare program) are categorized by OMB as "transfer" programs (e.g., because they move funds from taxpayers to program beneficiaries) rather than as "social" regulations which lead to a net changes in societal welfare (OMB 2004). The only recently finalized, economically significant HHS rules with quantified human health impacts were promulgated by FDA.

FDA is responsible for protecting human health by ensuring the safety of drugs, medical devices, food supplies, and other products.³⁵ FDA includes six centers responsible for food safety and applied nutrition, drug evaluation and research, veterinary medicine, devices and radiological health, toxicological research, and biologics evaluation and research. In addition, it contains a number of offices with cross-cutting responsibility for legal counsel, policy development, regulatory affairs, and other areas.

USDA is also a major Federal agency, responsible for issues related to food, agriculture, natural resources, and similar concerns.³⁶ It divides its mission into seven categories: farm and foreign agricultural services; food, nutrition and consumer services; food safety; marketing and regulatory programs; natural resources and environment; research, education, and economics; and, rural development. Most of these mission areas involve more than one USDA agency. USDA's economically significant rules generally do not directly address human health, instead

³⁴General information about HHS is taken from: <http://www.hhs.gov/about/whatwedo.html> as viewed September 2004.

³⁵General information about FDA is taken from: <http://www.fda.gov/oc/orgchart/html> as viewed September 2004.

³⁶General information about USDA is taken from: http://www.usda.gov/wps/portal/!ut/p/.s.7.0.A/7.0.1OB?navtype=MA&navid=ABOUT_USDA as viewed October 2004.

dealing with the operation of agricultural markets, the use of natural resources, and implementation of its programs. The only recently finalized, economically significant USDA social regulation with quantified human health impacts was promulgated by FSIS.

FSIS is the component of USDA responsible for ensuring that the commercial supply of meat, poultry, and egg products is safe for human consumption and appropriately packaged and labeled.³⁷ FSIS is divided into several offices with cross-cutting responsibilities which are further subdivided into divisions responsible for particular areas. For example, its Office of Public Health Science includes divisions responsible for zoonotic diseases, microbiology, human health sciences, and risk assessment as well as several field laboratories that provide program support.

Neither FDA nor FSIS, nor their parent departments, have developed overall guidance for the conduct of regulatory analysis. Instead, these agencies rely on the guidance provided by OMB supplemented by their own research. The following sections describe their regulatory development processes, summarize their general practices for benefits valuation, describe recently finalized rules, and then note rules that are forthcoming.

4.1 Regulatory Development Process³⁸

Within FDA, responsibility for regulatory analysis is divided between the Center for Food Safety and Applied Nutrition (CFSAN) and the Economics Staff within FDA's Office of Policy and Planning. At CFSAN, most of the work on the economic analysis of regulations is completed by the Division of Market Studies within the Office of Scientific Analysis and Support, with assistance from other offices as needed. The risk assessments supporting the economic analyses involve health scientists within individual CFSAN offices, coordinated by a team in the Office of Science. The FDA-wide Economics Staff contributes to and reviews CFSAN's analyses and also prepares the analyses for rules completed by other FDA components.

CFSAN generally relies on its internal staff for the economic analyses of proposed and final rules, and uses contractors primarily for data collection and model development. Its Division of Market Studies employs about 10 economists who work on economic valuation, seven health scientists who characterize the changes in risks associated with the regulations, and nine other staff who conduct research on likely consumer responses to different CFSAN initiatives. Center staff note that it is difficult to estimate the amount of time or resources devoted to individual economic analyses, since staff are generally involved in multiple rulemakings and other projects. The FDA-wide Economics Staff relies on outside contractors for some portions of its analyses, and employs about 10 economists who are involved in both regulatory assessment and research on other economics issues of concern to the agency. In addition, FDA occasionally undertakes new research to support these analyses, often conducting related studies in-house.

³⁷General information about FSIS is taken from: http://www.fsis.usda.gov/About_FSIS/index.asp as viewed October 2004.

³⁸This section is based on information provided by the agency staff identified on the Acknowledgments page of this report as well as review of the regulatory analyses summarized in Section 4.3 below.

Responsibility for the economic analysis of regulations is also split within USDA, but with a somewhat different structure. At FSIS, responsibility for these analyses is largely delegated to its Office of Policy, Program, and Employee Development, with help from other offices. The risk assessments that support the rulemakings are conducted by the Office of Public Health Science, general oversight and review is provided by the USDA-wide Office of the Chief Economist, and the USDA Economic Research Service often conducts supporting studies.

FSIS primarily relies on its internal staff for its economic assessments, at times using contractors for certain portions of the analysis. The FSIS Office of Policy, Program, and Employee Development employs about five economists who work on regulatory analysis for both economically significant and less major rules throughout the various phases of the rulemaking process. FSIS estimates that the preliminary and final assessments of an economically significant rule can involve from 1.0 to 3.0 full-time equivalent (FTE) staff depending on the complexity of the rule, with about 0.75 to 1.5 FTE devoted to the benefits analysis. At the USDA-wide level, the Office of the Chief Economist employs several economists and health scientists who work on issues related to agricultural markets and the economic implications of policy decisions, as well as benefit-cost analysis and risk assessment. In addition, the USDA Economic Research Service employs over 450 staff. However, these staff work on a wide range of issues that are largely unrelated to the analysis of particular health and safety rules, including the economics of food and rural areas, markets and trade (national and international), and agricultural and natural resources.³⁹

FDA and FSIS are also similar to the other agencies discussed in this report in terms of the timing of the analytic work. Much of the work on the analytic approach for a particular rule usually occurs before the rule is proposed; for the final rule, the analysis may be adapted to reflect new information and public comments as well as any changes in the regulatory requirements. The rulemaking schedule and budget, as well as the regulatory requirements considered, are somewhat unpredictable and can change substantially over the course of the rule development process.

4.2 General Analytic Approach

While neither FDA nor FSIS have formal internal guidance for the conduct of the economic analysis of regulations, both agencies have developed standard procedures that they generally follow.⁴⁰ This section introduces their approach to benefits valuation. It does not describe their approaches for estimating costs or other impacts, which are based on the OMB guidance already discussed in Chapter 2 of this report and summarized briefly for individual rules in Section 4.3 below.

The FSIS approach for valuing human health impacts is relatively simple. For premature mortality, FSIS applies value of statistical life (VSL) estimates (as discussed in more detail

³⁹Information about the Economic Research Service is taken from: <http://www.ers.usda.gov/AboutERS> as viewed October 2004.

⁴⁰This section is based on information provided by the agency staff identified on the Acknowledgments page of this report as well as review of the regulatory analyses summarized in Section 4.3 below.

Chapters 2 and 3 of this report). For morbidity, FSIS relies on estimates of the hospital costs, recognizing that this approach is likely to understate the value of risk reductions because it ignores other medical costs as well as lost productivity and pain and suffering.

The FDA approach to valuing benefits is more complex. For premature mortality, FDA also relies on VSL estimates. For morbidity, FDA considers a much broader set of impacts, combining information on medical costs and quality of life effects. FDA's approach includes three steps.

1. FDA estimates the impact of nonfatal illness on the quality of life, considering its effects on functional capacity and pain and discomfort. In some cases, FDA uses existing studies to estimate these impacts, relying largely on research reported in the Harvard Center for Risk Analysis' Catalog of Preference Scores.⁴¹ In other cases, FDA experts apply health-related quality of life (HRQL) indices using data from the National Health Interview Survey or other sources. For example, in the analyses addressed in Section 4.3 below, FDA analysts apply the Bush et al. "Quality of Well-Being" scale to pathogen-related gastrointestinal effects (as referenced in Mauskopf et al. 1988) and reactive arthritis. For coronary heart disease associated with other rules, FDA relies on work by Cutler and Richardson (1997). For forthcoming rules, FDA has also used the Cutler and Richardson approach to develop QALY estimates for reactive arthritis.
2. FDA values these quality of life impacts by first converting VSL estimates to a per year or per day value [i.e., the dollar value per Quality-Adjusted Life Year (QALY) or Quality-Adjusted Life Day (QALD)], then scaling this value by applying the condition weights resulting from the prior step. The VSL conversion involves estimating the average number of years of life remaining for individuals included in the underlying studies, then annualizing VSL over these years using a three or seven percent discount rate.⁴² The resulting Value of Statistical Life Year (VSLY) estimates are either used directly as the value per QALY, or divided by 365 days to estimate the value per QALD. For the analyses discussed later in this section, the VSLY estimates generally range from about \$100,000 to \$400,000, including in some cases the values used in sensitivity analysis.
3. FDA then adds the medical costs of illness to the value of the quality of life impacts to determine the total dollar value of the benefits for each health outcome assessed.

The basic framework for this approach was initially developed in an FDA contractor report (Mauskopf et al. 1988), and has been since updated and modified to reflect new research and the results of peer review. FDA staff are now working on updating the condition weights used in their analyses.

⁴¹For information on this catalog, see: <http://www.hsph.harvard.edu/cearegistry/> as viewed September 2004.

⁴²Annualization is similar to an amortization process, and involves calculating a set amount that, if paid annually, would be equal to the present value of a stream of unequal payments over time.

In recent regulatory assessments, FDA has responded to the new OMB *Circular A-4* requirements for cost-effectiveness analysis by using the quality of life methods described under Step 1 above. For example, in the bar code regulatory analyses discussed below, FDA reports the QALY gains attributable to the rule, both undiscounted and discounted at three and seven percent. FDA divides these QALY gains by the costs of the rule to determine the cost per QALY. In the earlier *trans* fat analysis, FDA also reports the costs per QALY.

FSIS staff note that, in their preliminary analysis of interim regulations for controlling bovine spongiform encephalopathy (BSE), they incorporate a cost-effectiveness analysis based on the risk of human exposure. More generally, in the analyses of forthcoming rules, FSIS staff indicate that they are planning to use cost-effectiveness analysis where valid effectiveness measures are available or can be developed, and are considering approaches similar to those used by FDA.

4.3 Recent Regulatory Analyses

This section summarizes the characteristics of each agency's economically significant health and safety rules, focusing on those finalized between January 1, 2000 and June 30, 2004 that were subject to OMB review under Executive Order 12866 and include quantified estimates of costs and health impacts. The subsections describe the general characteristics of each rule, present the overall results of the analyses, and discuss the approaches used to value benefits in more detail. More detailed information on these rules is provided in the *Federal Register* notices and supporting analyses referenced below.

4.3.1 Characteristics of Recent Major Health and Safety Rules

Since January 2000, FDA has finalized five economically significant health and safety rules that include quantified estimates of costs and human health impacts; FSIS has finalized one such rule. These rules are listed in Exhibit 11 below and discussed in the following sections. As in the summaries provided in the previous chapter, it is important to note that it is impossible to fully capture all of the characteristics of these analyses in this type of brief overview, and agency practices continue to evolve in response to OMB *Circular A-4* and other factors.

Exhibit 11			
FDA AND FSIS MAJOR HEALTH AND SAFETY RULEMAKINGS			
January 1, 2000 – June 30, 2004			
Regulation	Publication Date	Federal Register Citation	Statutory Authority
<i>HHS/FDA:</i>			
Shell egg labeling and storage	December 5, 2000	65FR76092	Federal Food, Drug, and Cosmetic Act; Public Health Service Act
Juice processing	January 19, 2001	66FR6138	Federal Food, Drug, and Cosmetic Act; Public Health Service Act
<i>Trans</i> fat labeling	July 11, 2003	68FR41434	Federal Food, Drug, and Cosmetic Act
Dietary supplements containing ephedrine alkaloids	February 11, 2004	69FR6788	Federal Food, Drug, and Cosmetic Act
Bar codes for human drug products and blood	February 26, 2004	69FR9119	Federal Food, Drug, and Cosmetic Act; Public Health Service Act
<i>USDA/FSIS:</i>			
<i>Listeria</i> control in meat and poultry	June 6, 2003	68FR34208	Federal Meat Inspection Act; Poultry Product Inspection Act
<p>Sources: Information on statutory authorities was taken from the <i>Federal Register</i> notices cited. Rules finalized between January 1, 2000 and September 30, 2003 were identified through review of: (i) U.S. Office of Management and Budget (OMB). 2001. <i>Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, p. 30 and Table 4; (ii) U.S. Office of Management and Budget (OMB). 2002. <i>Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, pp. 46-47 and Table 9; (iii) U.S. Office of Management and Budget (OMB). 2003. <i>Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, p. 6 and Table 4; (iv) U.S. Office of Management and Budget (OMB). 2004. <i>Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, p. 3 and Table 4. Rules finalized between October 1, 2003 and June 30, 2004 were identified through on-line search of the <i>Federal Register</i> (http://www.gpoaccess.gov/fr/index.html) completed in September 2004 as well as information provided by agency staff.</p>			

The general characteristics of the rules listed in Exhibit 11 are summarized below.⁴³

FDA food and drug rules: In recent years, FDA has finalized five economically significant rules that address different aspects of food or drug safety, including the following.

⁴³Information in the following sections is based on the *Federal Register* notices identified in Exhibit 11 unless noted otherwise.

- The *shell egg* rule sets requirements for safe handling labels of eggs not treated to destroy *Salmonella* as well as for refrigeration of eggs at retail establishments. The rule was proposed in July 1999 and finalized in December 2000.
- The *juice processing* rule requires fruit and vegetable juice processors to apply Hazard Analysis and Critical Control Point (HACCP) principles to prevent foodborne illness. The regulation sets a performance standard for reducing microbial pathogens which industry can meet through pasteurization or other treatment methods. The rule was proposed in April 1998 and finalized in January 2001.
- The *trans fat labeling* rule requires the inclusion of information on *trans* fatty acids on nutrition labels for foods and dietary supplements. The rule was proposed in November 1999 and finalized in July 2003.
- The *ephedrine* rule declares dietary supplements containing ephedrine alkaloids “adulterated” because they impose unreasonable risks, which effectively removes these products from the market. The proposed rule was discussed and amended in a series of *Federal Register* notices published between 1997 and 2003, then finalized in February 2004.
- The *bar code* rule establishes labeling requirements for certain human drug and blood products to reduce medication errors. The rule was proposed in March 2003 and finalized in February 2004.

The regulatory analyses for each of these rules consider a number of alternatives to the final requirements, including the option of taking no action. Depending on the rule, these alternatives may include different forms of regulation, such as prohibiting the sale of products, requiring process changes, mandating improved labeling, or increasing information dissemination. Some of the analyses also consider alternatives that vary depending on the type of product or affected establishment.

The major authorizing legislation for these rules is the Federal Food, Drug and Cosmetic Act. This statute provides FDA with extensive authority to regulate substances that present human health or safety risks and addresses registration, listing, and labeling requirements. FDA also relies on authority under the Public Health Service Act for some of these rules; this Act supports regulation of activities that would otherwise allow disease transmission across state lines.

FSIS Listeria rule: The *Listeria* rule addresses HACCP plans related to preventing adulteration of ready-to-eat meat and poultry products by *Listeria monocytogenes*. FSIS issued a proposed rule that addressed a number of different contaminants in addition to *Listeria* in February 2001, then finalized the *Listeria* requirements separately in June 2003 in response to recent outbreaks and recalls.

The June 2003 action is an interim final rule, which allows the agency to continue to take comments on some of its requirements at the same time that the rule is being implemented. In the

regulatory analysis, FSIS assessed three types of requirements (sanitation performance standards, testing requirements, and warning labels) in addition to the option of taking no action. The interim final rule is a modified version of the testing requirements considered in the analysis.

FSIS promulgated the rule under the Federal Meat Inspection Act and the Poultry Product Inspection Act. These Acts provide FSIS with broad authorization to develop regulations to ensure that products are appropriately packaged and labeled, wholesome and not adulterated, and processed in facilities with adequate sanitary conditions.

4.3.2 Results of Benefit-Cost Analyses

Caution must be exercised in comparing the results of the economic analyses for these rules, due to differences in how the results are reported, changing analytic practices, and the often substantial uncertainty in the findings.⁴⁴ However, as indicated by Exhibit 12, the impact of these six food and drug rules appears to be substantially less than the impact of the environmental protection rules discussed in Chapter 3. The quantified net benefits of the food and drug safety rules total roughly \$6 billion annually, while the quantified net benefits of the environmental protection rules total about \$176 billion annually. Of the food and drug rules, one rule, for bar codes, accounts for about 70 percent of the total net benefits. The monetized benefits of these rules, as reported in the exhibit, consist entirely of impacts on human health.

⁴⁴In addition, the FSIS approach to valuing nonfatal health effects is likely to result in lower values than the FDA approach, as discussed later in this section.

Exhibit 12			
SUMMARY OF ANNUALIZED MONETIZED IMPACTS: FDA AND FSIS RULES¹			
Regulation (dollar year)	Total Costs	Total Benefits (health and safety benefits as a percent of total benefits)	Net Benefits (total benefits minus total costs)²
<i>HHS/FDA:</i>			
Shell egg labeling and storage (dollar year not reported)	\$10 million ³	\$260 million (100 percent)	\$250 million
Juice processing (dollar year not reported)	\$23 million ⁴	\$151 million (100 percent)	\$128 million
<i>Trans</i> fat labeling (dollar year not reported) ⁵	\$12 million	\$1,341 million ⁶ (100 percent)	\$1,329 million
Dietary supplements containing ephedrine alkaloids ^{6,7} (2003 dollars)	\$49 million	\$88 million (100 percent)	\$39 million
Bar codes for human drug products and blood (dollar year not reported) ⁶	\$638 million	\$5,050 million ⁸ (100 percent)	\$4,400 million ²
<i>USDA/FSIS:</i>			
<i>Listeria</i> control in meat and poultry (dollar year not reported)	\$17 million	\$135 million (100 percent)	\$118 million
Total	\$749 million	\$7,025 million	\$6,264 million ²
Sources: Calculated from information provided in the <i>Federal Register</i> notices cited in Exhibit 11 above.			
Notes:			
1. Exhibit reports “best” or “central tendency” estimates for the final rule based on information provided by the agencies unless otherwise noted, and does not reflect the often extensive analyses of uncertainty contained in the underlying analyses nor the analyses of regulatory options.			
2. Net benefits may not equal benefits minus costs due to rounding in the results reported in the <i>Federal Register</i> .			
3. Excludes first year costs estimated as \$56 million.			
4. Excludes first year costs estimated to range from \$44 - \$58 million.			
5. Represents initial costs annualized at three percent over 20 years as reported in the <i>Federal Register</i> notice; reported total benefits are the mid-points of two values, annualized over twenty years using a three percent rate.			
6. Values in exhibit are mid-point of range reported in the <i>Federal Register</i> notice.			
7. Assumes consumer behavior does not already incorporate knowledge of the health risks associated with these products.			
8. Consistent with the information provided in the <i>Federal Register</i> notice, reported value excludes benefits related to efficiency gains in hospitals (which may range from \$360 to \$600 million per year) due to the high level of associated uncertainty.			

These rules vary in the both the types of costs and benefits assessed as well as in the magnitude of the resulting estimates. The types of costs assessed for each rule, as well as the

discount rates used, are summarized below; the following section provides more information on the benefit analyses.

FDA food and drug safety rules: The cost analyses for the FDA rules consider the following factors.

- In the *shell egg* analysis, FDA considers the costs of inventory disposal, label redesign, administration, and new refrigeration equipment, including both one-time initial costs and subsequent annual expenditures. In addition, FDA assesses the costs of the changes in consumer practices suggested by the new labeling requirements.
- The *juice processing* rule analysis considers the incremental costs associated with the new hazard analysis, plan development, corrective action, verification, recordkeeping and training and other requirements. FDA considers both the one-time initial investment needed to implement the rule and ongoing expenditures.
- For the *trans fat labeling* rule, FDA assesses the costs associated with testing, relabeling and reformulating affected products. FDA assumes that these are one-time investments associated with the initial implementation of the rule, and that on-going costs are likely to be negligible.
- The *ephedrine* cost analysis includes the one-time costs of reformulating and relabeling affected products and the utility loss for consumers who are forced to switch from their preferred (ephedrine-containing) products to a less preferable option. The exhibit provides the mid-point of the reported cost range, which reflects uncertainty in the underlying assumptions (particularly in the valuation of utility losses). FDA also notes that, if consumer behavior already incorporates understanding of the health risks associated with ephedrine, then the utility losses reflected in the cost estimates would already reflect the health benefits and there would be no additional risk reductions.
- The analysis for the *bar code* rule addresses direct regulatory costs to manufacturers, retailers, and others for label changes and upgraded scanning equipment, as well as the FDA administrative costs. In addition, FDA quantifies the costs of accelerated hospital adoption of bar-code systems. The cost estimates in Exhibit 12 are the mid-point of the total of these annualized costs; the benefit values exclude the highly uncertain estimates of hospital efficiency gains.

The more recent FDA rules present costs and benefits discounted at both three and seven percent rates, while the older rules apply only a seven percent rate, consistent with the evolving OMB guidance. All of the rules include qualitative discussion of key uncertainties, as well as the results of probabilistic modeling and/or sensitivity analysis in the economic assessment for the proposed and/or final rule. FDA also notes in many of these rules that some costs and offsetting cost-savings are not quantified.

FSIS Listeria rule: For the *Listeria* rule, the costs of complying with the rule will depend on the current practices of the affected meat and poultry producers. For example, these

establishments may need to validate existing treatments, install new treatments, conduct additional testing, or alter their production to meet the regulatory requirements and respond to any identified *Listeria* problems. The estimate in the exhibit includes both annualized capital costs and on-going annual costs associated with these activities. Capital costs are annualized using a seven percent discount rate, consistent with the OMB guidance in place at the time. No discounting is needed for benefits, which are reported on an annual basis. FSIS notes that it was not possible to quantify some of cost impacts of the rule, including its effects on related markets, and does not report any quantitative analysis of uncertainty for the cost estimates for the final rule.

4.3.3 Approaches for Valuing Human Health Impacts

Each of the food and drug safety rules addresses somewhat different health impacts; the approach for valuing these impacts was introduced in Section 4.2 and is described in more detail below. Selected aspects of the benefits analyses are summarized in Exhibit 13.

Exhibit 13					
VALUATION OF ANNUAL HEALTH IMPACTS: FDA AND FSIS RULES¹					
Regulation	Premature Mortality		Morbidity		Significant nonquantified impacts
	Cases averted	VSL per case²	Types of health impacts averted	Valuation approach	
<i>HHS/FDA:</i>					
Shell egg labeling and storage (dollar year not reported)	not reported	\$5.0 million	Acute and chronic gastrointestinal illnesses and reactive arthritis associated with <i>Salmonella enteritidis</i>	COI and HRQL	Health effects associated with other pathogens
Juice processing (dollar year not reported)	2 pathogen-related	\$5.0 million	Acute and chronic gastrointestinal illnesses and reactive arthritis associated with four pathogens	COI and HRQL	Health effects associated with pesticides and other chemical and physical hazards
<i>Trans</i> fat labeling (dollar year not reported)	240-480 coronary heart disease-related	\$5.0 - \$6.5 million	Coronary heart disease	COI and HRQL	Not reported
Dietary supplements containing ephedrine alkaloids (2003 dollars)	0.7-1.2 ephedrine-related	\$6.5 million	Myocardial infarction, stroke, other cardiovascular, neurological, and psychiatric effects, seizures	COI and HRQL	Health effects not captured in FDA adverse event reports
Bar codes for human drug products and blood (dollar year not reported)	not reported	\$5.0 million	Numerous symptoms related to adverse drug reactions and preventable acute hemolytic transfusion reactions	COI and HRQL	Not reported
<i>USDA/FSIS:</i>					
<i>Listeria</i> control in meat and poultry (dollar year not reported)	27 <i>Listeriosis</i> -related	\$4.8 million	<i>Listeriosis</i>	COI	Health effects associated with products other than deli meats
Sources: <i>Federal Register</i> notices cited in Exhibit 11 above.					
Notes:					
1. Exhibit reports “best” or “central tendency” estimates for the final rule provided by the agencies, and does not reflect the often extensive analyses of uncertainty contained in the underlying analyses nor the analyses of regulatory options.					
2. These VSL estimates are converted to dollars per year or per day (per QALY or QALD) to value the quality of life impacts of nonfatal illnesses as described in Section 4.2 above.					

FDA food and drug rules: The benefits assessment in each of the FDA rules addresses different health outcomes and relies on somewhat differing approaches to the risk assessment. However, the valuation approach used in each of these rules is very similar, as discussed in Section 4.2 above. The risks considered include the following.

- The *shell egg* rule addresses risks associated with *Salmonella enteritidis*, including varying severities of acute and chronic gastrointestinal illnesses and reactive arthritis. FDA estimates the effects of the rule using two different risk assessment models.
- For the *juice processing* rule, FDA considers varying severities of acute and chronic gastrointestinal illnesses and reactive arthritis associated with four microbial pathogens: *B. cereus*, *Salmonella*, *E. coli* O157:H7, and *C. parvum*. To estimate the number of cases averted by the rule, FDA relies on data from nine outbreaks and applies a multiplier to adjust for under-reporting.
- The *trans fat labeling* rule addresses the risks of coronary heart disease associated with *trans* fat intake. FDA estimates *trans* fat intake from available survey data, and uses two different methods to assess the changes in cholesterol levels and heart disease risks.
- The *ephedrine* rule benefits analysis is based on information from adverse events reports received by FDA combined with assumptions regarding the percentage of these events that are linked to ephedrine use. FDA quantifies the effects of the rule on myocardial infarctions, strokes, other cardiovascular effects, seizures, other neurological impacts, and psychiatric impacts.
- The *bar code* rule analysis is based on data reported on adverse drug events and preventable acute hemolytic transfusion reactions. The health effects addressed in these reports range from relatively minor impacts (such as rashes, itching, fever or chills) to more severe effects (such as cardiac arrhythmia and renal failure). In the analysis, FDA tests the effects of assuming different rates of reduction in these events on the estimated benefits of the rule.

In each of these rules, fatal effects are assessed using VSL estimates ranging from \$5 million to \$6.5 million, which are similar to, although often somewhat lower than, EPA's base values for the same time period (adjusted for inflation but not for differences between the study scenario and the regulatory scenario).⁴⁵ These estimates are converted to yearly values ranging from \$100,000 to \$400,000 depending on the rule, as discussed earlier.

As described in more detail in Section 4.2, FDA values nonfatal effects by first using a HRQL approach to estimate the quality of life impacts on functional disability and pain and suffering, then monetizes these impacts based on a dollar per QALY or per QALD calculations derived from the VSL estimates reported above. Medical costs are then added to these

⁴⁵The EPA values are discussed in more detail in Chapter 3 of this report.

monetized quality of life impacts.⁴⁶ The two most recent rules include information on the costs per QALY as well as reporting the monetized net benefits that result from this valuation approach.

In the *Federal Register* notice for each rule, FDA provides detailed information on the approach used to estimate risks, including related uncertainties. Some of the regulatory analyses use probabilistic risk assessment models, and most also assess uncertainty through sensitivity analysis. In many cases, FDA notes that some health risk reductions associated with the rule were not quantified.

FSIS Listeria rule: For the *Listeria* rule, benefits were only estimated for only one product group, deli meat, both because it poses the highest risks and because the risk assessment for these products is well developed. FSIS relies on a probabilistic (Monte Carlo) risk assessment model (part of which was developed jointly with FDA) that uses Centers for Disease Control epidemiological data to evaluate the effects of different producer responses to the rule. FSIS adjusts the results downward by 50 percent to account for uncertainties in the baseline levels of risk, notably the difference between prevalence levels found by FSIS and those reported in other sources. FSIS reports the median, 5th percentile, and 95th percentile values from the model runs to reflect the uncertainty in the estimates.

FSIS values nonfatal cases of *listeriosis* based on hospital costs (\$10,300 - \$28,300 per case), while fatal cases are valued using a VSL of \$4.8 million.⁴⁷ FSIS notes that focusing on hospital costs will understate the value of avoiding morbidity impacts, since it excludes the value of pain and suffering and lost productivity associated with nonfatal cases of illness.

4.4 Characteristics of Potential Future Rules

FDA and FSIS are developing proposed or final versions of several economically significant rules with quantified health impacts. Based on the most recent version of the “Unified Agenda” (published in the *Federal Register* on June 28, 2004), the rulemakings listed in Exhibit 14 are likely to be promulgated in the near future. The exhibit includes all economically significant rules listed in the Agenda that are likely to involve quantified estimates of impacts on human health.⁴⁸ No such rules were identified for other USDA or HHS agencies.

⁴⁶In a few cases (i.e., for the seizures, other neurological impacts, and psychiatric impacts of bar code rule), nonfatal effects are valued based only on medical costs.

⁴⁷This value corresponds with EPA’s unadjusted VSL estimate for 1990, based on work completed by Viscusi and others as discussed in Chapter 3 of this report.

⁴⁸As indicated in the exhibit notes, some of these rules were published subsequent to the time period that is the focus of this report; i.e., after June 28, 2004. (Some rules initially planned for publication in 2004 have not yet been promulgated.)

Exhibit 14		
FORTHCOMING HHS AND USDA MAJOR HEALTH AND SAFETY RULEMAKINGS^{1,2} (June 28, 2004 “Unified Agenda”)		
Rule	Status (“Unified Agenda” citation)	Potential Quantified Health Impacts (proposed rule citation)
<i>HHS/FDA</i>		
Prevention of <i>Salmonella Enteritidis</i> in Shell Eggs	Proposed rule planned in 2004 (69FR37444) ³	<i>Salmonella enteritidis</i> related illness
Current good manufacturing practices (CGMP) for blood and blood products, hepatitis C virus (HCV)	Final rule planned in 2004 (69FR37452)	HCV-related acute and chronic liver disease, end-stage liver disease, hepatocellular carcinoma (65FR69378)
CGMP for dietary ingredients and supplements	Final rule planned in 2004 (69FR37452)	Numerous acute and chronic effects; including, for example, allergic reactions, gastrointestinal effects, and cardiovascular effects (68FR12158)
Maintenance of records pursuant to bioterrorism preparedness	Final rule planned in 2004 (69FR37454) ⁴	Foodborne illness (68FR25188)
<i>USDA/FSIS</i>		
Egg products inspection	Proposed rule planned in 2004 (69FR37277)	Pathogen-related illness
Performance standards for meat and poultry ⁵	Final rule planned in 2005 (69FR37231)	<i>Listeriosis</i> (68FR34208)
Nutrition labeling of single-ingredient products and ground or chopped beef and poultry products ⁶	Final rule planned in 2005 (69FR 37231)	Cancers and coronary heart disease (66FR4970)
<p>Sources: The “Unified Agenda” published in the <i>Federal Register</i> on June 28, 2004 (specific page numbers are cited above), supplemented by information from the <i>Federal Register</i> notice for the proposed rule where referenced.</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. Includes rules identified as economically significant for which human health-related benefits are likely to be quantified. 2. No rules were identified that meet the criteria in Note 1 above for components of HHS and USDA other than FSIS and FDA. 3. This rule was proposed on September 22, 2004 (69FR56824). 4. This rule was finalized on December 9, 2004 (69FR71562). 5. This is the final version of the interim final rule discussed earlier in this section, referred to as the <i>Listeria</i> rule. 6. This rule is not identified as economically significant in the “Unified Agenda” but was recently so-designated by OMB (Personal communication from Charles Williams, FSIS Office of Policy, Program, and Employee Development, November 2, 2004.) 		

These forthcoming rules address a broad range of acute and chronic health effects. While four of these rules address exposure to foodborne pathogens, the other CGMP and labeling rules

address several other types of impacts. As indicated by this exhibit, the agencies' reported plans extend only over the year or two, although at times rulemakings may be delayed beyond their expected completion dates. It is difficult to predict whether Congress is likely to make significant alternations in either agency's authorizing legislation that will require a significant change in regulatory activity, or whether rules developed farther into the future are likely to address a similar range of health outcomes.

5.0 TRAFFIC, WORKER, AND PRODUCT SAFETY

Several Federal agencies are responsible for developing regulations that protect the population against injuries or other health impacts stemming from work place risks, traffic accidents, or product hazards. Responsible Cabinet-level departments include the U.S. Department of Labor (DOL) and the U.S. Department of Transportation (DOT). In addition, the Consumer Product Safety Commission (CPSC) is responsible for product-related safety. CPSC differs from the other agencies considered in this report in that it is an independent agency not subject to OMB regulatory review under Executive Order 12866. However, this section briefly discusses CPSC practices because it is in the process of developing economically significant regulations.⁴⁹

Review of recent rules indicates that, within DOL, only the Occupational Safety and Health Administration (OSHA) has finalized economically significant regulations with quantified costs and health impacts since January 2000. Within DOT, both the National Highway Traffic Safety Administration (NHTSA) and the Federal Motor Carrier Safety Administration (FMCSA) have promulgated regulations meeting these criteria. CPSC has not finalized any economically significant rules during this time period. All of these agencies, except FMCSA, are in the process of developing major rules with health-related impacts.

DOL is a Cabinet-level Federal organization, responsible for a broad variety of issues related to labor and employment.⁵⁰ It consists of a number of agencies responsible for employment and training, pay and benefits, disabilities, and pensions, as well as for occupational safety and health. Review of recent rulemakings suggests that DOL is responsible for relatively few economically significant rules, and that its rules generally do not involve quantification of human health impacts.⁵¹ Several of these rules are classified by OMB as “transfer” rather than as “social” regulations; for example, because they move funds from taxpayers to program beneficiaries (OMB 2001b, OMB 2002a, OMB 2003b, OMB 2004).

⁴⁹Review of the annual OMB reports on the costs and benefits of Federal regulations suggests that the U.S. Nuclear Regulatory Commission (NRC) may be the only other independent agency likely to promulgate major rules with human health or safety impacts. (OMB 2001b, pp. 32-33; OMB 2002a, pp. 61-62; OMB 2003b, p. 15-16; OMB 2004, p. 21-22). However, review of the “Unified Agenda” (as discussed in Section 5.4 below), suggests that NRC is not currently developing any economically significant regulations that are likely to include quantified human health effects (see 69FR38628). NRC has, however, issued guidance on the conduct of regulatory analysis which generally follows the framework established under Executive Order 12866 and OMB *Circular A-4*. (NRC 2004).

⁵⁰General information about DOL is taken from: <http://www.dol.gov/dol/organization.htm> as viewed October 2004.

⁵¹Within DOL, the Mine Safety and Health Administration (MSHA) also addresses work-related health and safety risks. However, MSHA has not recently finalized, and is not developing, any economically significant regulations; therefore its practices are not discussed in detail in this report. MSHA is prohibited from conducting benefit-cost analysis under its statute and therefore reports the number of injuries and fatalities prevented by its regulations, but not their monetized values. Otherwise, it generally follows the OMB *Circular A-4* guidance. (Personal communication from Robert Stone, Office of Standards, Regulations, and Variances, MSHA, July 1, 2004 and November 1, 2004.)

OSHA is the only DOL agency identified that has promulgated economically significant final rules with quantified health or safety impacts since January 2000. OSHA is responsible for ensuring worker safety and health by providing training and other types of outreach as well as by setting standards.⁵² OSHA's Directorate of Standards and Guidance includes several offices responsible for different types of physical, biological, and chemical hazards. Other Directorates are responsible for a wide range of functions including state programs, enforcement, and research.

DOT is also a major Cabinet-level organization, and is responsible for myriad transportation issues. It contains several agencies responsible for particular transportation modes – including aviation, highways, commercial motor carriers, railroads, mass transit, merchant marine, motor vehicles, and the transport of hazardous materials – as well as groups responsible for the Saint Lawrence Seaway, interstate surface transportation, and collection of transportation statistics.⁵³ Relatively few of its recent regulations both meet OMB's criteria for economic significance and include assessment of quantified impacts on human health. The only recent DOT final major rules with quantified human health impacts were promulgated by NHTSA and FMCSA.

NHTSA is responsible for reducing crashes, injuries, and deaths stemming from the use of motor vehicles.⁵⁴ NHTSA's programs address vehicle defects, fuel economy standards, passenger restraints, and other issues. It is divided into two major program divisions responsible for traffic injury control and vehicle safety, as well as offices responsible generally for policy and operations and other agency-wide concerns.

FMCSA was established as a separate agency in 2000, and was formerly part of the Federal Highway Administration.⁵⁵ Its goal is to reduce crashes, fatalities, and injuries related to commercial motor carriers, including large trucks and buses. Its programs address motor carrier operations and safety, driver qualifications, and the transport of hazardous materials and household goods. In addition to containing offices with responsibilities for these different issue areas, FMCSA also includes offices with cross-cutting responsibilities in areas such as statistics, legal counsel, and policy and regulatory development.

CPSC is substantially smaller than the Cabinet-level departments and agencies discussed in this report, and (as an independent agency) is not subject to OMB regulatory review. CPSC is responsible for protecting the public from unreasonable risks of injury or death from consumer products.⁵⁶ Its Office of Hazard Analysis and Reduction includes directorates that

⁵²General information about OSHA is taken from: <http://www.osha.gov/html/oshdir.html> as viewed October 2004.

⁵³General information about DOT is taken from: <http://www.dot.gov/summary.htm> as viewed October 2004.

⁵⁴General information about NHTSA is taken from: <http://www.nhtsa.dot.gov/nhtsa/whatis/overview> as viewed October 2004.

⁵⁵General information about FMCSA is taken from: <http://www.fmcsa.dot.gov/aboutus/aboutus.htm> as viewed October 2004.

⁵⁶General information about CPSC is taken from: <http://www.cpsc.gov/about/offices.html> as viewed October 2004.

address a range of related issues such as epidemiology, health sciences, engineering, and economics. It also includes several offices responsible for agency-wide functions such as legal counsel, compliance, and internal operations.

5.1 Regulatory Development Process

OSHA, NHTSA, FMCSA, and CPSC all develop their regulations through processes that are similar to those discussed for other agencies in the previous sections of this report.⁵⁷ Their regulatory development teams are generally led by individuals or groups with technical expertise in the area of concern, supported by other agency offices. A separate office within each agency is responsible for conduct of the economic analyses of regulations.

Within OSHA, the Office of Regulatory Analysis is responsible for completing the economic assessments for individual rules, with assistance from and review by other offices. The Directorate of Standards and Guidance assesses worker exposures to risks, which are then applied in economic analyses by the Office of Regulatory Analysis. The Office of Regulatory Analysis relies on its internal staff (including about 10 analysts) to complete its economic assessments. It also receives contractor support totaling perhaps \$600,000 per year across the analyses performed for both economically significant and insignificant rules in different phases of the regulatory development process. The Office generally does not fund primary research to collect related data or develop analytic methods.

NHTSA recently reorganized, and its regulatory analyses are now conducted by the Office of Regulatory Analysis and Evaluation in its National Center for Statistics and Analysis. This office primarily relies on its internal staff (including about seven analysts with diverse backgrounds in economics, engineering, and related fields) to complete the regulatory assessments, including estimating the injuries averted by the rules. The cost estimates are provided by a separate NHTSA office. NHTSA spends roughly \$300,000 per year on contractor support for these analyses, but almost all of this funding is devoted to estimating regulatory costs (e.g., the costs of equipment installed to comply with a rule). NHTSA only sporadically uses contractors for small special projects related to benefits valuation.

Within FMCSA, the Analysis Division of the Office of Research, Technology and Information Management is responsible for conducting regulatory analyses and also estimates the numbers of injuries avoided. This group relies on about four economists to complete the analyses for all of its rules, with contractor support totaling less than \$1 million per year. The Office only occasionally spends money on projects designed to update its estimates and analytic methods.

Within CPSC, the Directorate for Economic Analysis in the Office of Hazard Analysis and Reduction is responsible for conducting the regulatory assessments of potential rules. Support is provided by other offices; for example, the CPSC epidemiology staff usually estimates the numbers of injuries associated with different products, and the engineering staff generally reviews and evaluates possible product safety improvements. The Directorate for

⁵⁷This section is based on information provided by the agency staff identified on the Acknowledgments page of this report as well as review of the regulatory analyses summarized in Section 5.3 below.

Economic Analysis relies on its internal staff of about 10 economists to complete the regulatory assessments for all of its rules. Most analyses are completed in-house, involving several staff over two or more years. The Directorate has no discretionary budget, but may request funding for contractor support occasionally to help estimate the societal costs associated with product hazards or to conduct surveys to help evaluate exposure.

As with the other agencies addressed by this report, it's very difficult to estimate the dollar costs or level of effort devoted to individual regulatory analyses by the agencies addressed in this chapter. The level of effort and amount of calendar time required varies significantly across rules depending on their scope and complexity. The framework for the economic analysis is usually developed before the rule is proposed, then updated to reflect new information and public comments as well as any changes made in the regulatory requirements.

5.2 General Analytic Approach

The agencies discussed in this section have varying approaches to regulatory analyses, as introduced below.⁵⁸ Because these agencies generally follow the OMB guidance (discussed in Chapter 2) when estimating costs and economic impacts, this section focuses on their approaches to analyzing health-related benefits. Section 5.3 provides examples of the approaches used in both the cost and benefit analyses for recent rules promulgated by these agencies.

Until recently, OSHA's approach for valuing human health impacts applied much lower values than used by most of the other agencies considered in this report. OSHA did not assign values to fatal risk reductions and relied solely on cost of illness (COI) estimates for nonfatal impacts, as reflected in the analyses summarized in Section 5.3 below. The types of costs addressed for nonfatal effects varied by rule, but could include medical costs, lost productivity (direct and indirect), lost tax revenue, and costs related to processing claims for insurance or worker's compensation. OSHA is now altering its approach to valuation and incorporating estimates of willingness to pay (WTP) for both fatal and nonfatal effects. For example, its proposed rule for hexavalent chromium uses WTP estimates for fatal and nonfatal lung cancers from recent EPA analyses, and also reports the cost per cancer case avoided.

The approach applied by the DOT agencies is more complex. DOT has developed general guidance on certain aspects of benefits valuation.⁵⁹ Specifically, DOT currently recommends use of a \$3.0 million VSL (which is substantially lower than the values used by the agencies discussed in the previous sections of this report), and is now in the process of reviewing this value (DOT 2002c). DOT has also developed relatively detailed guidelines on valuing changes in travel time attributable to its programs (DOT 2003b). Otherwise, each DOT agency has developed somewhat differing standard procedures for assessing the benefits of its rules.

⁵⁸This section is based on information provided by the agency staff identified in the Acknowledgments section of this report as well as review of the regulatory analyses summarized in Section 5.3 below, unless otherwise referenced.

⁵⁹DOT has also developed a primer for State and local agencies interested in assessing the impacts of highway programs (DOT 2003a).

For many years, NHTSA conducted only cost-effectiveness analysis of its rules, and has only recently begun to prepare benefit-cost analyses. These analyses of cost-effectiveness involve converting injuries to “equivalent lives saved” (ELS) based on the relative dollar value of each injury type, including both economic costs and monetized quality of life impacts. ELS is a fractional value that indicates the relationship of injuries to fatalities. For example, if an injury has an ELS value of 5 percent, its dollar value is 5 percent of the value of a life saved, and averting 20 such injuries would have the same value as averting one fatality. NHTSA then reports the impacts of a rule as costs per ELS.

NHTSA’s ELS estimates are calculated for a given year for different injury categories, based on data from all motor vehicle crashes that occurred in that year. The fractional values that result are then used in subsequent rulemakings. The completed regulatory analyses discussed in Section 5.3 are based on 1994 data; more recent rules are based on data from 2000 that are described in more detail below (DOT 1996, DOT 2002d).

NHTSA’s current approach includes the following steps.

1. Crash-related injuries are categorized (by body part affected) using the Abbreviated Injury Scale (AIS), which is a simple numerical system for ranking and comparing the severity of crash-related injuries in terms of their threat to life.⁶⁰ A score of “0” indicates that there were no injuries, whereas a score of “6” indicates that the injury was likely to be immediately fatal; intermediate scores of 1 through 5 indicate injuries of increasing severity. When multiple injuries occur, they are scored according to most life-threatening injury; i.e., the Maximum AIS or MAIS.
2. NHTSA then estimates the economic costs of crashes for each of the MAIS categories. These costs are divided into two components: “non-injury related” costs include those stemming from travel delays and property damage; “injury-related” costs include expenditures related to medical treatment, emergency services, lost workplace and household productivity, employer replacement costs for workers with disabilities, legal and court fees stemming from litigation, and administration of insurance claims (DOT 2002).⁶¹
3. NHTSA next estimates the quality of life impacts based on injury-related changes in functional status over time (Miller et al. 1991, Miller et al. 1995). NHTSA uses a functional capacity index that considers the effects of injury on seven dimensions: mobility, cognitive/psychological, self-care, cosmetic, sensory, pain, and ability to work. The resulting quality of life scores (weighted and combined across dimensions) are then multiplied by the value of a statistical life year, after first subtracting the value of after-tax wages and household production. The resulting monetary value of these quality of

⁶⁰See AAAM (2001) for the most recent version of the AIS. The regulatory analyses discussed in Section 5.3 rely on earlier versions of this scale.

⁶¹These categories are from the report for the year 2000. The 1994 report uses slightly different methods to estimate these costs, and includes two additional types of “injury-related” costs: premature funerals and vocational rehabilitation (DOT 1996).

life impacts is then added to the economic costs discussed above to determine the total (or “comprehensive”) average per-case costs of injuries in each MAIS category.

4. Finally, NHTSA divides the comprehensive dollar values for each nonfatal MAIS category by the value of fatalities to estimate the ELS ratio for injuries in that category.

The estimates resulting from these steps are provided in Exhibit 15 for the year 2000. As illustrated by the exhibit, NHTSA estimates that the total value (economic and quality of life combined) of an injury in the least severe category is \$15,017. Because \$15,017 is 0.45 percent of the per fatality value, NHTSA assumes that each injury in this category is equivalent to 0.45 percent of a life saved.⁶²

⁶²As noted earlier, the regulatory analyses described in Section 5.3 use older estimates of these values.

Exhibit 15					
NHTSA RELATIVE VALUES OF INJURIES AND FATALITIES					
(2000 dollars, 4 percent discount rate)					
Injury Severity Category (examples)¹	Injury Related Costs²	Non-Injury Related Costs³	Quality Of Life Impacts	Total Costs (Comprehensive)⁴	Relative Value⁵
MAIS 1: Minor Injury (whiplash, bruise, broken tooth)	\$5,941	\$4,621	\$4,455	\$15,017	0.45%
MAIS 2: Moderate Injury (closed leg fracture, finger crush)	\$62,020	\$4,800	\$91,137	\$157,958	4.69%
MAIS 3: Serious Injury (open leg fracture, amputated arm, major nerve laceration)	\$178,358	\$7,739	\$128,107	\$314,204	9.33%
MAIS 4: Severe Injury (partial spinal cord severance, concussion with neurological signs (unconscious less than 24 hours))	\$337,301	\$10,832	\$383,446	\$731,580	21.73%
MAIS 5: Critical Injury (complete spinal cord severance, concussion with neurological signs (unconscious more than 24 hours))	\$1,077,567	\$18,594	\$1,306,836	\$2,402,997	71.38%
Fatal	\$957,787	\$19,421	\$2,389,179	\$3,366,388	100.00%
<p><u>Source:</u> MAIS examples: Miller, T., J. Viner, S. Rossman, N. Pindus, W. Gellert, J. Douglass, A. Dillingham, and G. Blomquist. 1991. <i>The Costs of Highway Crashes</i>. Washington, D.C.: The Urban Institute, p. 10. Dollar values: U.S. Department of Transportation (DOT). 2002d. <i>The Economic Impact of Motor Vehicle Crashes, 2000</i>. National Highway Traffic Safety Administration, Table A-1.</p> <p><u>Notes:</u> 1. Maximum Abbreviated Injury Scale (MAIS) categories reflect the severity of the worst injury in terms of risk to life. 2. Per person values for medical treatment, emergency services, lost workplace and household productivity, replacement costs for workers with disabilities, legal and court fees stemming from litigation, and administration of insurance claims. 3. Per person values for travel delay and property damage. 4. Details do not add to total in source document, presumably due to rounding. 5. Relative values are calculated by dividing the comprehensive value for the severity category (in the previous column) by the dollar value of a fatal risk (i.e., by \$3,366,388). These fractions are then used in the calculation of equivalent lives saved.</p>					

The “all crash” values for each injury category are applied across all regulatory analyses, and are not adjusted for variations in the types of crashes averted nor the characteristics of the individuals injured, except to the extent that these differences are reflected in the distribution of

injuries across the different categories. For example, NHTSA's 1999 child restraints rule used the ELS estimates for injuries from all crash types (affecting adults and children) in calculating the benefits of avoiding injuries to children (DOT 1999).

In the analyses of final rules discussed in Section 5.3, NHTSA does not report a total dollar value for the injuries and fatalities averted and hence does not calculate net benefits (benefits minus costs). In more recent proposed rules, NHTSA has used the dollar values from the approach described above to monetize regulatory benefits. Hence NHTSA is now reporting the results of both cost-effectiveness and benefit-cost analyses, consistent with the requirements of OMB *Circular A-4*. In addition, NHTSA is exploring the use of a new Functional Capacity Index to calculate the quality of life impacts of its rules (DOT 2002d)

The valuation approach used for FMCSA is similar to the approach used for NHTSA in that it includes both economic costs and monetized quality of life impacts. FMCSA periodically issues reports that estimate per crash costs for large trucks and buses, the most recent of which was published in 2002 (Zaloshnja and Miller 2002). (The regulatory analysis discussed in Section 5.3 relies on an older version of this report.) The 2002 report found that the present value of lifetime costs (discounted at a four percent rate) for victims averaged \$32,548 per crash. This estimate includes the economic costs associated with medical care, emergency services, property damages, and lost productivity. It also includes the monetized value of pain and suffering and quality of life impacts based on the approach used by NHTSA (Miller et al. 1995). The report provides per crash costs by type of crash and severity of injury, which can then be used as relevant for particular regulatory analyses. FMCSA reports the results of its analyses as net benefits, rather than using NHTSA's ELS approach for cost-effectiveness analysis.

The CPSC approach to benefits valuation is somewhat similar to those used by the agencies discussed above. CPSC applies VSL estimates to value fatal risks, and combines information on the economic costs of illness with estimates of quality of life impacts to value nonfatal injuries. For acute injuries, CPSC developed a Injury Cost Model to provide a standard approach for estimating benefits (Miller et al. 2000). This model addresses three categories of economic costs: medical costs (including hospital and emergency treatment and claims processing), work losses (including household and paid work, as well as caretaker losses and employer replacement costs), and product liability insurance and litigation costs. While the model also includes a fourth category that addresses quality of life and pain and suffering impacts, this component is generally not used in CPSC analyses. The model includes two options for valuing quality of life impacts, one based on jury awards for pain and suffering and a second based on functional capacity ratings.⁶³ However, CPSC generally relies on other sources for estimates of pain and suffering or quality of life impacts.

⁶³The functional capacity ratings in this model address six categories (bending/grasping/lifting, cognitive, mobility, sensory, cosmetic, and pain), based on the approach used by NHTSA (Miller 1995).

5.3 Recent Regulatory Analyses

This section discusses recently finalized regulatory analyses for economically significant rules promulgated by the agencies included in this chapter.⁶⁴ It addresses rules completed by OSHA (in DOL) and FMCSA and NHTSA (in DOT) between January 1, 2000 and June 30, 2004. Because CPSC did not finalize any economically significant rules during this time period, it is excluded from this part of the discussion.

The following subsections first summarize the characteristics of each agency's economically significant health and safety rules, focusing on recent final rules that were subject to OMB review under Executive Order 12866 and include quantified estimates of costs and health impacts. The subsections describe the general characteristics of each rule, present the overall results of the analyses, and discuss the approaches used to value benefits in more detail. More detailed information on these rules is provided in the *Federal Register* notices and supporting analyses referenced below.

5.3.1 Characteristics of Recent Major Health and Safety Rules

Between January 2000 and June 2004, OSHA, NHTSA, and FMCSA finalized five economically significant health and safety rules that include quantified estimates of costs and human health impacts. These rules are listed in Exhibit 16 below and discussed in the following sections. As in the summaries provided for other agencies, it is again important to keep in mind that it is not possible to fully capture all of the characteristics of these analyses in this type of brief overview, and agency practices are continuing to evolve in response to OMB *Circular A-4* and other factors.

⁶⁴Information in the following sections is based on the *Federal Register* notices identified in Exhibit 15, supplemented by the regulatory analyses listed in Exhibit 16 unless noted otherwise.

Exhibit 16			
OSHA, NHTSA, AND FMCSA MAJOR HEALTH AND SAFETY RULEMAKINGS¹			
January 1, 2000 – June 30, 2004			
Regulation	Publication Date	Federal Register Citation	Statutory Authority
<i>DOL/OSHA:</i>			
Ergonomics program ²	November 14, 2000	65FR68262	Occupational Safety and Health Act
Steel erection safety	January 18, 2001	66FR5196	Construction Safety Act, Occupational Safety and Health Act
<i>DOT/NHTSA:</i>			
Occupant crash protection (air bags)	May 12, 2000	65FR30680	Transportation Equity Act for the 21 st Century
Tire pressure monitoring ³	June 5, 2002	67FR38704	Transportation Recall Enhancement, Accountability, and Documentation Act
<i>DOT/FMCSA:</i>			
Truck driver hours of service ⁴	April 28, 2003	68FR22456	Interstate Commerce Commission Termination Act
<p>Sources: Information on statutory authorities was taken from the <i>Federal Register</i> notices cited. Rules finalized between January 1, 2000 and September 30, 2003 were identified through review of: (i) U.S. Office of Management and Budget (OMB). 2001. <i>Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, p. 30 and Table 4; (ii) U.S. Office of Management and Budget (OMB). 2002. <i>Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, pp. 46-47 and Table 9; (iii) U.S. Office of Management and Budget (OMB). 2003. <i>Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, p. 6 and Table 4; (iv) U.S. Office of Management and Budget (OMB). 2004. <i>Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i>, p. 3 and Table 4. Rules finalized between October 1, 2003 and June 30, 2004 were identified through on-line search of the <i>Federal Register</i> (http://www.gpoaccess.gov/fr/index.html) completed in September 2004 as well as information provided by agency staff.</p> <p>Notes: 1. CPSC did not finalize any economically significant rules during this time period. 2. Rule was withdrawn in April 2001 in response to Congressional action (66FR20403). 3. Rule was vacated by the U.S. Court of Appeals in August 2003 (69FR37923). 4. Rule was remanded by the courts, then temporarily reinstated by Congress. (Personal communication from Chuck Rombro, FMCSA, November 8, 2004.)</p>			

The general characteristics of the rules listed in Exhibit 16 are summarized below.

OSHA worker safety rules: In recent years, OSHA has finalized two economically significant rules that address different aspects of worker safety, including the following.⁶⁵

- The *ergonomics* rule sets requirements for determining whether work conditions pose hazards that warrant examination by employers and for establishing a program to address such hazards, focusing on musculoskeletal disorders. The rule was proposed in November 1999 and finalized in November 2000. However, OSHA withdrew this rule in April 2001 in response to Congressional disapproval, and is now issuing guidance rather than developing regulations to address these types of hazards.
- The *steel erection* rule revises the construction industry safety standards to better protect workers involved in steel erection, setting performance criteria to the extent possible for related activities. The rule was proposed in April 1998 and finalized in January 2001.

The regulatory analyses for the ergonomics rule considers a number of alternatives to the final rule, including differing action levels, requirements for medical intervention, and scopes for the requirements. The steel erection rule was a negotiated rulemaking, and OSHA notes that a number of regulatory and nonregulatory options were considered throughout the negotiation process. However, the costs and benefits of these options were not assessed.

The major authorizing legislation for these rules is the Occupational Safety and Health Act, which includes a number of considerations that DOL must take into account in developing standards. For example, the standard must be economically and technologically feasible and cost effective, and achieve significant risk reductions. For the steel erection rule, OSHA also relies on the Construction Safety Act, which authorizes the establishment of standards to reduce construction-related injuries.

DOT transportation safety rules: In recent years, DOT has finalized three economically significant rules that address different aspects of transportation safety, including the following.

- The NHTSA *occupant crash protection* rule sets new requirements for testing air bags to reduce the risk of air bag-related injuries and improve frontal passenger protection. The rule was initially proposed in September 1998, with a supplementary proposal in November 1999, then finalized in 2000. A subset of the requirements were issued as an interim final rule to allow NHTSA to continue to collect additional data.
- The NHTSA *tire pressure* rule requires the installation of monitoring systems that warn the driver when tires are under-inflated. The standard applies to passenger cars, trucks, and small buses. The rule was proposed in July 2001 and finalized in June 2002. It was then vacated by the U.S. Court of Appeals in August 2003; NHTSA is now working to revise the rule.

⁶⁵Some of the information on the OSHA rules discussed in this section was provided by agency staff, due to problems in accessing parts of the cited documents. (Personal communications from Robert Burt, Office of Regulatory Analysis, OSHA, November 8, 2004.)

- The FMCSA *hours of service* rule sets requirements to allow increased sleep opportunities for drivers of commercial motor carriers. The rule was proposed in May 2000 and finalized in April 2003.

The regulatory analyses for each of these rules consider a number of alternatives to the final requirements in comparison to continuation of the status quo. For the occupant crash protection rule, NHTSA considered three alternative crash tests; for the tire pressure rule, NHTSA considered four options that vary in terms of point at which the loss in pressure is considered great enough to trigger the warning light. For the hours of service rule, FMCSA considered one option proposed by an industry group, one proposed by a public interest group, and one developed by its internal staff. FMCSA compared these alternatives to two different baselines, reflecting different assumptions regarding compliance with existing rules.

The DOT rules all respond to statutory mandates. The NHTSA occupant protection rule was required under the Transportation Equity Act for the 21st Century, and its tire monitoring rule was required under the Transportation Recall Enhancement, Accountability, and Documentation Act. The FMCSA rule on hours of service was mandated under the Interstate Commerce Commission Termination Act.

5.3.2 Results of Benefit-Cost Analyses

As indicated by Exhibit 17, it is difficult to compare the quantified net benefits of these five rules to the results for the rules considered in the previous sections of this report due to differences in the benefits valuation approaches and other factors. For the two NHTSA rules, the agency reports the number of injuries averted, but not the dollar values. If we consider only those three rules for which monetized benefits estimates are available, these rules appear to have substantially smaller impacts than the environmental protection rules discussed in Chapter 3 (which lead to monetized net benefits totaling about \$176 billion annually). The net monetized benefits appear similar to the impacts of the food and drug safety rules described in Chapter 4 (which lead to net benefits of roughly \$6 billion annually). However, it is important to note that the estimates in the exhibit do not reflect related uncertainties, which may be substantial in many cases.

Exhibit 17			
SUMMARY OF ANNUALIZED MONETIZED IMPACTS: OSHA, NHTSA, AND FMCSA RULES¹			
Regulation (dollar year)	Total Costs	Total Benefits (health and safety benefits as a percent of total benefits)	Net Benefits (total benefits minus total costs)
<i>DOL/OSHA:</i>			
Ergonomics program (1996 dollars)	\$3,900 million ²	\$9,100 million (100 percent)	\$5,200 million
Steel erection safety ³ (1998 dollars)	\$78 million	\$29 million (100 percent)	(\$49 million)
<i>DOT/FMCSA:</i>			
Truck driver hours of service (2000 dollars)	(\$905 million)	\$228 million (not reported) ⁴	\$1,133 million
Subtotal, rules with monetized benefits	\$3,073 million	\$9,357 million	\$6,284 million
<i>DOT/NHTSA:</i>			
Occupant crash protection (1997 dollars)	\$2,000 million ⁵	not reported ⁶	not reported
Tire pressure monitoring (2001 dollars)	\$784 million ⁷	not reported ⁸	not reported
Total	\$5,857 million	N/A	N/A
<p>Sources: Calculated from information provided in the <i>Federal Register</i> notices cited in Exhibit 15 above, supplemented by: U.S. Department of Transportation (DOT). 2002a. <i>Regulatory Impact Analysis and Small Business Analysis for Hours of Service Options</i>. Prepared by ICF Consulting Incorporated and Jack Faucett Associates; U.S. Department of Transportation (DOT). 2000. <i>Final Economic Assessment, FMVSS no. 208, Advanced Air Bags</i>; and U.S. Department of Transportation (DOT). 2002b. <i>Final Economic Assessment, Tire Monitoring System, FMVSS no. 138</i>.</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. Exhibit reports “best” or “central tendency” estimates for the final rule provided by the agencies unless otherwise noted, and does not reflect the analyses of uncertainty contained in the underlying analyses nor the analyses of regulatory options. 2. Total social costs, including private and governmental costs; costs to employers are higher due to work restriction protection provisions. 3. Assumes full compliance with existing standards; does not include a value for reductions in fatal risks. 4. Neither the <i>Federal Register</i> notice nor the <i>Regulatory Impact Analysis</i> provide detailed information on the valuation approach, which includes averted property damage costs as well as injuries. 5. Estimate provided in the <i>Federal Register</i> notice; represents the maximum expected compliance costs and does not net out savings associated with decreases in inadvertent air bag deployment. These savings could be as high as \$1.3 billion per year. 6. NHTSA reports the number of injuries avoided but not their monetary value, instead calculating costs per equivalent life saved (ELS) for different compliance options. These costs are reported in the <i>Final Economic Assessment</i> as ranging from negative values to \$9 million per ELS. 7. Mid-point of range reported in <i>Federal Register</i> notice; includes compliance costs and savings due to increased fuel economy and decreased tread wear. 8. NHTSA reports the number of injuries avoided but not their monetary value, instead calculating costs per ELS of \$5.8 million. 			

These net benefits would be much lower, however, if the ergonomics rule (which has been withdrawn) was excluded. The ergonomics rule accounts for over 80 percent of the total monetized net benefits of these rules. The reported benefits of these rules consist entirely of impacts on human health for the OSHA rules, but also include crash-related property damage in the case of the DOT rules.

The types of costs assessed for each rule, as well as the discount rates used, are summarized below; the following section provides more information on the benefit analyses.

OSHA worker safety rules: The costs assessed in the two OSHA rules include the following.

- In the *ergonomics* rule analysis, OSHA considers the costs of each component of the program for each type of affected establishment as well as state and local government, including both social costs and costs to the employer. Employer costs are higher than net social costs due to the shifting of work restriction protection costs to the employer. OSHA notes that this analysis does not reflect changes in the economy over time and assumes that current conditions continue into the future.
- The *steel erection* rule analysis considers the incremental costs associated with each type of protective measure required under the rule (e.g., nets and guardrails), as well as training and recordkeeping, for each type of affected establishment. OSHA considers both the costs of increased compliance with existing standards and the incremental benefits of the new requirements compared to this full compliance baseline.

Both rules apply a seven percent discount rate, consistent with the OMB guidance in place at the time. The *Federal Register* notices for these rules include limited discussion of uncertainty and nonquantified impacts.

DOT transportation safety rules: The cost analyses for the three DOT rules consider the following factors.

- In the *occupant crash protection* rule, NHTSA considers the costs associated with meeting the new standards under two alternative sets of assumptions regarding the characteristics of the sensors and air bags likely to be used. NHTSA also considers the cost savings associated with reduced property damages due to unnecessary air bag deployment when estimating the net cost of the rule for consumers. NHTSA discusses a number of uncertainties related to the decisions manufacturers will make in terms of how to comply with new test requirements and reports the results in ranges that reflect this uncertainty. A seven percent discount rate is used throughout the analysis, consistent with the OMB guidance in place at the time that the analysis was completed.
- The NHTSA *tire pressure* rule assesses the incremental costs associated with installing, maintaining, testing, and operating each type of tire pressure monitoring system that manufacturers may install. These costs are assessed for each of two compliance options.

NHTSA also assesses the economic benefits (cost-savings) attributable to the rule, including increased fuel economy and increased tread life, and notes that some maintenance costs as well as the value of time needed to re-inflate tires were not quantified. NHTSA also uses a seven percent discount rate in this analysis.

- For the *hours of service* rule, FMCSA first assesses the costs of complying with the regulations assuming that demand for trucking services remains constant, and then considers the effects of the rule on decisions to use rail rather than truck services. FMCSA estimates the changes in wages and benefits related to the change in the number of hours that an individual may drive, as well as associated costs such as truck operation and maintenance. The agency notes that there is substantial noncompliance with existing rules and finds that the new rule will lead to cost-savings compared to full compliance with current rules. FMCSA also reports the costs of achieving full compliance with the existing regulations. FMCSA does not note the discount rate used in the *Federal Register* notice nor in the *Regulatory Impact Analysis* for the final rule, but includes discussion of the uncertainties in the analysis.

5.3.3 Approaches for Valuing Human Health Impacts

The approach for valuing the impacts of these rules on worker and traffic was introduced in Section 5.2 above and is described in more detail below. Selected aspects of the benefits analyses are summarized in Exhibit 18, and described in the following paragraphs. As noted earlier, these practices are evolving in response to the requirements of OMB *Circular A-4* and other factors.

Exhibit 18					
VALUATION OF ANNUAL HEALTH IMPACTS: OSHA, NHTSA, AND FMCSA RULES¹					
Regulation	Premature Mortality		Morbidity		Significant nonquantified impacts
	Cases averted	VSL per case	Types of health impacts averted	Valuation approach	
<i>DOL/OSHA:</i>					
Ergonomics program (1996 dollars)	none	N/A	musculoskeletal disorders	COI	Benefits related to early detection and prevention.
Steel erection safety (1998 dollars)	22 accident-related	none	accident-related injuries	COI	None reported
<i>DOT/NHTSA:</i>					
Occupant crash protection (1997 dollars)	179 crash-related	\$2.8 million ²	Crash-related injuries	COI and HRQL ³	None reported
Tire pressure monitoring (2001 dollars)	79-124 crash-related	\$2.8 million ²	Crash-related injuries	COI and HRQL ³	Excludes consideration of certain types of crashes
<i>DOT/FMCSA:</i>					
Truck driver hours of service ⁴ (2000 dollars)	41crash-related	Not reported	Crash-related injuries	Not reported	None reported
<p>Sources: <i>Federal Register</i> notices cited in Exhibit 15 above, supplemented by: U.S. Department of Transportation (DOT). 2000. <i>Final Economic Assessment, FMVSS No. 208, Advanced Air Bags</i>; U.S. Department of Transportation (DOT). 2002b. <i>Final Economic Assessment, Tire Monitoring System, FMVSS no. 138</i>; and, U.S. Department of Transportation (DOT). 2002a. <i>Regulatory Impact Analysis and Small Business Analysis for Hours of Service Options</i>. Prepared by ICF Consulting Incorporated and Jack Faucett Associates.</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. Exhibit reports “best” or “central tendency” estimates for the final rule provided by the agencies, and does not reflect the often extensive analyses of uncertainty contained in the underlying analyses nor the analyses of regulatory options. 2. NHTSA estimate per fatal case, based on VSL estimates net of lost productivity. Total value per equivalent life saved is \$2,854,500 including economic costs. (DOT 1996). These values are used in the equivalent lives saved (ELS) calculations for cost-effectiveness analysis as described in Section 5.2 above. 3. For the rules in this exhibit, these methods are used to calculate ELS ratios as an input for cost-effectiveness analysis rather than to monetize benefits in benefit-cost analysis. 4. Neither the <i>Federal Register</i> notice nor the <i>Regulatory Impact Analysis</i> provide detailed information on the valuation approach, which includes property damages as well as the value of injuries. However, the benefits analysis appears to be based on the COI and monetized HRQL approaches discussed in Section 5.2 above. 					

OSHA worker safety rules: The benefits assessment for the OSHA rules address the following considerations.

- The *ergonomics* rule addresses job-related musculoskeletal disorders based on Bureau of Labor statistics data, adjusted for under-reporting. OSHA determines the value of averting these disorders, including the costs of lost productivity, lost tax payments, and administering workers' compensation claims. OSHA estimates these costs as \$27,700 per currently reported disorder and \$7,000 per currently unreported disorder, assuming that disorders in the latter category are likely to be significantly less severe. OSHA notes that this approach excludes consideration of avoided pain and suffering, family losses, or lost household productivity, and hence results in conservative estimates.
- For the *steel erection* rule, OSHA also relies on data from the Bureau of Labor Statistics, supplemented in this case by OSHA inspection data, to estimate the injuries averted. To value nonfatal risk reductions, OSHA includes the costs of lost productivity (direct and indirect), medical care, and administering insurance claims; fatal risks are not assigned a monetary value. For nonfatal effects, the average value per lost-workday injury is approximately \$35,000. OSHA indicates that this approach excludes the value of liability claims, and notes that the results greatly underestimate the true value of the rule's benefits.

OSHA does not apply VSL estimates in either rule; no deaths are averted by the ergonomics rule and fatalities averted by the steel erection rule are not valued. This approach results in benefits estimates that are likely to be much lower than the estimates applied by other agencies. The *Federal Register* notices for these rules contain only limited discussion of uncertainty or nonquantified effects. As noted earlier, OSHA is now altering its approach to valuation, incorporating estimates of WTP for both fatal and nonfatal effects.

DOT transportation safety rules: The benefit assessments in each of the three DOT rules address the decrease in injuries associated with the crashes averted by the rules, applying the methods discussed in Section 5.2 above.

In both the NHTSA *occupant crash protection* and *tire pressure* rule, NHTSA relies on reported crash data to estimate the number of baseline injuries and fatalities, and considers the impacts of different assumptions regarding the effectiveness of the rule in averting these impacts. NHTSA uses the ELS approach discussed above to value these health effects, and reports the results as costs per ELS.

Implicit in the NHTSA approach are estimates of the economic costs of illness and quality of life impacts; the later are valued based on a \$2.8 million VSL, which has been adjusted to exclude the value of lost productivity. This value is lower than the VSL estimates used by the agencies discussed in the previous sections of this report, and has been updated by only a small amount for more recent proposed rules (see Exhibit 15 above). For both rules, NHTSA discusses the uncertainty related to compliance options and expresses the results as ranges that reflect this uncertainty. In the tire pressure rule, NHTSA notes that it was not possible to quantify the

impact of the rule on certain types of crashes, and that the monetary value of the property damage or travel delays associated with fewer crashes is not included in its estimates.

While the analyses of these final rules report the results only in terms of cost-effectiveness, NHTSA has used the dollar values that underlie its ELS approach to monetize the value of regulatory benefits in its more recent proposals. Hence more recent rules report the results of both cost-effectiveness and benefit-cost analyses.

The FMCSA *hours of service* rule relies on baseline information on fatigue-related crashes primarily from police reports. To estimate the change in the number of crashes attributable to the rule, FMCSA determines the changes in driver schedules, assesses the link between these changes and the amount of sleep, determines the effect of sleep on alertness, and then estimates the effect of alertness on crash risks. FMCSA considers both the direct impact of the rule on fatigue-related crashes, and the indirect impact due to the rule's effect on the number of inexperienced drivers and vehicle miles traveled. The benefit estimates address injuries, fatalities, and property damage, with an average value of \$75,637 per crash. FMCSA discusses uncertainties related to the effects of hours driven on crash risks and the percent of crashes attributable to fatigue, and presents sensitivity analysis with different assumptions.

5.4 Characteristics of Potential Future Rules

Review of the regulatory plans for DOL, DOT, and CPSC suggests that these agencies are in the process of proposing or finalizing several economically significant rules that are likely to include quantified health impacts in the supporting analyses. Based on the most recent version of the "Unified Agenda" (published in the *Federal Register* on June 28, 2004), the rulemakings listed in Exhibit 19 are likely to be promulgated over the next several years. The exhibit includes all economically significant rules listed in the Agenda that are likely to involve quantified estimates of impacts on human health.⁶⁶ No such rules were identified for DOL agencies other than OSHA, for DOT agencies other than NHTSA, or for independent agencies other than CPSC.⁶⁷

⁶⁶As indicated in the exhibit notes, some of these rules were published subsequent to the time period that is the focus of this report; i.e., after June 28, 2004. (Other rules initially planned for publication in 2004 have not yet been promulgated.)

⁶⁷As noted earlier, it appears that NRC may be the only independent Federal agency (other than CPSC) likely to promulgate major rules with human health or safety impacts. However, review of the "Unified Agenda" suggests that NRC is not currently developing any economically significant regulations that appear likely to include quantified human health effects (see 69FR38628).

Exhibit 19		
FORTHCOMING DOL, DOT, AND INDEPENDENT AGENCY MAJOR HEALTH AND SAFETY RULEMAKINGS^{1,2} (June 28, 2004 “Unified Agenda”)		
Rule	Status (“Unified Agenda” citation)	Potential Quantified Health Impacts (proposed rule citation)
<i>DOL/OSHA:</i>		
Occupational exposure to crystalline silica	Pre-rule planning (69FR37820)	<i>Silicosis</i> (chronic obstructive pulmonary disease), cancer, tuberculosis, and other respiratory diseases
Hearing conservation for construction workers	Pre-rule planning (69FR37822)	Hearing loss
Occupational exposure to beryllium	Pre-rule planning (69FR37821)	<i>Berylliosis</i> (chronic obstructive pulmonary disease), lung cancer
Occupational exposure to hexavalent chromium	Proposed rule planned in 2004 (69FR37823) ³	Lung cancer
Confined spaces in construction	Proposed rule planned in 2005 (69FR27824)	Suffocation, explosion-related injuries
<i>DOT/NHTSA:</i>		
Side impact testing ⁴	Proposed rule planned in 2004 (69FR37921)	Crash-related injuries
Tire pressure monitoring ⁵	Proposed rule planned in 2004 (69FR37923)	Crash-related injuries
Rear center lap/shoulder belts	Final rule planned in 2004 (69FR37932)	Crash-related injuries (68FR46546)
<i>CPSC:</i> ⁶		
Flammability of upholstered fabrics	Pre-rule planning (69FR38485)	Fire-related health effects
Open-flame ignition of mattresses and bedding ⁷	Pre-rule planning (68FR38486)	Fire-related health effects
Source: The Unified Agenda published in the <i>Federal Register</i> on June 28 2004 (specific page numbers are cited above), supplemented by information from the <i>Federal Register</i> notice for the proposed rule where referenced. Notes: 1. Includes rules identified as economically significant for which human health-related benefits are likely to be quantified. 2. No rules were identified that meet the criteria in Note 1 above for components of DOL and DOT other than OSHA and NHTSA, or for independent agencies other than CPSC. 3. This rule was proposed on October 4, 2004 (69FR59306). 4. This rule was proposed on May 17, 2004 (69FR27990). 3. Additional health effects information for forthcoming OSHA rules was provided in personal communications from Deborah Aiken and Robert Burt, Office of Regulatory Analysis, OSHA, June 29, 2004. 4. Recently completed analysis suggests that this rule will be economically significant, although it was not identified as such in the “Unified Agenda.” (Personal communication from Jim Simons, Office of Regulatory Analysis and Evaluation, NHTSA, November 5, 2004.) 5. This rule would replace the 2002 regulation vacated by the Court and discussed above. 6. CPSC is not subject to OMB regulatory review under Executive Order 12866. 7. Recently completed analysis suggests that this rule will be economically significant, although it was not identified as such in the “Unified Agenda.” (Personal communication from Greg Rodgers, Office of Hazard Analysis and Reduction, CPSC, November 9, 2004.)		

For OSHA, the impacts of forthcoming rules appear quite different than the impacts of the recent rules addressed above. Many of these regulations address exposure to hazardous substances that cause varying types of fatal and nonfatal illness, rather than the types of injuries addressed by earlier rules. For NHTSA, forthcoming rules address crash-related injuries similar to those addressed previously, while both CPSC rules consider fire-related injuries and deaths.

As indicated by this exhibit, the schedule for several OSHA rules are uncertain since the agency is in the early stages of the rulemaking process. For the other agencies, the reported plans extend only over the next couple of years. It is difficult to predict whether Congress is likely to make significant alterations to any of these agencies' authorizing legislation that will require a significant change in regulatory activity, or whether regulations developed farther into the future are likely to address similar health impacts.

6.0 SUMMARY AND CONCLUSIONS

This report provides background information on the current practices used by Federal agencies to assess the health and safety benefits of major regulations in their economic analyses. Until recently, these practices were implemented in the context of benefit-cost analysis by most agencies. Under new government-wide guidance (provided in the U.S. Office of Management and Budget's (OMB's) *Circular A-4*), cost-effectiveness analysis also will be required whenever possible for all economically significant health and safety rules subject to OMB review (OMB 2003a). The effective date for the new OMB requirements is no later than January 1, 2004 for proposed rules and January 1, 2005 for final rules. Hence agencies are required to begin applying integrated effectiveness measures in advance of when the Institute of Medicine (IOM) Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation completes its related work.

This report focuses on those types of regulations and practices explicitly addressed by the new OMB guidance that led to the chartering of this IOM Committee; i.e., economically significant regulations for which both costs and health or safety benefits can be quantified. The OMB guidelines and the Committee's recommendations are likely to have broader impact, however. Federal agencies may follow the recommended approaches for regulations that are not economically significant and/or not subject to OMB review. In addition, the OMB guidance and the Committee's recommendations will be an important source of information on "best practices" for regulatory analysts outside of the Federal government, including those working in State and local government, industry associations and public interest groups, and academia.

The preceding chapters of this report provide information on general government-wide guidance for regulatory analysis as well as on the approaches used by individual agencies to assess regulatory costs and benefits. This concluding chapter summarizes the information on current practices, first briefly discussing the processes used to develop regulatory analyses across agencies, then describing the general approaches used to value health and safety-related benefits. It next summarizes the results of recent regulatory analyses and concludes with a discussion of the types of health impacts likely to be addressed in forthcoming rules.

In reviewing the results of this analysis, it is important to note that it is not intended to be a comprehensive assessment of all of the factors that influence regulatory decision-making, nor is it intended to address all economic analyses of Federal regulations. Rather, its goal is to provide the IOM Committee with a factual summary focused on those current practices that may be most affected by their recommendations.

6.1 Regulatory Development Processes

This report describes the practices of the seven Federal agencies that finalized economically significant rules with quantified health and safety impacts between January 2000 and June 2004 and/or that are currently in the process of developing such rules. These agencies include the following.

1. U.S. Environmental Protection Agency (EPA)
2. Food and Drug Administration (FDA), U.S. Department Of Health And Human Services (HHS)
3. Food Safety and Inspection Service (FSIS), U.S. Department Of Agriculture (USDA)
4. Occupational Safety And Health Administration (OSHA), U.S. Department Of Labor (DOL)
5. National Highway Traffic Safety Administration (NHTSA), U.S. Department Of Transportation (DOT)
6. Federal Motor Carrier Safety Administration (FMCSA), DOT
7. Consumer Product Safety Commission (CPSC)⁶⁸

These agencies generally follow similar processes for completing the analyses that support these rules, as summarized below.

Agency regulatory development teams usually are led by individuals or groups with technical expertise in the area of concern, supported by staff from other offices. These teams are generally responsible for crafting the regulatory requirements as well as for conducting a range of supporting analyses. In many agencies, the economic analyses (sometimes referred to as the regulatory impact analyses) are completed by a separate office, with assistance from agency risk assessors and other groups involved in the regulatory development process. Some agencies rely on contractor support for help in completing the analyses for individual regulations, while others use contractors only for occasional projects related to data collection, methods development, and/or updates of widely-used values. A few of these agencies have separate department-wide internal research groups that also provide supporting studies.

It is difficult to estimate the level of effort or dollar resources used to complete these economic analyses, either in the aggregate or on average. None of these agencies track the resources devoted to the economic analysis of individual rulemakings. Accounting for these costs on a “per rule” basis is quite difficult since both agency staff and contractors are often involved in projects that support more than one rulemaking or contribute both to the economic analysis and other aspects of the regulatory development process. In addition, a number of different offices and individuals are often involved in each analysis to varying degrees, and many staff split their time across multiple proposed and/or final rules (as well as both economically significant and less major rules) that the agency is concurrently developing. Agency staff also note that the resources used will depend on the scope and complexity of the assessment as well as the nature of the competing demands for the limited resources available.

⁶⁸As discussed in Chapter 5, CPSC is an independent agency not subject to OMB review but is included in this report because it is currently working on economically significant rules with safety impacts.

Many agencies provided estimates of the number of individuals employed by the offices with lead responsibility for economic assessment and/or the dollars these offices devote to funding contractor services. These estimates are not comparable across agencies, however, because of differences in the overall workload and allocation of staff. For example, to varying extents, all of these agencies are involved in a number of rulemakings other than those addressed by this report; i.e., that are not economically significant or do not involve quantified health impacts. In addition, the extent to which other offices or contractors contribute to the analyses varies; e.g., some economic analysis groups conduct their own risk assessments while others rely on health scientists from other agency offices.

However, the information provided by agency staff suggests that the resources available for economic analysis are generally constrained and that they often face difficult allocation decisions. A substantial proportion of these resources may be devoted to components of the analysis that are more uncertain or difficult to assess than the valuation of health-related benefits. For example, EPA air office staff note that most of their resources are devoted to modeling changes in air quality and emissions, while NHTSA staff note that most of their contract funding is used to determine compliance options and costs. Review of individual analyses also suggests that significant resources are needed to develop the approach for quantifying risk reductions and assessing resulting uncertainties.

These agencies generally develop the key components of the analytic approach for a particular rule before the rule is proposed. For the final rule, the analysis may be adapted to reflect new information and public comments as well as any changes made in the regulatory requirements. Once the rulemaking process is initiated, the agencies rarely have the time or resources to engage in new primary research on benefits values and usually rely on pre-existing studies.⁶⁹ The length of time that elapses between the start of the rule development process and publication of the proposed rule is often constrained by statutory requirements, court orders, and/or political pressures; typically the process lasts one to two years, but may last longer. The economic analysis must be largely completed well in advance of the rule publication date since it is needed to brief upper level management as well as for OMB review. Thus the development of new methods for benefits valuation often occurs as part of projects completed independently of the rulemaking process, such as EPA's retrospective and prospective studies of the Clean Air Act, and NHTSA's periodic reports on the costs of motor vehicle crashes (EPA 1997, EPA 1999, EPA 2003a, DOT 1996, DOT 2002d).

The time available for the analysis, the budgetary and staff resources, and the types of regulatory options considered can change substantially during the rule development process due to legislative or judicial action, changes in agency or Administration priorities, or responses to preliminary analytic results. Economic analyses of regulations are often completed under tight time frames with limited staff and budgetary resources. All of these factors pose significant challenges to the analysts involved in assessing the impacts of individual regulations.

⁶⁹ Federally-funded survey research must be cleared through OMB under the Paperwork Reduction Act, which substantially increases the amount of time needed to complete such projects.

6.2 Benefits Valuation Approaches

The economic analyses for major health and safety rules now must generally include three components, consistent with government-wide statutory and administrative guidance: (1) a benefit-cost analysis that addresses the net national impacts of the rule on social welfare; (2) for forthcoming rules, a cost-effectiveness analysis; and (3) an analysis of the distribution of the impacts across certain subgroups of concern. The details of these analyses are determined in part by OMB guidance and in part by individual agency decisions regarding how to implement this guidance.

6.2.1 General OMB Guidance

OMB's current guidance on regulatory analysis, contained in *Circular A-4*, provides a general framework for assessing the impacts of regulations but allows the agencies substantial leeway in determining the details of the approach to valuation for both benefit-cost and cost-effectiveness analyses. The approaches used for assessing costs, which may include direct compliance costs, resulting market impacts, and any cost-savings attributable to the rule, are described in the prior chapters of this report. These approaches are generally the same for both benefit-cost and cost-effectiveness analysis. However, in the case of cost-effectiveness analysis, care must be taken to ensure that the numerator in the cost-effectiveness ratio accounts for all relevant costs and savings without double-counting impacts captured in the divisor.

OMB's guidance on valuing benefits in the context of benefit-cost analysis has evolved over several years. To determine the dollar value of benefits, OMB recommends that agencies rely on estimates of willingness to pay (WTP) to the extent possible. For premature mortality, OMB recommends that agencies apply "value of statistical life" (VSL) estimates, which reflect individual WTP for small changes in the risk of premature mortality. OMB discusses the range of estimates recently used and allows agencies to apply the approach that they deem most appropriate, which leads to the application of differing VSL estimates across agencies. For morbidity, OMB recommends that agencies apply estimates of individual WTP supplemented by estimates of any net changes in economic costs to society that are not captured in the WTP values. When WTP estimates are not available, OMB notes that agencies may combine the results of health utility studies with dollar values; i.e., apply monetized estimates of health-related quality of life impacts. Hence the OMB guidance allows for a range of approaches to valuing nonfatal as well as fatal health and safety risks.

The new 2003 guidance represents the first time that OMB has required agencies to complete cost-effectiveness analysis along with benefit-cost analysis for economically significant health and safety rules. OMB discusses two general approaches for measuring benefits in these cost-effectiveness analyses. The first could involve the use of physical measures of effectiveness. In this case, analysts would choose a primary benefit category to use as the effectiveness measure, then subtract the dollar value of the other benefits from regulatory costs before calculating the cost-effectiveness ratio. For example, analysts could calculate costs per life saved after subtracting the value of morbidity impacts from the costs attributable to the rule.

Under the second approach, analysts could use quality of life indices that convert different types of health impacts into a single metric, which then becomes the divisor in the cost-effectiveness calculation. These metrics include the approaches that are the focus of this IOM Committee, variously referred to as health-adjusted life expectancy (HALE), quality-adjusted life year (QALY), or health-related quality of life (HRQL) measures. Because different measures of effectiveness may yield varying results and provide different perspectives, OMB recommends that agencies apply more than one effectiveness measure in their analyses.

In addition to calculating the national net benefits and cost-effectiveness of regulatory options, agencies must address the distribution of the impacts across certain subgroups of concern. At minimum, the distributional analysis must address statutory requirements for considering the costs imposed on small businesses and state and local governments. Existing Executive Orders also require consideration of whether the rule has disproportionate adverse impacts on low income and minority groups or children. In some cases, the agencies will also disaggregate the results of the national analysis to reflect the risk reductions for particularly vulnerable groups, such as sensitive subpopulations with pre-existing conditions, children, or the elderly.

Generally, these disaggregate results use the same approaches for benefits valuation as applied in the national analysis. The current OMB guidance reflects concerns about the equity of the valuation approach applied in both the national and distributional analyses. In particular, OMB suggests that agencies avoid approaches that appear to assign lower values to life years saved for persons with disabilities and instead apply population averages. OMB also notes that the monetary values used for children in benefit-cost analysis generally should be at least as large as the values for adults.

6.2.2 Agency Approaches for Valuing Mortality and Morbidity

Each of the seven agencies considered in this report have developed somewhat different valuation approaches for health and safety impacts, and these approaches continue to evolve. Historically, six of the seven agencies have focused on the use of these valuation approaches in the context of benefit-cost analyses, while one (NHTSA) traditionally used monetary benefits values as an intermediate step in developing measures of cost-effectiveness. However, in response to the new OMB guidance, these agencies are now developing approaches for cost-effectiveness analysis, and NHTSA has begun to report the results of both benefit-cost and cost-effectiveness analysis.

To value premature mortality in benefit-cost analyses, all seven agencies now use VSL estimates in some form. However, the base values and adjustments to these estimates vary, as allowed under the current OMB guidance. In the analyses of economically significant rules finalized between January 2000 and June 2004, the following approaches were used to value fatal risks.

- Recent EPA regulatory analyses apply base VSL estimates ranging from \$5.9 to \$6.8 million and then adjust these values for two potentially counterbalancing effects: changes

in income over time, and the timing of the risk (i.e., latency or cessation lag). This range in base values largely reflects the impact of inflation over time.

- FDA and FSIS use slightly lower VSL base estimates (\$4.8 to \$6.5 million), but do not make the adjustments implemented by EPA.
- Current DOT guidance recommends use of a significantly lower VSL estimate (\$3 million), and notes that this value is being reviewed. NHTSA adjusts this estimate to exclude the value of productivity losses and include the economic costs of crash-related deaths. The result of these counterbalancing but relatively small adjustments is currently \$3.4 million per fatality; older analyses rely on a value of \$2.8 million. FMCSA does not report a VSL estimate in its recent regulatory analysis, but appears to follow the DOT-wide guidance.
- In the final rules reviewed for this report, OSHA did not assign a value to fatal risks, but is now relying on EPA's VSL estimates in its forthcoming analyses.
- CPSC did not finalize any economically significant rules reports during this time period, but often reports a range of VSL estimates.

This variation in values reflects at least in part the uncertainties in the underlying research, which provides a range of estimates and generally addresses types of risks that are dissimilar in some respects to the risks addressed by the regulatory programs of these agencies. To some extent, this range of values may also reflect the difficulties inherent in changing long-standing approaches that have become well-established within each agency.

For nonfatal illnesses and injuries, each agency uses a slightly different approach; many combine estimates of the economic costs of illness with monetized estimates of quality of life impacts (sometimes referred to as pain and suffering). For economically significant rules finalized between January 2000 and June 2004, the following approaches were used to value nonfatal risks.

- EPA values morbidity based on WTP estimates to the extent possible. When suitable WTP estimates are not available, EPA relies on estimates of the costs of illness (COI).
- In the past, OSHA relied solely on economic costs of illness to value injuries, but is now adopting WTP estimates developed by EPA to value averted health impacts.
- FDA, FSIS, NHTSA, FMCSA and CPSC all use quality of life indices when valuing nonfatal illnesses and injuries. The details of the approach vary across agencies; however, each agency monetizes these values based on VSL estimates. In addition, each agency adds the economic costs of illness to these monetized quality of life measures, although the types of costs considered vary across agencies.

Again, this variation in practices is consistent with the range of approaches allowed under the current OMB guidance. While the preferred approach to valuation is to rely on estimates of

WTP (supplemented by estimates of any economic costs not included in the WTP value), such estimates are available for only very few illnesses or injuries. Thus the agency approaches described above in many cases reflect the lack of suitable, high quality WTP studies that address the various health outcomes of concern.

Most of these agencies are in the process of developing methods for valuing benefits in the context of cost-effectiveness analysis to implement the new OMB guidelines, including the following.

- EPA is developing approaches that rely on the results of completed studies for key health effects of concern; e.g., transferring estimates of quality of life impacts from the Harvard Center for Risk Analysis' Catalog of Preference Scores (Hubbell 2004, EPA 2003a).
- FDA already uses monetized quality of life measures in its benefit-cost analyses, and has started to report costs per QALY in its recent analyses. The FDA approach includes transferring estimates from the Harvard Catalog, using expert judgment to apply existing indices (e.g., the Quality of Well-Being Scale) to the health effects of concern, and calculating condition-specific QALY weights based on an approach developed by Cutler and Richardson (1997). FSIS reports that it is considering approaches similar to those used by FDA.
- NHTSA has traditionally used monetary values (that include economic costs and monetized quality of life impacts) to convert injury estimates to "equivalent lives saved" (ELS), and then reports the results as a cost-effectiveness ratio (i.e., as costs per ELS). However, NHTSA has now begun to use these monetary values to also calculate net benefits.
- The likely OSHA, FMCSA, and CPSC approaches to cost-effectiveness analysis are uncertain.

In general, it appears that the agencies are not engaging in new primary research to develop measures of effectiveness, at least in the near term. Instead, they are relying on available indices and studies from the health economics literature.

In sum, the review of current practices across agencies suggests that there is significant variation in the approaches used to value benefits within the framework of benefit-cost analysis, due in part to the limitations of the available empirical research. Those agencies that currently use integrated measures of effectiveness generally rely on estimates transferred from existing HALE studies or use expert judgment to apply available HRQL indices to the health effects of concern, rather than conducting new research on quality of life impacts.

6.3 Recent Regulatory Analyses

To provide more detailed information on the approaches used in recent economic analyses, this report includes a review of recently finalized regulatory actions. This inventory focuses on Federal regulations that were:

1. published in final form in the Federal Register between January 1, 2000 and June 30, 2004;
2. defined as economically significant social regulations subject to OMB review; and,
3. included quantitative assessment of both costs and health-related impacts (i.e., cases of injury or illness avoided).

The first criterion reflects the IOM Committee's interest in focusing on current Federal agency practices, which are evolving due to a number of factors. The starting point for the inventory was OMB's annual reports on the costs and benefits of Federal regulations, the most recent of which covers regulations reviewed through September 30, 2003 (OMB 2001, OMB 2002a, OMB 2003b, OMB 2004). More recent regulations were added based on information contained in *Federal Register* notices and derived from conversations with agency staff. These newer rulemakings are of particular interest since they reflect agencies' initial responses to the revised OMB guidance for regulatory analysis (i.e., *Circular A-4*), which was published in September 2003.

The second criterion reflects the focus of the *Circular A-4* guidance on rules that are defined by Executive Order 12866 as economically significant, i.e., that "[h]ave 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." (Executive Office of the President 1993). Rules that meet this criterion are few in number but account for the majority of the health and safety impacts of all Federal regulations, and the analytic approaches applied for other (more minor) rules are often modeled on the approaches applied for these major rules.

The third criterion focuses attention on those health and safety rules that potentially could be subject to cost-effectiveness analysis. Such analysis will not be feasible if costs cannot be quantified or if it is not possible to estimate the physical impacts of the rule on health or safety (e.g., the number of cases of illness or injury averted). These impacts may not be quantified if they are expected to be negligible or if the available data are not sufficient to support any sort of numerical analysis. As noted earlier, while the resulting regulations are those that are most directly affected by the *Circular A-4* guidance on cost-effectiveness analysis, the IOM Committee's impact is likely to extend beyond these types of rulemakings.

The rulemakings that meet these criteria are a small fraction of all Federal regulations. Most rulemakings have either minor impacts or require transfers between different groups (e.g., between taxpayers and beneficiaries) rather than imposing significant social costs or benefits. For example, in fiscal year 2003, only 349 of the 4,312 final rules published in the *Federal Register* were subject to OMB review. Of these 349 rules, only 37 were considered "major," and of the 37 major rules, only 12 were expected to impose significant social costs or benefits (the remainder are mostly transfer programs). However, OMB suggests that these 12 major social regulations were likely to account for the majority of the costs and benefits of all rules subject to their review. Of these 12 major social regulations, only three included quantified health and safety benefits. The others focused on non-health topics (e.g., bird hunting, health record

privacy), quantified outcomes that have only indirect links to human health (e.g., fuel savings, water use), or have impacts that are difficult to quantify in terms of “cases avoided” (e.g., homeland security) (OMB 2004).

6.3.1 Characteristics of Recent Major Health and Safety Rules

Over the time period covered by this report (January 2000 to June 2004), 18 final regulations were published that meet the criteria discussed above. Exhibit 20 summarizes these rules, which are described in more detail in Chapters 3, 4, and 5 of this report.

Exhibit 20		
SUMMARY OF RECENT MAJOR HEALTH AND SAFETY RULEMAKINGS		
January 1, 2000 – June 30, 2004		
Agency	Authorizing Statute(s)	Rulemakings
<i>Environmental Protection</i>		
EPA: Office of Air and Radiation	•Clean Air Act	<ul style="list-style-type: none"> •New vehicle emissions •Heavy duty diesel engines •Spark ignition engines •Reciprocating internal combustion engines •Nonroad diesel engines
EPA: Other Offices	<ul style="list-style-type: none"> •Toxic Substances Control Act •Safe Drinking Water Act 	<ul style="list-style-type: none"> •Lead in paint •Arsenic in drinking water
<i>Food and Drug Safety</i>		
FDA (HHS)	•Federal Food, Drug, and Cosmetic Act and Public Health Service Act	<ul style="list-style-type: none"> •Shell egg labeling and storage •Juice processing •<i>Trans</i> fat labeling •Dietary supplements containing ephedrine alka loids •Bar codes for human drug products and blood
FSIS (USDA)	•Federal Meat Inspection Act and Poultry Product Inspection Act	• <i>Listeria</i> control in meat and poultry
<i>Traffic, Worker, and Product Safety</i>		
OSHA (DOL)	•Occupational Safety and Health Act; Construction Safety Act	<ul style="list-style-type: none"> •Ergonomics program •Steel erection safety
NHTSA (DOT)	<ul style="list-style-type: none"> •Transportation Equity Act for the 21st Century •Transportation Recall Enhancement, Accountability, and Documentation Act 	<ul style="list-style-type: none"> •Occupant crash protection (air bags) •Tire pressure monitoring
FMCSA (DOT)	•Interstate Commerce Commission Termination Act	•Truck driver hours of service
Sources: Exhibits 6, 11, and 16.		

As indicated by the exhibit, many of the agencies considered in this report were only responsible for one or two major health and safety rules with quantified impacts over this time period. The exceptions are EPA and FDA; EPA finalized seven rules (five from its Office of Air and Radiation), while FDA finalized five rules. Two of the rules in this exhibit, the OSHA ergonomics rule and the NHTSA tire pressure monitoring rule, were withdrawn as a result of action by the courts or Congress. CPSC did not finalize any economically significant rules during the time period covered by this inventory.

This report includes only a brief discussion of the statutory authorities under which these rules were developed based on information provided in the *Federal Register* notices for each rule; it is not a comprehensive assessment of all the legal issues that affect these rulemakings. This review suggests, however, that the statutes vary in the extent to which they dictate the specific requirements that must be included in the regulations, as well as in how they define regulatory goals. Within the confines of these statutory prescriptions, it appears that much of the legislation under which these 18 regulations were promulgated is silent on the use of benefit-cost or cost-effectiveness analysis in regulatory decision-making. The exceptions include certain sections of the Clean Air Act, which require that EPA consider the availability of control technology, costs, and other impacts, as well as cost-effectiveness, for regulations addressing certain mobile sources. This Act also requires the use of maximum achievable control technology for certain stationary sources. In addition, the Safe Drinking Water Act mandates that EPA set standards at the lowest feasible level unless benefits are not commensurate with costs, and the Occupational Health and Safety Act requires consideration of feasibility and costs and requires significant risk reductions.

6.3.2 Results of Benefit-Cost Analyses

The exhibit below provides the “best” or central tendency estimates of costs and benefits for each of these 18 rules. These estimates should be approached with caution, because they reflect differing approaches to valuation and ignore the often substantial uncertainty discussed in the underlying analyses. (The assumptions used to calculate these estimates are provided in the previous chapters.) For costs, these estimates generally include compliance-related expenditures, and in some cases also include market impacts and/or offsetting savings. The benefits estimates are almost exclusively comprised of human health and safety impacts; ecological effects account for a small percentage of the quantified estimates of the EPA air emissions rules. The exhibit includes monetized impacts only; the nonquantified benefits of several of these rules are expected to be substantial, particularly in the case of the EPA rules.

Exhibit 21			
SUMMARY OF ANNUALIZED MONETIZED IMPACTS^{1,2,3}			
Regulation (Agency)	Total Costs	Total Benefits	Net Benefits
<i>Environmental Protection</i>			
New vehicle emissions (EPA/air)	\$5,300 million	\$25,200 million	\$19,900 million
Heavy duty diesel engines (EPA/air)	\$4,200 million	\$70,400 million	\$66,200 million
Spark ignition engines (EPA/air)	(\$554 million)	\$7,880 million	\$8,434 million
Reciprocating internal combustion engines (EPA/air)	\$248 million	\$280 million	\$32 million
Nonroad diesel engines (EPA/air)	\$2,000 million	\$80,500 million	\$79,500 million
Lead in paint (EPA/toxics)	\$2,682 million	\$4,683 million	\$2,001 million
Arsenic in drinking water (EPA/drinking water)	\$193 million	\$169 million	(\$24 million)
Subtotal, environmental protection	\$14,069 million	\$189,112 million	\$176,043 million
<i>Food and Drug Safety</i>			
Shell egg labeling and storage (FDA/HHS)	\$10 million	\$260 million	\$250 million
Juice processing (FDA/HHS)	\$23 million	\$151 million	\$128 million
Trans fat labeling (FDA/HHS)	\$12 million	\$1,341 million	\$1,329 million
Dietary supplements containing ephedrine alkaloids (FDA/HHS)	\$49 million	\$88 million	\$39 million
Bar codes for human drug products and blood (FDA/HHS)	\$638 million	\$5,050 million	\$4,400 million
Listeria control in meat and poultry (FSIS/USDA)	\$17 million	\$135 million	\$118 million
Subtotal, food and drug safety	\$749 million	\$7,025 million	\$6,264 million
<i>Traffic, Worker, and Product Safety</i>			
Ergonomics program (OSHA/DOL)	\$3,900 million	\$9,100 million	\$5,200 million
Steel erection safety (OSHA/DOL)	\$78 million	\$29 million	(\$49 million)
Occupant crash protection (NHTSA/DOT)	\$2,000 million	not reported	not reported
Tire pressure monitoring (NHTSA/DOT)	\$784 million	not reported	not reported
Truck driver hours of service (FMCSA/DOT)	(\$905 million)	\$228 million	\$1,133 million
Subtotal, traffic, worker and product safety	\$5,857 million	\$9,357 million + NHTSA	\$6,284 million + NHTSA
Total, all rules	\$20,675 million	\$205,494 million+NHTSA	\$188,591 million+NHTSA
Sources: Exhibits 7, 12, and 17.			
Notes:			
1. Exhibit reports “best” or “central tendency” estimates for the final rule and does not reflect the analyses of uncertainty nor of regulatory options.			
2. See referenced exhibits for more information on the calculation of these estimates, as well as for explanations of the discrepancies between reported net benefits and benefits minus costs and of the different approaches used for valuation.			
3. Dollar year varies; consistent with evolving OMB guidance, older analyses use a 7 percent discount rate for both costs and benefits, and more recent analyses present the results using both 3 and 7 percent rates.			

Care must be taken in interpreting the results reported in this exhibit because the monetized value of benefits was not reported for the two NHTSA rules, the reported results reflect different approaches to valuation, and the exhibit does not account for the often substantial uncertainty noted by the agencies. However, for the agencies that report net benefits, this exhibit suggests that monetized benefits exceed costs for all rules except the arsenic and steel erection rules. In the case of the arsenic rule, EPA was not able to quantify all of the significant health-related benefits. In the case of the steel erection rule, averted fatalities were not assigned a dollar value and the approach used to monetize benefits is likely to substantially understate their value. Review of the analyses for these 18 rules suggests that the benefit estimates are often more uncertain than the cost estimates (due largely to uncertainties in the risk assessment), and often include impacts that cannot be quantified. Hence the value of benefits reported above may understate the overall benefits of these rules.

This exhibit also suggests that the national impacts of these rules are determined largely by rules addressing environmental protection, particularly rules for air emissions. Several of the individual EPA rules have costs and benefits that exceed the impacts of all the rules in the other categories. The monetized net benefits of the EPA rules exceed \$176 billion, while the monetized net benefits of all the food and drug safety rules, and of all the traffic, worker and product safety rules, are slightly over \$6 billion each.

6.3.3 Approaches for Valuing Human Health Impacts

The starting point for the benefits analyses in these rules are the risk assessments, which use available data to estimate the changes in the risks of premature mortality, illness and/or injury prevented by the rules. Several of these agencies (e.g., FDA, OSHA, NHTSA, FMCSA, CPSC) maintain or have access to routine injury or adverse event reporting systems that they use to estimate baseline risks. In these cases, the agencies then estimate the decrease in these risks likely to be associated with the regulatory options based on available data on effectiveness. Outbreak data are also used in a similar fashion for some of the pathogen-related rules promulgated by FDA. For other illness-related risks (e.g., those addressed by EPA, FDA, and FSIS), agencies rely on existing epidemiological studies and general health science research to estimate dose-response relationships associated with the predicted changes in exposure attributable to the rule.

The health impacts addressed by each of these rules as well as the general valuation approaches applied are summarized in Exhibit 22 below. (See Section 6.2.2 above for more information on the valuation approaches.)

Exhibit 22		
VALUATION OF HEALTH IMPACTS		
Regulation (Agency)	Quantified Health and Safety Impacts	Valuation Methods
<i>Environmental protection:</i>		
New vehicle emissions (EPA/air)	Morbidity and mortality associated with various acute and chronic particulate matter and/or ozone related respiratory and cardiovascular conditions	Mortality: VSL Morbidity: WTP, or COI if WTP estimates are not available
Heavy duty diesel engines (EPA/air)		
Spark ignition engines (EPA/air)		
Reciprocating internal combustion engines (EPA/air)		
Nonroad diesel engines (EPA/air)		
Lead in paint (EPA/other)	IQ point loss	COI
Arsenic in drinking water (EPA/other)	Morbidity and mortality associated with lung and bladder cancer	Mortality: VSL Morbidity: WTP transfer
<i>Food and drug safety:</i>		
Shell egg labeling and storage (FDA/HHS)	Morbidity and mortality associated with acute and chronic gastrointestinal illnesses and reactive arthritis associated with <i>Salmonella enteritidis</i>	Mortality: VSL Morbidity: Monetized HRQL estimates plus COI
Juice processing (FDA/HHS)	Morbidity and mortality associated with acute and chronic gastrointestinal illnesses and reactive arthritis related to four pathogens	
Trans fat labeling (FDA/HHS)	Morbidity and mortality associated with coronary heart disease	
Dietary supplements containing ephedrine alkaloids (FDA/HHS)	Morbidity and mortality associated with myocardial infarction, stroke, other cardiovascular, neurological, and psychiatric effects, seizures	
Bar codes for human drug products and blood (FDA/HHS)	Morbidity and mortality associated with numerous symptoms related to adverse drug reactions and preventable acute hemolytic transfusion reactions	
Listeria control in meat and poultry (FSIS/USDA)	Morbidity and mortality associated with <i>Listeriosis</i>	Mortality: VSL Morbidity: COI
<i>Traffic, worker and product safety:</i>		
Ergonomics program (OSHA/DOL)	musculoskeletal disorders	Mortality: not valued Morbidity: COI
Steel erection safety ³ (OSHA/DOL)	accident-related injuries	
Occupant crash protection (NHTSA/DOT)	Crash-related injuries	Mortality: VSL Morbidity: Monetized HRQL estimates plus COI
Tire pressure monitoring (NHTSA/DOT)	Crash-related injuries	
Truck driver hours of service (FMCSA/DOT) ¹	Crash-related injuries	
Sources: Exhibits 8, 13, and 18.		

This exhibit suggests that several rules address respiratory and cardiovascular effects, pathogen-related illnesses, and injuries. However, a broad range of numerous other health impacts are addressed by these rules. As noted earlier, the valuation approaches used by each agency are evolving, and all agencies (including OSHA) now use VSL in some form to value fatal risks. The exhibit suggests that all agencies other than OSHA generally used estimates of WTP or monetized HRQL to value nonfatal risks, however, OSHA is now applying WTP estimates in more recent forthcoming rules.

6.4 Characteristics of Potential Future Rules

Review of the regulatory plans for these agencies indicates that they are in the process of proposing or finalizing several economically significant rules that are likely to include quantified health impacts in the supporting analyses. Based on the most recent version of the “Unified Agenda” (published in the *Federal Register* on June 28, 2004) and supplemented by information from agency staff, forthcoming rulemakings are likely to address the health impacts listed in Exhibit 23. The exhibit summarizes the impacts of all the economically significant rules listed in the Agenda that are likely to involve quantified estimates of impacts on human health. No such rules were identified for FMCSA or for other agencies not listed here.

Exhibit 23	
HEATH EFFECTS LIKELY TO BE QUANTIFIED IN FORTHCOMING MAJOR HEALTH AND SAFETY RULEMAKINGS	
Agency	Potential Quantified Health Impacts
EPA	<ul style="list-style-type: none"> •Numerous cardiovascular and respiratory conditions •Lung, stomach, bladder, and other cancers •Pathogen-related illnesses
FDA/HHS	<ul style="list-style-type: none"> •Pathogen-related illness •Hepatit is-C related liver disease and other effects •Numerous conditions associated with dietary supplements
FSIS/USDA	<ul style="list-style-type: none"> •Pathogen-related illness •Cancers and coronary heart disease
OSHA/DOL	<ul style="list-style-type: none"> •Chronic obstructive pulmonary disease and other respiratory conditions •Lung and other cancers •Hearing loss •Suffocation and explosion related injuries
NHTSA/DOT	<ul style="list-style-type: none"> •Vehicle crash-related injuries
CPSC	<ul style="list-style-type: none"> •Fire -related injuries
Sources: Exhibits 9, 14, and 19.	

This review suggests that cardiovascular and respiratory conditions will continue to be a significant concern in regulatory analysis, as will pathogen-related illnesses and injuries. In addition, cancers and a broad range of other conditions will also need to be addressed. Thus the IOM Committee will face the challenge of developing recommendations that can be applied in cost-effectiveness analyses for a wide range of health conditions.

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APPENDIX A: EPA EXPERT PANEL RECOMMENDATIONS ON QALY-BASED COST-EFFECTIVENESS ANALYSIS

The following extracts are taken from: Advisory Council on Clean Air Compliance Analysis (ACCACA). 2004. *Review of the Revised Analytical Plan for EPA's Second Prospective Analysis – Benefits and Costs of the Clean Air Act 1990-2020*. Prepared for the U.S. Environmental Protection Agency. EPA-SAB-COUNCIL-ADV-04-004.

The Council is chaired by Dr. Trudy Ann Cameron, and members include Dr. David T. Allen, Ms. Lauraine Chestnut, Dr. Lawrence Goulder, Dr. James Hammitt, Dr. F. Reed Johnson, Dr. Charles Kolstad, Dr. Lester B. Lave, Dr. Virginia McConnell, Dr. Bart Ostro, and Dr. V. Kerry Smith. Other Science Advisory Board members involved include Dr. Dale Hattis, and consultants include Dr. John Evans, Dr. D. Warner North, and Dr. Thomas S. Wallsten.

Page 3 (Executive Summary):

The Council understands the Agency's interest in conducting cost-effectiveness analysis since this is being required by OMB in addition to benefit-cost analysis for major regulations. The Council has had difficulty, however, in coming to full agreement about the appropriateness of Quality Adjusted Life Years (QALYs) for use in this context. The limitations of the measure have led some members to want to recommend against using it at all, but others are more comfortable endorsing exploratory efforts to apply the measure, even though they also acknowledge the same limitations. The deliberations of the Institute of Medicine's Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulations can be expected to be of considerable value in resolving some of the Council's concerns. In addition, the Council wants to emphasize that there are important limitations of any cost-effectiveness analysis for a regulatory program as broad as the Clean Air Act Amendments, because there are many other classes of benefits besides human health benefits to be taken into consideration. While cost-effectiveness analyses do not belong in the main 812 Analysis, because the latter is defined as a benefit-cost analysis, the Council recognizes that the Agency may wish to develop alternative cost-effectiveness analyses and these are appropriate for consideration with the "Learning Laboratory."

Page 59-63 (Section 11):

11. QALY-BASED COST EFFECTIVENESS

11.1. Charge Question 24:

For the 812 Report, EPA has decided to perform a cost-effectiveness analysis of the Clean Air Act provisions using quality-adjusted life years as the measure of effectiveness. This is the standard approach used in medicine and public health and this type of analysis has previously been recommended by the SAB. Moreover, the recent NAS Report (2002) on benefits analysis discussed how this method could be applied to the health gains from air pollution control.

a. Do you agree that QALYs are the most appropriate measure of effectiveness for this type of analysis? Would you suggest any alternative measures to replace or supplement the QALY measure? (This question relates to effectiveness measures, not monetary benefit measures as used in benefit-cost analysis).

b. OMB has suggested that EPA plan a workshop with clinicians, social scientists, decision analysts and economists to examine how the specific diseases and health effects in the 812 Report should be handled with respect to longevity impact and health-related preference. Participants would have knowledge of the relevant clinical conditions, the related health preference studies, and the stated-preference literature in economics. The recent RFF conference has laid the groundwork for this type of workshop. Is there a superior approach to making sure that the CEAQALY project is executed in a technically competent fashion and that the details of the work receive in-depth technical input in addition to the broad oversight provided by this Committee?

c. Does the Council support the specific plans for QALY-based cost-effectiveness described in the current draft blueprint? If the Council does not support specific elements of these plans, are the alternative data, methods, or results presentation approaches which the Council recommends?

11.2. Summary of Council Response:

The Council understands the Agency's interest in conducting a cost-effectiveness analysis since this is being required by OMB in addition to benefit-cost analysis for major regulations. Some cost-effectiveness analysis for the Section 812 Analysis has also been suggested in previous Council recommendations (EPA Advisory Council on Clean Air Compliance Analysis, 2001). In this Advisory, the Council cautions the Agency to proceed carefully in this regard and keep the primary focus on the benefit-cost analysis.

- This Council has had difficulty coming to full agreement about recommendations regarding the appropriateness of QALYs for use in this context. The limitations of the measure have led some members to want to recommend against using it at all. Other members acknowledge the limitations, but are more comfortable endorsing exploratory efforts by the Agency to apply the measure in a cost-effectiveness analysis.
- There are important limitations of any cost-effectiveness analysis that need to be recognized. Focusing exclusively on human health effects relegates the other benefits of the CAAA to the sidelines. There are also other problems with respect to the selection of an effectiveness measure for reductions in human health risks (e.g., QALY).
- The Council's reservations about QALYs stem primarily from concerns about QALY weights on health state attributes being inconsistent with the utility-theoretic models that underlie benefit-cost analysis unless excessively strong assumptions are made. All members agree that there should be no attempt to develop utility-based monetary valuations for QALYs (such as WTP per QALY) as these are conceptually inconsistent approaches.

- The deliberations of the Institute of Medicine's Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulations can be expected to be of considerable value in resolving some of the Council's concerns. This study was requested by the Office of Information and Regulatory Affairs of the Office of Management and Budget and is supported by a consortium of federal agencies that are responsible for assessing and reducing environmental, occupational, and consumer risks to health and safety. The committee's report will not be available until late in 2005. The Council advises that the Agency forestall any efforts to conduct cost-effectiveness analysis using QALYs until that report is available.

11.3. Challenges and limitations of CEA

Cost-effectiveness analysis (CEA) calculates costs per unit of effectiveness. A metric of effectiveness therefore needs to be defined that reflects the expected outcomes of the program. Benefit-cost analysis (BCA) estimates net benefits, which is an indication of how much better off society as a whole is likely to be if the program is implemented. In BCA both costs and benefits are defined in terms of changes in well-being or utility, and both are quantified in monetary units. In BCA, analysts' measurements of benefits are grounded conceptually in individual preferences.

Although the conceptual basis for valuation of benefits in BCA is clear, the empirical implementation is fraught with difficulties and limitations, especially when the primary effects of a program are non-market goods and services, such as protection of human life and health and quality of the natural environment. CEA, therefore, has some appeal because it avoids the need to determine how much better off individuals are with the program. It simply measures the effect in some selected metric, such as numbers of acres restored, number of deaths prevented, number of accidents prevented, etc. The calculation of the cost per unit of effect is helpful in determining which of several programs, designed to achieve the same goal, is most cost-effective. However, it does not inform about whether the program is worthwhile, i.e., whether the value of the benefit of the program exceeds the costs. CEA also says nothing about how to allocate resources among programs that achieve different effects (e.g., saving trees or saving people).

The Council concedes that CEA is widely used in other public-health domains and that some users of the Second Prospective Analysis will wish to compare the cost-effectiveness of the CAAA as a form of public health policy with the cost-effectiveness of other health programs. CEA comparisons may be a reasonable way to approach alternative medical treatments where all of the benefits of each alternative treatment accrue as changes in health status. For the CAAA, however, a strategy that attributes all of the costs of the policy only to the increases in health status does not provide a valid comparison, regardless of the health measure used (QALY, lives saved, life-years saved, etc.). There are other non-human-health benefits associated with the CAAA (e.g., ecosystem benefits). Furthermore, since the costs of the policy are joint costs that cannot be attributed separately to the different classes of benefits from the CAAA, there is no way to apportion these costs to arrive at a cost just for the health changes produced. Apportioning these costs is essential before any meaningful cost-effectiveness comparison can be attempted between the CAAA and private medical interventions as alternative means of

improving human health. Researchers have invested heavily in the fine-tuning of standardized cardinal physical measures for human health improvements, but these measures cannot capture the broader benefits of clean air policies.¹

The proposed remedy for this problem is to calculate net costs by subtracting all the non-health benefits that have been monetized in the benefits assessment. Such a procedure, however, remains a less than satisfactory solution when there are many potential non-health benefits that are poorly measured or not quantified at all. Some Council members find this approach troubling because it mixes benefit-cost analysis with cost-effectiveness. The Council acknowledges elsewhere in this report that the task of monetizing ecosystem benefits is a particularly difficult one. In general, when policy costs are non-separable and additional benefits cannot readily be monetized, it is extremely difficult to arrive at a cost that applies only to the health outcomes produced.

Separability in preferences is also a pervasive concern in cost-effectiveness analysis. Some of the important nuances in the QALY-WTP discussion hinge upon the extent to which health affects the marginal utility of income or wealth. The possibility that marginal utility of income depends on health means that WTP for health, environmental quality, or anything else may depend on health. This implies that one should account for the effect of population heterogeneity in health states when estimating WTP.²

11.4. QALYs as a Measure of Effectiveness

The Council acknowledges that it has previously recommended that QALYs be considered as candidate measures for “units of physical benefit” for the human health benefits of air quality improvements. Nevertheless, the composition of the Council has changed over time and the opinions of some of its members have been influenced by new information. Some of this information was provided in a special conference hosted by Resources for the Future entitled “Valuing Health Outcomes: An Assessment of Approaches” which took place in Washington, DC, on February 12-14, 2003. The subject matter of the conference was “the conceptual and empirical bases for alternative health-benefit measures, the ways in which such measures are used and could be used in policymaking, and whether the choice of measure would actually make a difference in policy outcomes.” In attendance were diverse groups of “experts, government officials, and stakeholders,” and the tenor of much of the discussion concerned the relative appropriateness of cost-per-QALY measures versus WTP measures.

It is likely that the Second Prospective Analysis will provide sufficient detail about benefits and costs that some audiences will be tempted to make cost-effectiveness calculations even if the Agency does not provide them. However, in view of the standards to which the Council has held other dimensions of the Section 812 Analysis, QALY-based analyses should be

¹One Council member points out that omitted non-health benefits of clean air policies are also a qualification affecting formal benefit-cost analyses, so this problem is not exclusive to QALY analysis. The two methods merely handle this problem differently.

²Different members of the Council express different degrees of concern about the consequences of assuming separability between health and income.

subjected to comparable scrutiny. The usual applications for QALY-based cost-utility comparisons involve only well-defined human-health benefits. The Clean Air Act and its amendments do not fit neatly into this framework. Members of the Council have articulated a number of additional specific reservations about the use of QALYs in the context of the Section 812 Analyses. These reservations concern consumer sovereignty and representativeness, ordinality versus cardinality, heterogeneity in health states, and the notion of willingness to pay for a QALY. Details about these concerns appear in Appendix F.

The Council would prefer to present the Agency with an unambiguous conclusion on the QALY cost-effectiveness matter. However, after several rounds of discussion on the topic, spanning several meetings, the Council has been unable to reach a unified view. The Council agrees that the jury is still out on whether QALY cost-effectiveness measures can be successfully adapted, in the future, to reflect both sufficiently general consumer preferences and the full array of non-human-health benefits also stemming from air quality improvements. Some Council members note that there is likely to be strong demand for QALY measures; others are firm in their convictions that the Agency should not be pressured by the wide acceptance of what they believe to be incorrect practices into using them in the Second Prospective Analysis.

The Council thus supports the Agency's plan to do a benefit-cost analysis as the main analysis and to treat any cost-effectiveness analysis as an ancillary calculation. In the current round, QALY-based methods should, at best, be included among the various methods and procedures to be considered for the "Learning Laboratory" where possible future enhancement are explored, tested and vetted by experts in all relevant fields.

11.5. Summary:

The Agency seems obliged, in complying with OMB guidance, to consider cost-effectiveness measures. The current Council, however, would prefer that the Agency not interpret this mandate as specifically requiring that this cost-effectiveness analysis take the form of explicit cost-per-QALY assessments. While QALYs may capture the majority of benefits from private individual medical treatments such as surgeries or medications, QALYs are not able to fold in all of the diverse benefits of a public good like clean air. Clean air may produce substantial human health benefits, but it may also provide substantial benefits to ecosystems. In general, it is not possible to accurately attribute shared costs to different categories of benefits. Only with an assumption of complete separability among costs and benefits across human health and other benefits can non-health benefits be treated as cost offsets and netted out of the cost-effectiveness calculations. Assessment of this separability assumption is a task for the Learning Laboratory the Council is advising the Agency to develop to support the Section 812 Analyses.

In cases such as the Section 812 Analysis, it may currently be possible to go no further than describing the costs and listing the array of known, estimated, and speculative physical benefits from the Clean Air Act and its amendments. QALYs could of course be entertained as one category of these physical benefits, but it should be made clear that overly simple cost-per-QALY calculations will be biased upward for the Section 812 Analysis, relative to alternative, exclusively health-enhancing, programs with which stakeholders may wish to make comparisons. If separability could indeed be assumed and if the monetary value of the non-health

benefits is first subtracted from costs, then the cost-effectiveness ratio is biased upward if and only if the monetary benefits of the non-health effects are underestimated.³ Without separability, it may not even be possible to sign the direction of the resulting bias.

The Council advises the Agency to determine whether this type of accounting, with costs and an enumeration of all classes of physical benefits (perhaps including, but not limited to QALYs) would satisfy the OMB requirement for cost-effectiveness analysis. However, the core of the Second Prospective Analysis should concentrate on using generally accepted and thoroughly vetted benefit-cost methodologies, as the proposed main analysis currently does. The Council does not endorse any substantial effort to calculate QALYs or benefits in the form of WTP per QALY as part of the main analytic agenda for current Section 812 assessment. The Council recommends that the Agency reserve judgment on this matter at least until the Institute of Medicine report becomes available in late 2005. The mandate to conduct some type of cost-effectiveness analysis suggests that the Agency devote attention to alternative strategies for meeting this mandate. However, the Agency should explore candidate methods under the category of Learning Laboratory activities, rather pursuing such analyses on an equal footing with the main benefit-cost analysis. In general, cost-effectiveness analyses should be presented as “alternative” analyses even when (or if) they are mainstreamed into future Prospective Analyses.

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APPENDIX F: SPECIFIC RESERVATIONS ABOUT THE USE OF QALYS IN THE CONTEXT OF THE SECTION 812 ANALYSES

Members of the Council have articulated a number of specific reservations about the use of QALYs in the context of the Section 812 Analyses. These reservations concern consumer sovereignty and representativeness, ordinality versus cardinality, and heterogeneity in health states. Details about these concerns follow.

F.1. Consumer sovereignty and representativeness:

Much progress has been made over the last dozen years in rendering QALY weights more fully representative of general population preferences, but some of the assumptions they require still trouble economists. There is no basis in economics for QALY weights based solely on the opinions of experts. Consumer sovereignty is a hallmark of the economic framework for benefit-cost analysis. The weights on different health states--used in the aggregation of a vector of health state characteristics into a one-dimensional index of well-being--should be based on the tradeoffs that a representative sample of consumers is willing to make between those states.

State-of-the-art QALY-weight estimates used to convert a bundle of health-state attributes into a one-dimensional index now tend to be determined ex ante with respect to the degraded health states in question, by random samples from the population of consumers, so

³In this situation, however, the net benefits in any benefit-cost analysis will also be biased in a way that makes the CAAA look less favorable.

there is a greater expectation that these weights are representative. Departures from this strategy are sometimes justified as approximations, but acknowledged to be conceptually inferior. The Agency, if it elects to use QALYs in future cost-effectiveness calculations, should insist upon weights that are based on general public/consumer preferences, rather than experts' opinions, and that these weights reflect ex ante rather than ex post tradeoffs. This was a recommendation of the Panel on Cost-Effectiveness (see Gold et al. 1996). Some members of the Council are concerned, however, that there do not yet exist sufficient numbers of general-population estimates of QALY weights for the Agency to be confident in any estimates it might use.

F.2. Ordinality versus cardinality.

Economics is clear that tradeoffs with respect to health need not necessarily be expressed in terms of the marginal utility derived from a health attribute divided by the marginal utility derived from money (which is the manipulation that produces a WTP estimate for changes in health states). Any numeraire will do. The choice of a monetary unit is merely convenient. WTP measures the rate of substitution between some change in a health state (or lottery over health states) and income, where income is a measure of the consumption of "all other goods and services." In contrast, QALY weights measure the rate of substitution between a change in health state and length of life, so length of life is the numeraire. To this point, then, the marginal rates of substitution in both the WTP and QALY approaches require only ordinality in preferences. The subtle difference, however, is that while empirical QALY studies typically elicit ordinal utility scales, they give the scale a real zero (i.e. death), which gives the scale ratio properties,

In the case of QALYs, the shift to a cardinal interpretation seems to come about in one of two ways. The first is when practitioners want to add QALYs across people. This creates a need to interpret QALYs as measuring interpersonally-comparable utilities, so that sums of QALYs across people can remain consistent with utilitarian welfare. Many QALY practitioners clearly treat QALYs as cardinal by adding utility across time and across individuals. Second, if practitioners want to evaluate uncertain health risks by calculating expected QALYs, it seems necessary to assume that QALYs reflect a von Neumann-Morgenstern utility function, which is necessary for the expected value to be a meaningful summary of utility under uncertainty. (It is of course also necessary to assume that expected utility theory is consistent with human behavior). QALYs are derived from von Neumann-Morgenstern utility under uncertainty. However, in practice, QALY calculations violate the postulates of expected-utility theory by treating an ex ante interval utility scale as if it were an ex post ratio utility scale.

In the case of WTP calculations, it is not necessary to rely on direct interpersonal utility comparisons, so it is likewise unnecessary to think about WTP as a cardinal utility measure. WTP can be summed across individuals because the Kaldor-Hicks compensation principle provides for this to be a way to identify potential Pareto improvements. In contrast, any analogy to the idea of Pareto improvements is harder to apply to the QALY story, since the idea of winners actually compensating losers by handing over some of their net improvements in health seems like it would be impossible, even in principle. The analogy to the Kaldor-Hicks intuition would still suggest that the net health gains of winners should exceed the net health losses to losers. Across many simultaneous health-improvement policies with different distributions of

winner and losers, if net gains across all programs exceed net losses across all programs, society as a whole would be better off in terms of health.

F.3. Heterogeneity in health states

QALY practitioners have focused on heterogeneity in health states and the desire for a one-dimensional index of health that controls for this heterogeneity. WTP researchers have emphasized utility-theoretic strategies in support of benefit-cost analysis, but early empirical estimates did not distinguish between health states beyond just “alive” versus “dead.” The latest generations of empirical WTP analyses now incorporate information about disease types, age differences, latencies in effects, comorbidity, and other types of heterogeneity. Most economists would agree that the ideal approaches to both benefit-cost analysis and cost-effectiveness analysis should include both adequate recognition of heterogeneity in health effects and a utility-theoretic framework. QALY approaches are relatively strong on the first count, but lacking on the second count. WTP approaches are strong on the second count, and gaining rapidly in terms of the first.

F.4. Economic benefit analysis using QALYs?

A cul-de-sac in the QALY-WTP literature attempts to bring the medical decision-making and economic approaches to efficiency questions somewhat closer together. Some QALY researchers have considered the demand for the improved health states offered by different policies, not just the costs of these improvements. Instead of just cost-effectiveness analysis, something approaching a full benefit-cost analysis can be sought. See Hirth, et al. (2000), Hammitt (2002), Klose (2003), and Gyrd-Hansen (2003). Even in this endeavor, though, the standardization of health units embodied in a QALY still tends to raise objections from economists. One QALY-based WTP method has two steps: a) model QALYs as a function of a wide array of health state attributes and calculate the non-economic cardinal QALY index for a specified bundle of health attributes, then b) determine WTP for a QALY with the assumption that each QALY has equal value. Some studies have also tried (incorrectly) to derive WTP per QALY using VSL, or to regress WTP estimates on QALY estimates from the same sample. However, there has been little sustained interest in using such estimates to evaluate health outcomes.

In conducting a WTP analysis, it is reasonable to question whether an intervening QALY step is even necessary. The economic approach is presently evolving to model WTP directly as a function of heterogeneous health state attributes--in one step. This approach models WTP to avoid a future health state as a function of the vector of attributes of that health state, allowing inferences about the marginal WTP for distinct health state attributes, holding other attributes constant. Forcing WTP to fit a QALY model seems to place unnecessary and perhaps undesirable constraints on WTP. There is no reason why an individual would have to place the same monetary value on every QALY. This implies linearity of WTP with respect to changes in life expectancy, an assumption that does not appear to be supported empirically (e.g., Krupnick et al., 2002).